May 9, 2022

Carole Johnson
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Re: Request for Information on ways to strengthen and improve the Organ Procurement and Transplantation Network

Dear Administrator Johnson:

The American Kidney Fund appreciates the opportunity to provide comments on the Request for Information (RFI) referenced above.

The American Kidney Fund (AKF) fights kidney disease on all fronts as the nation's leading kidney nonprofit. AKF works on behalf of the 37 million Americans living with kidney disease, and the millions more at risk, with an unmatched scope of programs that support people wherever they are in their fight against kidney disease—from prevention through transplant. Through programs of prevention, early detection, financial support, disease management, clinical research, innovation and advocacy, no kidney organization impacts more lives than AKF. AKF is one of the nation's top-rated nonprofits, investing 97 cents of every donated dollar in programs, and holds the highest 4-Star rating from Charity Navigator and the Platinum Seal of Transparency from GuideStar.

AKF commends the Health Resources and Services Administration's (HRSA) efforts to improve the Organ Procurement and Transplantation Network's (OPTN) engagement with donors and patients and its focus on opportunities to strengthen equity, access, and transparency in the organ donation, allocation, procurement, and transplantation process. AKF's mission is to fight kidney disease and help people live healthier lives, including helping people access kidney transplants. AKF's financial assistance helped 1,889 low-income dialysis patients afford their health insurance and receive a kidney transplant in 2021— 7% of all kidney transplants performed in the U.S. last year. Kidney failure has a disproportionate impact on people of color, and fighting health disparities has long been an integral part of AKF's mission. Many of the people we help each year with financial assistance that leads to a kidney transplant are from communities of color.

We focus our comments on the following question, with an emphasis on people with kidney failure:

Question E.4
Increasing Organ Donation and Improving Procurement
How can HRSA best incorporate the NASEM report's recommendations on increasing equitable access to transplants?

AKF agrees with recommendation 3, "Achieve equity in the U.S. organ transplantation system in the next 5 years," in the National Academies of Science, Engineering, and Medicine (NASEM) report: *Realizing the Promise of Equity in the Organ Transplantation System*. Particularly, we strongly support the recommendations on expanding oversight and data collection, shared decision making with patients and public education, and elevating the voices of those facing disparities. In its report, NASEM recommends that:

- HHS should extend its regulatory oversight of the organ transplantation system beginning, at least, at the time a patient reaches end-stage organ failure and extending beyond 1 year posttransplant.
- HHS should update the OPTN contract to require the collection of disaggregated data by race and ethnicity, gender/sex, age, as well as language and the creation of new measures of inequity in the transplant system.
- HHS should develop, implement, and evaluate rigorous approaches for transplant teams to communicate routinely with (1) potential transplant recipients about their status and remaining steps in the process of transplant evaluation; (2) wait-listed candidates about organs offered to them, including information about the benefits, risks, and alternatives to accepting different types of organs to facilitate shared decision making about whether to accept the organ; and (3) wait-listed candidates about the number of organs offered and declined.
- HHS should develop, implement, and evaluate rigorous approaches for routinely educating the public about the benefits, risks, and alternatives to organ transplantation as a treatment option for end-stage organ disease or for those needing transplantation of tissue or a functional unit.
- HHS should conduct ongoing culturally targeted public education campaigns to convey the need for organ donation to save lives, to eliminate misconceptions about organ donation and transplantation, and to increase the trustworthiness of the transplantation system.

To incorporate these recommendations and increase equitable access to transplants, AKF suggests HRSA consider the following related issues and approaches to address them. We previously outlined these issues and suggestions in our comment letter to the Centers for Medicare and Medicaid Services' (CMS) RFI on transplant programs, organ procurement organizations (OPO), and end-stage renal disease (ESRD) facilities:

- As noted in the NASEM report, there are data gaps within the transplantation system that make it difficult to assess the socioeconomic status of transplant candidates, and the report noted the ongoing work of the OPTN Minority Affairs Committee to consider proposed

efforts to collect additional socioeconomic information related to disparities in access to kidney transplantation. AKF is supportive of efforts to improve data collection and data on the social determinants of health (SDOH). Transplant programs and OPOs should be aware of SDOH in their policies, but it needs to be very clear that the SDOH should not disqualify a kidney patient from being listed on the transplant waiting list or being asked to be a living organ donor. Transplant centers and OPOs should be cognizant that people have been denied treatment due to race, but also based on their income level, where they live and whether decision makers think that their living environment is going to be conducive for them to maintain their transplant. We should ensure that data around SDOH should not be used to discriminate against patients. Transplant centers and OPOs should focus on equity in-and-of itself. When transplant centers and OPOs focus solely on the outcome, all the SDOH creating the disparities that get patients to dialysis are reenacted in transplant patients.

- Patients commonly experience challenges in getting information to and from transplant coordinators, and many do not understand the various steps in the evaluation process. The volume of communications—especially at large transplant centers—can make it difficult for coordinators to be responsive to patients with their questions. The current transplant evaluation process should be easier for patients to navigate.

- HHS can work with patient and provider groups to lay out a framework or a start-to-finish set of expectations for patients. For example, it should include a list of needed tests to be done by their primary care provider and to whom they need to send the results. The framework will let patients know where they are in the process. It can be written, but also made into a video or podcast. Both written and oral education needs to be provided in easy-to-understand language and provided in the primary language of the patient. The educational materials should also include information on the organ procurement process and organ allocation system.

- Create outreach programs to contact dialysis patients who are in communities of color. For example, Northwestern University and George Washington University have outreach programs to specifically assist kidney patients from communities of color to educate them on kidney transplantation.

- HHS could require transplant programs or OPOs to conduct an organizational literacy audit and create documents for patients to show how to interact with the transplant program.

- Peer mentors and care navigators can be utilized to a greater degree to assist new patients with the process.

- Education should also be provided early in the process so more patients can be placed on the transplant list preemptively or soon after beginning dialysis. A focus on getting appropriate patients waitlisted or receiving living donor transplants earlier in their dialysis treatments is a strategy that both the community and HHS could adopt. It is regrettable when a patient has access to a living donor and could have been transplanted in the first or second year of dialysis, but could not get the transplant until the fourth or fifth year because of the transplant process.

- The cohort of people who get preemptive transplants have higher education levels and have a higher socioeconomic status. Those with lower socioeconomic status, inadequate

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insurance, or who live in underserved areas can face barriers to kidney transplantation.[1] Education and assistance should be provided to people from communities of color, underserved communities and rural communities earlier in the process.

- Once individuals are on the waitlist, access to transplantation is generally equalized. However, there is potential in bias in the decisions to refer patients to the waiting list and in the timing of the physician assessment of appropriateness for transplant. Data shows that there are racial disparities in that process. There can also be a lack of knowledge at both the dialysis center and referring physician levels about the organ allocation system, which can lead to less timely referrals.
- Focusing on cultural competency can better ensure that transplant centers are aware of individual organ recipient's unique support systems post-transplant. They need to be aware of possible implicit bias when assumptions are made about a patient's ability to follow transplant instructions, a patient's unique support system, and the patient's financial challenges.

Thank you for the opportunity to provide comments on this RFI. If you have questions on our response or would like to further discuss these issues, please contact Holly Bode, Vice President of Government Affairs, at hbode@kidneyfund.org.

Sincerely,

Holly Bode
Vice President of Government Affairs

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[1] David A. Axelrod, Mary K. Guidinger, Samuel Finlayson (2008). Rates of Solid-Organ Wait-listing, Transplantation, and Survival Among Residents of Rural and Urban Areas. *JAMA,* 299(2):202–207. https://jamanetwork.com/journals/jama/fullarticle/1149365
https://jamanetwork.com/journals/jama/fullarticle/1149365

SECTION A. COVER PAGE

Notice number: 541611

Notice Title: Organ Procurement and Transplantation Network (OPTN)

Date of issuance: 4.08.2022

Name: Cleveland Clinic

Address: 9500 Euclid Avenue, Cleveland, OH 44195

Point of contact, phone & email: Dr. Maryam Valapour, email: valapom@ccf.org, phone: 216.445.4071

SECTION B – RESPONSES TO QUESTIONS

We appreciate the opportunity to provide feedback on this very important topic. You will find our comments divided into two sections. First is a brief overview of Cleveland Clinic and our partnership with IBM. Next, we address questions A(1) a-e and A(3). Our response reimagines the U.S. transplant system where a new contemporary modality of data management and data science infrastructure will efficiently integrate data and scientific findings to allow patients to benefit from the most advanced scientific discoveries in real time.

OVERVIEW

Cleveland Clinic is a nonprofit, integrated healthcare system dedicated to patient-centered care, teaching, and research. Last year, our system cared for 2.9 million unique patients, including 10.2 million outpatient visits and 304,000 hospital admissions and observations. Cleveland Clinic is a multi-specialty academic medical center comprised of 10 patient-centered institutes based around single diseases or organ systems. Each institute combines medical and surgical services at the same location under the same leadership to improve patient care and experience; our Transplant Center has become fully integrated with all of them. Our Lerner Research Institute ranks as the fifth-largest research institute by funding in the United States.

Cleveland Clinic-IBM Discovery Accelerator

Cleveland Clinic and IBM have partnered to establish a Discovery Accelerator with the mission to advance the pace of discovery in biomedical research and healthcare by advancing and applying state-of-the-art computing technologies across Artificial Intelligence (AI), Hybrid Cloud and High-Performance Computing, and Quantum Computing.

IBM is a world leader in developing next-generation computing technologies to advance the pace of scientific discovery across a broad range of domains, including healthcare and life sciences. Recent examples where IBM is working to accelerate progress in healthcare include:

- Deep knowledge integration of multi-modal sources for holistic population-level risk modeling, including clinical and non-clinical factors and the potential impact on the healthcare system for enhanced clinical trial design (EU Horizon funded program).
- AI-driven simulation to predict effect sizes for behavioral interventions with continuous, automated extraction of results from randomized controlled trials from the scientific literature (Wellcome Trust funded).
- Generative probabilistic models of clinically relevant disease states for Huntington's Disease leading to biomarkers for better monitoring of disease progression (Collaboration with the Cure Huntington's Disease Initiative Foundation).
- Identifying candidate drugs for repurposing, using real-world data extracted electronic health records and medical claims data (Parkinson's Disease study with TEVA Pharmaceuticals).

Advances across a range of technologies – including deep-knowledge integration, multi-modal data fusion, AI-enriched simulations, generative modelling for hypothesis creation, and

automation of experimentation – are all driving important progress on these critical challenges.

We propose that these advanced computational technologies could be used to make available data from multi-modal sources on a scale beyond human capability, and in record time, to simulate incorporation of new data into existing systems (e.g., organ allocation systems), and to accelerate discovery of new models in the future (e.g., probabilistic models of organ availability).

Cleveland Clinic Transplant Quantitative Science and Policy Expertise

The Cleveland Clinic enterprise includes some of the largest and most innovative transplant programs in the United States. Since the inception of our first transplant program in 1963, we have performed 15,880 transplants to date (as of May 6, 2022), with 930 transplants in 2021. Our programmatic commitment to providing all patients with access to transplant despite surgical and medical complexities has resulted in a nationwide referral base for all solid organ transplants and collaborations with transplant centers, donor hospitals and organ procurement organizations throughout the U.S. We have a deep understanding of the workings and complexities of the U.S. transplant system.

In addition, we are engaged in discovery in every aspect of transplantation, including increasing the supply of donor organs, improving organ utilization, and improving transplant outcomes and policies. As it relates to this request for information, three members of our transplant program were instrumental in evaluating and formulating the recommendations of the National Academies of Science, Engineering, and Medicine (NASEM) report, "Realizing the Promise of Equity in the Organ Transplantation System." We also have been active participants in the governance structure of the Organ Procurement and Transplantation Network (OPTN) with many members of our team serving on OPTN committees. I also have served as Senior Investigator for Lung Transplantation for the Scientific Registry of Transplant Recipients (SRTR) since 2010 and have funding from the National Institutes of Health to evaluate the integration of electronic health records into current OPTN data structures to reduce disparities in access to transplant and to improve the allocation algorithm in general.

This environment, our collective expertise, and our interest in improving the performance of the OPTN to serve patients provides the background for our response to this request for information. We will focus our commentary on the OPTN Technology and Data Collection activities.

Questions A.1 (a-e) and A.3
Current U.S. Transplant System Data Collection and Analytic Framework

The U.S. organ transplant system is governed by two major contracts, the OPTN and the SRTR. The OPTN contract calls for policy development, data management and organ allocation. It has been held by United Network for Organ Sharing since 1984, the year of inception of the federal transplant system. The SRTR contract calls for research and evaluation of U.S. transplant data to improve timely transplant access and outcomes. Since 2010, it has been held by Hennepin Healthcare Research Institute, where I serve as Senior Staff for Lung Transplantation and oversee the analysis of U.S. lung transplant data and allocation modelling. In this role, I serve as an ex-

officio member on several OPTN committees, including the Data Advisory Committee and the Lung Transplant Committee.

A key observation I have made in this role and as an outcomes and policy researcher, that is shared by other scientists and policymakers, is the many years' lag in incorporating data and scientific findings into the organ allocation system to benefit patients. In addition, as the NASEM report states, a key gap in evaluating disparities in access to transplant is the lack of data about patients prior to listing for transplant. Currently, the U.S. transplant registries only capture patients after they are listed for transplant, missing all potential transplant candidates with end stage organ disease who did not access the list at all. While the kidney transplant system can rely on the United States Renal Data System to try to fill this gap, all other solid organs have no such recourse. This gap can only be filled by an efficient incorporation of electronic healthcare records on a nationwide large-scale basis which cannot be fulfilled with the current system structure.

Proposed Transplant System Data Collection and Analytic Framework

The ever-growing available population, along with the individual and genetic level data that impact each person's health, coupled with the vast body of scientific literature that informs our understanding of survival from the pre- to post- transplant phase, require a reimagining of the structure of data collection and analytic framework for the U.S. organ transplant systems. We propose a separate contract, Transplantation Data Innovation and Technology (TDIT), whose mission will be to transform the data science capabilities of U.S. organ transplant systems by deploying, managing, and operating an accelerated discovery platform consisting of the next generation technologies described in this proposal. In summary, the TDIT will provide the U.S. organ transplant ecosystem with next-generation computing technologies, domain & technical expertise and the support needed to accelerate current operations, and drive future advances, in analytics for organ transplantation. The TDIT would operate as a link between the SRTR and the OPTN.

	SRTR	TDIT	OPTN
Mission	Research/ policy evaluation	*Data management and data science infrastructure*	Organ allocation/policy development
Data & System responsibilities	Inferential analyses/allocation modeling	*Research data sharing /optimization of OPTN IT architecture. State of the art data science, modelling & analytics capabilities*	Data collection
Contractor	Hennepin Healthcare Research Institute (HHRI)	*Cleveland Clinic – IBM*	United Network for Organ Sharing (UNOS)

Table 1: Proposed tripartite structure for managing U.S. transplant research, data management, and policy development

Cleveland Clinic - IBM Discovery Accelerator Modern Use of Data, Computing and Analysis

The figure below illustrates our vision of how our experience in accelerated discovery has the potential to transform data collection and analysis for the U.S. organ transplant ecosystem.
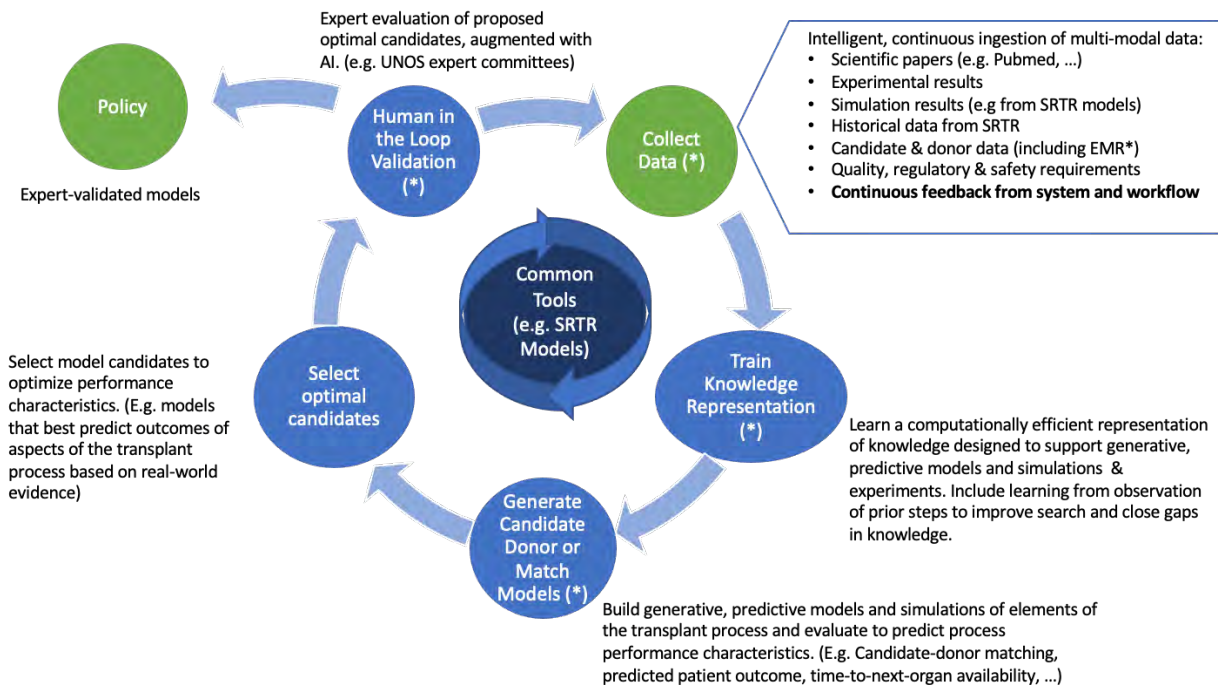

Figure 1. Transformed workflow for organ transplant data science using accelerated discovery technologies. Elements marked with an asterisk (*) indicate key points where AI can be used to augment controls for sources of bias that may lead to potential disparities in the organ transplantation ecosystem.

For ease of discussion of Figure 1, we use the specific example of candidate-donor matching models as a concrete and familiar example to discuss. This is for clarity of discussion only, and the proposed system is intended to be used to accelerate discovery of many types of models.

Collect Data

Continuous ingestion of data, augmented by Natural Language Processing and Machine Learning, extracts relevant data from a variety of sources such as scientific reports, historical data, or models from the SRTR, and candidate and donor data collected by OPTN. The process of data collection is designed to be readily extended, allowing sources such as electronic health records systems, for example, to be connected to the system. This is a major area where additional data sources outside of the transplant registries can provide data to determine if there are disparities in access to transplant. Here, we can also easily add new sources of data that capture better measures of socioeconomic position of donors and candidates.

Train a Knowledge Representation

Extracted data is loaded into a computationally efficient structure called a knowledge representation. A key benefit is that data items in a knowledge representation can readily be given

formal structure and meaning (semantics), allowing both people and computers to process them in an efficient and unambiguous manner, insulated from how the underlying data was implemented. Decoupling implementation from usage in a knowledge representation means that adding new sources of data, or changing the format of existing sources, has minimal impact on users and programs using the data, and makes it simpler to add new data elements to existing knowledge. Another key benefit of a consistent view across multiple sources of data is that data can be readily assessed to identify inconsistencies, imbalances and biases before data is used in analytics.

Generate Candidate Donor or Match Models
Using our example of candidate-donor model development, the runtime system can be configured to automatically generate candidate-donor models by selecting from the variables available in the knowledge representation and choose model parameters to yield the best result. The number of candidate models created and evaluated can be enormous, depending on the complexity of the knowledge representation. In this way, thousands of models or more can be evaluated automatically with little human effort and in a fraction of the time required for a human. As new variables are added to the knowledge representation, these are available for inclusion in future models. It is also possible to constrain the generation and configurations of models by, for example, introducing rules to control for biases or to require inclusion or exclusion of certain types or combinations of variables. This strategy can be a powerful step for finding the best donor matches for transplant candidates who are sensitized, (i.e., difficult to match to donors), who are disproportionately minorities and women. IBM has successfully applied technologies for automated model development in the machine learning, chemistry, and material science communities.

Select Optimal Candidates
Here, a subset of candidate-donor models is selected from the (possibly many thousands of) generated candidates based on a specified quality measure (for example, accuracy, specificity, sensitivity of models versus real-world observations). We may, for example, ask the system to select every candidate-donor model with an accuracy exceeding a specified threshold for further assessment. This recognizes that in some circumstance, it may be preferable to accept a slightly lower accuracy from a model for increased simplicity or faster execution time. By choosing a subset of optimal candidates, we can compare models in a more use-case appropriate way.

Human in the Loop Validation
In this step, an expert committee, such as a UNOS expert committee, could evaluate a proposed candidate-donor model prior to releasing it as a policy or approved model. A human expert assessor has access to all the knowledge in the system. This includes data such as evaluation and test results, explanations of variables used in models – the intent is to assist an expert assessor to make an informed decision about the quality and ease of use of a model. In addition, in this step there will be another review of the model to ensure that the final allocation models do not disadvantage groups of candidates for access to transplant or compromise their survival on the waiting list or post-transplant.

Results from each of the steps in Figure 1 are captured as knowledge by the system so that future iterations may be improved by, for example, adjusting the valid ranges of parameters used by

candidate models to reduce biases reported during expert assessment. This feedback loop captured from use of the system enables the system to adapt continuously through active learning.

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

We believe that creating a dedicated Transplantation Data Innovation and Technology contract, a data management and data science infrastructure, as a new scientific arm of the U.S. transplant system offers an exciting opportunity to preserve the expertise and capabilities of existing SRTR and OPTN operations, while also enabling the U.S. transplant system to benefit from the latest advances in technology through a cutting-edge technology infrastructure and deep expertise of Cleveland Clinic and IBM. We see a dedicated transplantation data innovation and technology infrastructure, underpinned by the accelerated discovery technologies outlined here, as an opportunity to evolve and transform, while respecting the achievements and capabilities already developed through many years of transplant system operations. On this basis, Cleveland Clinic, in partnership with IBM, would be pleased to supply a proposal for a future solicitation from HRSA should the opportunity arise, and are available should you wish to discuss any aspect of this document further.

Maryam Valapour, MD, MPP
Director, Lung Transplant Outcomes
Cleveland Clinic

RESPONSE TO

HEALTH AND HUMAN SERVICES - HEALTH RESOURCES AND SERVICES ADMINISTRATION

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN) REQUEST FOR INFORMATION

NOTICE ID HSB115C1031

APRIL 8, 2022

COMMUNITY PSYCHOLOGY HEALTH COLLABORATIVE

12 WALNUT AVE

WYOMING, OHIO 45215

POINT OF CONTACT:

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A.1.c – Enhancement of patient-facing user interfaces to support increased transplant center engagement with patients in organ acceptance decisions in turn improves the efficiency of the organ allocation system. There would inevitably be an increase in 'time to organ acceptance' by incorporating the patient into the decision-making process though that could be minimized by a candidate training regimen at time of listing. The obligation to optimize the matching of organs within the transplant apparatus is acknowledged. However, the point at which organ allocation optimization devolves to risk aversion by programs seeking to protect their outcomes metrics and reputations, the patient is marginalized. Shared decision-making creates a 'check and balance' of transplant programs' assessments of organ offers in furtherance of patient autonomy.

There is an asymmetry of information in the current organ offer scenario. Patients seek to maximize the longevity of graft survival and minimize morbidity, but research suggests candidates are most concerned with time on the wait list. Providers, being more well versed in the science of matching and limitations of program skillsets and techniques, engage in a much more fervent analysis prior to organ acceptance. Patients require decision-making supports to participate in the organ offer process in real-time if the patient-provider interaction is to be truly collaborative. The United Network of Organ Sharing (UNOS) has been developing predictive models that automate and illustrate much of the science of matching in a way that supports transparency and empowerment for the patient. Tools in this mold in effect lessen the information gap between the candidate and the transplant professional, though the patient-provider relationship is still paramount in a cooperative matching scenario.

A.1.e – Maximizing tools to advance the nation system of organ transplantation is critical to continuous improvement of the system. Yet it is important to recognize that patients are currently experiencing a constriction at the access point for transplant. Research suggests this is due to many variables including ethnicity, body mass index, socioeconomic status, socially undesirable characteristics, physician-defined frailty, and certain other stigmatized factors. While many of these patients are never listed or are deactivated due to non-standardized transplant evaluation criteria, many wait listed patients languish on the waiting list for longer than expected durations.

Improved transparency and shared decision-making in organ offers has the potential to add time to the allocation process, increase less than optimal patient outcomes, and perhaps negatively impact the incidence of clinical errors. However, some of this is to be expected if providers are tasked with taking on less ideal patients and organs in the operating room. There must be a balance between the constant push for better clinical metrics and increased access to transplant. HRSA should expect and willingly accept an increase in transplant centers triggering program reviews as organ discard rates and patient wait times decrease. As such, messaging and education are a critical factor in this move towards shared decision-making in organ offers, especially for prospective patients and wait listed transplant candidates.

B.1 – The development of performance metrics and benchmarks for the organ donation, procurement, allocation, and transplant system should be a qualitative and quantitative process. Analysis of pre-, intra-, and post-transplant metrics provides a necessary evaluation of system and center performance. Creating a system based off of that current state information, however, limits the future state and may not move the system towards the ideal state of transplant in the United States. Qualitative data

collection in the form of surveys, interviews, town halls, etc. employ the creativity of the various stakeholder groups in a way that statistical analysis cannot.

This is especially true for patients. The model utilized by the Scientific Registry of Transplant Recipients (SRTR) Task 5 initiative is submitted as a methodology that is respectful of prospective patient and recipient experiences. Participants were identified ahead of the qualitative data collection and indoctrinated into the purpose of the instruments and the terminology that would be base to participation in the conversations with providers present. Patients were thus empowered to be active participants rather than ratifiers of data collected for them versus with them. The resulting mixed method data set provides bi-directional interpretive benefit through patient activation versus patient attendance.

While the inception of public metrics and benchmarks is a project that requires dedicated resources and defined timelines, the ongoing management of the metrics and benchmarks should be considered in the storming and norming phases of this work. For patient-facing metrics and benchmarks specifically, ensuring that the voice of the patient is a significant factor in the management and ongoing development of the tools represents a challenge given the current constitution and function of OPTN board. HRSA should consider a 'Patient & Donor Affairs Caucus' that includes the Executive Committee and the PDA members of the board to provide patient-centric guidance for patient-facing metrics and dashboards. This would make more effective use of the PDA role and maximize patient influence in patient specific matters.

B.2.d - Structuring data collection and reporting mechanisms to create public OPTN national, regional and local performance dashboards is interdependent. Local data is important to patients as their chosen transplant center is most likely to be within a certain radius of their home. Reviewing this information prior to listing enhances the efficiency of the transplant system by appropriately matching independent patient characteristics with the strengths of a transplant program. Real time and standardized dissemination of local information is critical for this purpose so national collection and reporting enhances the functionality of this data.

Alternatively, regional data is an optimal methodology for benchmarking, evaluation and cross-pollination of practices. At the regional level programs can coordinate technical training and policy development that decreases some of the variability between programs. Transplant centers could also develop referral pathways for certain patient presentations to influence matching patients to appropriate transplant centers and decrease wait times at the regional level. For instance, centers in a three-state region could develop protocols for transferring renal patients with BMI greater than 40 kg/m^2 to the transplant center in their region with robotic-assisted kidney transplant program in place. Similarly, patients with a non-matched living donor could be forwarded to a center within the region with a robust paired donation program in place.

The data points for facilitating this regional structure are different from those collected at the national and local level and thus require a different structure for data collection and reporting. The OPTN recently underwent a consultation with EY to evaluate the future of the regional framework as continuous allocation begins to make the current region concept obsolete. Infusing regional standardization, collaboration, and network weaving principles into the revised OPTN region framework could provide a new purpose and energy to an existing yet waning vestigial function. It also creates new

opportunities for patients, donors, and families impacted by transplant and donation to become involved in the policy-making process.

G.1 – The NASEM report's recommendations on increasing racial, ethnic, professional, and gender diversity on the boards and committees responsible for developing OPTN policies is honorable but requires targeted recommendations. For instance, the majority of the racial and ethnic diversity currently on the OPTN board lies in the Patient & Donor Affairs representatives. Ensuring that physician, OPO and transplant professional representatives reflect the myriad diversity of the transplant system is key to a fair and just policy making process for all patients. Additionally, the diversity of the OPTN contractor is important to the inclusivity of the policy making process. Currently the OPTN contractor is far too homogeneous in its makeup yet holds an important role in every policy that is developed for the nation's organ transplantation system. Requirements for improved diversity of the contractor's policy-making support staff should be included in the next RFP.

G.2 – Seeking engagement with external organizations who possess expertise in guiding federal programs through unique challenges in leadership and stakeholder collaboration is a worthwhile endeavor. Specific points of emphasis for this engagement would be diversity as mentioned above and in the way projects are introduced through the Policy Oversight Committee and shepherded through the policy making process. A method for stakeholders and stakeholder organizations to propose improvement concepts to the board would enhance collaboration with the transplant community but retain the oversight provided by the board and its committees. Creating this path would eliminate the need for transplant adjacent organizations to plant representatives of their organizations on the board and justify a reprimand for board members who openly lobby for the desires of organizations over the good of the transplant system.

Further, creating a mechanism for board members to be tasked with the role of 'sherpa' for a project during their tenure on the board would create a greater sense of ownership and in-depth understanding of proposals. Especially for the Patient & Donor Affairs representatives, this enhancement would provide a bridge for them to jump right into the proposal investigation, optimization, operationalization, and advocacy needed to churn out a policy. This could also put a check on the power the OPTN contractor's associates have in the policy-making arena.

G.3 – As mentioned above, standards of conduct and integrity are stressed when board members openly proselytize for transplant industry organizations. This is also true for board members who put the well-being of their employer above the interests of the system overall. The OPTN contractor needs to make it abundantly clear from the time of orientation and throughout board service that openly lobbying for anything other than the efficiency and safety of the transplant system will result in reprimand or removal from the board.

G.4 – A significant yet potentially seismic improvement to OPTN operations and policy development processes that HRSA should consider is to decentralize the OPTN contract. While much of the data aggregation, innovation, collaboration and so forth needs to be administered by a single agent, the widely held interpretation of the National Organ Transplantation Act and Final Rule legislations places a premium on institutions as the customers of the OPTN contractor. This often puts the best interests of the patient at odds with the best interests of the institutions. To that point, the current OPTN contractor

has not developed a bi-directional information system for patients since its first contract was awarded in 1986. This lapse was laid bear during the coronavirus pandemic where there was no central point of information for patients concerning risk, vaccination, therapeutics, or antibody therapy for patients.

Requiring the OPTN contractor to serve two masters is not the optimal solution as it has developed its culture and processes around servicing the transplant system: a necessary pursuit in itself. As stakeholders, patients, families, and donors deserve dedicated resources as well. A separate contract with an organization that could, in conjunction with the other OPTN contractor(s), provide education, advocacy, innovation, fundraising and IT support to the potential candidates and wait listed patients would further true shared decision-making between the transplant stakeholders.

STATEMENT OF INTENT

CPHC does not intend to supply a proposal on any future solicitation related to this requirement. As patient researchers and consultants in the transplant space, we wish to provide a patient perspective to many of the items that impact the lives of those in need of transplant. The responses are informed by the experiences and research of our President, who serves as a Patient & Donor Affairs representative on the OPTN Board of Directors (2020-2023).

Cystic Fibrosis Foundation

4550 Montgomery Ave.

Suite 1100 N

Bethesda, MD 20814

Title: Organ Procurement and Transplantation Network (OPTN)

Notice ID: HSB115C1031

Updated Date of Issuance: May 5th, 2022

May 9th, 2022

Administrator Carole Johnson
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857 U.S.A.

Re: Request for Information; Organ Procurement and Transplantation Network

Dear Administrator Johnson:

The Cystic Fibrosis Foundation writes in response to the Health Resources and Services Administration's (HRSA) request for information on *Ways to Strengthen and Improve the Organ Procurement and Transplantation Network.* We thank HRSA for the opportunity to provide feedback on potential changes and improvements to the Organ Procurement and Transplantation Network (OPTN).

Background on Cystic Fibrosis and the CF Foundation

Cystic fibrosis (CF) is a rare genetic disease that affects over 30,000 people in the United States. In people with CF, defects in the CFTR gene result in a buildup of thick mucus in multiple organ systems, including the lungs and pancreas. In the lungs, mucus obstructs the airways and traps bacteria, leading to infections, extensive lung damage, and eventual respiratory failure. Historically, over 200 individuals with CF have received an organ transplant each year with CF; this accounts for approximately 10-15% of the annual lung transplant volume. Although lung transplants have declined dramatically since 2019 due to the development of highly effective modulator therapies, many individuals with CF will continue to require lung transplantation. Some people with CF will also develop liver or kidney failure and require transplantation of those organs. Additionally, combined pancreas transplant occasionally occurs as pancreatic exocrine insufficiency and CF related diabetes are common in this population.

To address the needs of people with CF living with advanced lung disease, including those considering transplant, the CF Foundation launched the Lung Transplant Initiative in 2016. Through this initiative, the Foundation is working to improve and standardize care for people with CF for whom transplant is an option. We therefore appreciate HRSA's recent request for information regarding ways to strengthen and improve the OPTN. In particular, we view this comment opportunity and the upcoming renewal of the OPTN contract as an opportunity to refocus the transplant process around patients and their experiences. Based on the mission of our organization and the needs of our community, we offer the following comments.

Data Collection Activities (Sec. B.1, Sec. B.2.a - B.2.e)

One of the first steps to creating an equitable organ procurement and transplant system is expanding data collection to include disaggregated demographic information such as race, ethnicity, gender, language, and socioeconomic factors. We appreciate HRSA's commitment to doing so and recommend including quality of life metrics when tracking health and non-health metrics along with long-term health outcomes. Data collection should encompass donors, recipients, and potential transplant candidates; to the extent possible, the OPTN should attempt to backfill this information on previous donors, recipients, and potential transplant candidates when setting up their enhanced data collection parameters.

Throughout these efforts it is critical that the OPTN keep in mind its obligations to vulnerable and underrepresented populations. We share and support the OPTN's goal of strengthening equity and access in the organ donation, allocation, procurement, and transplantation process. Data from the CF patient registry (which includes data on race/ethnicity, marital status, education level, employment, insurance type, zip code, and distance to transplant centers) indicate that patients with greater socioeconomic barriers access transplant half as often as those with fewer barriers, regardless of disease severity. Because disparities in the process frequently occur prior to the time of listing, collecting these data at time of referral would be valuable for characterizing and addressing referral bias. Though logistically challenging, these efforts could begin in collaboration with patient advocacy groups, particularly those with registries, such as the CF Foundation, the Pulmonary Hypertension Association, and the Pulmonary Fibrosis Foundation.

We encourage the development of a standardized set of metrics regarding access and performance of transplant centers and organ procurement organizations (OPOs), as well as the creation of a publicly available dashboard to track those metrics across the organ procurement and transplant system. Data elements included should be chosen in consultation with donor patients and families, individuals with chronic disease, transplant candidates and recipients as well as their families to ensure that the information provided is relevant and patient centered. It should be incumbent upon the OPTN to reach out to these community stakeholders and actively solicit feedback regarding these metrics.

Organ Usage (Sec. F.1-F.3)

Organ non-usage represents an unnecessary failure of the transplant system, and measures to decrease discard and increase usage of organs may be implemented at multiple stages of the procurement and transplant process. Procured organ discard can be decreased by working with transplant centers to develop standardized, evidence-based criteria for organ quality assessment by OPOs prior to organ allocation, thereby mitigating non-usage due to discrepancies in standards between transplant centers and OPOs. Increased utilization of local or regional procurement teams by transplant centers may facilitate more rapid procurement of organs without taking surgeons away from planned procedures. These efforts may further be aided by the establishment of donor care units managed by OPOs or housed within transplant hospitals which may result in more control and optimization of donor management and procurement

timing. Lastly, we support standardization of protocols related to donation after circulatory death through such channels as the OPTN's collaborative OPO DCD procurement project. Continued effort in this domain is crucial to reduce variability in practice and increase organ utilization around the country.

To better prepare themselves to accept offered donor organs whenever they become available, hospitals with transplant centers should be required to prioritize transplant surgical scheduling and maintain the capacity to open an operating room expeditiously in case of a transplant procedure.

Given the disincentives for transplant centers to accept medically complex organs or recipients, the OPTN should additionally consider developing a risk stratification system for performance metrics. Establishing such a system with performance metrics for standard and medically complex allografts and recipients would help prevent hospitals that accept such cases from being "penalized" for doing so. Utilization of organs with marginal or less optimal quality and transplantation of medically complex recipients may be further improved through sharing of "best practices" from groups that perform such procedures. Standard criteria for each of these categories would need to be developed to remove subjectivity and avoid overuse.

To implement meaningful change, the OPTN will need to innovate with courage. We are not advocating for an approach that encourages undue risk taking and results in poor outcomes for patients; rather, we recommend the adoption and promotion of a calculated risk framework for organ transplant using a quality improvement approach that allows for learning and advancement. For example, some patients with cystic fibrosis are chronically infected with organisms known to be associated with poorer post-transplant outcomes. A system in which a few select centers with expertise in clinical care and quality improvement methodology are equipped to transplant these high-risk individuals would prevent these patients from being denied a lifesaving transplant. These centers would not be penalized for below average one-year outcomes; instead, they would be given the opportunity to learn and improve their approach to these high-risk patients. Indeed, the OPTN has already piloted this type of approach with the COIIN project (https://unos.org/news/improvement/what-we-learned-coiin/), which is intended to leverage transplant center and OPO partnerships to increase the use of higher-risk kidneys. We further emphasize a focus on intermediate and long-term outcomes (three- and five-year survival), rather than one-year survival, given that some individuals with below-average one-year survival have comparable three- and five-year survival to average-risk lung candidates.

We appreciate HRSA's investment in improving transparency of the organ matching and acceptance process for patients and other stakeholders. To bolster accountability, transplant centers should be required to keep patients on the transplant waiting list informed of the number of, and justification for, declined organ offers for themselves as individuals. Accurate identification of the reasons for organ declinations and barriers to organ acceptance will necessitate increased granularity of refusal codes and reduced risk of penalization for use of particular refusal codes. The OPTN should further be required to investigate methods to promote effective communication between patients and transplant teams during the organ offer process.

This process will be naturally facilitated by thorough patient education during the evaluation and listing period, as discussed below.

Stakeholder Engagement (Sec. H.1-H.3)

We believe that federal oversight and stakeholder engagement should begin earlier than the time of listing. Having a process in place that includes steps to ensure patients are being identified as potentially needing a transplant and subsequently referred for evaluation should be considered; timely referral may be improved through educational and patient awareness programs targeted at commonly transplanted patient groups. Importantly, these educational efforts should address the referral bias described above by highlighting existing disparities and working with stakeholders to increase referral rates among marginalized populations.

The OPTN should also develop standardized, streamlined educational materials (printed and online) regarding patient rights, as well as information on the transplant process and system, including the OPTN and OPOs. Ideally, patients should be provided this information at time of referral or initiation of transplant evaluation, depending on feasibility. These tools may be paired with improved OPTN website navigability and increased solicitation of patient engagement, including both candidates and recipients, as well as donor families. Efforts to improve the patient experience from the outset of the transplant process would be bolstered by the establishment of an optional peer mentorship program to provide guidance to those entering the system. The entirety of this program, including mentor training, database maintenance, and peer matching, should either be run through the OPTN or subcontracted out to other entities to avoid transplant center bias.

Quality Improvement

We believe that enhanced quality improvement programming is one of the most important considerations for the OPTN contract renewal. Continuous quality improvement must be embedded through the transplant system—including OPOs and donor hospitals, not just transplant centers—to improve and reduce variations within the transplant process. These efforts should begin with identification of potential transplant candidates and continue through post-transplant care and should align with the performance metrics described above. We stress that patient and community voices must be included in this process and that stakeholder representation should be required during program creation, evaluation, and policymaking.

In addition to existing collaborative improvement projects, we recommended the establishment of regional quality improvement collaboratives and networks to promote dissemination of best practices and lessons learned, with the goal of creating high value, high performing transplant processes and systems, improving relationships between all entities involved in the transplant process, and ensuring exceptional care for transplant patients and their families. Other than the Individual Member Focused Improvement pilot initiative, there are currently few resources for developing and adhering to best practices for processes such as creation of patient family advisory boards and provision of quality improvement team education. The OPTN should develop and require participation in training and peer mentorship programs for each stakeholder in the process, including donor hospitals, OPOs, and transplant centers. Critical to quality

improvement is the systematic sharing of best practices, both by OPTN and other nexuses of the transplant process, including OPOs and transplant centers. This will require active cultivation of a collaborative model of information sharing and the development of a platform through which entities are able to do so easily.

<div align="center">*************</div>

We thank HRSA for this opportunity to provide feedback on this request for information regarding *Ways to Strengthen and Improve the Organ Procurement and Transplantation Network.* We are happy to serve as a resource and look forward to working alongside HRSA in the future on this matter.

Sincerely,

Albert Faro, M.D.   Mary Dwight

Vice President, Clinical Affairs   Chief Policy and Advocacy Officer
Cystic Fibrosis Foundation   Cystic Fibrosis Foundation

Cover Page

Business: DaVita, INC

Notice Number: HSB115C1031

Title: Organ Procurement and Transplantation Network (OPTN) RFI

Date of Issuance: 04/08/2022

Point of Contact:

Kayla L. Amodeo, PhD
Director, Government Affairs
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202-210-1797

May 9th, 2022

Office of Acquisition Management & Policy
HHS/HRSA/OAMP
5600 Fishers Lane,
Rockville, MD 20857-5600

Submitted via email to NInazawa@hrsa.gov

RE: [HSB115C1031] Organ Procurement and Transplantation Network (OPTN) RFI

DaVita is pleased to respond to the Request for Information; Organ Procurement and Transplantation Network (OPTN) RFI. We are dedicated to transforming the delivery of kidney care. Today, our more than 65,000 teammates care for more than 200,000 patients receiving dialysis. DaVita supports our patients across the kidney care continuum – educating them prior to a diagnosis of end stage renal disease (ESRD) and helping them elect the treatment option of their choice. DaVita is the nation's largest home dialysis provider, and our growth in home continues to outpace our in-center growth. We also are proud to have supported more than 100,000 patients in receiving a kidney transplant over the past two decades.

We appreciate HRSA's efforts to increase accountability in OPTN operations, enhance the usability and performance of the OPTN IT system and related tools; and strengthen equity, access, and transparency in the organ donation, allocation, procurement, and transplantation process. DaVita is equally committed to improving the uptake of transplantation equitably across the patient population. With respect to transplantation, we recently augmented our existing capacity to track referrals and waitlist status by overlaying an innovative software tool that streamlines the evaluation process and other steps necessary to remain active on the waitlist. We are focused on closing equity gaps at every step of the kidney care journey. We believe more must be done to address racial and ethnic disparities in the incidence and prevalence of kidney disease and opportunities to receive a transplant. DaVita has taken several steps to advance our health equity goals including work to ensure that our education programs are culturally competent and meet our patients' diverse needs.

Our responses to several questions can be found below. As a note, some of these responses were also submitted to the Centers for Medicare and Medicaid Services in response to *CMS-3409-NC – Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities.* We found that some of our responses were worth reiterating in this RFI.

OPTN Technology - IT System

(A.1.a) 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.

We would suggest that any "cloud-native" platform will very likely need to be a FedRAMP (likely High Baseline) authorized solution. This would address many of the operational and security-related items viz-a-viz the underlying NIST 800-53 control requirements (currently rev 4 with a transition this year to rev 5). AWS GovCloud and Google's Government cloud (as well as Salesforce and Azure) have heavily templated FedRamp authorized (ATO) infrastructure for meeting or exceeding those stringent requirements, including security, reliability and performance requirements. There are roughly 425 mandated controls that a FedRAMP High Baseline ATO covers, a significant portion that can be inherited from the underlying "gov cloud".

Additionally, DaVita suggests that a modern PaaS+SaaS, built atop those gov clouds' serverless/containerized control plane, using their elastic compute and storage capabilities, should offer superior price-to-performance compared to on-prem options, with a capital-efficient ramp-up, and a highly automated operating model without the legacy high fixed labor costs. We believe this would provide a significant benefit, as these clouds also bring advanced analytical, real-time, and ML/AI capabilities "off the shelf" that would help address innovation challenges along the axes noted by HRSA such as transparency, equity, and agility.

(A.1.b) 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.

DaVita believes having standard APIs from UNET data sources would allow our systems to integrate more easily and facilitate the needed transparency to help with the referral and maintenance process. For example, standard Blue Button-like APIs to allow patients to access and grant access to their data, ideally in a FHIR data format.

We also encourage a machine-readable policy specification API and central database maintained by OPTN that clearly defines individual transplant center selection criteria. The creation of API access to this database would also assist patients and other providers in the organ waitlisting process.

Overall, more timely sharing of clinical information will better ensure that all providers have a complete understanding of a patient's health status, which is essential to the effective management of kidney disease. We encourage CMS to support policies that facilitate data sharing with patients' consent as part of its work on data interoperability regulations through the Medicare Blue Button Initiative and with the Office of the National Coordinator for Health Information (ONC).

<u>Increasing Organ Donation and Improving Procurement</u>

(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.

DaVita appreciates the roles that the agencies (CMS, HRSA, and the FDA) play in regulating the diverse group of providers and organizations that comprise our nation's transplant ecosystem. Each provider and organization have specific responsibilities in helping patients and their families navigate the transplant process. As such, the regulatory framework must hold the appropriate entity accountable for aspects of the transplant process within its control. At the same time, the involvement of multiple Department of Health and Human Services (HHS) agencies necessitates strong coordination to minimize overlapping or conflicting regulations, which contribute to inefficiencies, can cause delays at various decision points, and create unnecessary burdens for patients and their families.

Regulatory overlap occurs with respect to patient education, social work, and nutrition services requirements. We strongly agree that patients need and benefit from multiple contacts to ensure they have the information and support to navigate the transplant process. However, the current approach can result in a process that can seem disjointed for patients and their families. As part of the work to harmonize policies, we encourage HRSA to consider and revise requirements in these areas to ensure delivery of comprehensive and cohesive services.

We also recommend that the agencies review conditions for coverage (CfC) requirements to identify those that may inhibit dialysis centers from performing certain elements of the pre-transplant waitlisting workup upon a transplant center's request. Clearer rules regarding arrangements with dialysis facilities for this purpose could alleviate backlogs in processing referrals that some transplant centers have experienced due to ongoing staffing shortages, which have been further exacerbated by the public health emergency (PHE). Specifically, we encourage the agencies to clarify the CfCs such that transplant centers are allowed to enter arrangements with dialysis facilities to conduct aspects of the pre-transplant waitlisting workup. Additionally, given that laboratory tests comprise much of the workup, the agencies could clarify that any laboratory test ordered on behalf of a transplant center would qualify for an AY modifier and reimbursement outside of the ESRD Prospective Payment System (PPS) bundle. Coordination of laboratory draws would further reduce patient burden and costs, while improving dialysis facility and transplant center efficiencies.

In addition, we encourage the agencies to collaborate on a minimum, uniform data set to be transacted between dialysis facilities and transplant centers for initial listings and maintenance of listings. A defined data set would mitigate inefficiencies that result from variability in required elements across transplant centers. Differences in data elements also contribute to unnecessary confusion for patients who receive similar, but not identical, information from various transplant centers. Although not necessarily a condition of participation (CoP) or CfC-related matter, it also would be helpful for CMS to support development and adoption of technological advances that

promote better data flow and communication between all providers involved in caring for patients pursuing a transplant. Improved communication would enhance the efficiency and efficacy of the waitlisting process and provide much needed, real-time transparency to patients, transplant centers, and dialysis facility staff.

(E.2) What additional research could contribute to improving organ procurement?

HRSA should consider additional research on issues related to health literacy and cultural sensitivity that affect patients' ability to understand and accept the information regarding transplantation and organ donation. Although there may be opportunities to address these issues through the CoPs/CfCs, other steps including additional support for broad-scale information campaigns, grants to support community outreach, and public-private education partnerships could be helpful.

Stakeholder Engagement

(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.

Improving transplant education and creating better connections within underserved communities about organ donation depend on all participants in the transplant ecosystem conveying consistent information with one voice. HRSA and other agencies, such as CMS, could advance this work by convening stakeholders to support the development of unified messaging and clear, non-branded materials accessible to patients with differing levels of health literacy for patient advocacy groups to use with patients. Partnering with local organizations and applying strategies, such as peer support and community leader involvement, also should be considered as part of these efforts.

In addition, steps are necessary to address other barriers that can disproportionately affect transplant opportunities for patients from underserved communities, including lack of reliable transportation to medical appointments necessary to secure and maintain a waitlist placement; limited incomes to meet cost sharing obligations; and transplant centers waitlist criteria, such as requirements for dental clearance and the availability of post-transplant insurance coverage.

The Agencies should consider policies that would allow providers to use incentives/rewards to promote patient engagement in behaviors and activities that can help them stay transplant ready. A growing body of research demonstrates the role financial incentives play in supporting behavior modifications. DaVita believes that subject to sufficient protections to ensure the right motivations and protect against abuse, cash incentives can be effective in promoting greater uptake of interventional services and recommended lifestyle changes, that will help patients stat transplant ready. We have and continue to encourage the Office of the Inspector General (OIG) to amend the existing "Patient Engagement and Support Safe Harbor" (42 CFR §§1001.952(he)) to permit these types of beneficiary incentives.

<u>Conclusion</u>

DaVita appreciates that the breadth of questions reflects the ecosystem's intricacies. Although we limited our responses to certain sections, HRSA should not construe this approach to indicate that we view questions posed in other sections as less critical. Rather, we focused on areas in which we believe we could offer the most thoughtful and informed recommendations. If you have questions or need any additional information regarding any portion of these comments, please contact Kayla L. Amodeo, PhD, Director of Government Affairs at kayla.amodeo@davita.com or via phone at 202-210-1797.

Sincerely,

Kathleen A. Waters
Chief Legal and Public Affairs Officer

May 6, 2022

Agency/Office: HHS/HRSA/OAMP
Contracting Office Location: 5600 Fishers Lane, Rockville, MD.
Title: Organ Procurement and Transplantation Network (OPTN)
NAICS Code: 541611

RE: Organ Procurement and Transplantation Network (OPTN) RFI

To Whom It May Concern,

Global Liver Institute (GLI) is a nonpartisan, nonprofit patient advocacy organization committed to improving the lives of individuals and families impacted by liver disease by promoting innovation, encouraging collaboration, and scaling optimal approaches to help eradicate liver diseases. As the only global liver health organization, we hear the concerns of our patients and transplant professionals regarding the current inequity within the organ donation, recovery, and transplant system. Central to improving the organ donation and recovery system, and addressing health inequities, is to ensure the network responsible for the technology that connects the organ transplant ecosystem as well as overseeing the country's 57 OPOs is modernized.

Each year, more than 28,000 viable organs are wasted - including almost 8,000 livers. 33 Americans die every day due to lack of an available organ for transplant.[1] With 95% of Americans supporting organ donation, more Americans would have a chance at a life-saving organ transplant if the government contractors on the frontline of coordinating donation – OPOs – were effectively performing their required duties.[2]

On average, before the COVID-19 pandemic, there were more than 13,000 liver patients in the U.S. waiting for a lifesaving transplant every year and three people would die everyday waiting.[3] Now with the increased risk of organ failure in addition to the serious health outcomes due to COVID-19, and the shifting of hospital resources to respond to COVID-19, those same patients with liver disease on the waiting list are at an even greater risk of death.[4] [5]

Every step within the organ donation and recovery process is an opportunity for inequity to arise and result in disparate access to organs for typically underserved patients of minority race, ethnicity, and low socioeconomic status.[6] This fostering of racial discrimination is no more evident than when we consider the complete lack of transparency in the current OPO process and response to donation and recovery data.

People of color are 1.5 to 4 times more likely to have conditions leading to kidney and liver failure, but less likely to receive transplants.[7] Lower referral rate for liver transplant and inferior outcomes among Black and Latinx compared to White patients[8] in addition to race/ethnicity, sex, and health literacy strongly correlated with the likelihood of listing.[9] OPO staff are less likely to approach families of color for consent, engage in less frequent conversations, spend less time in those conversations, and demonstrate bias in assumptions of who would be eligible or willing to donate.[10] [11] [12] Research shows that the family of a Black patient is only about half as likely to even be approached by an OPO as that of a White patient's family and, even when they do show up, OPOs provide families of color with inferior and less compassionate treatment.[13] [14]

Connected to this point is the reality that inequity within OPOs has been perpetuated by a convoluted governance structure. As you know, while Health Resources and Services Administration (HRSA) is responsible for the regulation, oversight, and awarding of the contract for the Organ Procurement and Transplantation Network (OPTN), the Centers for Medicare & Medicaid Services (CMS) pays for much of the network through transplant listing fees to the OPTN and its contractor UNOS (which the Senate Finance Committee identified as a potential double charging) and reimburses OPO expenses. This dual responsibility leads to both CMS and HRSA/OPTN overseeing OPOs - along with the OPTN - and creating opportunities for equity to fall through the cracks.

Adding to the governance challenges, each OPO uses a variety of software solutions increasing the strain on the ability of HRSA, CMS, or the public to have the critical window needed into health equity data, and to make smarter, data-driven management decisions in response. You also know that HRSA has few tech staff to effectively audit or implement technical best practices. To underline this point, most of the software used is considered closed and proprietary, blocking any chance of innovation or competition from outside actors. What's more, alumni of the United States Digital Service (USDS) have called existing OPTN contractor technology "antiquated," noting alarming statistics such as 17 percent of kidney offers going to dead people, and hundreds of organs getting lost in transit on UNOS' watch. Put simply: the status quo is a failure, with damning statistics showing that the "OPTN and OPOs are mischaracterizing organ donation data to block system reform."

To this end, the entire system needs to be modernized, with highly competent leaders at the helm. The organ donation system should be pushing technology forward, and supporting a market of innovative technology options to address transplant health equity issues. In response, we urge HRSA to take vital actions that would elevate equity in donation, recovery, and transplantation, and address organ donation inequalities:

1. Work with CMS to hold OPOs accountable for their performance using transparent, reliable, and public data to show evidence of effectiveness and equitable service; and work with CMS on increasing training quality for OPO staff requesting authorization from families of donors to include communication best practices, implicit bias, and trauma-informed care; and standardize protocols for hospitals on identifying and referring potential donors.
2. Ensure adequate agency support and staffing of OPTN, aided by experts from the USDS, and that future OPTN contractors use open-source, cloud-based technology, and that OPTN contractor(s) are collecting and publicly releasing data to allow for timely, critical insights into evidence of effective and equitable patient care.
3. Increase competition by subdividing the OPTN contract into the core functions of policymaking and technology, and opening the technology component to all innovators, and eliminate the need to designate as many organ donation functions and objectives to one contractor; in the process, reabsorbing OPO oversight within HHS due to OPTN failures to serve this function.
4. Reform and deconflict OPTN governance so that the OPTN board is separate from the boards of any OPTN contractors, and that all potential conflicts of interest of board members are immediately disclosed.
5. Invest resources in culturally appropriate education, and work collaboratively with the patient advocacy community on awareness efforts.
6. Centralize governance and oversight to contractors working on organ donation within one department at HHS.

The passing of the "[Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations](#)" (OPO Final Rule) was a step forward to improved quality and greater transparency requirements for OPOs. HRSA should match this data-driven, pro-patient reform with reforms of the OPTN so that going forward there is institutional-level awareness and structural competency to promote true health equity within the organ donation system. We plead for HRSA to consider the previously highlighted actions, and put in place infrastructure with the accountability to address health inequities. This process begins with critical self-assessment and training on how staff behaviors by government organ contractors (both OPOs and the OPTN) and institutional racism directly contribute to inequity in transplantation. We also must modernize the technology used as a matter of urgency, to put the lives of patients, the hopes of donor families, and innovation at the forefront.

As a liver health advocacy organization, we speak with transplant patients and families, physicians and coordinators hoping to save their patients' lives every day. We are united in our conviction that we are finally on the brink of creating a properly functioning organ donation system. We look forward to working collectively to improve the organ donation system. If you have any questions please don't hesitate to reach out to Global Liver Institute's VP of Policy and Public Affairs, Andrew Scott, at ascott@globalliver.org or 831-246-1586.

With appreciation and respect,

Global Liver Institute

Global Liver Institute is a 501(c)3 non-profit organization founded in 2014 by Donna Cryer, who received a life-saving liver transplant in law school after years of living with an autoimmune disease. On the 20th anniversary of her transplant, she realized her experience as a patient, lawyer, and professional health systems consultant could help fellow patients and those impacted by liver disease.

Our values of patient-centeredness, collaboration, integrity, inclusion, and results drive our mission to improve the lives of individuals and families facing liver-related issues.

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[1] https://www.washingtonpost.com/graphics/2018/national/organ-transplant-shortages/?utm_term=.e38eb78b98aa

[2] https://www.organdonor.gov/statistics-stories/statistics.html#donation

[3] Organ Procurement Transplantation Network, U.S. Department of Health and Human Services

[4] https://www.journal-of-hepatology.eu/article/S0168-8278(20)30305-6/fulltext#%20

[5] https://natap.org/2020/AASLD/AASLD_116.htm

[6] https://aasldpubs.onlinelibrary.wiley.com/doi/10.1002/hep.31986

[7] https://bloomworks.digital/organdonationreform/Inequity

[8] Wahid N, Rosenblatt R, Brown RSJ. A review of the current state of liver transplantation disparities. Liver Transplant 2021;27:434-443.

[9] Bittermann T, Dwinnells K, Chadha S, Wolf MS, Olthoff KM, Serper M. Low health literacy is associated with frailty and reduced likelihood of liver transplant listing: a prospective cohort study. Liver Transplant 2020;26:1409-1421.

[10] Guadagnoli E, McNamara P, Evanisko MJ, Beasley C, Callender CO, Poretsky A. The influence of race on approaching families for organ donation and their decision to donate. Am J Public Health. 1999;89(2):244-247. doi:10.2105/ajph.89.2.244

[11] https://journals.lww.com/ccmjournal/Abstract/2003/01000/Comparison_of_black_and_white_families_.23.aspx

[12] https://link.springer.com/article/10.1007/s40615-020-00806-7

[13] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1508526/

[14] https://link.springer.com/article/10.1007/s40615-020-00806-7

COVER PAGE

Notice Number:	HSB115C1031
Title:	Request for Information on the Organ Procurement and Transplantation Network (OPTN)
Date of Issuance:	April 8, 2022
Name:	Kidney Transplant Collaborative
Address:	2020 Pennsylvania Avenue NW
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Phone:	+1 202-508-1470
Email:	ldiamond@kidneytransplantcollaborative.com

May 9, 2022

Via Electronic Submission to NInazawa@hrsa.gov

Health Resources and Services Administration
Department of Health and Human Services
Office of Acquisition Management & Policy
5600 Fishers Lane
Rockville, MD 20852

RE: Request for Information by the Health Resources and Services Administration regarding the Organ Procurement and Transplantation Network (OPTN) – Notice # HSB115C1031

To Whom it May Concern:

The Kidney Transplant Collaborative ("KTC") thanks the Health Resources and Services Administration ("HRSA") for the opportunity to respond to its Request for Information ("RFI") seeking to strengthen and improve components of the Organ Procurement and Transplantation Network ("OPTN") contracting process.[1] We specifically offer comments on how HRSA can increase organ donation with a focus on improving kidney donation by incorporating several of the recommendations made by the National Academy of Sciences, Engineering and Medicine ("NASEM") in its recent February 2022 report on transplantation. We hope our comments will aid the Office of Acquisition in both improving OPTN operations and in improving patient outcomes and significantly increase donor organs utilization for transplantation, thereby also increasing transplantation equity and accessibility.

About KTC:

KTC is a national non-profit advocacy organization that is dedicated to increasing kidney transplants while decreasing the financial obstacles and other challenges kidney recipients, donors, and families often experience during the kidney transplantation process. KTC is a relatively new organization, founded in February 2021, with the sole and specific mission of supporting programs and policy solutions to increase kidney transplants and reduce transplant barriers. KTC has engaged experts with technical, clinical, and quality expertise from the renal

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[1] *See* Press Release, Health Resources and Services Administration, HHS Releases Request for Information on Ways to Strengthen and Improve the Organ Procurement and Transplantation Network (April 8, 2022) https://www.hrsa.gov/about/news/press-releases/hrsa-releases-organ-procurement-transplantation-network-rfi.

and transplant community to serve on the Board of Directors and Expert Advisory Panel (EAP), who assess the organization's grant and policy priorities.

In the past four months, KTC has authorized approximately $3.2 million to fund five grant proposals directed towards increasing kidney transplants. The grants will address pulstile perfusion of kidneys from procurement to delivery, using machine learning to improve utilization and reduce discards, using shared decision making in the kidney transplant process, rapid organ recovery from donation after uncontrolled circulatory death, and exploring deceased kidney donor chains. Notably, following the kickoff of its grant program in mid-2021, KTC received nearly four times the anticipated number of grant proposals from nationally recognized institutions across the country, with 70 different proposal seeking over $43 million in funding. Several common themes and issues emerged from the proposals, including improving living donor compensation, expansion of paired and chain kidney donation programs, patient engagement regarding organ acceptance and discard rates, and transplant waitlist management. Projects proposed various strategies to address these issues, including educational, medical and technological interventions, engaging in strategic partnerships and implementing creative models to address staffing, processes and organizational infrastructure.

We highlight our recent experience because the grant proposal response, as well as the information contained in the proposals, underscores that significant gaps continue to be prevalent in the kidney transplant system today which the upcoming HRSA contract could address.

RESPONSE TO QUESTIONS:

HRSA Question F: "Organ Usage -- The NASEM report identifies concerns with the current high level of organ non-usage (discards), estimated at an unacceptable 25%. Over the past several years, the OPTN Collaborative Improvement and Innovation Network (COIIN) projects and the current CMS/HRSA End Stage Renal Disease Treatment Choices Learning Collaborative (ETCLC) have worked to build and share best practices models to aid the community in addressing variables that adversely impact organ usage. HRSA is seeking feedback related to the following questions on increasing organ usage and simultaneously decreasing organ non-usage (discards).

> 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.

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

> 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."

KTC Response: KTC applauds HRSA's request for this information and urges the upcoming procurement to address the issues identified in the NASEM Report. As identified in the report, organ discard rates are unacceptably high, and many discarded organs represent a lost transplant

opportunity to an individual on the waiting list. For this reason, we urge HRSA to incorporate the following recommendations of the NASEM Report, including those addressing organ discard rates:

- Improving equity (Recommendation 3);

- OPTN accelerate continuous distribution framework (Recommendation 4) and eliminate pre-dialysis waiting time (Recommendation 5);

- OPTN resolve discrepancies in organ allocation algorithms, (Recommendation 7), including the calculation of eGFR;

- Increased transparency around organ offers/declines and engagement and partnership with patients; (Recommendation 10);

- Align reimbursement with decided behavior and outcome (Recommendation 14);

- make it easier for transplant centers and surgeons to say yes to organ offers and ensure transplants can occur seven days per week (accounting for the "weekend effect") (Recommendation 9);

- Development of national quality goals (Recommendation 1), including development of a national quality dashboard and partnership with the National Quality Foundation;

- Require donor care units for each OPO (Recommendation 11);

- Embed Quality Improvement across the transplantation system (Recommendation 13);

- Improve OPTN policy making process (Recommendation 2); and

- Create a state-of-the-art data system (Recommendation 8).

We appreciate that many of these recommendations touch on other questions posed in the RFI, but urge HRSA to take a broad and expansive view of the recommendations identified above as we believe they will fundamentally alter and improve the transplant process for all stakeholders. For example, improving health equity within the transplant program will result in less discarded organs, as well as deliver numerous other tangible benefits to the transplant program. Similarly, requiring that the OPTN implement practices across the country to ensure that transplant centers "say yes" to available organs, and also address the delays in scheduling procedures due to the "weekend effect" will significantly improve transplant programs across the country.

The NASEM report includes numerous comprehensive recommendations on each of the subject areas noted above, as well as those addressed in several of the other questions posed in the RFI. We encourage HRSA to incorporate the NASEM proposals identified in the above response in its upcoming OPTN bid documents.

****

We again thank HRSA for its thoughtful and wide-ranging RFI and hope the above comments will assist the Agency if further formulating new policies to address and improve kidney transplantation in the United States through the upcoming OPTN contract process. As the Agency itself points out, the current waiting list is too long and growing, and more needs to be done to increase kidney transplants across our country. We welcome further partnership with HRSA on these important issues. To that end, we thank you for consideration of these comments and welcome any questions or follow up that you may have.

Please feel free to contact me at 301.832.2734 or ldiamond@kidneytransplantcollaborative.com if we can provide any additional information.

Sincerely,

Louis H. Diamond

Dr. Louis Diamond
President & CEO
Kidney Transplant Collaborative (KTC)

Request for Information (RFI) seeking input on ways to strengthen and improve the Organ Procurement and Transplantation Network (OPTN) through the upcoming Fiscal Year 2023 Request for Proposal (RFP)[12]

Response from MOTTEP

Clive O. Callender, MD
Transplant Surgeon and Professor of Surgery, Howard U. School of Medicine

Velma P. Scantlebury, MD

Transplant Surgeon and Professor of Surgery, Texas Christian University and Medical School

According to the announcement the RFI will+ support HRSA's efforts to increase accountability in OPTN operations, modernize performance of the OPTN IT system and related tools, and improve engagement with donors and patients…opportunities to strengthen equity, access, and transparency in the organ donation, allocation, procurement, and transplantation process in the contract arrangement that results from the forthcoming RFP… RFI *specifically solicits feedback on ways to incorporate the findings and recommendations of the February 2022 National Academies of Science, Engineering, and Medicine (NASEM) report titled Realizing the Promise of Equity in the Organ Transplantation System,*

This response is to section E of the RFI. [3] Below is the verbatim to NASEM, from the founder of MOTTEP (The National Minority Organ Tissue Transplant Education Program)[4] CEO Dr. Clive O. Callender, which directly addresses the issues of equity, access and transparently in organ donation, allocation, procurement and transplantation and racism. [5] This is followed by additional information and recommendations to address racial and ethnic inequities and disparities of organ transplantation.

I. **Aligning Incentives: What can be done to increase the Efficiency and Effectiveness of the Organ Transplant System**?

Presented to the National Academies of Science, Engineering Medicine

Thursday, July 15, 2021 11AM- 3:15PM

I am Dr. Clive Callender, Founder of National MOTTEP (The National Minority Organ Tissue Transplant Education Program) and Professor of Surgery at the Howard University College of Medicine. I have been a Transplant Surgeon since 1973.

Systemic (Institutionalized) Racism results in deep rooted conscious or subconscious classification of ethnic groups into superior and inferior classes and may be the most important obstacle to overcome as we try to eliminate its devastating negative impact on those deemed

inferior.

The following recommendations may help increase the effectiveness of our organ transplant system (which impacts dialysis and transplant patients).

1. Put in place dialysis and transplant <u>Advocates</u> and <u>Navigators.</u> There are many obstacles to getting a transplant and getting on dialysis. Many of these can be helped by providing this support for dialysis and transplant patients.
2. Provide literature for dialysis and transplant patients that is more culturally competent and linguistically appropriate and at the literacy level of these patients.
3. Ensure that the options for treatment of end-stage renal disease which should include transplantation is presented to dialysis patients in a manner that accurately reflects the mortality and quality of life difference between both options. (The annual mortality rate for dialysis patients is 10-20 times that of transplantation). Is there evidence that these options are clearly explained and understood?
4. Emphasize diversity and the use of more underrepresented minorities in the medical and the scientific presentations to elementary school levels and above.
5. Include more of the dialysis and transplant patients, community and social factors in the management plans and in all aspects of the Patients Care. Is it appropriate for one Social Worker to be assigned to multiple Dialysis Units? How can they effectively do their job?
6. Educate all Dialysis and Transplant Health Care Professionals about their implicit and explicit biases, and the impact these biases can play out as inappropriate treatment of patients.
7. Use culturally competent and linguistically appropriate mentors for all dialysis and transplant health care professionals regardless of their ethnicities.
8. Employ systems which make it comfortable and safe for dialysis and transplant patients to report racially inappropriate behavior without fear of reprisal.
9. There is the need for the development of a National Strategic Plan with goals and implementation dates which allow for community participation in an effort to eliminate Institutionalized (Structural) Racism in the organ transplant system.
10. There is the need for the majority and the minority communities to work together with dialysis and transplant health professionals to aggressively eliminate Systemic Racism.
11. There is the need for greater involvement of the minority communities in the education of the way to prevent the maladies identified by the adoption of healthier lifestyles.

Finally, these are some measures we can take to help eliminate the negative impact of Racist Policies and Practices, and to help provide more accountability when racist behaviors occur within the Organ Transplant System. These will help increase the efficiency and effectiveness of the Organ Transplant System, as it impacts all its participants.

ll. The lack of equity of organ transplantation for persons identified as "minorities" is well known.

African Americans make up the largest numbers of persons needing transplants in the USA. Yet according to the HHS Office of Minority Health, only 27% of Blacks, 30% of Latinos vs 47% of Whites on transplant waiting lists receive organ transplants. When one looks at the most common type of transplant, kidneys make up 84%.[6] Blacks have the highest burden of renal disease, followed by Latinos and Native Americans[7] due to the higher prevalence of hypertension and diabetes, leading to higher rates of end stage renal disease and the need for transplant. The misconception of "matching" within communities of color. The emphasis should be on compatibility, understanding the options for treatment, getting to the starting line with beginning the evaluation process and navigating the process, which includes getting on the waitlist or completing the evaluation for a living donor transplant.

III. Living Donations in African Americans is significantly below that of whites: In 2020, 16.4 percent of blacks were living donors as compared to 33.4 percent of white living donors. Much more needs to be done to educate minority communities about not only deceased donor transplantation but the benefits of living donation, while addressing the fears and reluctance of being a living donor. It should not be left up to the transplant centers and OPO's to address this need, as many do not have the culturally sensitive personnel to meet patients in their communities. The data also shows that non-whites have lower rates of pre-emptive kidney transplantation, especially for living donation. It is important to highlight these disparities and use fund opportunities to educate our communities of color.

IV. What else needs to be done in addition to addressing the disparities, and increasing the equity in transplantation in a culturally and linguistically appropriate manner as addressed by Dr. Callender at NASEM and through MOTTEP?

V. First we must help ourselves. So, in addition to MOTTEP, the nation's four HBCU medical schools [Charles R. Drew Medical School in Los Angeles, Howard University College of Medicine in Washington, D.C., Meharry Medical College in Nashville, and Morehouse School of Medicine] and members of the organ donation and transplantation community, today announced an initiative to increase the number of Black registered donors and transplant recipients and save thousands more lives. The initiative was spurred by the HBCU Medical Schools Collaborative and the Organ Donation Advocacy Group (ODAG)[8]to address the need for improved equity in the field of organ donation and transplantation and will involve the Association of Organ Procurement Organizations (AOPO)[9] and other donation and transplant organizations and experts."…. "Minorities and people of color have been consistently underrepresented throughout medicine, and the field of organ and tissue donation and transplantation is no exception," …This collaboration will allow us to save thousands of lives across the country by strengthening relationships between healthcare workers, Black and minority patients, and organ and transplantation professionals." 10

Many of the activities they will be focused on dovetail with those discussed by Dr. Callender at NASEM:

a. The use of mentoring and shadowing programs, that educate and expose our children to health careers in STEM as well as transplantation;

 b. the use of culturally and linguistically appropriate educational materials about transplantation for dialysis patients;

c. health fairs, organ donor drives providing education about living, deceased organ donation;

d. collaboration with faith base leaders and congregations;

e. Collaborating HBCUs that offer programs in nursing, public health, public policy and healthcare administration.

VI. Diverse individuals must have a seat at the table to participate in the authority, finance and control, in order to change the paradigm from health disparity to true health equity. This means there must be more oversight of the AOPOs. The presence of diverse representation at the highest administrative level must be a requirement. AOPOs compliance in this regard must be monitored. In addition, there must be mentoring, opportunities and funding for the education, training and fellowship to allow for the advancement of persons of color for these positions.

VII. Communities and organizations of color must have a share of the funding. This RFP is written to seek input to strengthen and improve the OPTN when it comes to addressing the inequities in transplantation. This information for request for RFI must give priority in notification to organizations of color. Priority in funding should be given to organizations made up of women of color and minorities-led programs. Specific allocations of funding in amounts proportional to the need for transplantation must be allocated in all of the areas related to Organ Transplantation for true change to occur. It is only in this way that OPTN can achieve health equity in organ transplantation. Persons of color, especially from HBCUs as well as persons of color from other institutions such as Hispanic serving programs, and Black organizations must have input and contribute to the writing of the RFP, as well as grant reviewers and grant recipients of the funding.

VIII. Transplant recipients and prior living donors as well as deceased donor families should be included and must also be at the table so that their voices can be heard for the entire process.

IX. An area that is discussed secretly is the role that Poverty and the social determinants of health play in Transplant Outcomes. Transplanting Poor and Black Patients results in poorer outcomes. This discourages Transplant Centers from transplanting those patients which are in this category. They are often rejected for transplantation because transplanting them will decrease transplant outcomes and this may result in the Transplant Centers becoming decertified. A system must be put in place that does not penalize a Transplant Center for transplanting such high-risk patients. This phenomenon is important but never discussed. This is a form of Institutionalized Racism and Bias that keeps the socio-economically deprived patients from being transplanted.

Regional and National paired donations are performed but they rarely benefit people of color, in the way that local paired donations do. Encouraging local paired donations is more beneficial to people of color; and is an option that should be incentivized and encourage.

X. There are 57 OPO's very few of these OPO's have persons of color at the highest administrative level (CEO or Chairperson of the Board of Directors). It is important therefore to increase the number of minorities (people of color). Nearly 60% of people waiting for transplant are minorities. Steps must be taken to provide oversight of the OPO high administration and Board of Directors membership at the Executive levels. This would require an Oversight Body that looks closely at their hiring policies and practices and ensure that OPO's significantly increase the number of minorities at the highest Executive levels and monitors their use of these exclusionary practices. Systems should be put in place to monitor OPO compliance in order to significantly increase the number of minorities in these positions. Oversight of this executive level disparity is completely lacking and is desperately needed now. This kind of oversight process is utilized in the National Football League and several other professional sports where minority participation at the Executive level is scarce.

Thank you for the opportunity to provide input.

References:

[1] https://www.hrsa.gov/about/news/press-releases/hrsa-releases-organ-procurement-transplantation-network-rfi, accessed May 5, 2022

[2] file:///C:/Users/traik/Downloads/OPTN+RFI+(4.8.22).pdf , accessed May 5, 2022

[3] E. **Increasing Organ Donation and Improving Procurement**
The NASEM report identifies concerns with organ donation rates, including geographic and demographic variations. HHS is actively taking steps to enhance the accountability of Organ Procurement Organizations (OPOs). HRSA is seeking feedback on the following questions regarding increasing the donation of organs and improving the procurement of organs. 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.2. How could the OPTN facilitate OPO engagement in research protocols to improve procurement?3. What additional research could contribute to improving organ procurement?4. How can HRSA best incorporate the NASEM report's recommendations on increasing equitable access to transplants?

[4] https://www.natlmottep.org/, Access May 5, 2022

[5] https://pubmed.ncbi.nlm.nih.gov/28238984/

[6]In the United States, the most commonly transplanted organs are the kidney, liver, heart, lungs, pancreas and intestines. On any given day there are around 75,000 people on the active waiting list for organs, but only around 8,000 deceased organ donors each year, with each providing on average 3.5 organs. Living donors provide on average only around 6,000 organs per year…. In the U.S, the most commonly transplanted tissues are bones, tendons, ligaments, skin, heart valves, blood vessels and corneas.
https://www.cdc.gov/transplantsafety/overview/key-facts.html , accessed May 5, 2022[7]

https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=27 , accessed May 5, 2022

[8] Organ Donation Advocacy Group (ODAG) ODAG is a working group of Organ Procurement Organizations (OPOs) dedicated to improving the nation's organ donation and transplantation system in order to save and heal more lives. ODAG collaborates with clinical colleagues, government entities and community partners to increase organs available for transplants, reduce disparities in donation and transplantation, drive innovation in the field, and advocate for policies that support system-wide reform.

[9] AOPO is the not-for-profit association leading the nation's Organ Procurement Organization (OPO) community to save and improve lives through organ, eye, and tissue donation. AOPO collaborates with system stakeholders to facilitate the continual advancement of the organ donation and transplantation process, focusing on advocacy, data-sharing, and education. Its 50K annual organ transplants in 2026 goal aims to reduce health inequities and increase the number of organ transplants in underserved communities. For more information, please visit www.aopo.org.

10. https://www.wjtv.com/living-local/focused-on-health/hbcu-medical-schools-to-tackle-organ-transp lant-disparities/?IPID=Health?ipid=promo-link-block1

Cover Page

Organ Procurement and Transplantation Network (OPTN)
Request for Information
Notice ID: HSB115C1031

Submitter:

New Jersey Organ and Tissue Sharing Network
691 Central Avenue
New Providence, NJ 07974

Point of Contact:

Joseph Roth
President and CEO
908.516.5605
jroth@njsharingnetwork.org

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NJ Sharing Network
saving lives through
organ and tissue donation

May 9, 2022

Ms. Carole Johnson
Administrator
Health Resources & Services Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

RE: Request for Information: Organ Procurement and Transplantation Network (OPTN)

Dear Administrator Johnson:

On behalf of the New Jersey Organ and Tissue Sharing Network (NJ Sharing Network), the organ procurement organization (OPO) serving New Jersey and affiliated with 56 tertiary care donor hospitals, we appreciate the opportunity to provide comments in response to the Health Resources & Services Administration (HRSA) Request for Information (RFI) on the Organ Procurement and Transplantation Network (OPTN). As an OPO, NJ Sharing Network is responsible for the recovery and placement of donated organs and tissue for the nearly 4,000 New Jersey residents currently waiting for a life-saving transplant. We are also part of the national recovery system, which is in place for the 110,000 people currently on the waiting list.

NJ Sharing Network believes the OPTN plays a critical role in ensuring the safety and effectiveness of the nation's organ donation and transplantation system, and we appreciate HRSA's goal of strengthening the OPTN through its next round of procurement. We offer the comments below in support of that goal.

OPTN Governance (D.1 and D.4)
NJ Sharing Network believes that changes to OPTN governance would help improve accountability and increase the effectiveness of the nation's organ donation and transplantation system. ***Specifically, we believe that the current structure – under which the same members of the OPTN Board of Directors serve on the Board of the United Network for Organ Sharing, the OPTN contractor – creates conflicts of interest that hinder the OPTN's ability to most effectively address the current challenges with organ donation and transplantation.*** The same board members are making policy decisions for both UNOS and the OPTN. This is an inherent conflict.

We further believe that the OPTN would benefit from greater representation of OPOs on the Board of Directors. OPOs serve an essential role in the organ procurement and transplantation

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process and hold a unique perspective on the challenges and opportunities facing the organ donation and transplantation system, yet their collective voice is under-represented relative to the importance of the role they play. With only 57 OPOs participating in the OPTN, compared to 252 transplant centers and 140 histocompatibility laboratories,[1] OPOs' perspectives are often drowned out by other OPTN member constituencies. Unfortunately, the OPTN charter and its parameters for composition of the Board of Directors perpetuate this disparity, requiring the Board be comprised of approximately 50 percent transplant surgeons and physicians (who often represent the interests of their transplant programs), 25 percent patients and families, and no specified percent of OPOs. ***NJ Sharing Network believes that updating minimum participation thresholds to ensure that OPOs have equal representation with transplant surgeons and physicians will help to ensure that OPOs perspectives and voices are adequately represented. We recommend allocation of board positions as follows: 25 percent for patients and families; 35 percent for OPOs; 35 percent for transplant surgeons and physicians; and 5 percent to other stakeholders.***

Organ Usage (F.3)

The RFI highlights the high rate of organ non-usage. Increasing the organ usage rate would accelerate patients' access to life-saving organs, reduce wait times on the national transplant waiting list, and ultimately save lives. However, current policies and incentive structures create barriers to optimal organ usage rates. In particular, there are conflicts between OPO donation criteria and transplant center acceptance criteria that contribute to high decline rates by transplant centers. Notably, there is also no uniformity in organ acceptance criteria across transplant centers. And tragically, once one transplant center rejects an organ, other transplant centers follow suit, assuming the organ does not meet criteria for transplantation.

In actuality, there are numerous reasons why an initial transplant center may not accept an organ for transplantation, for example a lack of available qualified surgeon, lack of patient availability, or highly conservative organ acceptance criteria. However, transplant centers' ability to understand the reason for decline is limited, based on the current limitations in how organ rejections are coded. ***Expanding the options for coding the reason for decline and thereby increasing transparency can help to increase the rate of organ acceptance at follow-on transplant centers that are only offered organs after an initial center declines. Increasing uniformity in acceptance criteria across transplant centers would also provide OPOs a clearer roadmap for when organs would be accepted for transplantation across a wide range of transplant centers.***

Finally, we also note that ***additional data collection and public reporting on organ acceptance rates and practices would help to improve accountability of transplant program.*** Important statistics to report include the number of organs offered, the number of organs accepted or declined, and the reasons for decline. In combination with already reported metrics on transplant programs' performance, such data would help inform patients' decision-making when selecting

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[1] HRSA. Organ Procurement and Transplantation Network: About OPTN membership. Downloaded from https://optn.transplant.hrsa.gov/about/about-optn-membership/ on May 2, 2022.

transplant hospitals and increase pressure on transplant programs to accept viable organs for transplantation.

* * * *

Thank you, again, for the opportunity to offer comments in response to the HRSA OPTN RFI. If you have any questions or would like additional information, please feel free to reach out via email at jroth@njsharingnetwork.org or by phone at 908.516.5605.

Sincerely,

Joseph Roth
President and CEO
NJ Sharing Network

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REQUEST FOR INFORMATION (RFI)
Agency/Office: HHS/HRSA/OAMP
Contracting Office Location: 5600 Fishers Lane, Rockville, MD.
Title: Organ Procurement and Transplantation Network (OPTN)
NAICS Code: 5416111
Issued April 8, 2022

Penn Medicine Transplant Institute
Perelman Center for Advanced Medicine
West Pavilion, 2nd Floor
3400 Civic Center Boulevard
Philadelphia, PA 19104
Point of Contact:
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     kristen.molloy@uphs.upenn.edu

May 9, 2022

Ms. Naomi Inazawa
Department of Health and Human Services
Health Resources and Services Administration
Office of Acquisition Management & Policy
5600 Fishers Lane
Rockville, MD 20857-5600

Subject: Request for Information seeking input on ways to strengthen and improve the
effectiveness of the nation's Organ Procurement and Transplantation Network (OPTN) through
the upcoming Fiscal Year 2023 Request for Proposal

Dear Ms. Inazawa:

I am writing on behalf of the Penn Medicine Transplant Institute, at the Hospital of the
University of Pennsylvania, to convey to the Office of Acquisition Management & Policy of the
Health Resources and Services Administration (HRSA) our views on your recently released
request for information seeking input on ways to strengthen and improve the Organ Procurement
and Transplantation Network (OPTN) through the upcoming FY 2023 request for proposal.

The Penn Medicine Transplant Institute is a global leader in the field of organ transplantation.
Since developing one of the nation's first kidney transplant programs in 1966 we remain on the
forefront of the discipline, providing the latest technology and discoveries in transplantation. We
have active programs in heart, lung, liver, kidney, pancreas, living donor, islet, uterus, and hand
transplantation along with partner programs at the Children's Hospital of Philadelphia.

The Penn Medicine Transplant Institute is recognized for exceptional clinical care and
groundbreaking research. To date we have performed more than 13,000 solid organ transplant
procedures, making us the largest provider in our region and one of the busiest transplant centers
in the country. We also are leaders in innovation in both clinical care and research, as
demonstrated by the numerous clinical trials in which we participate, large translational studies,
and the highest NIH funding for any department of surgery. We serve as a top training program
for those interested in pursuing careers in the surgical or medical discipline of organ
transplantation.

The Penn Medicine Transplant Institute would like to comment on five subjects that arise from
this RFI:

- equity in access to organs (general statement)
- OPTN technology – IT system (section A)
- OPTN finances (section C)
- increasing organ donation and improving procurement (section E)
- OPTN operations and policy development improvements (section G)

We address these subjects individually below.

Equity in Access to Organs

The Penn Medicine Transplant Institute believes the current manner in which the transplantation system pursues equity in access to organs is flawed and that the next contract for operation of the OPTN creates an opportunity to address these shortcomings.

While great interest has formally been expressed in improving equity in access to organs, the current approach specifically calls for the twin pillars of equity *and* utility to be upheld in organ allocation. The current kidney and pancreas allocation scheme, however, has largely sacrificed utility, with results such as increased costs, logistical difficulties, and an increased number of discarded organs, in the announced pursuit of equity. As a result, we have found that access to organs in the Pennsylvania/New Jersey/Delaware region that our program primarily serves has become significantly worse because the current distribution methodology so strongly favors the export of viable organs procured by our organ procurement organization (OPO) to the New York City area while the OPO in that area seriously underperforms in its sole responsibility of organ procurement. Our region includes zip codes with some of the highest rates of end-stage kidney disease in the country, many of them inner-city areas whose residents have limited means, limited access to care, and low health literacy. Such areas are fraught with inadequate patient access to transplant, and the incremental effect of reduced access to organs even for those patients who are listed further heightens the existing disparity in access to organ transplants for those who need them. Consequently, focusing so much on access once patients are listed ignores the much bigger problem of failure to grow the organ supply through better OPO performance and failure to refer patients in a timely manner for waitlisting.

The changes made in the liver allocation policy have had the same effect as seen in kidney/pancreas allocation: increasing cost, decreasing utility, and a large outflow of organs from our region to New York, leaving mostly marginal organs for the communities we serve.

An updated system must focus on improving OPO performance. OPOs must be held accountable for their efforts and live up to their responsibility to increase organ donation rates and secure the greatest number of organs possible so we can improve the fair distribution of organs to improve equity. Sharing among organizations must be tied not only to selecting the best organs – an approach generally referred to as "cherry-picking" – but also to rational logistics that do not lead to the discard and waste of organs. Sharing also should be between organizations that have high and similar benchmarks, not sharing from high-performing OPOs to low-performing OPOs (one-way sharing). Marginal organs are sensitive to prolonged preservation time and do not travel well, which renders impractical the current approach of

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allocating these organs through thousands of patients at hundreds of listing centers. In an ostensible pursuit of equity we are wasting organs: reducing the number of available organs through inappropriate distribution processes is not a useful step along the path to equity.

Another challenge is the manner in which organs are currently distributed. Current distribution practices favor the insured, the well-insured, and residents of areas that have more active transplant programs. Today, people everywhere are welcomed as organ donors but transplant candidates who happen to live in the "wrong" type of area – one where transplants are seldom performed or physicians do not have relationships with transplant programs or people earn less money or have less adequate health insurance – are far less likely to receive an organ if they need one. This is an inequity that a new approach must address.

We believe the OPTN's new pre-transplant mortality metric will likely have the unintended consequence of detracting from efforts to achieve equity. In the context of kidney transplantation in particular, for example, the metric is inappropriate because transplant centers do not participate in the day-to-day management of wait-listed patients; that responsibility rests with community nephrologists and primary care providers who often operate outside the purview of transplant programs. The role of the transplant center is to assess waitlist patients' readiness to take advantage of organs as they are offered. Enacting the NASEM-recommended metrics therefore poses a threat to equity because transplant centers that are concerned about waitlist deaths may choose to remove from their waitlists patients who need a transplant but who pose a greater risk of dying while on the waitlist because of medical or social comorbidities – often, medical or social comorbidities associated with inequitable access to care and other social determinants of health. This directly conflicts with the objectives of making more organs available and distributing them equitably.

OPTN Technology – IT System (section A)

The Penn Medicine Transplant Institute urges HRSA to include in the next OPTN RFP the full integration of transplant center electronic health records with the OPTN IT system to ensure timely and cost-effective data collection.

We also believe any policies involving data collection from transplant centers or OPOs should include an estimated time for completing the task and the number or percentage of FTEs projected to be needed to perform those tasks. This will help quantify uncompensated tasks the OPTN requires. The goal of this IT integration is to free transplant staff effort from low-value tasks related to information transmission to the OPTN so they can focus on supporting the clinical needs of patients.

OPTN Finances (section C)

This process needs greater financial transparency. To that end, the RFI should state that the OPTN should be required to provide an annual financial report to all members that shows all sources of revenue and the allocation of expenses.

Increasing Organ Donation and Improving Procurement (section E)

The Penn Medicine Transplant Institute offers five recommendations for increasing organ donation and improving procurement.

1. The OPTN should be required to publish detailed annual reports on the performance of all OPOs that include informative and agreed-upon benchmarks.

2. The OPTN should establish a training program for OPO administrators with continuing education. This should include the implementation of best practices from high-performing OPOs.

3. A past NASEM report outlined a research path to improve donor management and OPO performance, but its recommendations have not been adopted. They should be reviewed and, as appropriate, implemented.

4. The OPTN should reduce the expected survival rates for some populations, such as for older recipients and for organs that have inferior survival characteristics.

5. The OPTN should increase reimbursement to transplant centers that use organs with inferior survival characteristics and that serve recipients who pose greater financial risks.[1]

OPTN Operations and Policy Development Improvements (section G)

We believe OPTN organ allocation policy should be made more equitable. This can start by considering the entire population of potential recipients and not just those who have access to transplantation because of their socio-economic status or where they happen to live. Today, obtaining a transplant requires a patient to have private insurance or Medicare or live in a state with comprehensive Medicaid coverage. This approach discriminates against patients who have no insurance, who do not have adequate insurance, who live in states with poor Medicaid programs, or who live in states with poor Medicaid transplant coverage. Similarly, the uninsured rates in states differ, ranging from four to five percent in states like New York, Massachusetts, and California to 16 percent in Texas. This now results in shifting organs to some states and away from others. Today, anyone can donate an organ but not everyone can be a realistic candidate for organ transplantation for reasons having nothing to do with their medical need for a transplant. This is another form of inequity and disparity and it should be addressed in the next RFI and corrected by the next OPTN.

The Penn Medicine Transplant Institute also is concerned about the current practice of grading transplant centers' waiting list mortality rates, which we believe is inappropriate because transplant centers are not able to comprehensively manage waitlisted patients aside from monitoring their readiness for transplant. Candidates and their physicians also have a responsibility for maintaining their transplant readiness, which can be very challenging for

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[1] Axelrod, D.A., *et al.*, "The Changing Financial Landscape of Renal Transplant Practice: A National Cohort Analysis," *American Journal of Transplantation* 2017; 17: 377-389.
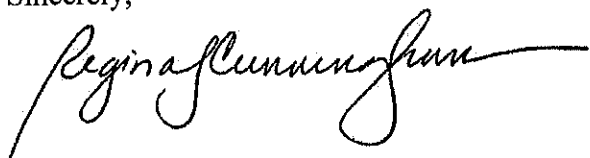
patients already affected by disparities in access to health care, socioeconomic status, and health literacy. The current and proposed metrics are a disincentive for transplant programs to list medically and socially complex patients for transplant, which further exacerbates the current, very real gaps in access and equity. If corrective action is not taken, patients who would benefit from transplant might be at risk for delisting from programs to avoid waitlist mortality or mitigate risk of inferior post-transplant outcomes – actions that are contrary to our interest in promoting equity.

<div align="center">*   *   *</div>

The Penn Medicine Transplant Institute appreciates the opportunity to share our views on these vital matters and welcomes any questions you may have about the recommendations we have offered.

Sincerely,

Regina Cunningham, PhD, RN, NEA-BC, FAAN
Chief Executive Officer
Hospital of the University of Pennsylvania

Response to Notice ID: HSB115C1031
Organ Procurement and Transplantation Network (OPTN) RFI

Contractual vehicle information:

- **CAGE:**   6TC84
- **DUNS:**   030990136

Indefinite Delivery/Indefinite Quantity (ID/IQ)

- **GSA Schedule Contract #**   47QTCA21D0071
- **Seaport NextGen Contract #**   N0017819D8444
- **ENCORE III Contract #**   HC102818D0032
- **GSA STARS III Contract #**   47QTCB21D0150

Socioeconomic business classification: **SBA HUBZone Certified, SBA 8(A) certified**

Business Size: **Small Business on all NAICS codes**

SBA 8(a) information:

- **SBA 8(a) case number:**   306099
- **SBA 8(a) exit date:**   01/02/2024

SBA HUBZone: **HUBZone Certified on 10/30/18**

Bonding capacity: **$5M on a single project and $12M in Aggregate**

MBE & DBE Certified: **State of NJ** → Valid until 04/23/24

                                                                       City of NY → Valid until 06/30/25

                                                                       State of NY → Valid until 06/30/25

                                                                       City of Philadelphia → Valid until 02/28/26

                                                                       State of PA → Valid until 02/28/26

                                                                       State of RI → Valid until 02/28/26

RV Global Solutions Inc.,
**247 E Front St, Suite # 1 Trenton, NJ 08611**
Point of Contact: Rahul Gangu, President
Phone: 732.802.0009 | Fax: 732.813.1569
Email: rgangu@rvglobalsolutions.com|
Web: www.RVGlobalSolutions.com

Team RV Global Solutions Inc., represented by RV Global Solutions Inc. (RVGS) and its teaming partners have more than 20 years of experience in facilities support services, design, development, process improvement, testing, and roll-out of enterprise discovery, asset management and its associated IT Service Management functions. We understand your concern about program execution risk (technical, schedule and cost). Our teaming partners have been supporting the Federal Government as a 'Prime' with demonstrated past performance and they represent a risk mitigation partner for your program. They are ISO 9001:2008 and ISO 20000-1:2011 Certified and CMMI-Dev and Services level 3 partners with several prime Federal contract implementations. In this context, we humbly submit that doing an **SBA HUBZone sole-source OR SBA 8(A) sole-source contract** with us can be an easy way of engaging Team RVGS on this project.
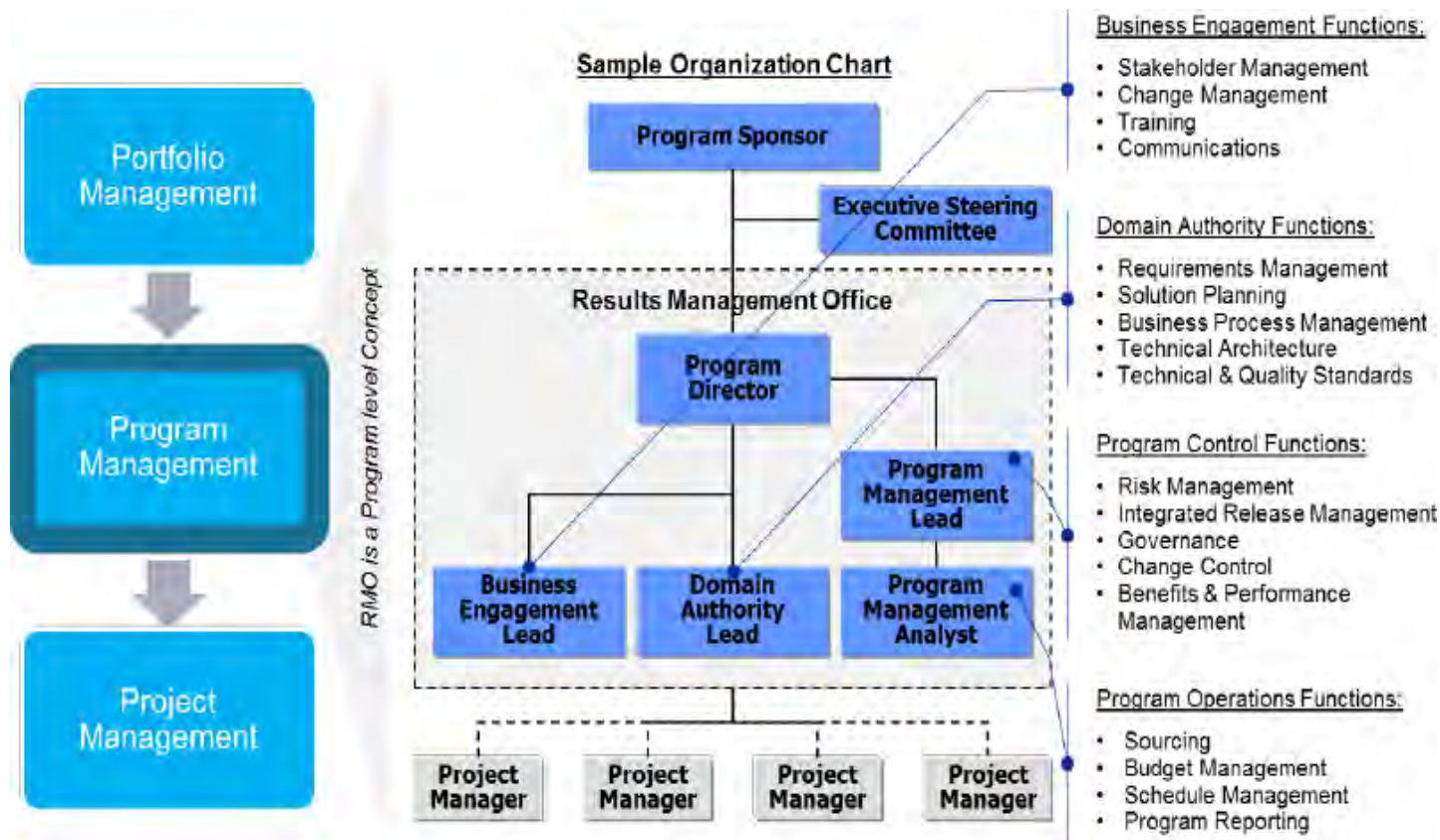
Figure 1: RVGS established and maintained Project Management Office (PMO) via the concept of Results Management Office (RMO) to cater to the needs of administrative support service functions

Secret Facility Clearance (FCL):

1. RVGS's Principal/Key Management Personnel received "Secret Clearance" on 11/04/20 paving the way for us to begin work on a classified project for the U.S Army Project Manager Close Combat Systems (PMCCS) at Picatinny Arsenal in New Jersey. This project involves the development, maintenance and systems integration of classified systems at the U.S Army. We anticipate no issues in obtaining a "Secret" or "Top Secret" clearance for our facilities and personnel.

2. RVGS received certification under U.S Joint Certification Program (JCP), Approved *Militarily Critical Technical Data Agreement, DD Form 2345*:
   a. JCP Certification number # 0080192
   b. Expiration date # 07/31/2023

Received Defense Contract Audit Agency (DCAA) Audit Compliance: As part of on-boarding a prime T&M contract with the U.S Army, RVGS had to go through a DCAA audit. After performing an audit spanning 6 months, DCAA completed their pre-award accounting system audit on 7/28/20. DCAA stated that our systems were "suitably designed, in all material respects, for award of a prospective contract in accordance with the criteria contained in FAR 53.209-1(f) Standard Form 1408 Preaward Survey of Prospective Contractor Accounting System."

MANAGEMENT CONSULTING SUPPORT SERVICES PAST PERFORMANCE:

RELEVANT EXPERIENCE		
PROJECTS WHICH BEST ILLUSTRATE OFFEROR'S RELEVANT EXPERIENCE FOR THIS CONTRACT		PROJECT IDENTIFIER # Contract Purchase Agreement (CPA) # 2191974
PROJECT TITLE # **Environmental Testing**		Contract type # Contract Purchase Agreement (CPA)
CLIENT'S INFORMATION		
CLIENT # **Sandia National Laboratories (U.S Department of Energy),** ALBUQUERQUE, NM 87185 Prime # RV Global Solutions Inc.	POINT OF CONTACT # Contracting Officers: Mr. John Paul Duman Mr. Todd Sakol Mr. Nathanial Roberts	POINT OF CONTACT DETAILS # Mr. John Paul Duman Email: jpduman@sandia.gov Mr. Todd Sakol Email: TSOKOL@sandia.gov Phone: 505-284-6610 Mr. Nathanial Roberts Email: NDROBER@sandia.gov Phone: 505-844-5176
DESCRIPTION OF PROJECT AND RELEVANCE TO THIS CONTRACT: **Here is an example of a competitive task order won by RV Global Solutions Inc. (RVGS):** Provide environmental test services to supplement SNL's internal capabilities. Single part testing will be requested, and services will be scheduled on an ad-hoc basis. Team RV Global must be registered with the Department of State to handle export control parts covered by the International Traffic in Arms Regulations (ITAR). The facility must be accredited by AL2A or NVLAP. Preliminary data on all tests including compliance with tolerances shall be provided to SNL personnel on site for approval prior to changing the test axis or facility. Final test reports shall be delivered within 10 working days and shall include raw electronic files from all test equipment in addition to an interpreted report. - Logistics execution, goods receipt and goods issue process, shipping and transportation - Logistics Execution: Stock (sensitive DOE equipment classified as ITAR) Transfer, Post Change, Physical Inventory. - Deep end to end logistics execution processes to drive the whole design to deliver. Safe transportation of the sensitive DOE equipment back to Sandia laboratories for reintegration. In the event of test equipment failure, we are responsible for identifying an available replacement either within our facility or an alternative lab within the United States no less than 10 working days from the originally scheduled date. Overtime, such as 2nd shift, 3rd shift or		

weekends is acceptable in the event of our primary test equipment failure with prior written approval (e.g., email) by Sandia's Delegated Representative (SDR). Overtime under normal operations may be required to meet schedules or to protect parts by ending the day in a more physically protected configuration. This option may be extended by any Sandia employee at the RVGS facility or remotely by the Sandia Delegated Representative (SDR). All these requests will be in writing (e.g., email) and include at a minimum the Sandia Delegated Representative (SDR) and a designated point of contact within our facility. All test facilities shall include, test equipment, qualified operators and RVGS test reports for the following:

- Thermal Chamber
- Electrodynamic Shaker (Random Vibration and/or shock)
- Altitude (or TVAC at ambient temperature)
- Centrifuge (please quote on all sizes eight feet and larger)
- Shock (e.g., Resonate Beam, Resonate Plate)
- Machining (e.g., Fixture modiFication or repair)

Here is an example schedule of a task order requesting environmental testing at our facility on this CPA:

Thermal Chamber		Weeks		Days	Start Date	
Electrodynamic Shaker		Weeks	3	Days	Start Date	11/2/20
Altitude / TVAC		Weeks	3	Days	Start Date	11/4/20
Centrifuge		Weeks		Days	Start Date	
Resonate Beam	1	Weeks		Days	Start Date	11/9/20

PERIOD OF PERFORMANCE: 09/08/2020 through 09/07/2025 [Base year + 4 option years]
Size: Task orders shall be issued on this Contract Purchase Agreement (CPA)

RELEVANT EXPERIENCE		
PROJECTS WHICH BEST ILLUSTRATE OFFEROR'S RELEVANT EXPERIENCE FOR THIS CONTRACT		PROJECT IDENTIFIER Contract # W15QKN-20-C-0058
PROJECT TITLE # **Managed Services Provider (MSP): Engineering Equipment Logistics (Hardware and Software maintenance**		ADDRESS # Picatinny Arsenal, NJ
CLIENT'S INFORMATION		
CLIENT # U.S Army, Picatinny Arsenal, NJ Prime # RV Global Solutions Inc.	POINT OF CONTACT # Contract Specialist: Mr. Alexander Plotkin	POINT OF CONTACT DETAILS # Mr. Alexander Plotkin Email: alexander.plotkin.civ@mail.mil Phone: 973-724-3343

DESCRIPTION OF PROJECT AND RELEVANCE TO THIS CONTRACT:
- This contract establishes and defines the requirements for providing ongoing support to the U.S.Army Research, Development and Engineering Center (ARDEC) as a Managed Services Provider (MSP) for laboratory test equipment. RV Global provides logistics support, service, repair, equipment/parts replacement, hardware upgrades, and associated calibration for laboratory test equipment located at Picatinny Arsenal, ARDEC, NJ. The lab equipment is used in performing Environmental Testing, Nondestructive Testing and Evaluation of Army materiel (such as bullets and pistols used by the war fighter), and Department of Defense (DoD) Tactical Behavior Research.
- Complete logistics support includes but not limited to:
  - Exploring in our Cloud sandbox environment : We are exploring AWS Cloud Internet of Things (IoT) Greengrass 2.0 to build and manage IoT apps with open source run-time for proactive/preventative maintenance of the engineering equipment.
  - Vetting and identifying reliable suppliers of parts to highly sophisticated engineering equipment
  - Identifying technicians to resolve complicated technical calibration problems
  - License renewals of hardware and software used by ARDEC users.
  - Arranging the supplies and collaborating with the technicians
  - Shipping supplies/materials and receiving them
  - Safely storage of the supplies at our local warehouse and complete ownership of RMA (Return Merchandize Authorization)
  - Safe Transportation of supplies/materials to and from the U.S Army base to the destination
  - Safe disposal of engineering waste materials in accordance with federal and state environmental laws/regulations and in accordance with logistical support best practices.
  - Performing tasks such as timely replenishment of CO_2 gas in engineering chambers by closely collaborating with trusted CO_2 vendors such as AirGas in the transportation, loading, refilling of CO_2. We track the arrival times of the CO_2 truck, track its progress and keep the customer informed throughout this logistics implementation process.
  - Logistics execution, goods receipt and goods issue process, shipping and transportation
  - Logistics Execution: Stock Transfer, Post Change, Physical Inventory.
  - Deep end to end logistics execution processes to drive the whole design to deliver.
  - Involved in the configuration of logistics execution shipping by defining basic functions such as shipping points, shipping conditions, loading groups, transportation groups and maintaining proposed shipping points.
  - Supported issues related to sales and distribution, including logistics execution, material management, finance, invoicing and controlling.
  - Fostered teamwork, motivation, and coordination of work that allowed the IT and/or engineering logistics team to complete various projects including additional 4PL roll-outs, new process implementations, and other cross-functional projects.
  - Provided key inputs for global TO-BE logistics process design including ideas for standardizing the delivery goods issues, shipping data, usage of shipment statuses, capturing actual delivery dates, and the inbound logistics process.

○ Wrote functional specification documents for several interfaces including transportation requests, shipment executions, tracking messages, and master data.

PERIOD OF PERFORMANCE: 09/14/2020 through 09/14/2023 [Base year + 2 option years]
CONTRACT VALUE: $1,089,542.25

RELEVANT EXPERIENCE	
PROJECTS WHICH BEST ILLUSTRATE OFFEROR'S RELEVANT EXPERIENCE FOR THIS CONTRACT	PROJECT IDENTIFIER Contract # AllTech_RVGS16
PROJECT TITLE # **Management consulting**	ADDRESS # Weehawken, New Jersey

CLIENT'S INFORMATION		
CLIENT # UBS New Jersey Sub-contractor: RV Global Solutions Inc.	POINT OF CONTACT # Contract Specialist: Mr Sunil Prakash	POINT OF CONTACT DETAILS # Mr Sunil Prakash Phone: 732-672-8482 Email: sprakash@alltechconsultinginc.com

DESCRIPTION OF PROJECT AND RELEVANCE TO THIS CONTRACT:
PROJECT DESCRIPTION AND SCOPE:

- Managed a portfolio of **$63 Million** and supported executive leadership in managing an overall **portfolio of $126 Million+** as part of multiple systems integration
- Complete Project ownership: Worked closely with Business Analyst's, Development, QA/UAT and Release Management teams to ensure a smooth project roll-out
- Worked with **CTO's to develop** a strategic road map for applications and infrastructures
- Performed **current state assessment** and gap-analysis. **Identified gaps and developed a roadmap/strategy** to migrate users from legacy systems
- Streamlined **Total Cost of Ownership (TCO) chargeback model** improving efficiencies by 50% using Six **Sigma business** process re-engineering. This enabled us to nip in the bud incorrect annual chargeback of **over $9 million**
- Provided a range of services relating to the management and use of records, Integrated records management into business systems and processes.
- Assigned responsibilities authorities, established promulgated procedures and records management guidelines.
- Decided the form and structure of records management, determined the type of metadata through record processes, ensured and maintained records in a safe and secure environment.
- Identified and evaluated opportunities, improved effectiveness, efficiency, quality of process, decisions and actions for better records management and creation.
- Determined records management requirements and retrieved records using transmitting between business processes and other users.
- Complied with legal and regulatory requirements, standards and organizational policy. Preserved records management for accessible business requirements and community

expectations.
- Worked closely with Business & Tech partners to develop project estimates. Once a project is approved, tightly managed the approved budget and project timelines
- Analyzed operations and procedures manuals to assist management in operating more efficiently and effectively manage administrative support functions
- Conducted organizational studies and evaluations, design systems and procedures. Analysis was performed to conduct work simplification and measurement studies.
- Advised managers on how to make organizations more profitable through reduced costs and increased revenues using principles of six sigma
- Looked out for overlaps across projects. Identified and managed risks and issues that could cause the wealth management program to fail
- **Collaborated** with senior program management to develop budgeting and forecasting
- Used **SWOT** (strengths, weaknesses, opportunities, and threats) analysis to assist program management identify critical success factors.
- Developed and closely monitored project plans
- Drilled excel reports for deeper dive discussions with senior management on where the allocated budget was getting spent and the 'burn-rate' of the allocated dollars in our portfolio
- Our approach to PMO was: Total project ownership with a positive attitude of taking all the stakeholders together as a team with the objective of getting the projects completed within budget, schedule and the expected quality
- As PMO, we worked closely with the development, QA, User Acceptance Testing (UAT) and business teams in defining roles, responsibilities and gameplan.
- Upon allocation of project budget, we worked hand in hand from requirements gathering through to development of software, quality assurance, UAT and rollout

PERIOD OF PERFORMANCE: Dec 2018 through current
CONTRACT VALUE: $748,527.00

RELEVANT EXPERIENCE		
PROJECTS WHICH BEST ILLUSTRATE OFFEROR'S RELEVANT EXPERIENCE FOR THIS CONTRACT		PROJECT IDENTIFIER Contract # IS Programming services 459 Discretionary purchases.
PROJECT TITLE # **Management & IT Services Consulting**		ADDRESS # Albany, NY
CLIENT'S INFORMATION		
CLIENT # New York State, Dormitory Authority for the State of New York (DASNY), Albany, NY Prime # RV Global Solutions Inc.	POINT OF CONTACT # Contract Specialist: Ms. Nicole White	POINT OF CONTACT DETAILS # Ms. Nicole White Email: nwhite@dasny.org Phone: (518) 257-3076

DESCRIPTION OF PROJECT AND RELEVANCE TO THIS CONTRACT:

PROJECT DESCRIPTION AND SCOPE:

- Application support/development, consulting for JD Edwards/Oracle World 9.3 with specific training in modules for General Accounting, Accounts Payable, Accounts Receivable, Financial Reporting (FASTR), Cash and Fund Accounting (Public Sector), Job Cost, Contracting and administrative support activities
- Change Management and purchasing, programming, training, systems design and development of applications in Microsoft SQL Server, SharePoint 2013, ASP.Net 2013, .Net Framework 4.5 and Visual Studio 2013
- Consulting, training, implementation support and/or project management for implementing Windows Server, Windows Active Directory, Exchange Server, Systems Center Configuration Manager, Internet Information Server and other Microsoft products
- Consulting, training, implementation support and/or project management for improving DASNY's networks: McAfee Spam/URL Filtering Appliances & Products, Monitoring Products: HP Insight Manager, NetIQ, Security Products: McAfee IronMail, Checkpoint Firewall/PointSec and IBM IPS
- Consulting, training, upgrade implementation support and/or project management for construction Project Management and Scheduling systems using Primavera (Oracle) Contract Management.

PERIOD OF PERFORMANCE: 2/1/2016 through 1/31/2021
CONTRACT VALUE: Discretionary purchases up to $200K for each task order. Any number of task orders can be issued on this 5 Year MBE Small Business contract

RELEVANT EXPERIENCE	
PROJECTS WHICH BEST ILLUSTRATE OFFEROR'S RELEVANT EXPERIENCE FOR THIS CONTRACT	PROJECT IDENTIFIER Contract # SRI_RVGS19
PROJECT TITLE # **Management Consulting**	ADDRESS # New Jersey
CLIENT'S INFORMATION	

CLIENT # Strategic Resources International, Inc.,, NJ Sub-contractor: RV Global Solutions Inc.	POINT OF CONTACT # Contract Specialist: Mr Bharath Sreerangam	POINT OF CONTACT DETAILS # Mr Bharath Sreerangam Email: bharath@sriusa.com

DESCRIPTION OF PROJECT AND RELEVANCE TO THIS CONTRACT:

PROJECT DESCRIPTION AND SCOPE:

- Setup Project Management Office (PMO). Recruited project managers and program managers
- Managed a **portfolio of $72 Million** of PMO funding
- Worked closely with senior management to set up budgets. Upon budget approval, closely tracked the amount consumed by projects and the amount left in the budget
- Reported budget variations to the senior management on our weekly PMO meeting

- **Leveraged Capacity Planning techniques such as** 'Linear Trend Analysis', 'Simulation Modeling' and 'Analytic modeling' to mitigate **service delivery** risks using principles of Risk Management
- **Instituted Project Governance to prioritize development work** and ensure that only those projects are taken up that are in-line with strategic business initiatives
- Worked closely with the technical managers/technical teams to track budget, schedule and quality of developed applications
- Designed the project into multiple stages and got stakeholders to sign-off on deliverables at each stage using administrative support .
- Established objective criteria for quality measurement for creative work with administrative support.
- Identified priorities, action plans, eliminated paperwork and extra processes. Avoided pushing out decisions and bottlenecking progress through administrative support.
- Worked with the departments leading finance and grants administration, procurement, events and marketing, information technology, human resources, facilities management with administrative support.
- Our administrative support team adopted a proactive mindset, tackled challenges and solved problems. Measured a desired outcome and took the initiatives and demonstrated it
- Helped our administrative support principal investigator on the oversight of grant rules and procedures, kept protocols up to date, wrote reports and fulfilled requests from the Institutional Review Board (IRB)
- Tightly managed the project management triangle of: Cost, Schedule and Quality and reported the minutest variations to senior management with potential suggestions to bring the project back on track
- We took a very positive proactive approach in PMO. We worked with development/technical managers/leads in the spirit of collaboration
- We take complete project ownership from initiation through to project completion
- Developed and closely monitored project plans
- Drilled budget reports in MS Excel and presented to the management on where we stood with budgets very clearly
- Evaluated hardware and software platforms for COTS products

PERIOD OF PERFORMANCE: Jan 2019 through current
CONTRACT VALUE: $728,000.00

RELEVANT EXPERIENCE	
PROJECTS WHICH BEST ILLUSTRATE OFFEROR'S RELEVANT EXPERIENCE FOR THIS CONTRACT	PROJECT IDENTIFIER Contract # 15A00021CAQA00163
PROJECT TITLE # **Material coordination logistics**	CONTRACT TYPE # Firm Fixed Price
CLIENT'S INFORMATION	

CLIENT # U.S Department of Justice Prime # RV Global Solutions Inc.	POINT OF CONTACT # Contract Specialist: Cameron Davis	POINT OF CONTACT DETAILS # Cameron.Davis@atf.gov (202) 648-9011

DESCRIPTION OF PROJECT AND RELEVANCE TO THIS CONTRACT:
PROJECT DESCRIPTION AND SCOPE:
Here are main tasks being performed by team RVGS on this contract:
- Task 1: Shipping Support: Labelling, documenting, packing and shipping materials (regular and delicate)
- Task 2: Receiving, Including USPS support: Process daily incoming shipments. Protect government property from inclement weather
- Task 3: Inventory Support: Manage the disposal, surplus and when appropriate destruction of Law Enforcement sensitive excess items and materials
- Task 4: Clerical Support: Manage the administrative staff with clerical activities, including but not limited to photocopying and scanning of documents, organizing training materials, document filing, maintaining updated files for efficient file archiving and retrieval.
- Task 5: Moving Logistics Support: Move, haul, transport items within the work location including, but not limited to boxed materials, office equipment, office supplies, cabinets, glass, storage media, computers, computer related accessories, ES equipment, Alkaline or Lithium batteries and other routine materials that are regularly shipped from this location. These items will vary in size and quantity from a single box to palletized items.

PERIOD OF PERFORMANCE: Base year + 4 option years [04/01/2021 through 03/31/2026]
CONTRACT VALUE: $474,931.21

RELEVANT EXPERIENCE	
PROJECTS WHICH BEST ILLUSTRATE OFFEROR'S RELEVANT EXPERIENCE FOR THIS CONTRACT	PROJECT IDENTIFIER Contract # FusionGS_RVGS_2020
PROJECT TITLE # **E Commerce Banking applications development on Cloud**	CONTRACT TYPE # T&M
CLIENT'S INFORMATION	

CLIENT # UBS Bank Sub-contractor: RV Global Solutions Inc.	COR/POC DETAILS # Mr. Saravanan R	POINT OF CONTACT DETAILS # Contracting Officer and/or COR/POC- Mr. Saravanan R Email: saravanan.r@fusiongs.com Phone: 469 782 9413

DESCRIPTION OF PROJECT AND RELEVANCE TO THIS CONTRACT:
PROJECT DESCRIPTION AND SCOPE:
- Building and deploying E-Commerce (banking) applications on 'NoMachine' Dev Cloud Server leveraging J2EE critical functions
- Leveraged AWS Cloud Amazon Glue Elastic Views to combine and replicate data across multiple data stores
- Developing Information Systems (IS)Toolset and FET products using DevOps and DevSecOps
- AWS Well Architected tool: Used it to leverage the APIs that allowed our clients and partners to extend AWS Well-Architected functionality, best practices, measurements, and learnings

into their existing architecture governance processes, applications, and workflows. By using the AWS Well-Architected Tool API, we effectively governed workloads across many applications specific AWS accounts, always stayed up to date on the latest best practices, and scaled AWS Well-Architected principles across other teams and systems

- Used Amazon Correto tool to deploy applications along with native distribution of JDK with advanced feature extensions with a range of databases such as MySQL, Dynamodb & Aurora & Athena
- Leveraged AWS Cloud Amazon Connect as a standard data access interface for connecting to various data sources such as Excel, Flat files & specialized data sources (datalakes)
- Designed and implemented elastic critical functions on AWS Cloud infrastructures to ensure scalability is achieved
- The two main parameters that were taken into account for sizing the Cloud Server host were:
  - The number of concurrent accesses in the bank
  - The method used for dispatching client connections to the child server (direct or tunnel). The first parameter can impact the time necessary to start the session on the child server. The second parameter instead can influence the session performance if the client connection is tunneled to the child server.
- We devoted ample time on business process workflow models for each discrete functionality that a planned product line needs to follow right from the rudimentary user story getting evolved into a group of tasks to support features and related epic
- LEVERAGED 'AWS Cloud 9' to create code stack along with in-memory change compilation of storage structures and variables configuration settings
- We continuously innovated our managed services model dealing with complex project components that follow a predefined but flexible 'definition of done' journey from null user story via features implementations over rudimentary epic ideas right from delivery to post-production support model process for our clients and are committed to their utmost satisfaction by regular analytics and monitoring reports on the applications.
- Performed periodic code reviews and code repository deltas: Performed regular milestone reviews and checkpoints thereby enabling solid product delivery
- Used 'AWS CloudArtifact' to store code builds by tags with a specialized cloud enabled versioning system integrated with Swagger.

PERIOD OF PERFORMANCE: 02/2020 through 02/2023
CONTRACT VALUE: $540,000.00

Some lessons learned from the above projects and best practices implemented:

- **Engineering:** At the U.S Army Picatinny Arsenal, our task involved repairing and installing parts for environmental test chambers that had the capacity of maintaining a temperature of -100F to +200F. The issue we faced was to fix the humidity percentage that is temperature specific. To maintain particular humidity levels, the controllable temperature/humidity range has been fixed with 10% to 98% RH for 41F to 185F using 44F dew point. The 44F dew point was indeed confusing, since the amount of moisture varied at every temperature, inside the chamber there was a refrigerated coil that is controlled at a temperature very close to the freezing point of 32F. Moisture in the chamber has attracted the cold surface and condensed but did not freeze. Thus, accumulated water drained out, lowering the relative humidity. This also made the equipment from rusting and other issues caused by stagnant water.
- **Program Management:** We did this by maintaining proper work timetables that are accessible to the

clients through an online calendar, work and budget related issues are discussed in meetings and minutes of meetings are noted down by our team and then shared with the client for transparency and accuracy.

- **Management Consulting:** We tightly managed the Project Management Office (PMO) of the above mentioned U.S Navy and U.S Army projects through all its PMO stages. Stages involved were design, constructability, long lead material issues, inter contract coordination, engineering and safety issues. Our team handled different stages by using software to generate reports, progress reviews, and conducted sessions that helped the efficiency at different stages and for different levels of personnel. We also conducted training sessions for our onsite employees to help them tackle issues. We conducted regular audits, quality diligence and delivery sessions in the team.

- **Financial Management:** To keep control over the costs and stay with-in the budget of the project, team RVGS used methods and techniques that helped restrict the costs. We used software for auditing and reporting. We had weekly reviews that help us point out places where budget can be constrained without compromising on the quality. We managed to stick to the quantity of material which was planned at the early stages of the project and restricted damage by proper supervision onsite.

- **Logistics:** For Logistics, we created a timeline of project stages planned in advance with a full inventory of materials and tools that would be used. We eliminated the complexity of the process by interacting with different teams using dedicated simulation software that helped us analyze, visualize and optimize logistics. In addition to keeping the PMO on schedule, we also enhanced cost savings and waste reductions using advanced auditing tools. Through logistical planning, we enabled materials to be stored correctly which improved efficiency and reduced the potential damage. Our onsite supervision team kept the site safe, clean and easy to move around.

Administrative support:

- **Quality Management System (QMS):** RVGS SS staff established and maintained a complete QMS program in accordance with the provisions specified in the contract. Our SS staff provide an effective and efficient means of identifying and correcting problems throughout the entire scope of operations. Some of the functions performed by RVGS SS staff as part of QMS are Accurate documentation of work processes, procedures, and output measures. We built a systematic procedure for assessing compliance with performance objectives and standards. Provided accurate documentation of quality inspections conducted throughout the execution of work. Assisted in the development of assessment-driven corrective actions and process adjustments as appropriate in a timely manner.

- **Quality inspection and Surveillance:** RVGS SS staff established and maintained an inspection and surveillance system in accordance with FAR clause 52.246-4, INSPECTION OF SERVICES – FIXED PRICE, to ensure that the work performed conforms to the contract requirements. Our SS staff diligently document and maintain a file of all scheduled and performed inspections and surveillances, inspection and surveillance results, and dates and details of corrective and preventive actions. The quality inspection and surveillance file shall be the property of the U.S Government and made available during the Government's regular working hours. The file shall be turned over to the KO within five calendar days of termination of the contract.

- **Quality Inspection and Surveillance Report:** RVGS SS staff prepare and submit the contractor quality inspection and surveillance report as required in the contract. Our Quality Inspection and Surveillance Report includes a summary and results of the quality inspection and surveillance events performed and assessment-driven corrective actions and process adjustments during the previous month. The Government may adjust the frequency of the submittal based on the Contractor's quality

of performance.

- **<u>System and Equipment Replacement:</u>** RVGS SS staff maintain the integrity and performance of existing energy saving, water conservation or other sustainability design features of systems and equipment in the performance of repair and replacement work.

- **<u>Key personnel report</u>**: Our SS staff submit to the KO a List of Key Personnel and their Qualifications and any additional information requested by the KO to certify their qualifications. Our SS team prepared an Organizational Chart. Showing lines of authority of the key personnel and on-site supervisor(s) for this contract. The chart shall include names of personnel and their position title in this contract. As a minimum, we include the PM, Quality Manager, Site Safety and Health Officer (SSHO), and on-site supervisor(s) and who they will report directly to for this contract.

- **<u>Enterprise-wide Contractor Manpower Reporting Application (eCMRA):</u>** RVGS SS staff prepare and report all contractor labor hours (including subcontractor labor hours) required for the performance of services provided under this contract via a secure data collection site. We are required to completely fill in all required data fields using the following web address: https://doncmra.nmci.navy.mil

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PAST PERFORMANCE DATA: RV Global Solutions, Inc.

<u>Quality Service:</u> Very good. All work performed met or exceeded the quality requirements.

<u>Timeliness of Performance</u>: Very good. All deliverables met the contractual requirements.

<u>Customer Satisfaction:</u> 100%. Customer satisfaction met or exceeded.

<u>Business Relations/Integrity/Effective Management:</u> Very good. Business relation with a client base is very good and provides effective management to control cost, schedule, and performance.

APPROACH OF TEAM RVGS FOR IMPLEMENTING YOUR REQUIREMENTS:

- **Automated records management:** Built effective records management capabilities into the tools that our staff members use every day. Automated the declaration of electronic records and ensured accuracy and reliability of the process. We developed Enterprise Content Management (ECM) tools, helped vendors, captured records during people's normal work processes and embraced records management solutions. Invested in data discovery classification tools, declared records, reviewed content and automatically revised records declarations when business needed change.

- **Document retention:** We ensured legal and regulatory compliance, maintained a comprehensive document retention policy for better records management. We provided professional assistance guidance on industry-specific and general regulatory requirements. Maintained good record retention policy, reduced legal risks, discovery costs and recovery effort time. Associated with legitimate lawsuits, documented every record accurately, indexed and categorized it. Located and distinguished records management between active files and archival documents.

- **Secured storage:** RVGS safeguarded records from physical damage by providing facilities such as National Fire Protection Agency (NFPA) and State of California Department of Public Health (CDPH). Utilized specialized climate and fire protection systems within the records management center and protected vital business documents. Limited access of advanced access controls, intrusion prevention systems and barcode tracking technology to authorized staff. Stored inactive files of business at an offsite storage facility for legal reasons. Provided facilities such as customized documents pickup, delivery and rotation schedules.

- **Specialized Facilities:** We offered special storage conditions including climate-controlled media vault and specialized records storage solutions. Provided facilities such as computer media and microfilm. Created secure records management solutions for our clients. Continuously adapted to processes and fulfilled the growing needs of our customers. Included life-safety standards for federal records storage such as Early Suppression Fast Response (ESFR) fire suppression system, restricted entry access, maintained 16 internal/external cameras to monitor activity, Built structures designed/approved by a structural engineer and fire safety systems approved by a fire safety engineer

Figure 2: The conceptual strategies of Project Management Office (PMO) planned by team RVGS to meet the needs of our client administrative support services

- **Record, track and monitor documents:** We developed a comprehensive Electronic Document and Records Management System (EDRMS). Recorded, tracked and monitored organisations intellectual property. Captured quality metadata, located the correct content records and classified metadata in the background. Managed content across repositories, found information saved in network drives, on

computer hard drives, within applications and in cloud repositories such as SharePoint and OneDrive. We also managed physical, digital and hybrid records including the email conversations and social media records. Preserved the metadata of the deleted record and traced information on historical actions taken on the record. Organisational content has been handled in accordance with the organisation's records management strategy and mitigated the risk of losing content at the expense of end-user's work processes.

- **Digitised physical records:** We digitized physical records, improved operational efficiency, reduced risk of losing records such as fire, flood and other disasters. Captured the digitised records using a records management system. We created versions of the digitised records management for processing purpose, maintained accuracy and quality controls. Developed and documented defensible digitisation process, covered both in-house and outsourced digitisation activities. Maintained Quality assurance checks and ensured fit of the digitised records management.

Optimal administrative support of RVGS:
- Adopted a proactive mindset, tackled challenges and solved problems. Measured desired outcomes and took the initiative to see it with administrative support. Demonstrated taking initiative being self-starter, independent, and highly motivated. Our administrative support team increased the likelihood of stability, progress and success for our research team and conducted the science. Acknowledged administrative support and anticipated the needs of the research team, especially the principal investigator. Our research teams managed multiple projects and grants, wrote new grant proposals, attended meetings, gave frequent presentations, facilitated lectures and traveled quite often among other tasks with administrative support.

- Planned administrative support for changes by streamlining, automating tasks and handling. Our principal investigator managed administrative budgets and recommended where funding should be allocated. Supervised the number of publications and citations using the altmetric tool, included the current positions held, evaluated the success on training, took actions for public engagement and communicated of science which include talks to general audiences, radio and TV interviews, articles in newspapers, blog posts using administrative support.

- Established administrative support with strong collaborations, network, had positive rapport, shared resources and learned from other disciplines valuable benefited in facilitating and Coordinated the needs of our research team. Established administrative support about baseline for quality that all stakeholders agreed to. Established administrative support with strong collaborations, network, had positive rapport, shared resources and benefited in facilitating jobs and coordinated the needs of our research team. Participated in the onboarding process using administrative support.

Mailroom support services by team RVGS:
Provided mailroom support for federal government agencies and private sector clients. Our management team of expertise managed and improved onsite mail receipt, processing, distribution and facilities management. Our comprehensive suite of mailroom support allowed us to provide the ultimate in support. Our team has quickly developed excellent delivery and performance in the mailroom support services sector. Through formal and on the job training and experience, we have mastered the ability to be responsive to our clients and anticipate their needs.
- RVGS embodies proven performance in mail service
- Relevant expertise and qualifications

- Balanced staffing and management approach
- Thoroughly trained, knowledgeable and stable workforce
- Corporate controls and reach-back capabilities.

On-site mailroom support management:

Provided on-site, full-service mailroom staffing and operations management, with a comprehensive set of services tailored to meet specific client requirements. From single mailroom staffing and courier services, to the coordination of multiple satellite locations, from basic in-house mail processing to secure off-site mail screening for high-security environments, RVGS drew on the expertise of senior-level staff with mailroom management experience.

RVGS mailroom support management solutions include:

1. Complete mailroom staffing in one or more locations
2. Automated inbound and outbound mail sorting
3. Accountable mail tracking and management
4. Mail handling equipment maintenance
5. Mailing list management
6. Courier services
7. Real-time screening for suspicious or harmful substances
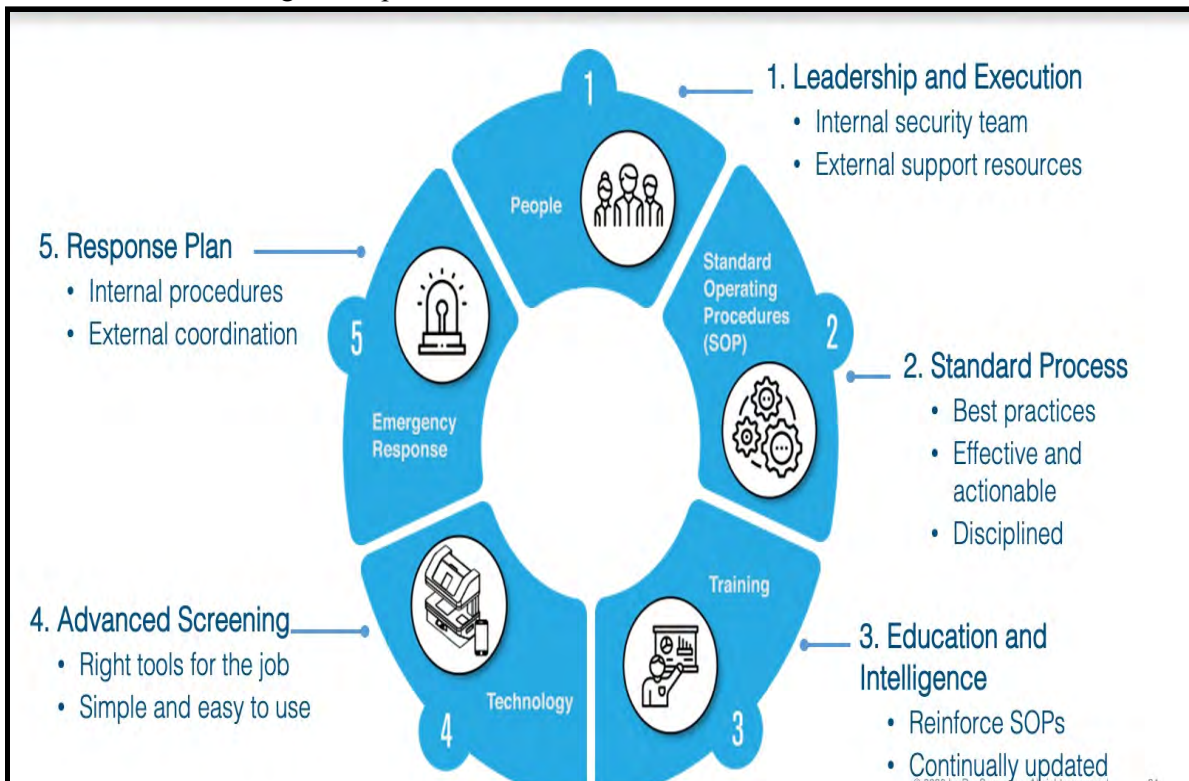
Figure 3: Five pillars of mailroom support security Standard Operating Procedures (SOP) developed by team RVGS as part of our administrative support services

1.1 Administrative Support Services and Management Consulting

1.1.1 Operational Schedules: Our team will establish a master calendar to cover short- and long-range operational schedules and to organize our contract support efforts and ensure their effective execution.

The master calendar will record, maintain, track, integrate, and report all milestones and events, including all events required by the attached contract deliverables, scheduled meetings, and other key actions. The calendar will enable our administrative manager and management to cross-reference and search these items to identify responsible individuals, item classifications, and status. To provide the level of service expected by your agency, our staff members are equipped with excellent computer skills and demonstrated knowledge of various basic and advanced functions of office automated word processing, spreadsheets, graphics, and administrative tools such as MS Office Suite (Word, Excel, PowerPoint, Access) and the Adobe Professional Suite (Illustrator, PhotoShop).

1.1.2   Scheduling Appointments, Meetings, and Coordinate Travel: We have seasoned professionals who use their logistical planning knowledge to plan, host and perform pre-meeting activities including site selection and setup, agenda preparation, onsite support and meeting minutes and debrief. This support may involve meetings where all attendees are in the Picatinny area, meetings with attendees dispersed internationally, or in our Virginia office. Our administrative assistants are involved in all aspects of meeting planning, including researching and obtaining subject materials and managing documentation.

1.1.3   Generate and Maintain (CONUS and OCONUS) Travel: Our staff includes experienced travel preparers; their skills range from travel clerks through lead VIP travel preparation specialists, who can generate and maintain CONUS and OCONUS travel schedules. Our staff has extensive experience and understanding of global tasks and travel as demonstrated by our recent support of traveling employees. Our proposed candidates will act as Travel Managers to manage our OCONUS travel planning to ensure that every effort has been made to the safety and health of our travelers. This planning includes but is not limited to, support for travel arrangements, visas, immunizations, passports, an internationally recognized credit card for emergencies, emergency evacuation plans, compliance with international laws, and other details related to the task. The database will be generated to include the travel information using Windows compatible software and will be made available to your agency, Administrative Assistants and Division Chiefs.

1.1.4   Arrange Meetings/Conference and Prepare Background Material: Our proposed employees will arrange meetings and conferences and prepare appropriate background material. Our employees will ensure that the conference room is available for the meeting.

1.1.5   Telephone Calls, Correspondence, and Suspense Records: Our employees will screen telephone calls and refer these calls to the appropriate personnel. In addition, our employees will review incoming and outgoing correspondence to include electronic mail, forwarding to the appropriate personnel generating correspondence, maintaining suspense records, and maintaining office files.

1.1.6   Administrative Directives: We can support the more advanced levels of administrative functions including those required in operational environments as well as those needed to support management staff. Our employees are prepared to provide in-depth research and analysis on a variety of personnel, administrative, and small purchasing issues to help improve existing procedures and processes. These administrative professionals routinely conduct and document research including data files and published information to identify information relevant and applicable to identify administrative and procedural program needs. They also prepare internal instructions, operating policies, procedures, and guidelines, and recommend required changes and adjustments to assure proper and adequate compliance.

1.1.7   Personnel Documentation Support: Our employees will maintain personnel records; prepare personnel documents; process personnel actions, training plans, performance standards and appraisals.

1.1.8   Processes/Documents: We will process and maintain all pertinent documents to send batch information to dedicated agency personnel. Our staff will maintain an electronic file database of all

documents and implement an administrative and historical filing system. We will maintain files of correspondence concerning new developments affecting changes in policies and programs related to this task order.

1.1.9   Distribution of Office Supplies and Equipment: Our proposed employees will distribute the office supplies and equipment. The logs will be generated and maintained for the records. Our proposed employees will ensure that the adequate supply is on hand.

2   Transition Plan:

Team RVGS understands the importance of a credible, low-risk transition plan that is based on solid business practices, repeatable processes, hands-on experience, and qualified and experienced managers. By drawing on our prior corporate experience in contract start-up and transition, by leveraging our team's experience and technical knowledge gained on the federal and state contracts, and by applying a proven management approach that is currently being applied successfully to execute tasking today, we can say with a high degree of assurance that our team provides the Government a very low-risk plan.

This plan ensures that our team will be ready to support your agency Technical Center on Day One of the contract and will transition all the personnel within 15 business days. We will successfully deliver 100% of our staff within 15 working days of contract award.

Our plan focuses on adherence to our staffing plan, open communication, clear assignment of resources and responsibilities, collaboration and close teamwork with our teammates.

Our Program Manager Mr. Rahul Gangu will assume the duties and responsibilities of the Transition Manager. He will be responsible for coordinating the corporate side of the stand-up including all efforts in contracts, subcontracts, human resources, recruiting, and security, providing a focus on the start-up and execution of day-to-day technical operations and customer interaction. He will conduct special sessions to resolve issues, problems, and schedules. None of the efforts of the actual transition are charged directly to the contract, as this is a corporate overhead function. Overall transition roles and responsibilities are shown in **Table 1**.

Table 1: Transition Team and Roles/Responsibilities: Dedicated, cost-effective team to ensure continuous, uninterrupted operations during the transition period.

Individual/Position	Roles and Responsibilities
Rahul Gangu, Program Manager	Daily interaction with your agency Schedule Contract Kick-off Meeting with your agency POCs Oversees execution of Transition Plan and Management Plan Validates and executes staffing plan with HR Manager Works with Task Managers to ensure start-up and transition of all tasking Executes Transition Plan (per this proposal); oversees and coordinates corporate stand-up including contracts, subcontracts, human resources, recruiting, and security.

Pavithra Bhaskaran, Project Manager	Provide Support to the Program Manager for Transition.
Paul Kandel, your agency Contract Administration	Provide project coordination to PM for Transition.

We provide experienced and recognized Key Personnel on Day One of the contract. Their experience and knowledge of this work and all related Government organizations will help ensure that this contract is transitioned and executed with as little disruption as possible.

By applying proven and successful management processes, procedures, and tools from the current and previous contracts, Team RGVS minimizes the risks associated with creating and implementing an untested management approach.

Team RVGS will have no learning curve of existing efforts including for technical, programmatic, organizational, and standard processes.

2.1 Post-Award Staffing Plan

Our Staffing Plan will ensure that 100% of our staff is on board and work in fewer than 15 days following the award as required. This is possible due to our use of available personnel, supplemented by other employees who are on board and working for team RVGS today. Our start-up staffing plan includes no "pending" positions, requires no recruiting or hiring, and avoids all risks associated with identifying, hiring, and on-boarding personnel.

Our Key Personnel will report on Day One of the contract. The balance of our personnel will be rapidly transitioned onto the contract from either current staff or from the pool of available new personnel providing your agency with a fully transitioned and operating staff in a matter of days.

2.2 Plan of Action and Milestones (POA&M)

Our ability to effectively transition contracts of this size and scope is based on our proven transition process, which consists of four key phases outlined below. Our plan shows the critical activities scheduled for accomplishment during each of our phases, which are aligned with the four-week transition period. Our detailed transition plan, created using Microsoft Project, will be presented at the kick-off meeting.

Phase 1: Pre-Award (Completed): Transition activities began as part of the teaming discussions between RVGS and team members and have continued as part of our proposal process. As a result of this teamwork, Team RVGS has 100% of our start-up staff identified and committed to the success of this start-up. Our transition team is already engaged, has participated in developing this transition plan, and is committed to maintaining continuous and uninterrupted service for your agency.

Phase 2: Transition Assessment/Project Orientation (To Be Completed Five Days after Award): As part of our pre-proposal and proposal activity, we have thoroughly assessed the unique requirements of the start-up and transition of this contract in terms of both management and technical topics. This assessment has also been incorporated into both the management and technical approaches in this proposal and is ongoing.

In regard to management features, our Program Manager and his team have been identified and are supporting planning efforts, and our HR and security teams are fully engaged and ready to transfer all employees in our staffing plan. We have assessed transition risks associated with our management approach, and have mitigated each through planning and development of our detailed POA&M.

In regard to our technical approach, we have conducted an assessment of requirements and determined all efforts that are critical to your agency's continued mission execution on day one to ensure they continue uninterrupted. The findings of this assessment will be incorporated into our final transition plan.

Phase 3: Readiness (Upon Contract Award): Upon award, we will immediately stand up our management team, and will implement our Transition Plan and our Management Approach. Within 3 days of contract award, we will conduct a Contract Kick-Off Meeting with your agency leadership including the COR, and the Contracting Officer. RVGS' executive leadership, Program Manager, Project Manager and Project Coordinator will participate to demonstrate our corporate commitment and to ensure we understand all requirements and expectations. We will implement our staffing plan, which provides key personnel on day one, with the remainder within 15 business days. We will complete all required transition and coordination with incumbent staff during this period if applicable.

Phase 4: Transition (15 Business Days from Contract Award): 100% of our staff will be onboard, we will have assumed full responsibility for executing all SOW requirements, and our management approach will be thoroughly implemented in no more than 15 business days following the contract award. Our first Monthly Status Report (MSR), which will summarize all transition and start-up activities, will be delivered at the end of this phase.

2.3   Transition Plan Measures/Metrics

To help track our transition progress, RVGS will maintain transition performance measures and metrics, which are provided in **Table 2**. Our Program Manager will provide updates and status on a daily basis.

Table 2: Transition Performance Measures and Metrics: Low-risk execution with a dedicated team to meet your agency expectations and achieve day-to-day results.

Tasks (Who and what)	Target timelines
Key Personal	All Key Staffing on board on day one
Contract Kickoff Meeting	At Customer convenience within 3 business days of contract award
Staffing Plan ramp-up of remaining personnel	Award + 15 days
Key Milestones Included in Transition Master Schedule	Updated daily
Staff Indoctrination	NLT Award + 15 days
Assume Full Responsibility for your agency SOW Requirements	100% readiness achieved days 15 business Days after contract award, with a signed agreement

2.4   Uninterrupted Workflow during Transition Process

The key components of our transition plan are based on best practices that have proven successful on prior task orders. Our plan will ensure uninterrupted service and minimal disruption during the transition period as a result of:

- A fully committed corporate leadership team and an incumbent management team that is dedicated and committed to this work.

- A strong focused management and transition team that will implement a management approach based on processes, tools, and reports.
- A detailed communications plan that will facilitate the meaningful exchange of information across all parties.
- Plan to seamlessly execute without risk of interruption.
- A staff that fully understands your agency operations, is experienced in executing all requested tasking and is experienced with the community.

Management Plan to Achieve the Objectives of Requirements (Management Plan Conclusion Statement)

Team RVGS has more than 40 combined years of demonstrated and relevant experience in managing representative task orders of relevant size, scope, complexity and geographical disbursement. Our management tools are based on years of successful management, insights, and capabilities sourced from the Defense Acquisition Management Guide, ISO 9000, and best industry practices. Our processes map to the unique Federal and State Government environment to ensure quality/timeliness for all tasks. All of our proposed staff members are ready to start work and are either on board now or have signed contingency offers.

2.5   Staffing Approach

RV Global understands the need to balance readiness and modernization, leverage technology and make every dollar count for your agency. To manage a qualified and capable workforce for programs the size and complexity of your agency, RV Global employs two types of planning: *Strategic* and *Operational*. Strategic staff planning looks at program-wide issues to support the broader program management plan, address external staffing factors that affect the entire program (e.g., consolidation of program responsibilities due to budget cuts), maintaining organizational capacity through activities such as training, and mitigating risk exposure.

Operational staff planning looks at work-unit issues and occurs at the supervisor level. The focus here is on sustaining the work unit's ability to execute to verify that staff has the right quantities and combination of competencies, skills, and training to perform current and future work. It also looks at performance measures to validate whether we are effectively conducting the work.

RV Global employs a cyclical staff planning process, with ongoing inputs, outputs, exchanges and coordination between various functions and phases. Inputs and outputs of the planning process link a variety of other program and resource planning processes. Our PMO conducts strategic planning activities annually with operational planning occurring on a monthly basis and reports outcomes as part of our monthly program management reporting to your agency. We also report this data quarterly as part of our company-wide internal program management reviews.

RV Global further defines Inputs into three elements: Issues, Goals, and Objectives/Desired Results. **Issues** include drivers such as changes to the external environment as in the broader your agency reorganization or internal changes such as anticipated workforce retirements. **Goals** are broad, high-level statements that address specific Issues. An example of a Staffing Goal for your agency is "Reduce impact to operations during the transition from the incumbent contractor to the incoming contractor." **Objectives** describe the measurable results expected when a goal is achieved. For example, during the transition, we have established a goal of maintaining 90% of the desired incumbent workforce. Our objectives will be tested against the following SMART criteria:

Specific – Does it address a clear and precise element of success?

Measurable or observable – Is it either quantifiable or clearly observable?

Action-oriented – Does it address the results of a specific action?

Realistic – Can the organization realistically influence the desired result?

Time-oriented – Is there a time limit within which the objective must be achieved?

From these inputs, the RV Global PMO will establish staffing strategies and action plans that determine how we will achieve our stated objectives. Our Staffing Plan encompasses several focus areas with corresponding strategies as shown in **Table 3**, below.

Table 3 - RV Global Staffing Strategies

Focus Area	Strategies
Recruitment	Recruitment strategies—e.g., outreach, marketing, branding—to address anticipated vacancies on a project-wide scale
Assessment	Screening and selection strategies to improve the quality of candidate pools
Retention	Retention strategies to prevent or mitigate turnover on a project-wide scale
Deployment	Project redistribution strategies to take better advantage of staff knowledge, skills and abilities
Training & Development	Project staff training strategies to address new work requirements
Succession	Succession programs and strategies to build internal pools for anticipated Vacancies
Employee Performance Management	Performance management strategies to address new requirements or deliverables. Also, project-wide strategies for redistributing or removing underperforming employees.

When necessary, RV Global will coordinate with your agency and the Contracting Office (CO) for the redistribution of support. The redistribution will be accomplished within the greater of either the Government requested time frame or two (2) weeks (14 calendar days) from the Government-requested modification.

Ability to Hire: RV Global will employ proven successful staffing processes to hire qualified and experienced personnel for your agency. Our hiring approach has two distinct phases – Transition and Steady State. During Transition, we will recruit with a preference for the qualified incumbent workforce to preserve institutional knowledge.

We will review with cognizant your agency leaders the incumbent personnel staffing. We will keep all qualified incumbents who meet RV Global hiring standards.

To support Steady State and rapidly fill vacant and new positions, RV Global recruiters will utilize pipelining (*Figure 4*) which builds an inventory or bench of pre-qualified candidates, thus ensuring we maintain a

"talent pool" of candidates at all times. In our highly competitive industry, we have already begun to build our pipeline by:

- Proactively identifying candidates with experience, qualifications, and education and making initial contact and creating a pipeline of candidates.
- Increasing our speed of hire by completing the sourcing "leg work" ahead of time.

We use several online tools and career forums, including Monster, Dice, Indeed; post jobs through technical user groups, and use connections via LinkedIn and other social media forums. Most importantly, we encourage employee recommendations of qualified personnel and use our employee referral program which provides bonuses for referrals that result in a hire. In addition, RV Global has an established working relationship with few nationwide recruiting firms that have assisted us with other programs.
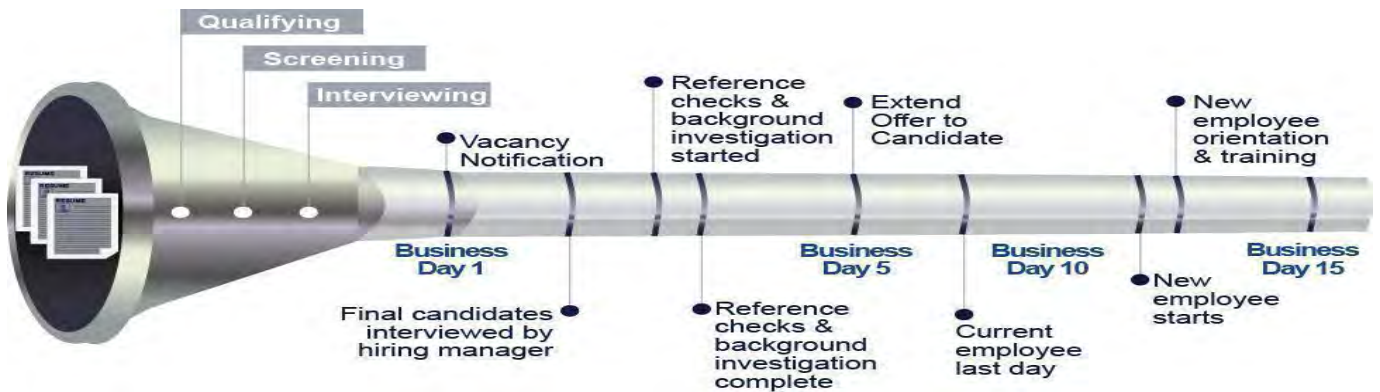
Figure 4 –Staffing Approach. Our "Pipelining" Staffing Approach results in the ability to quickly staff positions ensuring tasks continue uninterrupted.

We do and will foster open communications with the staff and your agency customers. Upon identifying the need for a new or replacement employee, we will escalate recruiting efforts. As shown in *(Figure 4)*, we will fill positions with qualified personnel who can meet the requirements of the position within 15 business days from when we first identify a need, to the start date of a new or replacement employee.

Interviewing Methods: The dedicated, knowledgeable corporate and professional recruiters for RV Global recruit today in a technical environment and understand the nature of the services performed. We are currently recruiting in other locations so that we have a ready view of the local workforce. All RV Global interviewers are trained in how to conduct appropriate interviews. Our interviewing methods will reinforce our commitment to hiring well-qualified applicants by:

- Describing the position requirements so they understand their role on the project, the performance objectives, and important ethical and corporate policies of the company
- Accurately reflecting company information, benefits, and the work environment
- Fairly and consistently evaluating candidates using similar questions and criteria for each position
- Carefully screening every candidate for education, experience, and clearance data
- Taking comprehensive interview notes and sharing them internally (as appropriate) and with the management team
- Avoiding inappropriate questions such as marital status, religion, politics, or gender, and
- Utilizing our HR/recruiting Manager and all HR/recruiters for fair salary determination
- Our approach to providing services in a timely manner from a project management point of view, communications point of view, and relationship point of view

TransMedics®

<u>COVER PAGE</u>

Notice Number: HSB115C1031
Title: Request for Information on the Organ Procurement and Transplantation Network (OPTN)
Date of Issuance: April 8, 2022
Name: TransMedics
Address: 200 Minuteman Rd
    Suite 302
    Andover, MA 01810
Point of Contact: Waleed Hassanein, M.D.
    President, and CEO
    TransMedics Group, Inc.
Phone: +1 617-510-3327
Email: whassanein@transmedics.com

May 9, 2022

Via Electronic Submission to NInazawa@hrsa.gov

Health Resources and Services Administration
Department of Health and Human Services
Office of Acquisition Management & Policy
5600 Fishers Lane
Rockville, MD 20852

> RE: Request for Information by the Health Resources and Services Administration regarding the Organ Procurement and Transplantation Network (OPTN): Notice # HSB115C1031

To Whom it May Concern:

TransMedics, Inc. ("TransMedics") thanks the Health Resources and Services Administration ("HRSA") for the opportunity to respond to its Request for Information ("RFI") seeking to strengthen and improve components of the Organ Procurement and Transplantation Network ("OPTN") contracting process.[1] We specifically offer comments on how HRSA can increase organ donation with a focus on improving heart, lung, and liver transplantation. We hope our comments will aid the Office of Acquisition in both improving OPTN operations and in improving patient outcomes and significantly increase donor organs utilization for transplantation, thereby also increasing transplantation equity and accessibility.

<u>About TransMedics:</u>

TransMedics is a medical device company founded to address the unmet need for more and better organs for transplantation, with a specific current focus on heart, lung, and liver transplants. TransMedics has developed the FDA-approved Organ Care System ("OCS") to replace the decades-old static cold storage standard of care that is significantly limiting access to life-saving transplant therapy for hundreds of thousands of patients worldwide. Since receiving FDA approval in 2021, we have initiated a national program to provide an end-to-end service and technology solution for donor organ surgical retrieval, OCS perfusion, and clinical assessment in collaboration with the existing OPTN, leading transplant programs and select Organ Procurement Organizations ("OPOs") across the U.S. with the primary goal of increasing utilization of donor organs for transplant. We urge the Office of Acquisition to include a requirement for the OPTN to utilize this network, or one like it, in the upcoming contracting process.
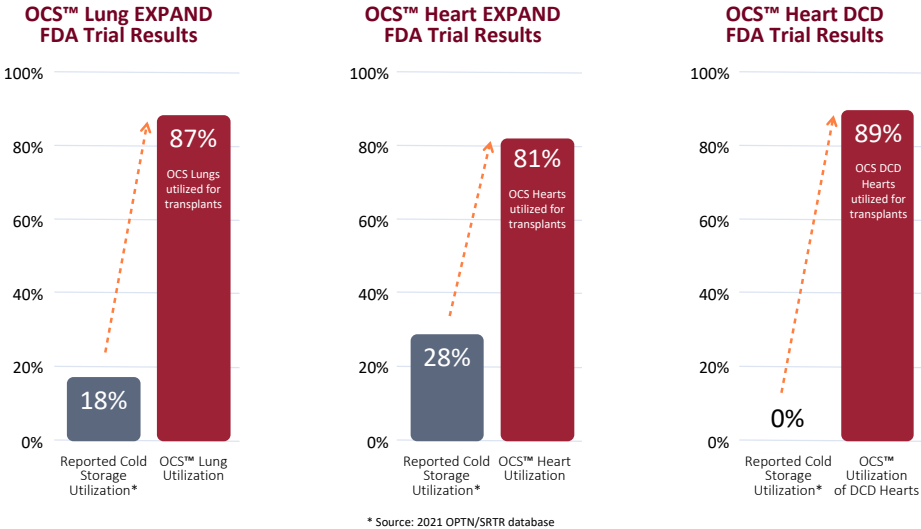
The OCS technology is the first portable, multi-organ platform for extracorporeal, oxygenated blood perfusion of solid donor organs in a living and functioning state (heart beating, lungs breathing, and liver producing bile), outside of the human body for eventual transplantation

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[1] *See* Press Release, Health Resources and Services Administration, HHS Releases Request for Information on Ways to Strengthen and Improve the Organ Procurement and Transplantation Network (April 8, 2022) https://www.hrsa.gov/about/news/press-releases/hrsa-releases-organ-procurement-transplantation-network-rfi.

into recipients who suffer from end-stage heart, lung, and liver failure. Unlike historic and traditional cold static-storage methods for solid organ preservation for transplants (ice coolers and ice to preserve precious vital human organs), the OCS technology replicates many aspects of the organ's natural living and functioning environment outside of the human body, which significantly reduces damage that occurs using cold-storage, enables optimization and clinical assessment of the donor organ viability for transplantation to maximize clinical confidence to transplant organs to recipients in need. As such, it represents a fundamental paradigm shift in organ preservation by allowing more organs to remain usable for longer and reach patients in better condition. The OCS transforms the standard of care in transplantation by increasing donor organ utilization, improving patient outcomes, and reducing transplant costs. To date, employment of the OCS has resulted in more than 2,000 organs transplanted. We hope to see that number grow significantly over the next several years.

OCS™ Lung EXPAND
FDA Trial Results

18% — Reported Cold Storage Utilization*

87% — OCS Lungs utilized for transplants — OCS™ Lung Utilization

OCS™ Heart EXPAND
FDA Trial Results

28% — Reported Cold Storage Utilization*

81% — OCS Hearts utilized for transplants — OCS™ Heart Utilization

* Source: 2021 OPTN/SRTR database

OCS™ Heart DCD
FDA Trial Results

0% — Reported Cold Storage Utilization*

89% — OCS DCD Hearts utilized for transplants — OCS™ Utilization of DCD Hearts

TransMedics appreciates that transplantation has always been a collaborative effort. Successful organ transplantation requires significant coordination and contribution from multiple parties including donors, their families, skilled surgeons and transplant programs, technology systems, OPOs, the OPTN currently run by the United Network for Organ Sharing ("UNOS"), and many other healthcare providers. As reflected in our comments below, TransMedics is committed to working with all current U.S. transplant stakeholders to develop and provide the best possible outcomes to those in need of organ transplantation.

As the February 2022 National Academies of Science, Engineering, and Medicine ("NASEM") report titled, "Realizing the Promise of Equity in the Organ Transplantation System," recognized—OPOs suffer from significant variations in performance, which leads to a system containing inefficiencies and inequalities. While many of NASEM's conclusions relate to kidney transplant access, NASEM also examined heart, lung, and liver transplants, which has not been effective for patients with end-stage organ failure. For the past decade or longer, donor lungs and hearts have been limited to 20%-30% of the available deceased donors annually. This significant waste of valuable and precious resources, at least with regard to heart, lung and liver transplants,

is primarily due to severe limitations of cold static storage preservation, compounded by the current system of OPO financial remuneration that incentivizes kidney transplants over those of other organs.

Given the significant advancements of innovative technologies that overcome historical limitations of cold static storage and the growing dedicated clinical expertise that is focused on non-renal organs (hearts, lungs and liver), TransMedics urges HRSA and your office to innovate and modernize the U.S. transplant system by creating a new, nation-wide, paradigm in the transplant ecosystem specializing in non-renal organs (heart, lung, and liver). Authorizing the addition of a new national Organ Management Organization ("OMO") specializing in non-renal organs (heart, lung, and liver), and leveraging the latest FDA-approved technologies that have demonstrated significant increase in donor heart, lung, and liver utilization from both donor after brain death ("DBD") and donors after circulatory death ("DCD") is needed to both dramatically increase thoracic and liver organ transplantation in the United States and to improve efficiency in the transplant eco-system.

While the RFI focuses on the operational structure of the OPTN and the OPOs as well as their processes, we believe our proposal would serve to greatly improve their respective operations, as well as further the goals of transplant equity, access, and transparency in the donation, allocation, procurement, and transplantation process. With those ends in mind, we believe that HRSA should consider a national OMO program and incorporate the proposal within the upcoming OPTN contract renewal. An OMO program would dramatically improve the performance of both OPOs, transplant programs to increase the non-renal organ utilization for transplantation in three possible ways:

1) It will maximize the utilization of non-renal organs that go unused today due to historical limitations of cold storage and logistical inefficiencies. This will improve the performance of existing OPOs to meet CMS performance metrics;
2) It will better allow OPOs to focus on renal transplantation and relieve the challenges facing OPOs in thoracic and liver transplantation.
3) It will enable transplant programs to focus on performing more transplants, by freeing their highly trained clinical staff to perform more transplants, while the organ procurement and preservation process is managed by a dedicated national OMO that maintains high quality of care and avoids learning curves.

The proposal would also support the OPTN in reducing variations in practices and procedures because it would enable OPOs to streamline and focus primarily on renal transplantation, while the OMO would focus on hearts, lungs, and livers. The OPTN, which would remain intact, would continue to provide quality standards for both the OPOs and the OMO, transplant programs would not need to change, and most importantly, transplant patients would reap the benefits of two parallel organizations specializing in renal and thoracic/liver organs respectively. This would result in a net gain in available transplantable organs thereby alleviating equity problems rooted in scarcity. By operating simultaneously OPOs and the OMO would see improvements to the practices and procedures facilitating organ donation and procurement that come from specialization.

<u>Summary of Comments and Key Recommendations:</u>

As noted above, the current transplantation system regulatory incentives and Medicare financial reimbursement incentives could drive OPOs to focus on renal organ transplants, which may inadvertently disincentivize the recovery and transplantation of non-renal organs. Successful kidney transplantation is inarguably a desirable goal with 37 million patients suffering from chronic kidney disease in the United States[2] and over 90,000 people waiting for kidney transplants.[3] However, successful kidney transplants should not come at the exclusion of successful heart, lung, and liver transplants. Unfortunately, these existing incentives crowd out thoracic and liver organ transplantation in favor of focusing on kidneys. The current OPTN and OPO infrastructure and resources lack the clinical and technical expertise for thoracic donor management and the utilization of new, innovative, medical technologies for extracorporeal perfusion of hearts, lungs, and livers to assess their clinical suitability for transplantation outside the donor body.

Americans deserve both—access to successful renal *and* thoracic and liver transplantation. We propose that HRSA maintain OPOs management of kidney transplantation and develop a parallel national OMO, also operating under the OPTN's standards, to assist OPOs and transplant programs in maximizing heart, lung, and liver donor organ utilization from DBD and DCD donors. The OMO would be responsible for managing the process of thoracic and liver organ surgical recovery in coordination with transplant programs and existing OPOs, as well as manage extracorporeal perfusion, clinical assessment, transportation, and allocation of non-renal organs according to UNOS allocation rules. We believe this bifurcation would maximize the utilization of both renal and non-renal organs for transplantation. This could be a win-win for all transplant stakeholders in the U.S. The net increase of thoracic and liver organs that would result from OMO management would greatly reduce and eliminate many of the scarcity-based barriers currently affecting underserved populations and serve the goal of equity in transplantation.

Creating a national OMO partner focused on handling thoracic and liver transplantation in parallel to the OPOs' management of renal transplantation is the natural next step for the regulatory framework to keep pace with the dramatic advancements in donor organ perfusion and clinical assessment capabilities, as well as the rapid growth of the use of DCD donors to improve the lagging thoracic and liver organ transplantation rates. A national OMO is now appropriate because this advanced <u>portable</u> extracorporeal donor organ perfusion technology resolves and eliminates the inherent geographical limitation of organ donation due to the limitations of cold static storage

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[2] Centers for Disease Control and Prevention, CHRONIC KIDNEY DISEASE INITIATIVE (2021), https://www.cdc.gov/kidneydisease/basics.html#:~:text=About%2037%20million%20US%20adults,dialysis%20treatment%20for%20kidney%20failure.

[3] Health Resources & Services Administration, *Detailed Description of Data*, ORGAN DONATION STATISTICS (2020, 2021), https://www.organdonor.gov/learn/organ-donation-statistics/detailed-description#fig1.

that originally caused the OPO regional structure to evolve into its current shape. Now, it is possible to use donor hearts, lungs and livers that were seldom used in the past based on limitations of cold storage. In addition, the OCS dramatically extends the reach of these donor organs that are perfused to transplant patients anywhere in the U.S. without time and distance limitations. Data from pivotal FDA trials of the portable extracorporeal donor organ perfusion technology clearly demonstrated the potential to significantly increase the number of successful heart, lung, and liver transplants from both DBD and DCD donors. In sum, the combination of the OCS technological advancements and the development of dedicated clinical expertise in clinical perfusion and assessment of non-renal organs removes previous regional boundaries for organ donation rooted in cold storage limitations and makes non-renal organ transplantation a national issue with a national solution—the national OMO partner.

Background on Non-Renal (Heart, Lung, and Liver) Organ Transplantation:

Before responding to HRSA's question regarding improving OPO performance and addressing the proposed OMO concept in more detail, we wish to highlight some of the statistics of heart, lung, and liver transplantation. In 2021, according to OPTN data, there were 13,863 deceased donors in the U.S. that agreed to donate their organs for transplant, of which, only 3,817 hearts, 2,524 lungs, and 8,667 livers were transplanted. This left the vast majority of deceased donor organs unutilized for transplantation due to limitations of the historical cold storage technique. This dismal utilization rates have been consistent for the past decade in the U.S. according to the OPTN national transplant database—see Figure 1 below. The severe underutilization of deceased donors for non-renal organs annually is devastating and limits the access of the most effective therapy for chronic end-stage organ failure. The need for organ transplantation is already large and increasing due to population demographics and the growth of the waiting list for patients in need of heart, lung, and liver transplantation. These data indicate that we need to do better, as America is losing ground, rather than reducing the waiting list, for these important organs.

Figure 1: U.S. Heart and Lung Deceased Donor Orgn Utilization for the Past Decade – OPTN National Data Jan 2022
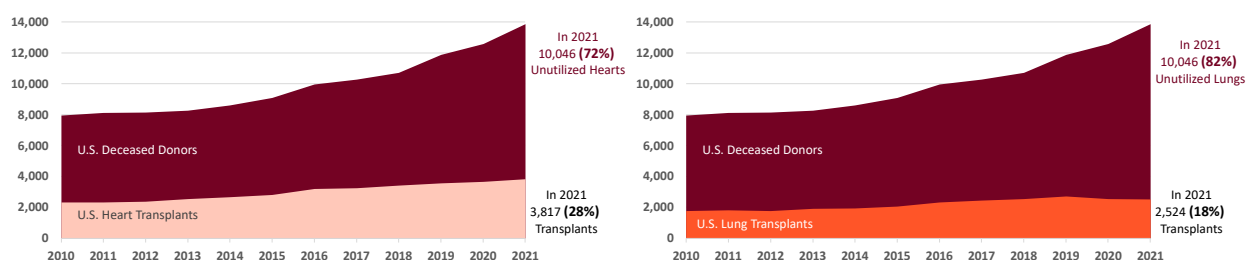
These figures represent a failure of the current transplant system to appropriately manage the recovery of hearts, lungs, and livers. But they also represent an incredible opportunity to increase transplantation, save government and health care costs, and improve patient outcomes in the coming years, as well as maximize access for patients across the U.S. to life-saving transplant procedures. The 2021 statistics are not an abberation and the 2020 statistics are no better—

compared to the 2,539 transplanted lungs in 2020, 10,049 lungs went unused.[4] Compared to the 3,658 transplanted hearts, 8,930 hearts went unused.[5] Livers totaled 4,173 unutilized livers compared to 8,415 used.[6] Significant annual underutilization of donor organs persists.

TransMedics has identified three reasons that thoracic and liver organ recovery so badly lags behind kidney transplantation. First, as will be explored in more detail below, current CMS coverage of OPO financial cost policies incentivize kidney recovery, and may inadvertently disincentivize pursuing the recovery and allocation of thoracic organs once kidneys are allocated. Second, due to their historical role and regional focus as required by law, OPOs do not have the clinical expertise nor the infrastructure available to clinically manage thoracic organs, especially with the advent of new breakthrough portable extracorporeal technologies to keep hearts, lungs, and livers living and functioning (heart beating, lung breathing and liver producing bile), outside of the donor body to maximize the probability for use during transplantation—an issue easily solvable if a national OMO partner with the needed national clinical expertise and technology infrastructure existed, and particularly appropriate now that portable organ perfusion technology is available and FDA approved for DBD and DCD clincial indications for lung, heart and liver transplants. Indeed, TransMedics is currently filling this gap today.[7]

Finally, the cold storage time-dependent severe ischemic injury imposed a historical time and distance limitation on non-renal organs which further limited the utilization of these organs for transplantation. Indeed, the current U.S. national allocation of donor organs to maximize access is not working for hearts, lungs and livers due to these historical limitations. This third barrier no longer exists following FDA approval of the TransMedics OCS for hearts,[8] lungs,[9] and

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[4] Organ Procurement & Transplant Network, NATIONAL DATA (2020).
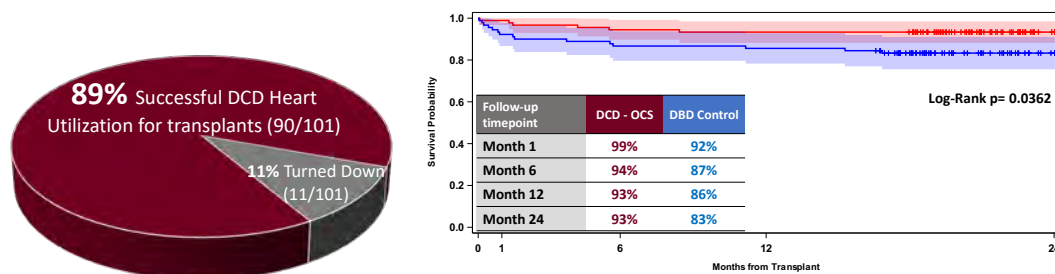
[5] *Id.*

[6] *Id.*

[7] The FDA approvals can be found at:
- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P180051S001
- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P200031
- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160013S002

[8] *See* Schroder, et al., *Successful Utilization of Extended Criteria Donor (ECD) Hearts for Transplantation - Results of the OCS™ Heart EXPAND Trial to Evaluate the Effectiveness and Safety of the OCS Heart System to Preserve and Assess ECD Hearts for Transplantation,* DOI:https://doi.org/10.1016/j.healun.2019.01.088, Journal of Heart and Lung Transplantation, April 1, 2019; Rojas, et al., *Cardiac Transplantation in Higher Risk Patients: Is Ex Vivo Heart Perfusion a Safe Preservation Technique? A Two Center Experience,* DOI:https://doi.org/10.1016/j.healun.2019.01.091, Journal of Heart and Lung Transplantation (April 1, 2019); *see also* https://www.fda.gov/medical-devices/recently-approved-devices/organ-care-system-ocs-heart-system-p180051 (FDA approval of OCS system for hearts).

[9] *See* Loor, et al., *Portable normothermic ex-vivo lung perfusion, ventilation, and functional assessment with the Organ Care System on donor lung use for transplantation from extended-*

livers.[10] TransMedics has solved for these limitations by creating medical technologies which are fully <u>portable</u>, multi-organ, normothermic extracorporeal perfusion and assessment technologies that mirror human physiology, minimize ischemia, and provide the ability to optimize the organ during preservation from donors to recipients.[11] In fact, over the past 2 years TransMedics OCS Heart technology enabled for the first time ever the use of DCD hearts for heart transplantation in the U.S. These are hearts that had stopped beating in the body of the donor and historically they have never been used for transplants. Over the past 2 years, due to OCS Heart system DCD heart transplants are growing in the U.S. and it expands the pool of donor organs for transplants by approximately 4,190 donors based on the 2021 OPTN U.S. national database. Below is a summary of the clincial results from the OCS DCD Heart randomized trial that was the FDA pivotal trial data used for FDA approval of this DCD heart indication in the U.S. and was just presented at the annual meeeting of the International Society for Heart and Lung Transplantation (ISHLT).

Follow-up timepoint	DCD - OCS	DBD Control
Month 1	99%	92%
Month 6	94%	87%
Month 12	93%	86%
Month 24	93%	83%

89% Successful DCD Heart Utilization for transplants (90/101)

11% Turned Down (11/101)

Log-Rank p= 0.0362

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criteria donors (EXPAND): a single-arm, pivotal trial, DOI:https://doi.org/10.1016/S2213-2600(19)30200-0, The Lancet (Aug. 1, 2019); Warneke, et. al., *Normothermic ex-vivo preservation with the portable Organ Care System Lung device for bilateral lung transplantation (INSPIRE): a randomised, open-label, non-inferiority, phase 3 study,* DOI:https://doi.org/10.1016/S2213-2600(18)30136-X, the Lancet (April 9, 2018); *see also* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160013 (FDA approval of OCS system for lungs).

[10] *See* Markmann, et al., *Impact of Portable Normothermic Blood-Based Machine Perfusion on Outcomes of Liver Transplant, The OCS Liver PROTECT Randomized Clinical Trial,* JAMA Surgery (published online), doi:10.1001/jamasurg.2021.6781 (Jan. 5, 2022); *see also* https://www.fda.gov/medical-devices/recently-approved-devices/organ-care-system-ocs-liver-p200031 (FDA approval of OCS system for liver).

[11] Although not addressed here, TransMedics acknowledges that it is not the only developer of such technologies.

The results demonstrated that the use of portable extracorporeal perfusion with OCS Heart technology resulted in 89% (90/101) successful utilization of DCD donor hearts for transplantation and with 1 and 2 year survival of 93% compared to 86% and 83% respectively from DBD donor heart transplants preserved using cold storage.

In sum, the OPTN transplant data indicate that heart, lung, and liver transplantation badly lags behind kidney transplantation (which itself is in need of substantial increase). The reasons explaining this phenomenon no longer exist. Yet, the present regulatory system continues to be limited by historical limitations that no longer are relevant and in significant need for modernization and innovation to leverage new technologies and processes to maximize access to the life-saving organ transplant procedures in the U.S. To redress this unfortunate reality, we kindly call upon HRSA to innovate and modernize the U.S. transplant system through the upcoming OPTN contract renewal by authorizing the creation of a new, national OMO partner structure to maximize the recovery and transplantation of available hearts, lungs and livers.[12]

Responses to RFI:

Section 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.*

The NASEM report acknowledged that the current organ transplantation system is fragmented, inefficient, and stands to benefit from system-level improvements. We agree; the transplantation system requires more significant regulatory innovation and modernization. Right now, technology for heart, lung, and liver transplants has drastically improved organ utilization from previous cold storage techniques. One of the reasons that the OPO regional structure evolved in the manner that it did was due to the inherent geographical limitation of organ donation due to the limitations of cold static storage and associated ischemic damage to the donor organs. With TransMedics' OCS technology, surgeons can recover hearts, lungs or livers and immediately peruse them with warm oxygenated blood to significantly reduce ischemic time to a minimum and the organs can travel over vast geographical distances without ischemic damage. Please see the map below with few examples of OCS lung, heart and liver transplants that wouldn't have been possible with cold storage

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[12] TransMedics welcomes the opportunity to explore in more detail with HRSA how the OMO would function. In brief, however, the OMO would partner with the OPTN and existing OPOs. The OPOs would retain their role of obtaining family consent to donation and all tissue typing. The OMO would assume responsibility for clinical management of thoracic organs, manage the allocation process (in coordination with the OPTN and transplant centers), coordinating procurement times and access, be responsible for organ traceability, manage data on donors/organs, organize transportation, meet relevant outcomes measures on utilization, and establish quality management system for the entire process.

This has resulted in significantly more "transplantable" thoracic and liver organs (see data chart below). But the existing regulatory framework does not effectively utilize, much less maximize, this life-saving innovation. Given the current regulatory framework, OPOs and transplant programs are not incentivised to use the new technologies to maximize donor organ utilization for transplant. Rather than trying to fit a square into a circle, HRSA can also innovate the existing regulatory framework to add an OMO partner system to join the OPOs and transplant programs in transplantation management to remove the barriers of utilizing new and innovative technologies in U.S. transplant system.
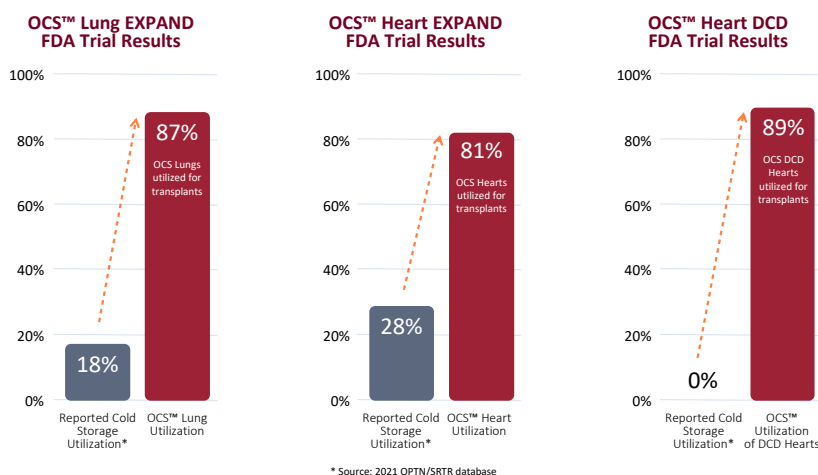
A single, or multiple, national contractor, working through the OPTN and operating a national heart, lung, and liver organ management organization would be able to overcome many, if not all, of the existing barriers to increasing organ recovery and transplantation. The OMO model would act in parallel to the OPO model, relying on OPOs when needed and working alongside OPOs for other tasks. The OMO would have authority to partner with transplant hospitals for non-renal organ procurement, perfusion and assessment for transplantation of hearts,

lungs, and livers. It would also have the authority and capability to transport hearts, lungs, and livers across the United States from donor locations to recipients' transplant programs while limiting ischemic damage and providing prospective clinical assessment metrics to support utilization of these organs for transplants. These capabilities would not only significantly expand the utilization of these donor organs, but also reduce the risk to potential recipients, given the assessment capabilities afforded by the portable perfusion technology. For example, the OMO would provide the capability to retrieve more "extended-criteria" and DCD organs that were seldomly used for transplant using the historical cold storage technique. Having the OMO be responsible for the entire donor organ procurement process from donor to recipient including extracorporeal perfusion and assessment, will standardize the clinical care of these precious organs to maximize utilization and undoubtedly improve post-transplant clinical outcomes. The transplant center teams would remain on-site at their transplant program, increasing efficiency in the system for a greater number of transplants without the drain of the organ procurement process on human resources at the transplant program. The national OMO would provide a consistent method for non-renal donor organs' surgical procurement avoiding the inconsistent policies across today's OPOs.

Further duties of an OMO would include the ability to help OPOs in allocating non-renal organs according to the existing UNOS (or future OPTN) allocation rules and under the OPTN/UNOS's oversight. An OMO specializing in non-renal organ transplantation would have the time, energy, and clinical resources to devote to these organs which would lead to a net increase in the number of usable organs. Having more usable organs available for transplantation will reduce or eliminate many existing barriers based in scarcity decision-making. As a result, instituting an OMO would greatly further equity in the transplantation process.

In accord with the NASEM report recommendations, we also envision the OMO developing an annual evaluation metric for measuring the effectiveness of the organization in acquiring, transporting, and maintaining potentially available hearts, lungs, and livers. This would help many of the existing OPOs to meet the CMS performance requirements and will also hold the OMO accountable for the same metrics. The net result is dramatic improvement in donor organ utilization for transplantation and increased access to this critical life-saving therapy in the U.S.

We also recommend that HRSA, through the upcoming OPTN contract specifications, modernize transplant program evaluation metrics to motivate transplant programs to do more transplants and not only focus on a high-post transplant survival rate at the one year mark. There are many patients that die on the waiting list because of the hesitation of the transplant program to accept what may appear as extended criteria donor organs because of their clinical concerns about meeting the CMS 1-year survival metric. This is a critical issue given that many thoracic organs are not utilized because of this issue.

However, OPO metrics alone may never be adequate to promote more donor organ utilization for transplantation. Transplant programs should also be assessed based new metrics of transplant volume growth, use of modern and latest FDA-approved portable organ perfusion, and assessment technologies to increase their transplant volume. They should also be assessed based on some metric of waiting list dynamics to incentivize transplant programs to accept more donor

hearts, lungs, and livers for transplantation for example. We kindly ask HRSA to consider including new and innovative metrics to motivate transplant programs to transplant more organs. For example:

- Assessment of transplant program volume growth year over year
- Assessment and public disclosure of the number of thoracic and liver organs refusals by each transplant program and reasons given
- Assessment and public disclosure of the number of thoracic and liver DCD organ utilization by each transplant program and reason for refusals
- Some risk adjustment of the 1-year outcomes to enable more large volume centers to balance their post-transplant outcomes with donor organ risk factors to avoid penalizing them on outcomes
- Include waiting list survival and time on the waiting list to motivate transplant programs to transplant more patients

We also urge HRSA to consider requiring the OPTN to implement greater communication between OPOs, donor hospitals, transplant programs, and other relevant stakeholders. The current breakdown of communications is driven in part by the above-described historical reimbursement structure that is incentivizing kidney-only procurement, and the transplant programs' hesitation to accept non-renal organs based on ischemic time and distance limitations of cold storage. HRSA could address these communication issues by requiring the OPTN to implement the national OMO model and have the OPTN work in concert with the existing OPOs and transplant programs to focus on maximizing donor hearts, lungs, and liver organ utilization for transplantation. Consolidation of thoracic and liver organ management organization would improve the effectiveness and timeliness of communication between the different entities in the transplantation ecosystem. This approach would benefit all stakeholders involved; OPOs, OMO and transplant programs transplants and will significantly increase the number of non-renal organs for transplantation.

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

The NASEM report identified the goal of creating a fairer, more equitable, cost-effective, and transparent organ procurement, allocation, and distribution system. We believe that health equity should be an explicit metric for the OPTN and OPO evaluation and measurement, as well as for the proposed OMO. A key driver of reduced access to transplantation by racial and ethnic minorities is related to the limitation, or scarcity, of donor organs. Subjective priority decisions take place within the transplant ecosystem and deem some would-be recipients riskier than others. More available organs would mean more access to transplantation for patients that may have previously been considered risky. Importantly, removing the historical time and distance geographical limitations on donor organ utilization would maximize access to patients across the U.S.

As explained previously, a national OMO partner model utilizing the latest FDA-approved medical technologies that have demonstrated unequivocally significant increase of donor organ utilization for hearts, lungs, and livers from both DBD and DCD donors would increase the net

availability of organs. It would allow the OMO to specialize in heart, lung, and liver recovery and remove obstacles that exist for non-renal organ transplantation. An OMO model would increase net organ availability and reduce disparities. We believe this would also remedy many problems plaguing African American access to transplantation as well. African Americans are more often put on very expensive medical devices (LVADs, as but one example) that result in lower survival durations than transplants and is plagued with high-rate of clincial complications that reduce quality of life and are costly. Faulty assumptions about quality of life and the ability to perform post-operative care limit access for African Americans to more transplants that would most importantly lengthen their lives, and secondarily, would reduce healthcare costs.

Many in the transplant community are unaware of the significant technological advancement of portable extracorporeal perfusion technology in the care of recovered thoracic and liver organs, and of the recent (2021) FDA approval of technologies to improve organ care for utilization of DBD and DCD donor organs that historically have gone unused for transplants. HRSA, through the various educational channels available at the OPTN, at OPOs, and otherwise, should do its part to highlight the availability of this technology to the entire transplant community and what it means for increased heart, lung, and liver transplantation.

Section 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.*

We agree with the NASEM report's concern that the existing organ discard rate is too high. Research and our hands-on experience at TransMedics show that many non-renal organs are never even recovered from deceased donors due to the above limitations of the current limitations of the historical cold storage technique and system. We believe that modernization of the current system to expand the focus on *all* solid organs and not limited to kidneys would be extremely helpful, and frankly—needed, to keep with the pace of technology and therapy advancements in transplantation (like the growing use of DCD heart, lung, and liver donors for transplantation). Allowing the creation of new national OMO partners that are solely focused on heart, lung, and liver transplants, equipped with latest portable organ perfusion clinical assessment technologies and staffed with clinical expertise that know how to utilize, resuscitate, and allocate these organs would dramatically increase the rate of utilization of these critical organs and will directly result in improving the perfomance metrics of existing OPOs to meet CMS perfomance guidlines. The key is there must be some form of system drive to enable the OMO to broadly work within the construct of the OPTN network to enable the OMO to truly maximize donor organ utilization across the U.S. system.

TransMedics has first-hand experience with this approach with excellent results. For the past 18 months TransMedics has been collaborating with leading transplant programs and select OPOs across the U.S. and we have demonstrated unequivocally that this proposed structure could significantly increase the utilization of thoracic and liver organs that today may go unused due to current system limitations. Importantly, the dramatic increase of DCD donor hearts for transplantation was a direct result of the OCS Heart technology's capability to resuscitate, preserve

and clinically assess donor hearts outside of the donor body and resulted in excellent post-transplant clinical outcomes.

Why are so many hearts, lungs, and livers not recovered? There are three main reasons:

1) Historical limitations of cold ischemic storage: heart, lung and liver transplantation are more prone to ischemic damage and given the clinical concerns of time/distance, lack of clinical optimization capabilities and lack of clinical assessment capabilities associated with cold ischemic storage, clinicians are more reluctant to use lungs, hearts and livers from distant donors, or from donors that may be considered extended criteria or DCD donors.

2) Two regulations that may inadvertently incentivize OPOs to recover kidneys and may forgo the more complex process of surgically procuring and allocating thoracic organs. First, although OPOs are paid a standard acquisition charge from the transplant center (or other OPO) that acquires any organ, the methodology to establish the OPO acquisition charge and the ability of an OPO to recover its operational costs, to the extent they are higher than the acquisition charge, differ between kidneys and non-renal organs. With kidneys, the standard acquisition charges are set by the Medicare contractor and are based on data from the OPOs prior cost report.[13] The payment of the standard acquisition charge from the transplant center also serves as an interim payment to the OPO until the end of the cost year. At the end of the cost year, the OPO will submit a cost report in which it identifies all of the OPO's actual costs attributable to the recovery of kidneys. The actual costs are then reconciled against the standard acquisition charges the OPO received from transplant centers and other OPOs. If the actual costs exceed the standard acquisition charges, the OPO receives a payment so that it recovers 100 percent of the reasonable costs of recovering kidneys (and if standard acquisition charges exceed costs, then CMS recoups the difference).[14] In sum, the federal government will cover 100 percent of the OPO's costs of procuring *kidneys*. In contrast, *non*-kidney acquisition charges are established by the OPO—not the Medicare contractor—and are based on its costs of procuring those specific organs. The payments that OPOs receive from transplant centers for non-kidney acquisitions are the final payments and there is no reconciliation to cost by the federal government or the transplant center. Thus, every time an OPO is presented with the opportunity to recover a heart, lung, or liver, it runs the risk that if these organs are not allocated for transplants for any reasons, they will reduce the overall CMS payments.

3) Second, and just as important, Medicare reimburses OPOs not only for the direct costs of recovering kidneys, but also the indirect costs—such as overhead (e.g., organ

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[13] 42 C.F.R. § 413.200(d); Provider Reimbursement Manual (PRM) 15-1 Ch. 31 § 3108(B).

[14] 42 C.F.R. § 413.200(e).

procurement education) and Administrative and General ("A&G" – e.g., salaries, benefits, office support, and supplies)—that support kidney acquisitions. These indirect costs are also reported on the OPO's cost report along with statistical data, including the number of kidney and non-kidney organs that the OPO procured or processed. Through a process called "cost finding," the OPO's indirect costs are allocated to various "cost centers" identified on the cost report that include the total direct costs for certain activities. Some of these cost centers are Medicare reimbursable and some are not.[15] Kidney acquisitions—and the direct costs accumulated there—are a reimbursable cost center, but heart, lung, and liver acquisitions are non-reimbursable cost centers. And similarly, any indirect costs allocated to the kidney cost center through cost finding are reimbursable, while indirect costs allocated to the non-renal organ cost centers are unrecoverable. The statistic that is used to allocate indirect costs between these costs centers is the number of organs recovered. The result of this reimbursement methodology is that the more kidneys an OPO recovers relative to other organs, the greater share of indirect costs can be recovered from Medicare. Not suprisingly, those studying this system have noted that: "the OPO full-reimbursement model has been insufficient to drive its intended goal of ensuring OPOs pursue all donation opportunities."[16] Put simply, many OPOs are concerned with losing CMS reimbursement of their overhead for every non-renal organ they recover, this may have a negative impact on recovering and allocating hearts, lungs, and livers.

Unfortunately, this historical regulatory structure and limitations of antiquated cold ischemic storage techniques have created an organ transplant system in which OPOs do not have the institutional focus or clinical experience to fully scale thoracic and liver organ utilization for transplants. Thus, rather than trying to reform the existing reimbursement process, we strongly recommend that HRSA in the next contracting round instead require the OPTN to create a new national OMO partner model to address the issue nationally and systematically, while maintaining the overall structure of the OPTN intact. The OMO would not replace OPOs, but would work as an equal partner with them to create a dedicated and specialized non-renal (heart, lung and liver)

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[15] The PRM 15-2, Ch. 33 instructs OPOs how to allocate overhead costs and A&G costs using the OPOs' organ statistics. In particular, section 3311 requires OPOs to allocate their overhead costs across various reimbursable and non-reimbursable cost centers.

[16] Rosenberg, *Transforming Organ Donation in America;* Appendix A (Dec. 2020) at 4, available at https://www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/Bridgespan-OPO-Report-FINAL-Appendix-A.pdf; *see also* CMS: *CMS Finalizes Policy that will Increase the Number of Available Lifesavings Organs by Holding Organ Procurement Organizations Accountable through Transparency and Competition,* https://www.cms.gov/newsroom/press-releases/cms-finalizes-policy-will-increase-number-available-lifesavings-organs-holding-organ-procurement (recognizing reimbursement policies influence OPO organ recovery);

organ transplant focus that would help OPOs achieve their CMS performance metrics (see footnote 11 describing the respective OMO and OPO rules). An OMO system would streamline organ procurement and utilization for thoracic organs.[17] Without the kidney-focused incentive structure that drives OPO decision making, the national OMO can be structured to align incentives to procure and place more hearts, lungs, and livers to benefits all transplant stakeholders in the OPTN network. Importantly, it would significantly expand access to life saving and most economically efficient treatment to patients with end-stage organ failure in the U.S.

Conclusion:

We again thank HRSA for seeking feedback on improving organ procurement and for actively taking steps to enhance the accountability and operations of the OPTN and OPOs. We hope our comments will enable HRSA to innovate and modernize in the transplantation regulatory space to match the pace and opportunity that has emerged in the organ preservation technology space. We believe that the creation of a national OMO partner in the OPTN network, with the primary focus on maximizing the utilization of non-renal organs for transplant will enable significant expansion of access to life saving transplant procedures to patients in need in the U.S., while maintaining high clinical standards and post-transplant outcomes. The existing OPTN would provide the right home for oversight of both the OPOs and the OMO. We kidnly urge HRSA to implement of a national OMO model for heart, lung, and liver transplants.

We welcome further partnership with HRSA on these important issues. To that end, we thank you for consideration of these comments and welcome any questions or follow up that you may have. Please feel free to contact me at +1 617-510-3327 or whassanein@transmedics.com if we can provide any additional information.

Sincerely,

Waleed Hassanein, M.D.
President, and CEO
TransMedics Group, Inc.

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[17] The proposed OMO also could be more cost effective. We propose the OMO would not be based upon a cost recovery regulatory regime such as that which guides OPO operations today. Instead, the OMO could be compensated entirely through organ acquisition charges it would set for transplant centers.

STATEMENT OF INTENT

I, Waleed Hassanein, M.D., President, and CEO of TransMedics Group, Inc. do not currently intend to supply a proposal on any future solicitation related to this requirement.

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American Transplant Congress
June 4-8, 2022
Boston, Massachusetts

Submitted via email to Ninazawa@hrsa.gov

May 9, 2022

Carole Johnson
Director
Health Resources and Services Administration
HHS/HRSA/OAMP
5600 Fishers Lane
Rockville, MD 20857

Notice number: 541611
Title: HHS/HRSA/OAMP Request for Information (RFI) on the Organ Procurement and Transplantation Network (OPTN)
Date of issuance: Friday, April 8, 2022
Name: American Society of Transplant Surgeons
Address: 1401 S. Clark Street, Suite 1120, Arlington, VA 22202

Dear Ms. Johnson:

The ASTS is pleased to have the opportunity to respond to the Request for Information (RFI) issued by the Health Resources and Services Administration (HRSA) soliciting comments on potential improvements in the contract arrangement between HRSA and the entity selected to function as the Organ Procurement and Transplantation Network (OPTN). ASTS is a medical specialty society representing approximately 1,900 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through patient care, research, education, and advocacy.

ASTS appreciates HRSA's taking prompt action to address the issues related to the organization and operation of the OPTN that were raised in the National Academy of Sciences, Engineering, and Medicine (NASEM) recent report entitled, *Realizing the Promise of Equity in the Organ Transplantation System (2022)* (the NASEM Report*).* We believe that, in light

of the substantial changes in the field that have taken place over the many years since the first OPTN contract was awarded, the time is ripe to assess how the system is functioning for the benefit of our patients and what improvements can and should be made. At the same time, it is equally important to recognize the accomplishment of the current system. The number of transplants performed in the United States has increased annually with **more than 41,000 organ transplants performed in the U.S. in 2021**. Transplant outcomes have improved substantially: In fact, at this stage, the average one-year patient and graft survival for kidney transplantation is about 96%, and only a handful of transplant centers have one-year graft and patient survival of less than 90%. While we most certainly agree that improvement—especially in the areas of access and equity—are critical, care should be taken to preserve the gains that have been made over the past decades.

While the NASEM Report may include some recommendations with which we disagree, this Report provides a reasonable blueprint for addressing important gaps in the current system. The NASEM Report clearly states—and we agree—that reform efforts must start with a clear statement of system goals and priorities and with improved coordination among the various components of the system, including regulatory bodies. As the NASEM Report observes:

> The current organ transplantation system is unduly fragmented and inefficient. The system's component parts—physicians caring for patients with organ failure, donor hospitals, OPOs, the OPTN, transplant centers, the Scientific Registry of Transplant Recipients, CMS, and other payers, among others—do not operate as a fully integrated system. Likewise, each of the entities with oversight responsibilities oversee particular components, but none monitors the performance of the system as a whole in producing predictable, consistent, and equitable results.
>
> The organ transplantation system could save additional lives and be more equitable if its component parts functioned in a more cohesive fashion and were overseen by a single entity, or by several entities operating in a coordinated fashion with common goals and unified policies and processes. Such alignment of all components and oversight responsibilities would allow the public and Congress to ascertain whether the system is fairly and efficiently maximizing the benefits provided by organ donation and transplantation.

NASEM Report at S-10. Any re-thinking of HRSA's contractual arrangements with the OPTN therefore should begin with a re-examination of the respective roles of the OPTN, the SRTR, CMS, the FDA, NIH and other components of HHS with authority over transplantation, with a view toward the avoidance of duplication and the coordination of potentially overlapping areas of jurisdiction.

Without this broader re-examination of the roles of each agency (or government contractor), any effort to reconfigure the OPTN contract is likely to perpetuate existing inefficiencies and inhibit system improvements.[1] We believe that this re-examination and the elimination of overlapping

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[1] Beginning in 2018, ASTS put forth a proposal to HRSA and CMS for the elimination of duplicative and overlapping oversight of Transplant Centers, which, among other things,

or duplicative areas of responsibility (especially as between the OPTN and CMS) should be undertaken before the next OPTN contract is awarded, potentially as part of the Development of National Transplantation Goals (NASEM Recommendation 1). Narrowing the focus of the OPTN's oversight functions to specific areas not already overseen by CMS or other agencies would focus the OPTN's efforts on core areas delegated to it under NOTA and the Final Rule. We also believe that, to the extent that overlapping or duplicative areas of responsibility cannot be avoided, HRSA evaluate the OPTN's coordination with CMS and other agencies as one component of its evaluation of OPTN performance.

The RFI solicits feedback on a number of aspects of HRSA's contractual relationship with the OPTN, including OPTN Technology/IT; Data Collection Activities; OPTN Finances; OPTN Governance; Increasing Organ Donation and Improving Procurement; Organ Usage; OPTN Operations and Policy Improvement; and Stakeholder Engagement (especially in connection with transparency of organ acceptance decisions). We offer the following comments and observations with respect to these areas:

A. **OPTN Technology – IT System**
   While the IT specifications that should be included in the OPTN contract are beyond ASTS' expertise, we do believe that, to the extent practicable, IT (as well as other) contract specifications should be drafted in a manner that does not restrict potential applicants to UNOS. A competitive process will help ensure that the OPTN contractor is incentivized to continually improve its performance. We also believe that, to the extent that implementation of significant IT modifications from the current system are included in the next OPTN RFP, the RFP also should include contractor requirements designed to ensure a smooth transition, so that critical OPTN functions, including for example, organ matching and transportation, are not disrupted.

B. **Data Collection Activities**
   The RFI solicits input on how a prospective contractor would implement a "metrics dashboard" to track performance and evaluate results and would modernize the data collection for deceased donor organ procurement, allocation, distribution, and transplantation. We believe that the mechanics related to data collection and dashboard implementation are secondary: The critical questions are "What data should be collected?" and "For what purposes?" We believe that new and continued data collection activities included in the OPTN scope of work moving forward should comply with the following principles, and that OPTN performance in this area should be measured against these benchmarks:

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includes one option that would accord CMS primary responsibility for overseeing transplant center performance from admission through discharge of the transplant recipient and would accord the OPTN primary responsibility for oversight of Transplant Center waitlist practices, waitlist management, compliance with allocation rules, and post-transplant follow up (including data submission).

- Data collection should be clearly tied to, and necessary for the achievement of, a clearly stated goal or objective that is one of the National Transplantation Goals.
- New data collection should be authorized only if the data is unavailable from any existing data source.
- The appropriate audience for the data should be clearly identified and consulted about the utility of the proposed data collection before date collection is instituted.
- The potential inadvertent repercussions of data dissemination should be thoroughly considered in advance.
- The data collection administrative burden on transplant centers should not be increased: If additional data elements are to be collected, an effort should be made to reduce or eliminate other data collection requirements.

These principles raise multi-faceted questions, which impact numerous stakeholders, including, but not limited to, transplant centers, transplant surgeons and physicians, patients, payers, and researchers. To the extent that the OPTN contract solicitation for 2023 anticipates substantial changes either in the type of data to be collected or in data collection processes and procedures, we urge HRSA to require the OPTN contractor to engage in a public decision-making process that involves all affected parties and to measure OPTN performance with respect to data collection based on its adherence to these principles.

We are aware that the current SRTR contractor has been tasked with exploring and rethinking the type of data that should be collected, with special attention to patients' perspectives with respect to the types of data that would be most useful to them. We are also aware that the OPTN has only recently substantially revised the transplant center performance metrics to measure waitlist mortality and organ offer acceptance. We believe that any data collection necessary to effectuate these metrics-related activities should be analyzed based on the principles described above before being incorporated into the OPTN scope of work for 2023.

F. **Organ Usage**
In responds to a recent CMS RFI, ASTS has submitted extensive comments on the issue of organ usage. These comments may be accessed here. Among other things, these comments include our recommendations regarding improvements in OPTN matching and organ allocation policies that should be made in order to increase utilization of hard to place organs suitable for transplantation.

G. **OPTN Operations and Policy Development Improvements**
ASTS supports increasing the diversity of the OPTN Board and Committees, within any constraints imposed by applicable law and subject to the Board composition requirements in the Final Rule. Generally, we believe that OPTN policy development processes can and should be streamlined.

More specifically, we believe that the OPTN should establish a mechanism to take into account the views of professional associations such as ASTS, as well as other organizations representing stakeholder, during the policymaking process. While the OPTN does include individual surgeons, physicians, patients, and others with special expertise in various aspects of transplantation in many of its policy committees, these individuals do not have the authority to speak for the stakeholder community. We believe that earlier involvement of transplant-related associations and other groups would result in greater consensus and overall support for OPTN policies during the public comment period.

In addition, logistical challenges have become much more substantial under new policies that have resulted in broader organ allocation. We believe that the process could be improved if the OPTN were to consult with independent organizations with special expertise with logistical issues, especially in areas such as organ transport and tracking.
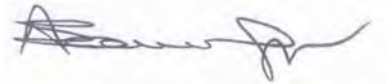
We believe that OPTN operations could be improved significantly if the OPTN were to conduct an assessment of the operational issues that the transplant community will face to implement each policy change. Such an assessment should take into account the views of the stakeholders whose own operations are likely to be impacted by the policy change, and should include an analysis of the resources likely to be required for the policy change to be implemented efficiently and effectively, with a view to minimizing or eliminating the potential impact of the policy change on patient care.

At the other end of the process, the OPTN—again with the input of affected stakeholders—should conduct an in-depth and objective post-implementation assessment of major new policies, in order to ensure that obstacles to efficient and effective implementation are identified and addressed. Post-implementation assessment that takes into account the actual experience of stakeholders has the potential to smooth implementation of future new policies.

H. **Stakeholder Engagement**. The RFI solicits public feedback on how the OPTN can and should encourage members to increase stakeholder involvement in organ acceptance decision making and stakeholder engagement strategies that advance equity, access, and transparency. ASTS believes that a number of steps can be taken to improve transparency and to facilitate shared decision making by waitlisted patients, and we would be delighted to work in cooperation with the OPTN, patient groups, and others to formulate processes to achieve these objectives. We strongly believe that any process that calls for notification or consultation with a patient at the time of an organ offer would be entirely unworkable and counterproductive, since any such process would substantially slow organ matching and increase organ discards overall. However, the patient voice most certainly can and should be heard at the time the patient is waitlisted and information should be provided to the patient periodically during waitlist period. We believe that the OPTN is the appropriate entity to bring all stakeholders together to design an information-sharing process that maximizes transparency while minimizing disruption and unnecessary delays in organ placement.

We appreciate the opportunity to comment on this important RFI, and look forward to continuing to work with HRSA to achieve improvements in the system while maintaining the system's hard won achievements.

Sincerely yours,

A. Osama Gaber, MD, FACS
President
American Society of Transplant Surgeons

Organ Procurement and Transplantation Network (OPTN)

May 23, 2022

Submitted to: Department of Health and Human Services (HHS) Health Resources and Services Administration (HRSA)

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CORPORATE INTRODUCTION

AgileTrailblazers® (ATB) is a management consulting firm focused on enabling Digital Transformation for our customers. AgileTrailblazers offer five primary service lines: business transformation, agile software delivery, DevOps, innovation, and training.We provide the tools to achieve this transformation regardless of your current solution delivery process maturity. AgileTrailblazers has successfully enabled agile transformations in regulated industries such as Healthcare, Financial Services, Retail, Insurance and Federal Government.

In the Healthcare space, AgileTrailblazers has created extraordinary and improved process workflows through a strong innovation implementation process: customer journey, stakeholder needs, analysis of the existing enterprise process and technical environments, and deliverables that exceed expectations. Additionally, these processes are established using best practices such as HIPAA, FedRAMP, NIST, CMMI, and ISO 27001, 9001, 20000.

AgileTrailblazers is a Small Disadvantaged Business (SDB) that has access to several GWACs including GSA IT Schedule 70, Federal Aviation Administration eFAST, DOD Joint Artificial Intelligence Center (JAIC) - Test and Evaluation Services, and DOD JAIC - Data Readiness for Artificial Intelligence Development (DRAID) Services. ATB has the experience of delivering a broad spectrum of software engineering services and constructing digital transformation to large cloud environments.

A. OPTN TECHNOLOGY - IT SYSTEM

The NASEM report recommends that the OPTN use a state-of the art information technology infrastructure that optimizes the use of new and evolving technologies to support the needs and future directions of the organ transplantation system. HRSA received similar feedback from the U.S. Digital Service as part of HRSA's 2019 market research. Additionally, organ procurement organizations and transplant programs currently do not submit data to the OPTN IT system in real time. HRSA seeks to enhance the usability and performance of the OPTN IT system and related tools, as well as ensure the OPTN IT system is protected from emerging and evolving security threats. HRSA is seeking feedback on the following questions:

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.

In order to help enhance usability and performance of the OPTN IT systems, we feel that taking a cloud native approach is a wise decision for a number of reasons:

Redundancy and Reliability - By migrating from traditional, data-center hosting of applications to a cloud platform, OPTN can deploy application instances across several "regions" provided by the cloud provider. This avoids outages caused by regional disruptions and provides greater fault

tolerance. In addition, this allows for application maintenance to occur without downtime; a given instance can be taken offline for upgrade or maintenance while others handle user demands. In addition, having several, geographically disparate instances of an application avoids downtime caused by network disruptions. Given the nationwide distribution of OPOs and health services organizations, regional availability of OPTN applications is understandably important and will be enhanced by deploying multiple application instances.

Performance - Applications built for cloud deployment can be more easily scaled up to meet user demands. Rather than needing to purchase and deploy additional hardware as in a traditional data center, OPTN IT administrators can easily increase capacity by deploying additional virtual machines, and in fact this can be done automatically based on application demand. Conversely, in times of decreased user demand, this infrastructure can be scaled back to help control cost. In addition, network latency can be reduced by deploying applications across multiple geographic regions, closer to groups of end users.

Shared Services - Applications running on a cloud platform have access to more prebuilt, shared services. For instance, each of the major cloud platform providers has provisions for artificial intelligence and machine learning (AI/ML) as a service. Rather than building this type of capability in house, the OPTN systems could leverage existing services that can add new capabilities for organ procurement and allocation aided by AI/ML techniques.

Development Speed - Cloud native applications are generally faster to build. Rather than needing to build architecture to support a new application, development teams can focus more on application functionality. This allows OPTN to add more capabilities faster.

Adopting a cloud native approach isn't just limited to new application development. Existing applications in the OPTN IT suite can be transformed and moved to cloud providers, and can leverage many of the benefits mentioned above.

In addition to utilization of a cloud native approach, utilizing modernized software development practices will be a major asset for OPTN as well. As our name suggests, AgileTrailblazers advocate an agile approach to systems development. Agility focuses on the end user and their interaction with the system. By focusing on and responding to end user needs, OPTN can continually adapt and update IT systems to serve a continually evolving group of users and organizations.

We also recommend a DevSecOps approach to development. DevSecOps provides development teams with tools and practices to rapidly develop, test, and deploy applications by leveraging both development practices and a high degree of automation.

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.

Effective use of APIs to enable data sharing and application integration requires both technical innovation as well as effective research, development, and occasionally negotiation.

Commonly, APIs are used in a "point to point" manner - one application communicating with another. While this is useful, it is also limited. In use cases like OPTN where there are many related applications, it may make more sense to build a cohesive API aggregation layer. Rather than point to point connections, this aggregation layer would make a given API available to all applications in the OPTN portfolio. This makes reuse much simpler. In addition, we can also add additional functionality, such as data caching, analytics, and triggering.

Event streaming from APIs is also highly useful in some specific OPTN use cases. Organ procurement and transplantation is by nature a time critical process. By using APIs to trigger and stream events to multiple systems, we can reduce latency. For instance, perhaps an EHR API feed could trigger early notification when a potential donor is identified, and then keep the regional OPO informed of developments so that a transplant coordinator can be pre-assigned.

As mentioned above, this is not simply a technical process. Available APIs must be identified, access obtained, and in some cases, changes negotiated. This can be facilitated by following the practice of User Centric Design, which we discuss later in this response, by helping to identify user needs and potential API based solutions.

API integration has proven highly successful within various facets of the healthcare industry. ATB works on both the provider and insurance sides of healthcare. We can provide two examples of our work with API integration in this space.

AgileTrailblazers recently completed a multi-year engagement with Nemours Children's Health System to develop a suite of mobile and web applications. These applications enable patients and their families to securely and conveniently access and update their health information. Through the app, patient families are able to upload critical health metrics such as vital signs and symptoms, and are also able to connect devices such as bluetooth enabled spirometers and pulse oximeters. With this data, healthcare providers are able to better manage care and proactively modify treatment plans to avoid issues when various conditions occur - for example, when adverse weather conditions are predicted that might affect an asthmatic patient, doctors can proactively prescribe medications and monitor effects. The system serves a large number of patients within the Nemours system and is fully accredited to handle PHI and HIPAA controlled information. The app is currently in production and available on the web, iOS, and Android.

A major part of our engagement with Nemours was the integration of several major APIs, starting with EPIC. We worked directly with the vendor to implement key changes in the EPIC API to facilitate real-time interaction with our application and its users. In addition, we also integrated telemedicine APIs from several platform providers.

As another example, ATB built a strategy to create a data center of excellence to securely ensure data sharing through APIs for one of the largest health systems in the Atlanta region. EPIC was

the EHR used in the hospital group. We worked through an assessment of all the data sets and defined the core data sets which needed to be shared within various systems

Figure A-1. Data Request and Flow

The hospitals had disparate data systems and each system had also duplicated data sets which was a huge pain point. Reports had to be submitted to external agencies, hospitals and other government agencies for various reasons.

EPIC had caboodle as the data warehouse where all providers and member data would be stored. Once we identified the core data sets. The team went through a data reclassification exercise to identify the master sources of data. This helped to validate the various data sources and the relationships between the various data sources. Next we built public and private APIs to incorporate an API rich interface for exchanging data.

Lessons learned:

    a.   Identify key data sources and data sets before building the API infrastructure
    b.   Security should be built in from the beginning and not an afterthought.
    c.   Build an API versioning strategy to roll out new updated APIs.
    d.   API performance is critical. Utilize cloud native or on prem monitoring tools to understand the current performance and scale up and/or down as required.
    e.   Build a health dashboard for APIs.

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.

Key in the ability to enhance usability and engagement is the practice of user centered design (UCD). UCD focuses on understanding the user's needs and interactions with the system and seeks to synthesize those needs into requirements and resultant solutions. We follow a five step process as shown below:
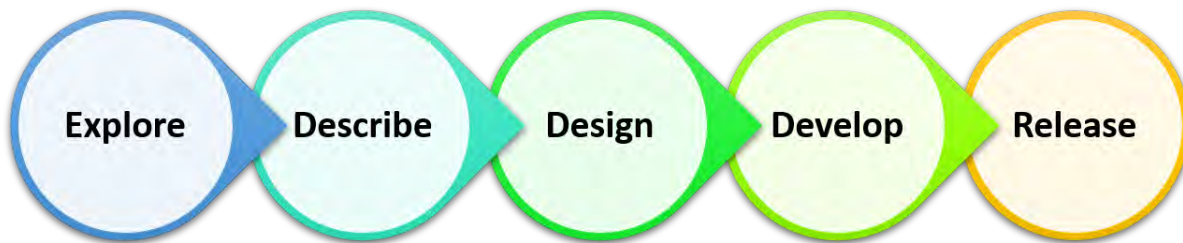
Explore: ATB Team conducts user-experience research (e.g., understanding how OPOs or healthcare systems interact with OPTN systems) to construct a common view of goals and requirements that provide context for defining an minimum viable product (MVP).

Describe: We synthesize inputs from user experience research and finalize the technical architecture and business requirements including target infrastructure.

Design: We then conceive, prototype, evaluate, and refine the MVP service experience. Specifically, we design the user interface and validate the design directly with deployed users to ensure it resolves their pain points.

Develop: Our developers work closely with user experience and interface design colleagues on the scrum teams to produce and deliver high-fidelity wireframes, prototypes, and code that reflect the user stories gathered in the 'Describe' phase. In short, we develop and integrate the solution per the established SDLC.

Release: We launch the solution in the production environment to target audiences in order to gather additional feedback following the user-centered design approach of continuous diagnostics and mitigation. If in scope, we conduct user training through in-person sessions, recorded videos, and/or one-page job aids to ensure system users have the knowledge, skills and resources to best utilize the solution.

In order to make the UCD process effective for OPTN, the user group needs to be varied. A primary mistake we commonly see with organizations practicing UCD is improper selection of cohort user groups. They are often made up of management level individuals, not end users, which limits true understanding. For OPTN specifically, we would recommend incorporating users from the entire scope of the organ procurement, allocation, and transport chain. This ideally would include patients and families, emergency services, OPO transplant coordination staff, management, transplant teams, and health system stakeholders.

Increasing ease of use also increases the likelihood that the system will be able to provide near real-time information. Delays usually result from two sources: system limitation, and ease of

use. By providing an easy to use, convenient system, users are more likely to enter data as events occur, rather than after the fact, so long as the system supports their ability to do so.

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

By utilizing the user centered design approach, we can help stakeholders express their program improvement requirements. Then, using BI tools that are integrated with various data streams, we can enable users to create their own dashboards and tools. In cases where those tools have a greater level of complexity, the development team can get involved to provide custom solutions.

Our teams at USAF provide similar functionality to end users to visualize targeting data derived from intelligence. The tools our team has developed enable intelligence analysts to describe, model, and communicate systems of targets in a rapid, high quality format. By providing easy access to the source data within their level of authorization as well as other related data streams like map data and geospatial intelligence data, they can independently build models and dashboards to rapidly communicate critical intelligence information.

With respect to reducing inequities, data quality is primary. In most projects, we initially start with data profiling to understand what type of data needs to be sourced first. Once we understand what the data needs are, the team has used profiling techniques and massage the data set to accurately represent the data.

An example for opportunity improvement was with our grievance and appeals work we did for a large healthcare insurance carrier. The team analyzed large amounts of grievances data to understand how the grievances and claims were handled by call center agents.. Based on the dashboards the team produced, it was clear that a certain standard set of grievances followed a very specific pattern. Once the pattern was documented, it was automated. This provided a significant program improvement for the call center agents as they could focus the efforts on more complex call scenarios rather than regular pattern based repetitive work.

Our team follows the story boarding approach for building dashboards. The steps our team focus on are
  a. Identify key user groupings with OPTN members. This helps to build the baseline by segments as well.
  b. Identify key dashboard groupings. Performance dashboards showcase various attributes which need to be studied holistically to understand insights.
  c. Define the privileged groups for dashboards
  d. Define the drill down and navigational flow for dashboards.
  e. Utilize tools to define correlation and generate data set hypotheses for the performance dashboards.
  f. Generate and Validate the insights.
  g. Apply the insights with the process maps to provide implementation recommendations.

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

An important aspect of the organ allocation process are the factors affecting each organ allocation whether it is the waiting time for the kidney, or how far the donor is from the hospital, or any other factor. The driving factors to optimize critical time savings are:

    a.   Having continuous data visibility towards the organ allocation process
    b.   Continuous recalibration of the priority list of the most-ill candidates
    c.   Improve efficiency by making the process simple and effective
    d.   Identify bottlenecks

Our experience in large enterprise healthcare is that understanding the problem and enabling a design-thinking approach helps to improve patient outcomes. As a similar case study, our team was challenged to build out a healthcare application for asthma. ATB built and tested the Nemours App for Nemours Children's Health System that has been awarded the "Innovation of the Year in Patient Care". This app allows patients and families to access and update health information, provides healthcare telematics, telemedicine, and records management. Each modality developed had direct impacts on newborn and infants lives. For example, the cardiac application decreased infant mortality by 50%.

This suite of mobile and web applications enable patients and their families to securely and conveniently access and update their health information. Through the app, patient families are able to upload critical health metrics such as vital signs and symptoms, and are also able to connect devices such as Bluetooth-enabled spirometers and pulse oximeters. With this data, healthcare providers are able to better manage care and proactively modify treatment plans to avoid issues when various conditions occur - for example, when adverse weather conditions are predicted that might affect an asthmatic patient, doctors can proactively prescribe medications and monitor effects. The system serves a large number of patients within the Nemours system and is fully accredited to handle PHI and HIPAA-controlled information. The app is currently in production and available on the web, iOS, and Android.

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?

In addition to our healthcare experience, our company roots as an all-online banking pioneer required the highest up-time metrics possible in a highly regulated industry.
We have found that there is increased pressure to keep a target of 99.999% uptime for critical applications. Even though claims are made by companies, what we have found useful is to consider active-active configurations or multi-master configurations across multiple data centers.

This might need reassessment and re-architecture of parts of the systems to be able to seamlessly provide the same functionality and same SLA for transactions from multiple data centers. Cloud applications are a good example of this. The more a system moves to 99.9% availability, the more cost and maintenance rigor have to be maintained at a very optimal level.

Developing a Business Continuity Plan helps to provide clarity on the transaction processing. If one system fails, the other takes the entire processing load and the business continues as usual. This lets IT take full advantage of the server processing power and can spread the data load across multiple systems. Some of the lessons we learnt while incorporating heavy availability are as follows:

a. Planning: Any server upgrade or patching should be mapped to continuous systems availability and using techniques like rolling upgrades to servers.
b. Practice maintenance: Our Software reliability engineers (SREs) continuously work to automate any maintenance without disrupting the application availability.
c. Continuous monitoring
d. Security is pre-built and not an add on later.
e. Hardware quality: Review the hardware and look for its redundancy features to avoid a failure.
f. Application Restructuring : Apps have to be restructured to maintain a high availability pipeline. The CI/CD process should be incorporated and be able to roll out new upgrades seamlessly.

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

Data collection is an important part of any data strategy. The most important aspect is to identify the data sources and what data sets need to be consumed as raw. Usually the raw datasets are pulled into a staging area. Our team does the data profiling of the source data and assigns tags based on predefined criteria. For OPTN data, which data sources can be mapped to obtain relevant data can only be done once the profiling of data sets is completed.

Right now all Data collected with OPTN is using the Unet web portal. This is primarily a push mechanism where hospitals update the data regarding transplants. Considering the complexity of data, there should also be a pull mechanism as well. We recommend an API driven approach where OPTN data can be also pulled effectively across multiple hospital chains and other data sources as well. The advantage of a push pull strategy is

a. Better timely data sets
b. More accurate information as data can be correlated between what the hospitals are managing.
c. Distributed computing. With an API driven approach the hospitals can be more interoperable and shared data as well as among themselves.
d. Better tagging and data governance

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

Automation and monitoring are both key tenets of systems security. In the past, much security testing was manual, and by nature, static. By incorporating automated security scanning into the software development process, we can avoid introducing security concerns. In addition, systems can be regularly and automatically scanned for vulnerabilities, and in many cases those vulnerabilities can be automatically remediated. Security enhancements also go hand-in-hand with migration of applications to a cloud environment. By deploying modularized and containerized applications to a cloud service, we can avoid the traditional issues associated with operating system vulnerabilities and physical infrastructure.

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

In a system such as the OPTN, data integrity and security are paramount both to meet regulatory requirements as well as ensure privacy and safety for patients and providers. We believe security starts from the beginning of the application - high quality source code is ensured by automated scanning tools, and then verified on a running system with penetration and scanning tools. Data is encrypted at rest and is segmented where appropriate to ensure that a full disclosure of protected data is unlikely.

We have experience obtaining and maintaining ATO on FISMA High systems used by the Air Force. These systems deal with intelligence data that is classified to the Top Secret/SCI level. Our teams are required to be familiar with NIST 800-53 and work within a framework of automated tools that monitor compliance. These tools also enable them to have a "Continuous ATO" and release frequently without additional manual intervention and approval - something that is generally unprecedented within the Department of Defense.

B. DATA COLLECTION ACTIVITIES

The NASEM report recommends the creation of a dashboard of metrics to track performance and evaluate results, and modernize the data collection for deceased donor organ procurement, allocation, distribution, and transplantation. Enhancing OPTN data collection and dissemination could improve performance assessment, reduce practice variation, and support quality improvement and innovation. HRSA is seeking feedback on the following questions:

Overall dashboard capabilities discussion:

Best Practices for Data Collection:
1. Identify and source from the system of record instead of secondary data sources
2. Source at the lowest granularity and not pre-aggregate the data
3. Build a detailed Data Lineage map across the entire ingestion pipeline

How do we build data quality:
1. Build a detailed data dictionary with each field having data type, valid values or ranges defined. Convert this information into data quality rules.
2. Use the rules to be part of the Source-Target mapping transformation logic and build error handling in the pipeline
3. A separate process for handling records that end up in the error pipeline. After a few iterations of test runs, the data controls become solid in identifying and separating bad records. This allows for upstream system owners to review the error records and determine the cause.

How do we review data errors:
1. data errors maintain their own pipelines separated from the main pipelines once a quality check is failed. These pipelines can then be adjusted to dump records in a general purpose error table or a collection of bad data files to be reviewed with upstream system owners.
2. The error codes explain which pipeline threw the error and which fields had the issue

How innovation works with data collection:
1. Data collection best practices ensure data quality and timeliness of data access and availability to fuel innovative activities and business process changes

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.

This ecosystem requires various interfaces and integrations of data touchpoints and once those are accomplished, the visibility and transparency of the entire supply-chain and ecosystem becomes accessible allowing the organization to make informed decisions faster.

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.

If the data collection best practices are adopted, the quality, timeliness and granularity of the available data enable accurate reporting and timely decision making on KPIs and metrics. The data collection mechanisms have to be accompanied by data storage and structure best practices as well to ensure Governance and security of healthcare data.

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

Once the datasets from across all the processes in the supply-chain for organs are collected and analyzed, newer benchmarks around matching and timeliness can be established with near real-time updates allowing for OPTN members to evaluate their processes and introduce improvements.

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

Data quality controls and data security measures ensure that good data around donors is available even if 3rd party data brokers or data sources are utilized. The acquisition of such datasets can be expensive and therefore advanced statistical methods should be used to procure data against sampling of patients and then extrapolate to the entire population. This should also be handled within the Data Ingestion and processing pipelines

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

The granularity of data collection ensures that users are able to slice and dice the data as they see fit. The structure of the data architecture should support multiple dimensions enabling users to create dashboards by Geographies, organs, time series and their hierarchies.

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

The data collection best practices require storing granular data and histories over time. A mature change-detect mechanism ensures that updated information on various entities like donors are tracked over time to create an accurate historical profile of the patients, organs and donors. Once

this data is available and linked to the patient outcomes overtime, insights and patterns can be identified that indicate critical data factors in improving patient outcomes.

C. OPTN FINANCES

Currently, the OPTN contractor charges additional fees (outside of OPTN registration fees) to provide services to the donation and transplantation community. Although no OPTN member is required to pay such fees in order to participate in the OPTN, in practice, many OPTN members may view them as necessary to receive the services they need from the OPTN contractor. HRSA seeks to increase accountability and transparency in OPTN financial structures. HRSA is seeking feedback on the following questions:

While building the first all online only banking company (ING Direct), ATB had to factor a current fee structure with customers into a "To Be" fee structure to fairly reflect an all digital environment with a reduced cost business model. ATB would work with the government on an initial User Experience sprint to gather stakeholder needs and empathy maps with accountability and transparency goals as outputs.

C.1. Describe how you would/vendors could ensure that any fees, beyond OPTN registration fees, charged to transplant centers or others:
C.1.a. Do not duplicate Medicare payment or result in unnecessary additional Medicare reimbursement.

C.1.b. Do not charge for functions that are OPTN contract-supported functions.
C.1.c. Are not perceived as mandatory for participation in the OPTN or for receiving core OPTN services.

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

D. OPTN GOVERNANCE

HRSA seeks additional robust accountability and oversight measures regarding the OPTN. Today, the same individuals concurrently serve as members of the OPTN Board of Directors and the OPTN contractor's corporate board, which may hinder implementation of such accountability and oversight measures. HRSA is seeking feedback on the following questions:

The OPTN has an opportunity to seek alignment of shared and agreed interests with an operational contractors' business interests. An approach may be to utilize existing Federal Enterprise Architecture (FEA) standards of interest alignment to build an OPTN BoD with shared membership between government, industry at-large, and vendor membership. The government can fund the board's operation (in the way a Project/portfolio Management Office or Center of Excellence can be run) but not give operational decision-making control to the vendor. ATB has experience creating functional PMOs/COEs and would work with the government to create such a structure.

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.

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

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

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.

E. INCREASING ORGAN DONATION AND IMPROVING PROCUREMENT

The NASEM report identifies concerns with organ donation rates, including geographic and demographic variations. HHS is actively taking steps to enhance the accountability of Organ Procurement Organizations (OPOs). HRSA is seeking feedback on the following questions regarding increasing the donation of organs and improving the procurement of organs.

This section is OPTN operational / administrative in nature. If the final procurement comes out with this scope of work, ATB will work with HHS and their subcontractors to support this scope of work.

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.

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

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?

F. ORGAN USAGE

The NASEM report identifies concerns with the current high level of organ non-usage (discards), estimated at an unacceptable 25%. Over the past several years, the OPTN Collaborative Improvement and Innovation Network (COIIN) projects and the current CMS/HRSA End Stage Renal Disease Treatment Choices Learning Collaborative (ETCLC) have worked to build and share best practices models to aid the community in addressing variables that adversely impact

ATB does not inherently have this domain-specific capability beyond stakeholder mapping and User Experience in the course of an innovation engagement. We will work with HHS and their subcontractors to support this scope of work.

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 IMPROVEMENTS

The NASEM report recommends making that the improvements to the OPTN policymaking process including increasing racial, ethnic, professional, and gender diversity on the board and committees responsible for developing OPTN policies. NASEM also recommended seeking engagement with external organizations, such as the National Quality Forum (NQF) or the National Academy of Public Administration, with expertise in guiding federal programs through unique challenges in leadership and stakeholder collaboration. HRSA is seeking feedback on the following questions:

ATB does not inherently have this domain-specific capability beyond stakeholder mapping and User Experience in the course of an innovation engagement. We will work with HHS and their subcontractors to support this scope of work.

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.

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

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.

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

H. STAKEHOLDER ENGAGEMENT

The NASEM report outlines how transplant centers should be required to improve their stakeholder engagement efforts and activities, specifically by making transplant candidates, transplant recipients, other affected patients, organ donors and family members aware of all organs they have been offered and by monitoring their changing health and attitudes impacting organ acceptance decisions. HRSA is soliciting feedback related to the following questions:

ATB does not inherently have this domain-specific capability beyond stakeholder mapping and User Experience in the course of an innovation engagement. We will work with HHS and their subcontractors to support this scope of work.

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.

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.

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?

Request for Information on Ways to Strengthen and Improve the Organ Procurement and Transplantation Network[1] [2]
Submitted by
Alisa M. Hughley
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My brother, Carey Hughley, III met his untimely death when at the age of 21 he was shot and killed by someone living with paranoid schizophrenia. Five years prior to this tragedy, my brother made the compassionate decision to join the organ donor registry when he received his first driver's license. Through the process of directed donation my brother's kidneys saved the lives of two church going women known by my family to be registered with UNOS and waiting. Carey also saved and enhanced the lives of several others through the anonymous donation of his lungs, liver and other tissues. I became active in the organ donation and transplantation ecosystem as a donor sister and began sharing Carey's story. I have been a volunteer with my local organ procurement organization, Washington Regional Transplant Community since 2011. I became a member of their Donor Family and Community Advisory Council in 2012 and from 2018 to 2019, I served as the Chair of this body.

I am also the National Chair of Linkages to Life, a Signature Program of The Links, Incorporated. The Links, Incorporated is an international, not-for-profit corporation, established in 1946. The membership consists of more than 16,000 professional women of African descent in 299 chapters located in 41 states, the District of Columbia, the Commonwealth of the Bahamas, and the United Kingdom.[3] It is one of the nation's oldest and largest volunteer service organizations of extraordinary women who are committed to enriching, sustaining and ensuring the culture and economic survival of African Americans and other persons of African ancestry.

The Links, Incorporated focuses five facets for our service and programming, including health. Specifically, the Health and Human Services[4] facet was established in response to the chronic health disparities that persist in black communities and result in the decreased life expectancy of African Americans and other people of African ancestry. Through education, advocacy, and outreach, The Links, Incorporated initiates and supports programs that support the maintenance of good health and the elimination of chronic health disparities in communities of color. The Organ, Tissue and Bone Marrow Donation Awareness Signature Program, "Linkages to Life" was established in response to the health disparities in organ, eye, and tissue (including bone marrow) transplantation. The goal of Linkages to Life is to decrease disparities in donor registration and transplantation in the African American community. Our members work to increase the number of registered donors through community-based events and multi-media awareness campaigns. In partnership with the national organization Donate Life America, we

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[1] https://www.hrsa.gov/about/news/press-releases/hrsa-releases-organ-procurement-transplantation-network-rfi, Accessed on May 8, 2022
[2] https://sam.gov/opp/005656500e5741538ce72d57b9b3d558/view, Accessed on May 9, 2022
[3] https://linksinc.org/the-links-incorporated/, Accessed on May 19,2022
[4] https://linksinc.org/health-and-human-services/, Accessed on May 9, 2022

strive to register hundreds of donors each year through a Links, Incorporated and Donate Life America co-branded national donor registration page.

I have collaborated with both Linkages to Life National Program committee members and members of The National Minority Organ Tissue Transplant Education Program (MOTTEP)[5] on this important issue. Based on my experiences serving in this ecosystem, I offer the following comments in response to the Request for Information and hope it will be valuable in determining the final policy.

In response to E.4.[6] Increasing Organ Donation and Improving Procurement: How can HRSA best incorporate the NASEM report's recommendations on increasing equitable access to transplants?

Leveraging trusted networks to emphasize organ donation and transplant opportunities.
There are many ways to connect members of the African American community to sources of information and knowledge related to organ and tissue transplantation. African American physicians are an excellent source for connecting with members of the African American community on this topic. Regardless of the physician's specialty, African American physicians as well as those serving African American patients should emphasize the benefits of organ and tissue transplantation. As discussed by MOTTEP Founder, Dr. Clive Callender at NASEM[7], the historically Black medical schools are a tremendous resource for instilling this message into minority and minority-serving physicians. The HBCU Medical Schools Collaborative and the Links, Incorporated are each positioned to underscore the need for improved equity in the field of organ donation and transplantation.

Some suggested ways to increase outreach include:
- Career exposure to STEM, medicine, health professions, and specifically inclusion of transplantation.
- Cultural and linguistically tailored materials geared to educate minority individuals about transplantation for those receiving dialysis.
- Augmented programming with HBCUs, medical schools, and schools of nursing, public health, healthcare administration, and allied health professions.
- Presence at health fairs and organ donor drives, distributing said materials focused on living and deceased organ donation; and
- Continued collaboration with service organizations, faith-based congregations, and community influencers around organ donations.

Members of the Links, Incorporated through local and national Linkages to Life programming have been engaging in several of these activities. There are numerous opportunities to expand this programming by integrating with the Services to Youth Facet[8] that includes the Links – STEMReady Signature Program and the National HBCU Initiative to encourage youth to pursue careers in the STEM fields. Additionally, I have served with

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[5] https://www.natlmottep.org/, Accessed on May 19, 2022
[6] https://sam.gov/opp/005656500e5741538ce72d57b9b3d558/view, Accessed on May 19, 2022
[7] https://www.nationalacademies.org/event/07-15-2021/a-fairer-and-more-equitable-cost-effective-and-transparent-system-of-donor-organ-procurement-allocation-and-distribution-virtual-public-listening-session, Accessed on May 19, 2022
[8] https://linksinc.org/services-to-youth/, Accessed on May 19

members of the Links, Incorporated who either work as clinical or healthcare professionals, are employed by an HBCU or both.

Recognizing the multiplying impact of poverty on social determinants of health on treatment access. Patients who are poor and African American are often rejected for surgery because transplanting them will decrease transplant outcomes. This, in turn may result in the transplant centers becoming decertified. A system must be put in place that does not penalize a transplant center for transplanting such high-risk patients. This phenomenon is important but never discussed. This practice is a form of institutionalized racism and bias that keeps socio-economically deprived patients from accessing organ and tissue transplants at rates proportionate to the prevalence of end-stage organ disease or other related injury. National and regional paired donations are performed but they rarely benefit people of color, in the way that local paired donations do. Encouraging local paired donations is more beneficial to people of color; and is an option that should be incentivized and encourage.

G.1. OPTN Operations and Policy Development Improvements: 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.

Staffing for cultural sensitivity and to minimize biases is an area of opportunity. Representation of culturally sensitive individuals and organizations at every level of OPTN operations and policy development is necessary to transform the current system for attaining health equity. Specifically, priority in notification should be given to organizations of color including Historically Black Colleges and Universities, Black Greek letter sororities and fraternities, and other Black services organizations and programs. Priority in funding should be given to such organizations as well as programs led by people of color. Additionally, specific minimum allocations of funding proportional to the need for transplantation (or the incidence of end-stage disease and organ failure) should be allocated in each area related to organ transplantation. Input from these individuals and organizations must also be integrated in the writing of RFPs and the review of RFP submissions.

Incentivizing equitable outcomes through oversight. Individuals from diverse backgrounds must have a seat at the table to participate in the authority, finance and control of OPTN operations and policy development, to change the paradigm from health disparity to true health equity. This means there must be more oversight of the OPOs to require the presence of diverse representation at the highest administrative levels. When negotiating collaborations between the Links, Incorporated and potential partner health organizations, we strive to leverage greater representation on their decision-making boards. This strategy has been met with varying results. OPO compliance in this regard must be monitored. In addition, there must be mentoring, opportunities and funding for education, training and fellowships to allow for the advancement of persons of color to these positions.

G. 4. OPTN Operations and Policy Development Improvements: What other improvements to OPTN operations and policy development processes can and/or should be incorporated into the OPTN contact?

Increasing the ethnic diversity of OPO executive leadership is an opportunity. There are 57 OPOs very few of these OPOs have persons of color at the highest administrative level (CEO or Chairperson of the Board of Directors)[9]. It is important therefore to increase the number of CEOs and Board Chairs who are people of color (African American, Hispanic or Latino, Asian, Pacific Islander or Native American). Nearly 60% of people waiting for transplant are people of color. Systems should be put in place to eradicate explicit and implicit exclusionary hiring practices and monitor OPO compliance. Increasing the proportion of individuals from diverse backgrounds in leadership positions to better reflect the ethnic diversity of the community of patients being served by the OPO is paramount. Currently, oversight to combat against the current level of executive disparity is completely lacking and desperately needed as indicated by the statistics previously cited.

Living donation policy is an area of opportunity for African Americans. We know the living donations among African Americans are significantly below that of whites, underscoring the need for augmented education of living donation opportunities. In 2020, 16.4 percent of blacks were living donors as compared to 33.4 percent of white living donors[10]. Instances of African Americans who receive a "second chance at life" through organ donation are celebrated in our community in churches, at family gatherings, in the workplace, and in our social and service organizations. It is important to peel back the crucial steps to allow these donations and transplants to happen, which begins with increasing the education outreach to minority communities about the benefits of living donation and simultaneously speaking to the fears, myths, and hesitancy associated with being a living donor. Overcoming this obstacle is best addressed with recipients and trusted community-based organizations delivering the information, not the transplant centers and organ procurement organizations. The education should be multi-generational and culturally tailored, addressing the most pressing concerns and highlighting the successes in minority communities.

The Linkages to Life National Program Committee has increased its awareness and advocacy specifically around living donation in the 2021-2022 program year with several recorded webinars on the topic. These efforts by The Links, Incorporated or other historically Black service and civic organizations may often be superior to those of the transplant centers and OPOs to address this need. The Links, Incorporated was able to produce culturally sensitive content to meet patients in their communities. The data also shows that non-whites have lower rates of pre-emptive kidney transplantation, especially for living donation. It is important to highlight these disparities and use fund opportunities to educate our communities of color. While serving as National Chair for Linkages to Life, I've learned that people cannot properly advocate for themselves if they lack awareness of all treatment options available. Our campaigns work to increase this awareness.

H.2-3 Stakeholder Engagement: Describe how you would/vendors could support the OPTN in requiring OPTN members to adopt improved stakeholder engagement strategies that advance

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[9] https://aopo.org/find-your-opo/, Accessed May 19, 2022
[10] https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=27, Accessed May 19, 2022

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

Bringing diverse voices to the table early and through the organ procurement process is a tremendous opportunity for system improvement. Stakeholders including transplant recipients, prior living donors and families members of deceased donors should be engaged early, often and meaningfully. Stakeholders from ethnically diverse backgrounds should be included in the oversight bodies referenced earlier in these comments. Executive search committees or contracted executive search firms should either include stakeholders from ethnically diverse backgrounds or specialize in diversity, equity and inclusion. Finally, through past experiences serving on stakeholder advisory boards for research funded by Patient Centered Outcomes Research Institute (PCORI), I consider them to have a portfolio of best practices[11] in engagement strategies. There is significant value in OPTN members together with a more diverse cross-section of stakeholders examine these engagement techniques and employ them at numerous levels of planning, policymaking and operations, including the development of a shared decision-making model for organ acceptance. If serving patients in need of organ and tissue transplantation is the goal, OPTN members will transform stakeholder engagement practices and where appropriate will hone engagement relations ships to meaningful collaboration and shared leadership to attain more inclusive health outcomes.

Each of these areas of increased emphasis must be met with thoughtful planning and financial resources. Critical to the proper planning is the involvement of organizations and individuals such as ours.

Thank you for considering this feedback.

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[11] https://www.pcori.org/engagement/value-engagement, Accessed May 19, 2022

NAICS 541611:
Organ Procurement and Transplantation Network (OPTN) Request for Information issued 4/8/2022

AMERICAN SOCIETY OF HISTOCOMPATIBILITY AND IMMUNOGENETICS
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May 20, 2022

HHS/HRSA/OAMP
5600 Fishers Lane, Rockville, MD

Dear Members of HHS, HRSA, OAMP and OPTN:

Subject: Request for information (NAICS Code 541611) related to OPTN

On the 9th of April 2022, Health and Human Services (HHS), through the Health Resources & Services Administration (HRSA), issued a request for information (RFI) related to strategic enhancement and optimization of the Organ Procurement and Transplantation Network (OPTN) through Fiscal Year 2023. As a stakeholder and partner in OPTN operations, the American Society of Histocompatibility and Immunogenetics (ASHI) appreciates the opportunity to respond to several of the RFI "Market Research Questions" provided.

ASHI has had the opportunity to review the recent responses by the OPTN to the National Academies of Sciences, Engineering and Medicine (NASEM) February 2022 recommendations report. ASHI wishes to commend the OPTN on the progress made in the last several years which not only bolstered transplantation throughout a global pandemic but supported the most robust transplant volumes in national history.

   A. **OPTN Technology - IT System**
       A.1. Describe how you would/a vendor would implement and utilize modern IT architecture to:

           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.

           • ASHI Response: ASHI encourages the OPTN to partner with histocompatibility software vendors with a goal of developing networked software to support 100% automated upload and transcription/entry of HLA Typing and unacceptable antigen data directly from vendor software into UNET to decrease manual data entry error. In addition to vendor software, OPTN IT would develop an automated download that would work with established software such as Microsoft Excel or Access. Upon development and validation, these systems should be a requirement for transplant center and laboratory use when interfacing with UNET for consistency, data integrity and

patient safety.

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.

- ASHI Response: Technology in the fields of histocompatibility and immunogenetics will soon allow for the wide-spread capability to rapidly HLA type donors at high resolution (2-field allele resolution) within hours. Given the time and effort required to update UNET system programing, it is recommended that the OPTN begin planning for UNET accommodation of 2-field HLA typing for waitlist candidates and donors.
  - Timothy L. Mosbruger et al. Utilizing nanopore sequencing technology for the rapid and comprehensive characterization of eleven HLA loci; addressing the need for deceased donor expedited HLA typing, Human Immunology, Volume 81, Issue 8, 2020, Pages 413-422, ISSN 0198-8859, https://doi.org/10.1016/j.humimm.2020.06.004.

- To allow transplant centers to fully utilize the potential of rapid high-resolution donor and patient typing, it is recommended that the OPTN also begin strategic planning for capturing high resolution HLA typing data when it becomes widely available and reported. These data will be valuable in performing analyses of transplant outcomes. An example for the successful use of high-resolution HLA typing data is illustrated by the National Marrow Donor Program (NMDP).
  - Lee SJ et al. High-resolution donor-recipient HLA matching contributes to the success of unrelated donor marrow transplantation. Blood. 2007 Dec 15;110(13):4576-83. doi: 10.1182/blood-2007-06-097386. Epub 2007 Sep 4. PMID: 17785583.
  - Huang Y et al. Assessing the utilization of high-resolution 2-field HLA typing in solid organ transplantation. Am J Transplant. 2019 Jul;19(7):1955-1963. doi: 10.1111/ajt.15258. Epub 2019 Feb 22. PMID: 30623581.

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

- ASHI response: As mentioned in response A.1.c., the OPTN should begin strategic planning for the UNET capability to accommodate centers having the option to enter high-

resolution HLA typing for donors and waitlist candidates. High-resolution donor/patient match-grade data collection will allow for assessment of HLA typing resolution and match-grade impacts and correlations with transplant outcomes.

- Broader organ sharing has increased the need and utility of virtual crossmatching for many HLA laboratories and transplant centers across the United States. Data should be collected by the OPTN regarding use of context of utility of these risk assessment modalities,

  - Puttarajappa CM et al. Trends and impact on cold ischemia time and clinical outcomes using virtual crossmatch for deceased donor kidney transplantation in the United States. Kidney Int. 2021 Sep;100(3):660-671. doi: 10.1016/j.kint.2021.04.020. Epub 2021 Apr 30. PMID: 33940109; PMCID: PMC8384718.

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

- ASHI Response: Automatic access should be given to those transplant center and histocompatibility personnel already approved to have UNET access for match run data associated with their waitlist patients

  - As of now, personnel external to previously defined "donor service areas" or organ procurement organizations (OPO) that need to access donor data for their waitlisted patients up for "import" deceased donor offers have to have access granted by each individual OPO to see donor data.

  - If a center's patient is on the match-run for a donor, the UNET approved personnel serving the patient transplant center and HLA laboratory should have automatic access to the Unet data associated with that offer without having to request access from the external OPO

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?

- ASHI Response: ASHI supports 99.999% uptime of the OPTN IT system as a reasonable and achievable goal

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

- ASHI Response: The OPTN should increase automation opportunities in UNET as much as modern IT support will allow and should seek to partner with technology firms to enhance automation in data entry and access, while remaining compliant with data security (HIPPA) rules.

- The OPTN should continue optimization and specification of "code-out" codes for clarity and optimal data tracking in organ offer decline.

A.4. How would you/a vendor ensure adherence to the latest industry best practices for IT security infrastructure, practices, and standards?

- ASHI Response: As there are currently no consistent "industry best practices" and IT security is complex, it would be beneficial for the OPTN to poll/survey transplant center IT systems for processes, boundaries and comfort levels with partnerships in IT data sharing and integration. The results of this data collection from a large pool of nation-wide transplant programs could lead to development of "best practices" and consistent paths forward in OPTN data security and program adherence.

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.

- ASHI Response: The OPTN should develop and distribute post-donation patient and donor family surveys to all transplant programs and OPO partners for data collection. Survey data collected at an early timepoint, perhaps post-consent to be a deceased donor or to receive a deceased donor transplant would also be beneficial. Having all national centers and OPOs collect the same survey data provided by the OPTN could strengthen consistency in data representation, collection and development of educational material. Survey responses could highlight gaps in public information and clarity regarding donation processes. The responses are suggestions for data collection with the goal of new metric discovery to improve allocation in the future.

B.2. Describe how you would/how vendors could structure data collection and reporting

mechanisms for the system:

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

- ASHI Response: The OPTN should begin actively/prospectively tracking HLA-DQ matching to collect real-time data to determine if adding this metric for match points would benefit patients rather than utilizing only retrospective data

  - Tambur AR et al. Significance of HLA-DQ in kidney transplantation: time to reevaluate human leukocyte antigen-matching priorities to improve transplant outcomes? An expert review and recommendations. Kidney Int. 2021 Nov;100(5):1012-1022. doi: 10.1016/j.kint.2021.06.026. Epub 2021 Jul 8. PMID: 34246656.

- ASHI Response: as mentioned in response A.1.c., the OPTN should begin strategic planning for the UNET capability to accommodate centers having the option to enter high-resolution HLA typing for donors and waitlist candidates. This data tracking could be utilized to assess HLA high-resolution match-grade impacts on national deceased donor transplant outcomes

- The OPTN should consider beginning to collect data on HLA eplet mismatch load, which could be utilized to assess the impact of HLA eplet mismatch impacts on national deceased donor transplant outcomes

  - Philogene MC et al. Eplet mismatch analysis and allograft outcome across racially diverse groups in a pediatric transplant cohort: a single-center analysis. Pediatr Nephrol. 2020 Jan;35(1):83-94. doi: 10.1007/s00467-019-04344-1. Epub 2019 Oct 10. Erratum in: Pediatr Nephrol. 2020 Apr;35(4):719. PMID: 31599339; PMCID: PMC6901410.

  - Tambur AR. HLA-Epitope Matching or Eplet Risk Stratification: The Devil Is in the Details. Front Immunol. 2018 Aug 31;9:2010. doi: 10.3389/fimmu.2018.02010. PMID: 30233594; PMCID: PMC6128220.

  - Wiebe C et al. HLA-DR/DQ molecular mismatch:

A prognostic biomarker for primary alloimmunity.
Am J Transplant. 2019 Jun;19(6):1708-1719. doi:
10.1111/ajt.15177. Epub 2018 Dec 15. PMID:
30414349; PMCID: PMC6563434.

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.

- ASHI Response: The OPTN should work closely with the Histocompatibility Committee and with ASHI to do more to support updates to federal regulations in support of virtual crossmatching.

  - April 4, 2022 ASHI response to RFI in regards to CMS-03326-NC related to 42 CFR attached

  - Morris AB et al. Out with the old, in with the new: Virtual versus physical crossmatching in the modern era. HLA. 2019 Dec;94(6):471-481. doi: 10.1111/tan.13693. Epub 2019 Oct 17. PMID: 31515937; PMCID: PMC7341023.

  - Sullivan HC et al. (F)Utility of the physical crossmatch for living donor evaluations in the age of the virtual crossmatch. Hum Immunol. 2018 Oct;79(10):711-715. doi: 10.1016/j.humimm.2018.08.001. Epub 2018 Aug 3. PMID: 30081064.

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

- ASHI Response: The OPTN could be an excellent resource for distribution of unutilized organs for research. OPOs could notify the OPTN of unutilized organs for OPTN facilitation of distribution or collaborative connection for research. An OPTN based research bank or database of unutilized organs could be developed. Increased communication with center-affiliated or other academic institutions who enroll fellows may be especially interested in such research studies.

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

- ASHI Response: As noted in response to point E.1., the OPTN

should actively support updates to federal regulations in support of virtual crossmatching.

F. <u>Organ Usage</u>

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.

- ASHI Response: The OPTN should consider development of additional tools to allow more focused evaluation of transplantation outcomes in use of higher risk organs and underserved patient populations. Access to data specifically generated from centers that routinely accept high KDPI donors and from centers that have the highest rate of transplant among underserved populations could help centers safely and reasonably adapt their organ acceptance practices to decrease organ discard. Data has shown that use of donors with KDPI>85 yields a better quality of life score than continued dialysis therapy. The OPTN needs to develop new quality metrics to incentivize and expand the reasonable and responsible use of high-risk organs in transplantation.

    - Bui K, Kilambi V. Mehrotra S. Functional-Status-Based Risk-Benefit Analyses of High-KDPI Kidney transplant vv Dialysis. Transpl. Int. 2019 December; 32 (12): 1297-1312 doi:1111/tri/13483

    - Jay C et al. Survival Benefit in Older Patients Associated With Earlier Transplant With High KDPI Kidneys. Transplantation April 2017

G. <u>OPTN Operations and Policy Development Improvements</u>

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.

- ASHI Response: ASHI has found great success in collaboration with groups focused on diversity and inclusion initiatives. The OPTN should seek to partner with patient and minority collaboratives to increase diversity and inclusion (below are examples).
    - Donate Life America/We Encourage Living Donation
    - Donor family groups
    - Women of the Federation of Clinical Immunology Societies (FOCIS)
    - Women in Transplantation
    - Association for Multicultural Affairs in

Transplantation (AMAT)
- Children's Organ Transplant Association
- National Minority Organ Tissue Transplant Education Program (National MOTTEP)
- African American Transplant Access Program (AATAP)
- Hispanic Kidney Transplant Program at Northwestern Medicine
- The Asian American Donation Program
- The Canadian Donation and Transplantation Research Program (First Nations and Indigenous support structure)

- OPTN should have personnel, committee and Board training materials that address diversity, inclusion and bias

- OPTN should increase the balance between patient, donor and caregiver representation on the board with transplant professional representation on the board

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

- ASHI Response: The relatively new "Offer Filters Explorer" tool developed by UNOS is not being utilized by many centers due to hesitance.

  - UNOS/OPTN should provide more evidence-based support for the tool

  - UNOS/OPTN should provide more education and more opportunities for the transplant community to understand how the tool works, along with pros and cons indicated by the system pilot data and phase I data

  - Education and encouragement to utilize the tool can be provided by webinar, sessions at transplant society meetings and more in-depth description on the UNOS website

ASHI intends to submit feedback and relevant proposals on future solicitations related to this requirement.

TO:

US Department of Health and Human Services

Health Resources and Services Administration

Office of Acquisition Management & Policy

5600 Fishers Lane, Rockville, MD 20857

Title: Organ Procurement and Transplantation Network (OPTN)

NAICS Code: 541611

Incumbent: United Network for Organ Sharing

Point of Contact: NInazawa@hrsa.gov

Issued: April 8, 2022

FROM:

The American Society of Nephrology

1401 H Street, NW, Suite 900

Washington, DC 20005

Title: Organ Procurement and Transplantation Network (OPTN)

NAICS Code: 541611

Point of Contact: David White, ASN Regulatory and Quality Officer, (202) 640-4635, dwhite@asn-online.org

Included: Response to questions only. No intent to supply a proposal on any future solicitation related to this requirement.

May 23, 2022

TO:
US Department of Health and Human Services
Health Resources and Services Administration
Office of Acquisition Management & Policy
5600 Fishers Lane, Rockville, MD 20857
Title: Organ Procurement and Transplantation Network (OPTN)
NAICS Code: 541611
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FROM:
The American Society of Nephrology
1401 H Street, NW, Suite 900
Washington, DC 20005
Title: Organ Procurement and Transplantation Network (OPTN)
NAICS Code: 541611
Point of Contact: David White, ASN Regulatory and Quality Officer, (202) 640-4635,
dwhite@asn-online.org

The Honorable Carole Johnson
Administrator, Health Resources and Health Administration (HRSA)

Dear Administrator Johnson:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 21,000
nephrologists, scientists, and other kidney health care professionals who are members of the
American Society of Nephrology (ASN), thank you for the opportunity to respond to the Request
for Information (RFI) issued by the Health Resources and Services Administration (HRSA)
related to the coordination and improvement of "the effectiveness of the nation's organ
procurement, distribution and transplantation systems and to increase the availability of, and
access to, donor organs for patients with end-stage organ failure."[i]

ASN wholeheartedly supports the primary objectives HRSA identifies in its RFI:

1. Increase accountability in Organ Procurement and Transplantation Network (OPTN)
   operations, including board governance, financial
   structures, data quality transparency, and policy development;
2. Enhance the usability and performance of the OPTN IT system and related tools; and
3. Strengthen equity, access, and transparency in the organ donation, allocation,
   procurement, and transplantation process.

To address these primary objectives, ASN specifically recommends three key steps:

1. Separating the technology portion of the OPTN contract as a stand-alone contract as recommended by the National Academies of Sciences, Engineering, and Medicine (NASEM) in its report *Realizing the Promise of Equity in the Organ Transplantation System*[ii] and ensuring technology systems developed for federally funded contracts belong to the Agency.
2. Requiring OPTN contractors make every effort to have complete and accurate data readily available so that all stakeholders can have timely evidence of equitable and effective treatment of donors and patients.
3. Enforcing OPTN and contractor(s) have separate governance boards as called for by HRSA in 2018 and reaffirmed by the U.S. Government Accountability Office (GAO).[iii]

Addressing **A. OPTN Technology** questions 1-5 and **E. Increasing Organ Donation and Improving Procurement.**

ASN strongly advocates for HRSA to implement transparent guidelines, including clear presentation of eligibility criteria for transplant candidate listing and transplantation, to ensure clear, useful, and easily accessible data so the patient, their nephrologist, their dialysis facility, and transplant center can coordinate the care and communications necessary to identify the right transplant center fit for a patient, inform sharing decision making in organ acceptance, and to keep the patient on the path to transplantation. For example, patients need data and transparency when deciding on accepting higher risk organs such as ones with a KDPI of 85+ or from Hepatitis C+ donors.

Regulations mandate that patients receive information on the transplant center's 1-year graft and patient survival based on Scientific Registry of Transplant Recipients (SRTR) data updated every 6-months and notify patients of significant changes. However, current requirements focus on too much information of limited differentiation provided by these outcomes as most centers have similar one-year graft and patient survival outcomes and not enough information on elements that patients highly value. Not only is it burdensome for centers to maintain current written disclosure of data that are of limited value to patients, but there are also several other challenges to these communications:

- The communication is not standardized. ASN recommends standardizing how information is shared with the patient, similar to how financial information sharing has been standardized by the Consumer Financial Protection Bureau (CFPB). Standardized communication is a key step in assuring clarity, objectivity of data and providing patients the ability to compare centers based on their results. Instead, the current system which allows centers to use different formats makes it difficult for patients to understand the information they are seeking. Even information shared by transplant centers on their websites is not standardized and can be difficult for patients to follow in order to make informed choices[iv].

- The information shared by transplant centers is driven by data produced by SRTR that do not correspond to the information that patients want while they are on the waitlist. This was described by Husain SA et al.[v], in a survey study of patients demonstrating clear preference for process measures such as time to transplant, ease of waitlisting, and

whether a center will accept patients like them on the transplant waitlist. Critically, emphasis on less important or insufficiently adjusted measures without full context also incentivizes transplant centers to only list and subsequently transplant patients with the fewest barriers to transplant, thus exacerbating disparities in access to transplant.

- While patients clearly prefer to receive information from their providers, there is a limited understanding of the organ allocation system or the processes of local transplant programs among dialysis staff, especially those at the patient bedside.[vi][vii] Websites from UNOS and SRTR are not always seen as primary sources of information by patient communities.

- Patient selectivity and transplant center thresholds are not always publicly shared with patients, dialysis providers, or referring nephrologists, making it unclear if patients are candidates for transplant at any given center. Large variations in the thresholds from center to center for accepting patients as transplant candidates make it difficult for patients and their care team to identify centers where they may have an opportunity to be listed for and to receive a transplant. As a result, regional studies in the US demonstrate significant variation in the proportion of referred patients who are subsequently waitlisted.[viii]

- In the last two decades, there has been an increase in selectivity by transplant centers and rapid delisting of patients from the waitlist, both of which may have a direct negative impact on access to transplant but have no associated transparency.[ix] As a result, the median survival of transplant candidates AFTER they are removed from the waitlist (for reasons other than transplant) is now approximately five years,[x] while waitlist mortality has steadily dropped to approximately 5% annually compared to an overall annualized mortality rate of 20% for ESRD patients.

- Patients on the waitlist are frequently unaware of their status on the waitlist and receive little or no information from the transplant centers. This paucity of communication between patients, their dialysis facilities, and transplant centers results represents a failure of the OPTN to improve communication between various stakeholders in transplantation creating both inefficiencies of allocation and silos of care. This dysfunction is highlighted by several troubling facts:

  a) Patients are often unaware that organ offers are being declined on their behalf without their knowledge.[xi] These offers are often for organs that patients might have accepted had they been asked.

  b) The waitlists are often poorly curated and maintained due to insufficient communication among transplant centers, dialysis facilities, and patients or their care partners. As a result, nearly one in five kidneys is now offered to a deceased person still on the waitlist because the transplant center is unaware that the patient is deceased.[xii] Deceased candidates receive a median of four organ offers before they are removed from the waitlist. A recent announcement from the OPTN of the abrupt addition of 35,000 verified deaths to their standard analytical files

highlights the lack of transparency around important data concerns as well as the failure to acknowledge the nonrandom missing nature of this data suggests the failure to understand the import of the problem.

c)   Patients must be informed if their centers either pause doing transplants or inactivate patients on the waitlist. Rapid inactivation of large numbers of patients was only recently introduced and the system urgently needs to leverage any communication tools the OPTN can provide.

d)   Almost all centers use an unofficial status of "internal hold" for patients who remain active on the waitlist and continue to receive offers but are not eligible to receive transplants. This practice is detrimental to the efficiency of the allocation system, often leads to confusion on the part of the patient and may be abused by centers. Patients on internal hold can continue to attract organ offers and be used to move organs to different Donor Service Areas (DSAs) by transplant centers before they are then declined forcing a local reallocation of that organ in a different part of the country than where it ought to have been used.

e)   Patients must be informed of the criteria used by a transplant center for accepting offered organs. These criteria are not currently shared with the patients. Knowledge of these criteria would give patients the choice of which center would suit them best. Bypass filters are used by transplant centers to automatically screen out offered kidneys from donors with certain clinical characteristics. For example, donor age criteria can be set such that centers are not offered national organ offers from donors above a prespecified age. While these filters were designed initially to help accelerate allocation, their use needs to be monitored to determine the impact.[xiii] These bypass criteria often can result in dramatic changes in the probability of transplantation because it shrinks the pool of donor organs to which patients at a given transplant center have access.

f)   Centers appear to be less willing to use organs for transplantation on the weekend, including for organs that are eventually accepted by other transplant centers. How this impacts the probability of transplantation is not currently understood nor shared with patients.[xiv,xv]

g)   Patients, dialysis facilities and referring providers are often not informed of the status the referral and evaluation process with little information available on where patients are in the process. Perhaps more troubling, these providers are often unaware of why some of their patients are not accepted for wait listing or why they were overlooked for organs that were transplanted into patients with lower priority scores. Additionally concerning are referrals declined by transplant centers without official evaluation by transplant center providers. Often decisions about accepting or declining referrals are made by transplant coordinators who are reviewing the medical record and not directly evaluating the patient in person. Transplant coordinators may have little to no clinical experience. This practice introduces inherent biases into the transplant process.

All these processes/events occur with limited transparency and without patient-centered communications that accurately convey what is happening within the process.

Addressing **B. Data Collection Activities** questions 1-2.

On creating public OPTN national, regional, and local performance dashboards, ASN believes patient-centered dash boards that are easy to decipher with a limited use of technical terms that provide ACTIONABLE information would help patients make informed choices is an urgent need. The information being provided should be tailored to the consumer of the data. Data reports, visualizations, summaries should be designed to different questions depending on whether these are patient facing or professional facing.

On tracking long-term patient outcomes and health and non-health-related factors that contribute to outcomes, ASN believes OPTN needs to be collecting data on social determinants of health in a responsible manner and leveraging this information to identify and mitigate disparities in access to transplantation. It is particularly important that OPTN also collect data on patients who are being denied an opportunity to be waitlisted (and the reasons for this) in order to be able to determine if there is a broader issue than the individual's medical or psychosocial suitability for transplantation. These data collection efforts can also be facilitated by the use of linkages to other datasets, both public and proprietary, for purposes of monitoring OPTN. These data linkages need to be robust, recurrent, and used to inform policies that would support equity in the allocation system and the development of interventions necessary to improve access to transplantation.

The OPTN data registry is an important asset for the transplant community, and yet the OPTN contractor has failed to ensure that there are important quality checks in place in the form of data validation, verification at the time of data entry, the elimination of biological implausible values and/or the ensuring that there is a robust, verifiable and reproducible method to confirm that all deaths and graft failures are accurately captured. Large errors for critical data suggest that the OPTN contractor does not view the maintenance of the registry as a critical function. The absence of a robust data dictionary with detailed instructions and definitions are another example of the failure to invest in the data capture system.

Transplant Patient Safety Data: Among patients selected for organ transplant, one-year post transplant graft survival is excellent, averaging ~ 97%.[xvi] Critical issues are the organ shortage and discard rate as well as the lack of transplant access for many patients who could benefit from increased uptake of transplantation (resulting in a shrinking waitlist), a process that would require improving the discard rate and organ shortages. Expanding practices to procure and utilize all usable organs, even those that are deemed not of the highest quality, requires a system-wide perspective that is framed around a comparison of the benefits of the patient receiving that organ versus continuing on dialysis. The current regulatory penalties incite transplant centers to reject less than ideal organs even if these organs would still greatly improve the quality of life and longevity of transplant recipients when compared to dialysis. The Kidney Donor Profile Index (KDPI) is a measure of organ quality relative to other organs that does not adequately reflect the value that organ provides to a specific recipient. As such, the KDPI is a seriously

flawed guide for clinicians, and it should never replace the quality-of-life perspective of the patient. While the idea of using a composite measure of organ quality to reduce cognitive load in evaluating organ quality is a good one, alternative strategies need to be considered along with ongoing research to improve kidney allograft quality measures. ASN recommends that the KDPI be withdrawn immediately, and the Kidney Donor Risk Index (KDRI) be used to overcome the inherent cognitive biases that result from a percentile score rather than a measure of relative risk of failure.

Living Donor Safety: OPTN has several mandates directed at living donor safety. Policy 14 defines minimal criteria that must be included in the living donor evaluation and informed consent. Policy 18 defines clinical and laboratory parameters that must be collected at 6 months, 1 year, and 2 years post donation. These data are summarized in SRTR Program Specific Reports, and complications (national level) in the Annual Data Report, although these reports are directed at professionals and are unlikely to be accessed by most patients.

Under its contract with HRSA, SRTR has recently started a project to create a lifelong living donor registry, the Living Donor Collective (https://livingdonorcollective.org/). The first phase of data has been published[xvii] with updated reporting appearing in a new Annual Data Report, and participating programs receive Program Specific Reports. Under this model, transplant centers register donors and SRTR conducts follow-up. At this time, participation is voluntary and transplant centers cite concerns for costs as a barrier to participation.

To ensure a meaningful commitment to living donor safety, ASN encourages OPTN, SRTR, and the Centers for Medicare & Medicaid Services (CMS) to partner to ensure access to post-donation follow-up and incentivize donor registration in the Living Donor Collective. ASN notes that there is little long-term data on the outcomes following kidney donation, particularly among racial and ethnic minorities, which has impeded the growth of living donation. More recent advances in genetics of kidney disease, including the APOL1 alleles, raises new concerns and questions for the long-term risk of potential donors with genetic markers of kidney diseases. These questions need to be answered in order to ensure optimal and equitable access to living donation and reassure potential donors and optimize their safety.

Recently, the OPTN Board of Directors approved a new policy combining pretransplant (offer acceptance, waitlist mortality) and posttransplant (90-day graft survival and conditional one-year graft survival) indicators to motivate attention to all phases of care by transplant centers. ASN does not support that new policy and hopes this RFI will lead to the reversal of that approval. This opposition is in part because of the inclusion of a waitlist mortality measure that would only encourage selective and delayed waitlisting of dialysis patients who continue to accrue waitlisting time from the time that they initiate dialysis. This approach has substantial adverse consequences to potential transplant recipients.

ASN notes that OPTN has moved forward with new measures while being fully aware of the effort from SRTR to develop new metrics for transplant centers ("The Task 5 initiative"[xviii]). This failure to coordinate is going to result in another compilation of a variety of quality measures from different agencies that will create confusion among transplant centers – much to the disadvantage of patients. The confusing array of quality measures from different agencies

also creates confusion for hospital leadership which adversely impacts their willingness to invest and support transplant programs and the much-needed quality improvement resources.

- Ensuring that centers are performing quality improvement activities on an ongoing basis requires the establishment of a robust effort in the form of a quality specialist focused on continuous improvement and monitoring of process and outcomes measures of the transplant center. This needs to be seen as a necessary investment on the part of hospitals with transplant centers and enforced by the OPTN contractor that has failed to discipline transplant centers that have not reported significant amounts of data for their patients.

- Incentivizing maximum access to waitlists, optimal organ use, and transplant rates, while maintaining post-transplant outcomes requires a harmonized, system-wide perspective. Published research shows that net survival benefit conferred by even the 'lowest performing' centers is far superior to dialysis.[xix] To avoid risk aversion, recertification should focus on achievement of an absolute survival benefit over dialysis.

Finally, transplant centers are not currently equipped to handle a deluge of patient referrals should nephrologists decide to indiscriminately refer all of their dialysis patients immediately for evaluation for transplantation. Improvements are needed in pre-referral evaluation and in communication among nephrologists, dialysis facilities, and transplant centers to optimize the pre-transplant evaluation process and eliminate disparities. Currently, reimbursement policies do not incentivize the adequate staffing of pretransplant programs to appropriately expand and manage transplant center waitlisting. The current policies are exacerbated by the absence of any meaningful reimbursement from private payers for pretransplant related coordination of care and other activities to maintain patients active on the waitlist.

In order for transplant programs to function optimally and to increase access to transplant, transplant programs require robust, adequately funded pre-transplant teams that will aid patients in navigating the multistep evaluation process and will keep patients informed of changes in a timely manner; additionally, these pretransplant teams also must ensure regular communication with dialysis units and nephrologists so that changes in health status that require either temporary inactivation or delisting (when truly indicated) happen in a timely manner.

Making the patients' experience of pretransplant evaluation easier is an important goal (that will require adequate funding) that should help to address some of the barriers to transplant that disproportionately affect patients who do not live in close proximity to a transplant center. Some transplant centers seek to perform much of the pretransplant testing locally at their center. However, in the age of electronic medical records, efforts should be made to allow much of this testing to happen in a location that is of most convenience to the patient and their families, obviating the need for travel costs, time off from work, and other challenges that may inadvertently create barriers to consideration for transplant.

Pretransplant testing is a significant source of revenue for many transplant centers. Maintaining the financial stability of transplant centers is clearly a crucial objective in order for them to remain open to provide transplants. Accordingly, if patient-centered changes are made to baseline pretransplant testing, it will be necessary to understand and mitigate any deleterious

impacts on the financial viability of transplant centers so that they can, in turn, continue to serve patients.
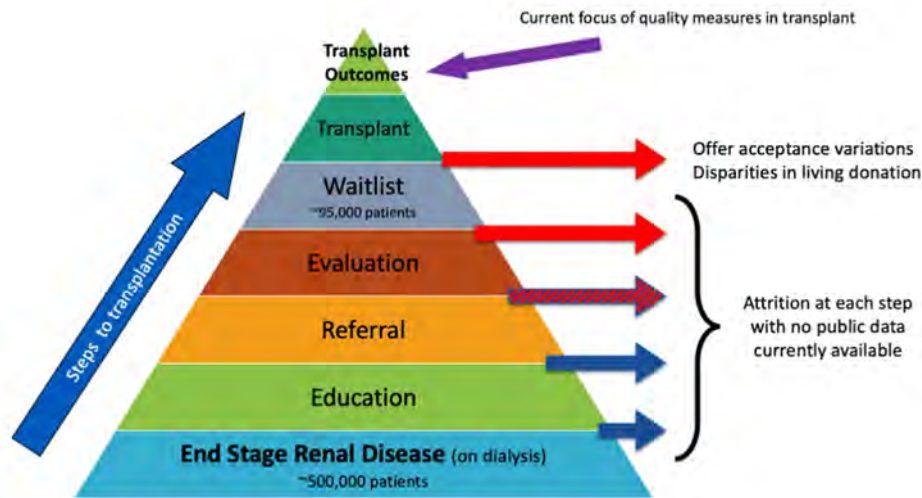
At present, interest in taking care of transplant recipients (and living donors) in the long-term plummets on the part of transplant programs after one-year post-transplant and there is no clearly established pathway to community care, to the detriment of patients. It would be beneficial to establish—as well as provide reimbursement to support—a pathway for these individuals to receive skilled care from professionals. A variety of approaches could be undertaken to achieve this goal, and the care would not necessarily have to be provided at the transplant center itself.

Telemedicine may be an ideal venue to provide these patients access to long-term, post-transplant or post-donation care. It may also be possible for transplant centers and transplant nephrologists to forge connections with internists with knowledge about transplant or general nephrologists to provide this care at the community level. HRSA should consider these approaches in its contracting efforts.

Similarly, referring nephrologists and transplant centers need to increase coordination when providing a continuum of care for patients post transplantation. Most patients are clinically stable after transplantation and could be managed by referring nephrologists in partnership with transplant centers, particularly as transplant recipients move beyond the early post-transplant period. Improved partnerships require the creation of systems that allow for easy referral back to centers in the event of complications, with a significant resource investment into coordination of care activities.

There is a need for physician practices, transplant centers, dialysis units, and independent laboratories to share patient results in a seamless manner, particularly if the care of these patients will be co-managed by two or more sets of clinicians in partnerships or transform patient care silos to integrated care along a continuum.

Currently the quality measures are focused almost exclusively on post-transplant outcomes. This singular focus has created several negative unintended consequences and encouraged increasing selectivity. Overcoming this situation will require recognition that we should be assessing care along the continuum of patient experience in the steps to transplantation. This approach would mean creating quality measures (process or outcomes measures) for each step in the process.

Current focus of quality measures in transplant

Offer acceptance variations
Disparities in living donation

Attrition at each step
with no public data
currently available

One method to potentially avoid unintended consequences is to calculate quality measures in such a way that considers the spectrum of the process from dialysis to transplant at any given time, to leverage the multistep nature of the process of education, referral, evaluation, waitlisting, transplantation, and post-transplant outcomes. Specifically, measures of quality should use the numerator from the prior step as the denominator for the next step along this continuum to discourage gaming of metrics or a singular focus on just one step of the process.

For example, the proportion of patients referred should be based on the number of patients who completed the education step, while the proportion of patients evaluated should be reported as a fraction of those patients who were referred for transplantation. This multistep process, however, spans different stakeholders – and would require that Conditions of Participation (CoPs) for transplant centers are aligned with Conditions for Coverage for dialysis facilities and with value care programs in which nephrologists are currently participating.

Post-transplant outcome measures currently focus on very short-term outcomes of graft survival and patient death but fail to account for the impact on quality of life. For example, patients who receive a transplant that is complicated by a prolonged hospital course, multiple readmissions, multiple complications with poor allograft function but is dialysis independent at the end of a year would be considered a success by the current CoPs but has potentially resulted in a significantly worse quality of life for the patient. Similarly, from an access and health equity perspective, focusing on short-term, time-limited outcomes post-transplant limit the opportunity to spur growth in transplantation.

Addressing **C. OPTN Finances** questions 1-2.

Regarding charging for functions that are OPTN contract-supported functions, currently the OPTN contractor charges a fee for certain data reports and visualizations that are needed by transplant centers and Organ Procurement Organizations (OPOs) in order to understand how the allocation system is working with respect to organ offers, organ acceptance, and bypass filters. Given that the current OPTN contractor is already being funded to do this, ASN believes that this practice should not be allowed to continue moving forward.

In addition, given that there are now quality measures that encourage transplant referral and waitlisting at the dialysis facility level, there is likely to be a substantial increase in the number of patients being referred to transplant centers that may overwhelm those centers. As a result, this is likely to change listing behavior on the part of the transplant centers by rapidly increasing the number of individuals who are listed as inactive with thousands of patients thus being waitlisted without any real hope of being evaluated in a timely manner yet incurring fees for waitlisting. ASN believe that HRSA should carefully monitor this situation and move quickly to address it if, and when, it sees this activity occurring.

Addressing **D. OPTN Governance** question 1.

The current governance of the OPTN contractor is perceived as opaque to the community with no clear process for how individuals who volunteer for participation are selected to serve on committees. The agenda setting for the committees is done by the contractor staff even though there is considerable staff turnover, limited institutional memory, or desire to change the status quo sometimes resulting in situations where the necessary expertise to make important decisions is lacking. ASN believes separate governance boards is an important first step in addressing this and other issues. In addition, there needs to be the ability to invite external experts or even require that committees identify experts who would be able to inform committee discussions.

Addressing **F. Organ Usage**

While organ utilization rates are plummeting, the OPTN contractor continues to plow ahead with the effort of continuous distribution without a meaningful effort to improve processes or communication that arise from the logistical challenge in the KAS250 form. With increasing focus on the ESRD Treatment Choices Learning Collaborative (ETCLC) and the need to improve organ utilization, the oversight of this challenge by the OPTN contractor is disappointing. The contractor failed to have a contingency plan that would be capable of identifying early process challenges and mitigating these problems before the rapid increase in discard rates took a hold further reinforces the general perception that the contractor is not actively engaged in the process.

The protracted process by which the current OPTN contractor commits resources to introduce changes in the information technology (IT) systems is problematic. For example, the long-drawn-out process of implementation of new organ decline codes took nearly five years, and the extensive delays as a result of inadequate IT resources committed highlight a problem that stems from inadequate resources to invest in infrastructure and the apparent absence of a desire to invest proactively in the system. Similarly, the lengthy delays in implementation of the data lock and protracted processes used for implementation of even the smallest of changes suggest a contractor invested in avoiding meaningful changes necessary to optimize an efficient organ allocation system.

ASN is committed to working with HRSA, HHS, OPOs, and transplant centers to ensure that every individual facing kidney failure has equal access to life-saving kidney transplantation should they so desire and are medically able. Currently, Black Americans, Latinx Americans,

Native Americans, and Native Hawaiian/Pacific Islanders as well as individuals with lower educational and socioeconomic status face disparities in nearly every step of the process for kidney transplantation. For example, Black Americans are less likely than White Americans to be identified as transplant candidates, referred for evaluation, placed on the kidney transplant waitlist or receive kidney transplants, especially living donor kidney transplants, while also being more likely to receive lower quality kidneys, have organ offers declined for them and have poorer transplant graft survival. These trends must be reversed – anything less is neither equitable nor acceptable.

Again, thank you for the opportunity to provide comments on HRSA's request for information. ASN stands ready to provide assistance in achieving the goals HRSA has identified in any way possible. To discuss this letter further, please contact David White, ASN Regulatory and Quality Officer, at dwhite@asn-online.org or (202) 640-4635.

Sincerely,

Susan E. Quaggin, MD, FASN
President

[i] file:///C:/Users/David/Downloads/OPTN+RFI+(4.8.22)-2.pdf

[ii] https://nap.nationalacademies.org/download/26364#

[iii] https://www.gao.gov/assets/b-416248.pdf

[iv] https://pubmed.ncbi.nlm.nih.gov/33353493/

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[vi] Patzer RE, Basu M, Smith KD, Plantinga L, Mohan S, Escoffery C, Kim JJ, Melanson T, Pastan SO. Awareness of the New Kidney Allocation System among United States Dialysis Providers with Low Waitlisting. Am J Nephrol. 2018;47(2):115-119.
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Notice Number: HSB115C1031

Title: Organ Procurement and Transplantation Network (OPTN)

Date of Issuance: April 8, 2022

Response From: American Society of Transplantation
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May 9, 2022

Via E-mail: *NInazawa@hrsa.gov*

Ms. Naomi Inazawa
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RE: OPTN RFI Response (NAICS Code: 541611)

On behalf of the American Society of Transplantation (AST), representing over 4,000 medical professionals engaged in the field of solid organ transplantation, we applaud your leadership and continuous efforts to improve the nation's organ donation and transplant system. We welcome the opportunity to respond to this request for information.

Overall, we believe that there is much to be done to align U.S. transplant system goals. We believe that the misalignment of incentives (patient outcomes and financial) must be reduced and stakeholders (e.g., OPTN, CMS and other payors, OPOs, and transplant programs) must exit siloes to work together effectively to make meaningful change. Common goals of increased organ utilization, increased transplantation, improved equity in access to and outcomes from transplantation need to be broken down into clear pathways for measurable success.

The AST provides the following comments for consideration. The AST does not intend to supply a proposal on any future solicitation related to this requirement.

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

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 recent National Academy of Science, Engineering and Medicine (NASEM) report suggests that the OPTN/HRSA should reevaluate paths to modernize the current IT architecture and data collection process in advance of the rebid process for the OPTN contract (i.e., deciding whether to separate the IT and policy/oversight contracts). This is absent from this RFI. We believe this is a critical element and recommend a delay on contract bidding if this cannot be completed in a timely manner.

   The OPTN system should leverage existing electronic health records (EHR) and registry application programming interfaces (API) to enhance modeling in multiple domains (survival models, organ acceptance models, potential donor models, etc.) by accessing

this existing data to evaluate additional model variables and therefore reduce the cost of and time required to complete prospective data collection for this purpose.

System redundancy to prevent catastrophic failure is critical. We recognize value in both on-site and cloud-based redundant storage to protect the integrity of the system. Protected health information requires careful safeguarding. The system is complex, holding hundreds if not thousands of data elements for both donors and potential recipients that must be sifted through rapidly to generate appropriate match runs for consideration. The system is a long-term repository that tracks data for living donors and organ recipients. It cannot fail. It cannot be down for maintenance. A modular approach that will allow for rapid programming modifications (which also require extensive testing before launch) of a smaller segment of the system seems ideal in this situation.

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.**
It is critical that that the application interfaces with EHRs accurately, effectively, and efficiently to avoid manual data transition to the donor, candidate, and recipient records. This leads to errors that can cause discard or even harm if not recognized and addressed.

Linkage to EHRs would enable innovation to improve system performance. For example, the use of artificial intelligence (AI) approaches to identify potential deceased donors admitted to hospitals rapidly with a high level of accuracy. Additionally, the addition of interfaces to collect patient-reported information will be important in advancing the capabilities of the system as patient reported outcomes (PROs) become an increasingly important element of patient care. Leveraging technology in this area will help facilitate patient engagement and increased patient monitoring between in person visits.

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.**
This is a critical element. Real time tracking and allocation with transparency to transplant centers and waitlisted patients would significantly improve the processes, organ acceptance and ultimately patient survival. We can see our Amazon or Fed Ex packages move across the country in greater detail than we can this precious and critical gift of life.

d. **Produce public performance dashboards and actionable data to identify opportunities for program improvement, reduce inequities, and benchmark OPTN member performance.**
We are supportive of the continued development and enhancement of performance dashboards to support program improvement. We are unaware of evidence linking public reporting to improved system performance and support generation of evidence to inform the optimal use of public reporting. We are not convinced that efforts to increase

transparency without specific and detailed education for the general public would be appropriate or valuable and would caution against potential unintended consequences.

e. **Maximize these and other tools to save critical time in the organ allocation process, minimize errors, and improve patient outcomes.**
Effective APIs to EHRs and other relevant data sources reduce opportunity for transcription error and unnecessary time and expense related to manual data submission. Automation of identification and referral of potential donors would be expected to increase the number of potential organ donors for evaluation.

Leveraging virtual technology to facilitate real-time communication between OPOs and transplant programs evaluating potential donors is critical. While COVID has forced increased comfort with telemedicine practices, we must harness these advances in organ donation and transplantation.

The use of virtual technology to facilitate timely evaluation of transplant candidates that would also facilitate standardization of the candidate evaluation processes between centers should be considered.

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 potential impact on patient lives necessitates the system uptime requirement be as high as reasonably achievable. This contract should also define the maximum downtime allowed during a single event for the purpose of requiring effective contingency plans that would protect system operations during a catastrophe.

A.3. **How can the OPTN ensure data collection is relevant, accurate, timely and streamlined in order to improve organ allocation processes?**
Effective APIs with EHRs to avoid data transcription errors and periodic auditing of data are critical.

Timely audit of recovered but non-utilized organs by an independent entity should be supported by the system. Such an entity could then inform data elements (both donor and recipient) that are required to ensure that every safely transplantable organ is utilized for transplantation.

A.4. **How would you/a vendor ensure ongoing security enhancements to protect against emerging and evolving IT security threats?**
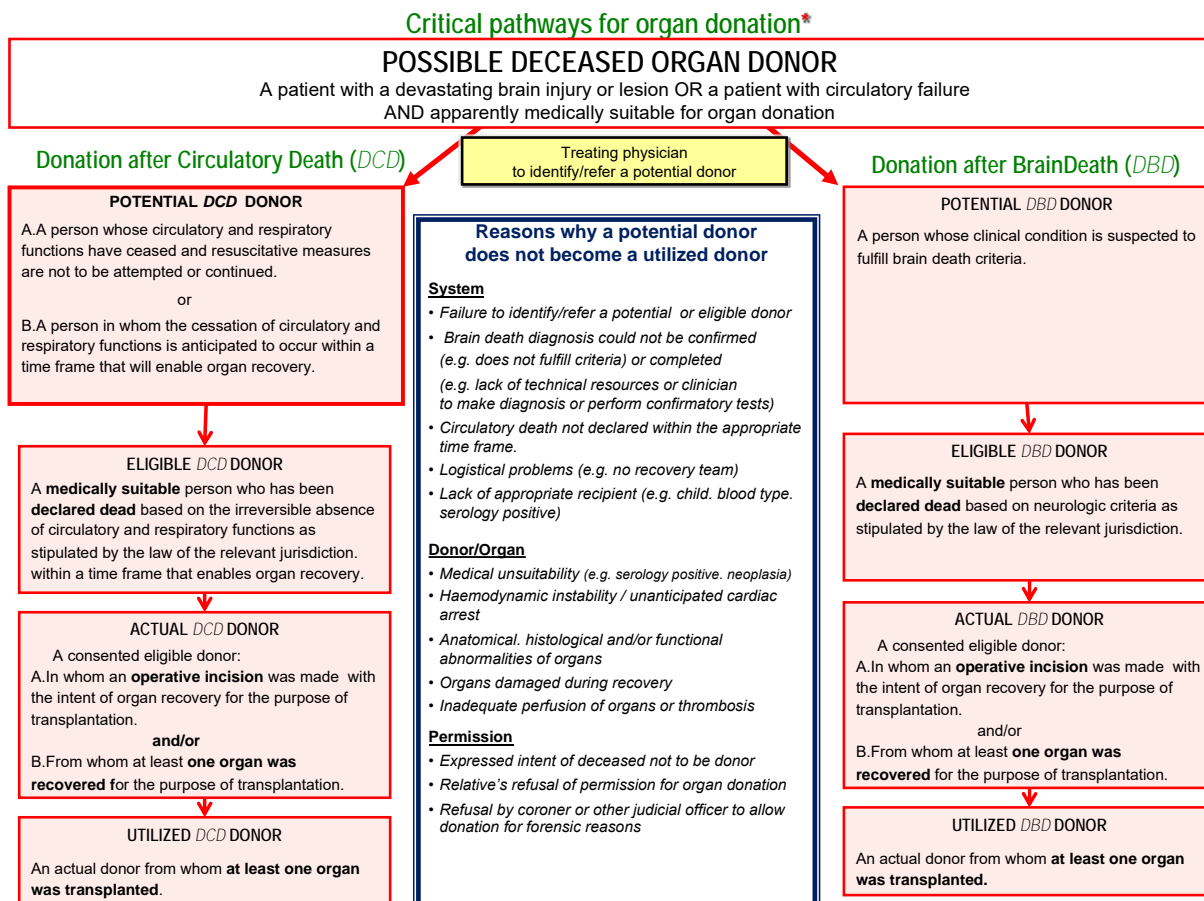
A.5. **How would you/a vendor ensure adherence to the latest industry best practices for IT security infrastructure, practices, and standards?**

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.

Organ Donation: There are established international metrics to monitor the proficiency of the deceased organ donation system (see figure below; reference- Transplant International 2011; 24: 373–378.). These metrics are predicated on accurate identification of potential donors admitted to hospital. AI approaches to identify potential donors through imaging and data already captured in EHRs should be advanced so that valid metrics that are dependent on accurate identification of potential donors can be produced. AI based approaches should be supplemented by periodic chart reviews which are the gold standard for identification of potential donors.

Critical pathways for organ donation*

POSSIBLE DECEASED ORGAN DONOR
A patient with a devastating brain injury or lesion OR a patient with circulatory failure
AND apparently medically suitable for organ donation

Treating physician
to identify/refer a potential donor

Donation after Circulatory Death (DCD)

POTENTIAL DCD DONOR

A.A person whose circulatory and respiratory functions have ceased and resuscitative measures are not to be attempted or continued.

or

B.A person in whom the cessation of circulatory and respiratory functions is anticipated to occur within a time frame that will enable organ recovery.

ELIGIBLE DCD DONOR

A **medically suitable** person who has been **declared dead** based on the irreversible absence of circulatory and respiratory functions as stipulated by the law of the relevant jurisdiction. within a time frame that enables organ recovery.

ACTUAL DCD DONOR

A consented eligible donor:
A.In whom an **operative incision** was made with the intent of organ recovery for the purpose of transplantation.
and/or
B.From whom at least **one organ was recovered** for the purpose of transplantation.

UTILIZED DCD DONOR

An actual donor from whom **at least one organ was transplanted**.

Reasons why a potential donor does not become a utilized donor

System
• Failure to identify/refer a potential or eligible donor
• Brain death diagnosis could not be confirmed (e.g. does not fulfill criteria) or completed (e.g. lack of technical resources or clinician to make diagnosis or perform confirmatory tests)
• Circulatory death not declared within the appropriate time frame.
• Logistical problems (e.g. no recovery team)
• Lack of appropriate recipient (e.g. child. blood type. serology positive)

Donor/Organ
• Medical unsuitability (e.g. serology positive. neoplasia)
• Haemodynamic instability / unanticipated cardiac arrest
• Anatomical. histological and/or functional abnormalities of organs
• Organs damaged during recovery
• Inadequate perfusion of organs or thrombosis

Permission
• Expressed intent of deceased not to be donor
• Relative's refusal of permission for organ donation
• Refusal by coroner or other judicial officer to allow donation for forensic reasons

Donation after BrainDeath (DBD)

POTENTIAL DBD DONOR

A person whose clinical condition is suspected to fulfill brain death criteria.

ELIGIBLE DBD DONOR

A **medically suitable** person who has been **declared dead** based on neurologic criteria as stipulated by the law of the relevant jurisdiction.

ACTUAL DBD DONOR

A consented eligible donor:
A.In whom an **operative incision** was made with the intent of organ recovery for the purpose of transplantation.
and/or
B.From whom at least **one organ was recovered** for the purpose of transplantation.

UTILIZED DBD DONOR

An actual donor from whom **at least one organ was transplanted.**

The "dead donor rule" must be respected. That is. patients may only become donors after death. and the recovery of organs must not cause a donor's death.

Allocation: Timely audits of organ allocation to determine deviations from established algorithms and accurate determination of the reason for non-utilization of organs should be performed.

Organ allocation strategies that incorporate candidate preferences should be explored. As per previous comment, we do not believe real time consultation with waiting list candidates about organ allocation offers is feasible. However, advancement of aggregate metrics of center level practices regarding acceptance of organ offers could be considered. Periodic interactions with

wait-list candidates to review their transplant options should be supported to ensure organ acceptance practices are medically appropriate are aligned with patients' preferences.

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

a.   **To report OPTN performance metrics including process, outcome, and patient engagement measures.**
In the past 10 years, the value of data integrity has become recognized as a key to demonstrating the success of transplantation at each transplant program. Data entered on the Candidate Registration TIEDI form, such as ethnicity and pre transplant diagnosis, follows the patient through the various phases of transplantation. Organ procurement coordinators enter data about the deceased donor for patients that is then used in the SRTR analysis of each program.

Almost all transplant centers now have at least one data coordinator to manage data entry and analysis; however, the standards for these positions vary with each center. How are those entering data educated on terminology such as cold ischemic time, DCD, race and ethnicity?   Many of these terms are within the SRTR Risk adjustment models and staff entering these data must be trained on how to accurately capture and report the data. In partnership with transplant centers and OPOs, the OPTN should recommend minimal standards for data personnel since the quality and integrity of this role in donation and transplantation is so powerfully impactful on outcomes.

Similar to the points made above, even a robust training program and supremely qualified staff will not completely eliminate data discrepancies as human error is intrinsic to manual data entry. HRSA should create incentives – either through the OPTN contract or otherwise – for EHR vendors, OPOs, and transplant hospitals to develop and maintain interfaces with UNet^SM and the OPTN data system to minimize the need for manual data entry.

b.   **To establish OPTN member performance benchmarks.**

c.   **To capture patient and donor demographics, including race, ethnicity, language, and socioeconomic factors.**
Allowing the opportunity for self-reporting of this type of data into the system may add an opportunity to gain efficiency in a small part of data collection and could be reviewed as part of the evaluation process or meeting with pre-transplant coordinator. It would be important to make this easily accessible by cell phone or tablet and have limited free text options, focusing on pull downs or multiple-choice fields.

d.   **To create public OPTN national, regional and local performance dashboards.**
Publicly available data dashboards will need to be easily understood and explained. There may be merit in having separate resources for professionals versus public or even layered data where you could click through to drill down into more detailed data.

e. **To track long-term patient outcomes and health and non-health-related factors that contribute to outcomes.**
Patient-reported outcomes will be a valuable addition here. It will be important to incorporate APIs that allow for input of this type of information from cell phones or tablets

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:

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.   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
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.
It is important that OPTN Board members can fulfil their fiduciary responsibilities to the OPTN, which may not necessarily align with the OPTN contractor's interests. Although we recognize that separating the Boards may assist in that regard, doing so will remove some of the influence the OPTN Board may have on the OPTN contractor. Moreover, a potentially significant conflict of interest that is not addressed in this RFI relates to the OPTN contractor executive director serving as the OPTN executive director. As these issues are intertwined with the need to improve the OPTN policy development process, we recommend that evaluation of the Board structures (independent vs. dual purpose, size, representation, etc.) as well as OPTN executive director COI be incorporated into the overall evaluation of the OPTN policy development process by an outside organization such as the NQF as mentioned in NASEM recommendation

D.2.   Describe the conflict of interest policies you would/vendors could implement to ensure independence of the OPTN board of directors.
See above comments about OPTN executive director conflict of interest.

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

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.

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.
In the current state It is unclear how the OPTN will have sufficient oversight of OPOs to make meaningful change. OPOs are primarily accountable to CMS. In contrast to transplant programs for which the OPTN can request that the HHS Secretary remove the designated transplant program status, the OPTN bylaws do not have a clear mechanism by which the OPTN Board can recommend to the HHS Secretary that an OPO lose its designation as an OPO for a given DSA. Moreover, any change in OPTN policy requirements pertaining to OPO member performance will not be automatically reflected in CMS conditions of participation. To achieve increased organ donation and improved procurement, shared OPO oversight and aligned accountability between the OPTN and CMS must occur. Finally, we recommend that the OPTN develop policies that incentivize collaborative efforts between OPOs and transplant centers to improve organ donation, procurement, and utilization.

E.2.   How could the OPTN facilitate OPO engagement in research protocols to improve procurement?
Support training of OPO staff to acquire skills to conduct and support research and provide financial support for research.

E.3.   What additional research could contribute to improving organ procurement?
AI approaches to identify potential deceased donors in hospitals. Evaluate public acceptance of centralized deceased organ donation. Financial support for research.

E.4.   How can HRSA best incorporate the NASEM report's recommendations on increasing equitable access to transplants?
The AST's recent response to the February 2022 CMS RFI and the NASEM report both emphasize the importance of increasing access to the waiting list and expanding the oversight of the OPTN to address this gap. We were surprised at the limited attention given to this topic within this RFI outside of this section. We believe that making advances in this area will have the greatest impact of any of the equity-related recommendations from NASEM or the RFI.

Advancement of programs to provide culturally sensitive support for deceased donor families should be considered. The availability of organ donation personnel with cultural sensitivity training and or language skills to optimally support deceased donor families by telehealth could be considered.

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.

HRSA should require the OPTN to incorporate strategies into OPTN Policy that incentivize innovation and usage of novel technologies to encourage greater usage of increased risk organs. Lessons from the Collaborative Innovation and Improvement Network (COIIN) - that strong partnerships between transplant centers and OPOs and adjustment of oversight to foster innovation lead to increased use of otherwise difficult to place organs – should be built upon and leveraged more expansively across the system. For example, and as alluded to in E.2, novel protocols to utilize specific measures (e.g., in vivo/ex vivo machine perfusion) in high-risk organs could be implemented by transplant centers in collaboration with OPOs.

F.2.   How can OPTN organ matching activities be modified to decrease non-usage (discards) of procured organs?
Support a work group to develop implement and evaluate novel strategies to increase utilization.

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.
The AST would happy to participate in a working group to advance a strategy to increase transparency on this complex issue.

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.
We suggest 'mandates' or at minimum board policy commitments to increase diversity on boards/committees, such as a certain percentage of underrepresented minorities, women, etc.

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

As outlined in NASEM Recommendation 2 (Improve the Organ Procurement and Transplantation Network (OPTN) policy-making process) we recommend that HRSA require the OPTN contractor to work with and receive support from an external organization with expertise in guiding federal programs through unique challenges in leadership and stakeholder collaboration with the goals of increasing diversity and quality of input to, efficiency in development of and effectiveness in monitoring of OPTN policy making process.

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.

G.4.   What other improvements to OPTN operations and policy development processes can and/or should be incorporated into the OPTN contact?
A better method of communication and engagement with stakeholders such as the AST is required. A call for public comment with short timelines and without context or commitment to

follow up or ongoing interaction suggests tokenism rather than a genuine effort to engage with stakeholders. We do not find this current method of obtaining input to be meaningful.

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.
The society is willing to participate in genuine efforts to improve the system.

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.

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?
Inclusion of recipients and donors, as well as their families, in a transparent organ allocation process will reduce barriers and increase interest in organ donation.

It is important to note that successfully including patients/stakeholders in shared decision models requires accurate estimates of the key decision-making elements (i.e., if this organ isn't accepted, what is the likelihood that the patient survives until another, more acceptable organ becomes available and what is the likelihood that accepting this organ will meet shared graft/patient survival/quality of life goals). Unless reasonably accurate predictions of these two elements can be provided to stakeholders in a meaningful way it will be difficult to operationalize shared decision models effectively.

On behalf of the Society, thank you for this opportunity to share our thoughts. Please do not hesitate if we can be of further assistance or provide any clarification to our comments.

Sincerely,

John Gill, MD, MS
President

Jan Finn, Kansas
President

Barry Massa, Ohio
President-Elect

Joseph Ferreira, Nevada
Immediate Past President

Glen A. Franklin, MD, Kentucky
Medical Advisor

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Colleen McCarthy, Wisconsin
Secretary/Treasurer
Member Representative OPO Group 1

Sarah Fewell, Iowa
Member Representative OPO Group 2

Kurt Shutterly, Pennsylvania
Member Representative OPO Group 3

Rick Hasz, Pennsylvania
Member Representative OPO Group 4

Steve Miller, CAE, Virginia
Chief Executive Officer

May 23, 2022

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Attached please find the response from the Association of Organ Procurement Organizations (AOPO) to the following Request for Information (RFI):

Notice Number: HSB115C1031
Notice Title: Organ Procurement and Transplantation Network (OPTN)
Original Date of Issuance: Friday, April 8, 2022
Updated: Saturday, May 7, 2022
Deadline: May 23, 2022 at 1 PM ET

Name: Association of Organ Procurement Organizations (AOPO)
8300 Greensboro Drive, #L1-620 McLean, VA 22102

Point of Contact: Mark Cribben, JD
Director of Government Affairs
mcribben@aopo.org
202-256-7255

AOPO does not intend to supply a proposal on any future solicitation related to this requirement.

Responses to Questions

A: OPTN Technology – IT System

A.1.b: Describe how to 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. Electronic referrals show great promise in creating greater efficiency in the donation process by helping to ensure that no donor is inadvertently missed and facilitating data collection that helps inform predictive analyses to increase the speed and accuracy of future organ matching. Similarly, APIs allow for seamless clinical integration, which helps automate the potential donor screening process and leads to earlier and more effectively managed donor referrals. Despite their great potential to drastically improve the donor hospital referral process and save lives, these technologies can be expensive, which has limited their adoption across system stakeholders to date. We strongly encourage OPTN to leverage APIs, but it will only be as useful as the degree to which all components of the organ donation and transplant system industry adopts them. Past CMS programs such as the EHR Incentive Program have proven successful at driving the rapid implementation of promising new technologies. We believe HHS should build off these past successes to drive the adoption of electronic referrals and APIs in organ referrals through a similar nationwide incentive program, if not through grants or supplemental funding initiatives. Equally important- these systems must all be interconnected, including donor hospital EHRs to truly leverage these abilities to more rapidly assess donation potential in real-time. The OPTN could be the coordinating entity for a robust data warehouse for this information exchange. This could be the foundational building blocks for a better more accurate and timely dataset to calculate a denominator for OPO metrics.

A.1.c: Describe how to enhance real-time tracking of donated organs to allocate organs more efficiently and support increased transplant center engagement with patients in organ acceptance decisions. System efficiency in offering organs in a manner that minimizes wasted time and offers and in accessing the most effective and timely transportation of accepted organs is needed. Cutting down critical hours between identifying a donated organ with potential matches could potentially allow more flexibility for patients to be more actively engaged in organ acceptance decisions.

Several promising tools have been piloted and tested on various levels both within the OPTN framework and independently, and the results of those pilot tests should drive the adoption of new technologies and systems across the system. Standardization of process, data metrics and interoperability of various technology platforms is critical for this to work effectively. Currently, different OPOs utilize different platforms that collect different data points and are not integrated with The OPTN's system (UNet) which is needed for a complete understanding of the time-process flow. Expense can be a barrier to implementing these new technologies, particularly for smaller OPOs and other stakeholders. We would urge HHS and OPTN to work with stakeholders to develop and implement these new systems and technologies in a coordinated fashion and to provide the necessary resources and support to make that happen. We would also urge that all resources developed be universally available to OPTN members.

A.1.d: Describe how to produce public performance dashboards and actionable data to identify opportunities for program improvement, reduce inequities, and benchmark performance. AOPO strongly supports the collection and dissemination of actionable data. OPOs and all transplant system stakeholders can leverage said data to find innovative ways to drive system-wide performance improvements and efficiencies and save more lives. We believe HRSA and OPTN should design dashboards with the specific audience and intended user in mind, like any performance data. For example, any information available to the public should be provided with proper context so that a layperson can

understand what the metric means. It should also be provided in a user-friendly format that does not overwhelm the average consumer so that the information can be useful to them. Notably, HHS needs to ensure any data, but particularly any that is made available to the public and/or used to compare performance, is sufficiently risk-adjusted, including accounting for population demographics, social determinants, or other factors. It is critically important to do this in such a way that does not bake separate standards into the system for different patient populations but also that does not unduly penalize OPOs, transplant centers, and other stakeholders that are attempting to engage historically underserved patient populations- which is a goal this administration has set that AOPO strongly supports. At the same time, public reporting of clearly defined, appropriately risk-adjusted metrics broken down by race or other demographic factors can be a powerful way to shed light on true system performance, monitor which interventions are most effective, and track progress on addressing inequities. AOPO believes this commitment to transparency will help rebuild trust in the organ donation and transplantation system and potentially improve both donation and transplant rates. We are fully committed to supporting OPTN in these efforts.

For purposes of performance reports for individual OPOs or other system actors, it would be helpful to provide a more detailed breakdown of system-wide data, including the ability to disaggregate data by race and other sociodemographic factors, as well as transparent, ideally prospective benchmarks as well as comparative information to other entities so that OPOs, donor and transplant hospitals, and others have a way to assess their relative performance and potential for improvement. Regardless of the method of collecting or sharing this data, it will be critically important to ensure it is transparently and consistently defined and properly risk-adjusted.

A.1.e: Describe how to maximize these and other tools to help ensure data collection is relevant, accurate, timely, and streamlined to save critical time in the organ allocation process, minimize errors, and improve patient outcomes. APIs, EHRs, GPS tracking, and artificial intelligence algorithms all have untold potential to facilitate a faster, if not real-time, sharing of information that can significantly speed the process of sharing and comparing relevant clinical information to decide which recipient would yield the best outcome. However, we come back to the same core themes of giving industry stakeholders the necessary resources and tools to implement these often-costly new technologies, as well as ensuring from the outset that these technologies are deployed as part of a coordinated implementation strategy and that each segment of this information sharing chain can appropriately relay information across technology platforms. This will require a joint effort from HHS, OPTN, OPOs, and other industry stakeholders.

B: Data Collection Activities

B.1: Describe the ideal process for developing superior performance metrics and benchmarks, including consulting with experts, subcontractors, transplant candidates, recipients, organ donors, and their families. Metrics should be consistent across stakeholders. To reach this end goal, the critical piece is engaging stakeholders throughout the process. Importantly, this group should be broadly inclusive and not over or underrepresent the voice of any particular stakeholder. It is also critically important to engage patients and other stakeholders from diverse backgrounds so that the industry can collectively better understand and improve any systemic inequities that exist throughout the organ donation and transplantation system. The National Qualify Forum may be helpful in this regard.

B.2.a.b.c.d.e: Describe how data collection and reporting should be structured as it pertains to: a) process, outcome, and patient engagement measures; b) OPTN member performance benchmarks; c) patient and donor demographics, including race, ethnicity, language, and socioeconomic factors; d) national, regional and local performance dashboards; and e) long-term patient outcomes and

relevant factors. With any data collection and sharing, the critical item of importance is alignment and consistency across the system, including aligned goals. To this end, we encourage HRSA and CMS to align their metrics with OPTN metrics. For example, CMS eliminated outcomes metrics as a condition of recertification of transplant centers to remove disincentives to utilize organs at risk of discard, which AOPO applauds. However, performance standards used by the OPTN to evaluate transplant centers for continued OPTN membership and SRTR-calculated public "star ratings" used by private payers to determine transplant center participation in payer networks, unfortunately, both continue to disincentivize increased organ acceptance or risk-taking for expanded criteria donors.

HHS should replace or modify existing metrics across agencies that may discourage its own goal of encouraging all stakeholders to work together towards maximizing every possible organ. For example, OPOs and other stakeholders should not be penalized for pursuing every potential organ with metrics that focus on unused organs or that exclude from the donor count a donor whose organs were recovered and declined by transplant centers. Ongoing development of innovative technologies (e.g. perfusion devices) that could meaningfully and rapidly change what organs are suitable for transplantation warrants collaboration to safely push boundaries rather than failing to recognize OPOs who follow CMS' directive to pursue all possible organs. CMS could achieve this by recognizing recovered organs later deemed unusable by counting them towards Medicare's organ count or separately accounting for them in some other way, provided they have a valid clinical reason that could not have been known before surgically removing the organ.

Another specific way CMS or OPTN could improve the data collection and reporting to drive improvement in the organ donation and transplantation system would be to encourage transplant programs to make organ acceptance criteria more transparent and predictable. Availability of transplant center acceptance criteria related to perfusion and other technologies that allow for repair of previously non-transplantable organs will create efficiencies and facilitate allocation of organs directly to transplant centers that have adopted the new technologies to repair previously non-transplantable organs.

Finally, it will be essential to collect information on and disaggregate outcomes data by racial, economic, and other social demographic factors with any data collection moving forward. This is the only way to understand better and address sources of inequities in the donation and transplantation system. We would particularly urge HHS and OPTN to collect demographic information for referred but not listed transplant patients. We understand that these patients face disproportionate barriers to completing the numerous screenings and meeting other criteria required for transplant. Designing interventions at this part of the transplantation process could help greatly reduce system-wide inequities. We also believe that transparently posting disaggregated outcomes data could help to build trust in the system and encourage higher donation rates among groups with hesitancies.

E. Increasing Organ Donation and Improving Procurement

The NASEM report identifies concerns with organ donation rates, including geographic and demographic variations. HHS is actively taking steps to enhance the accountability of OPOs.

E.1: Describe how changes in OPTN policies/requirements for OPOs could help reduce variations in practices and procedures, facilitate increased organ donation and improve procurement, and otherwise improve OPO performance. As explained in detail in responses to previous questions, creating a data collection and sharing system that is transparent, consistent across stakeholders and agencies, and one that is appropriately risk-adjusted and disaggregated by sociodemographic information is one of the most effective ways OPTN and HHS can drive system-wide improvement, including reducing inequities. Specifically, we would urge HHS to replace or modify metrics that dissuade OPOs or

any entity from pursuing every possible organ and transplantation opportunity, provided they have appropriate documentation to support their decision-making. We also emphasize the need for metrics to be aligned within the system such that incentives for OPOs to recover organs from more complex donors are paired with metrics that incentivize programs to use these organs. AOPO strongly supports the OPTN's recent passage of transplant center metrics that will increase transplant center accountability for organ utilization through metrics such as organ offers acceptance rates. AOPO supports the OPTN developing appropriate patient waitlist metrics to address NASEM's observation that many patients receive organ offers that are declined on their behalf without their knowledge.

E.3: What additional research could contribute to improving organ procurement? How could the OPTN facilitate OPO engagement in research to improve procurement? Right now, there are exciting, groundbreaking innovations that can turn previously unusable organs into ones that can be safely transplanted into waiting for recipients and save lives. For example, up to two-thirds of previously unusable lungs could be rehabilitated and transplanted thanks to new advances in perfusion technology, which is an exciting possibility considering only 20-25% of donated lungs are currently transplantable. However, these new technologies can be expensive. Certain perfusion technologies can reach upwards of $70,000 per lung. Similarly, APIs, EHRs, GPS tracking, and AI algorithms can rapidly improve the speed and accuracy of data sharing that could facilitate real-time organ matching in the not-so-distant future. OPTN and HHS must build metrics and policies that work not just for now but that support continued growth and innovation. Beyond OPTN supporting industry-wide metrics that encourage innovation, OPTN and HRSA could work together to coordinate implementation so that these various systems can communicate with one another and facilitate cost-effective ways to speed more widespread adoption. HHS should ensure this commitment to continued innovation is shared across its agencies. This might include CMS revising its standard acquisition charge (SAC) policies to accommodate new technologies that, while expensive, could be the difference between a life saved. While we believe this benefit is worth the cost, it may be more feasible to address these added costs on an ad hoc basis, particularly for less frequently transplanted organs, to ensure the system can withstand and support innovations, provided their use is appropriately justified and documented. This type of approach would allow the industry to have more stable SACs while still retaining the ability for singular cases to leverage all the tools at their disposal to pursue a lifesaving transplant.

E.4: How can HRSA best incorporate the NASEM report's recommendations on increasing equitable access to transplants? Increasing equitable access is a critical component of advancing overall system improvement, as evidenced by the fact that we touch on it in each response. Data collection, disaggregation, and transparency are vital ways to address system inequities and foster trust. In particular, we would encourage HHS and OPTN to explore potential barriers to patients in need of transplant being referred and subsequently listed for transplant, which based on our experiences and communications with other industry stakeholders, can disproportionately affect minority and other underserved populations as identified by NASEM and can be a substantial driver of downstream inequities across the system. In other words, if we devote resources to addressing what in some ways can be described as the root of the problem, we believe this will yield exponential positive downstream benefits.

F: Organ Usage

F.1: Describe how to support OPO performance improvement activities to decrease discarded organs and further increase the use of organs. Aligning incentives for all stakeholders and agencies, including performance metrics, is an important way to drive system-wide improvement, including collecting data on and incentivizing improvements in addressing system inequities. For example, HHS and OPTN could recognize organs that went through all the steps of being procured but were ultimately

deemed unusable provided an OPO can document that they made all the appropriate efforts to place the organ for transplant. At a minimum, performance metrics for OPOs (and other stakeholders) should not be penalized for pursuing every possible organ and transplant opportunity. HHS and OPTN should pursue reimbursement models that encourage innovation, including new technologies to recover organs previously deemed unusable, new IT infrastructure to support information flow, and real-time matching to improve the efficiency of organ matching and organ tracking. This should be complimented by reimbursement systems that keep costs low overall while retaining the ability to be dynamic and leverage technological advances. As noted previously- one such approach could be to allow OPOs to charge certain add-on fees in addition to standard acquisition charges in cases where a specific new technology or transport could result in an organ being placed and a life saved, provided appropriate documentation is provided.

F.2: How can OPTN organ matching activities be modified to decrease the non-usage (discards) of procured organs? The primary focus of the OPTN should be to reduce the use of "provisional yes" in a manner that results in late turn downs. AOPO strongly supports the OPTN's current work to change policies and procedures around transplant program use of "provisional yes" and the ability to turn down previously accepted organs late in the process without penalty – which often results in non-usage of organs. AOPO believes technology advancements, including APIs, EHRs, and AI algorithms, when used collectively, have the potential to drive rapid and meaningful improvements in the efficiency and effectiveness of organ matching. As stated previously, widespread adoption and successful implementation will rely on a coordinated approach in which the different systems can communicate and will also require the necessary investment to facilitate their widespread adoption.

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. AOPO strongly supports the public reporting of data that the average consumer can reasonably understand, is provided with appropriate explanation and context, and is appropriately risk-adjusted. In particular, collecting and disaggregating outcomes data by race and sharing this information could be an effective way to create transparency and possibly engender trust from groups with a historical distrust of the donation or medical system. AOPO believes transparency at every stage of the organ donation and transplantation process is critical but would encourage more data around discrepancies in patients referred for transplant compared to those listed to assess the barriers disproportionately experienced by minority and other underserved communities.

H. Stakeholder Engagement

The NASEM report outlines how transplant centers should be required to improve their stakeholder engagement efforts and activities, specifically by making transplant candidates, transplant recipients, other affected patients, organ donors, and family members aware of all organs they have been offered and by monitoring their changing health and attitudes impacting organ acceptance decisions. HRSA is soliciting feedback related to the following questions:

H.1: Describe how to support the OPTN by incorporating the NASEM report's recommendations to improve stakeholder engagement efforts and activities, including whether and how to improve patient awareness of all organs offered and by monitoring their changing health and attitudes impacting organ acceptance decisions. AOPO fully supports efforts by OPTN and others to engage patients in organ acceptance decisions more effectively and introduce more transparency in the process, including monitoring and publicly posting transplant program acceptance criteria and rates. We agree that

being transparent with patients throughout the process, including having difficult conversations in which they may not be the most appropriate candidate, provides transparency and builds trust within the process. We believe new technologies such as EHR integration, APIs, and AI algorithms could facilitate rapid sharing of information that would allow critical time for physicians to routinely engage patients in these decisions.

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. AOPO offers our total commitment to do our part to support these efforts. An important place to start is to continue engaging a diverse group of stakeholders, including patients, in OPTN policy development and standardizing metrics across stakeholders and agencies to work in unison towards shared goals. Also important is modifying or replacing metrics that could be discouraging stakeholders from pursuing every possible organ or transplant opportunity.

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? AOPO believes OPTN does a good job of engaging stakeholders but could take a closer look at the diversity of voices it is collecting, particularly from patients and donor families, and ensure that the various stakeholder voices are appropriately balanced and that one particular group is not over or under-represented. This may require targeted outreach to groups that have been less engaged in the past or are less familiar with the process, including patients, but we believe these perspectives are critical.

BLOOM WORKS

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Response to Request for Information:
Organ Procurement and Transplantation Network (OPTN)

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Notice number: NOTA; P.L. 98-507
Title: Organ Procurement and Transplantation Network (OPTN)
Date of issuance: Monday, May 23, 2022
Name: Bloom Works (Gov Bloom LLC)
Address: 19 Woodside Ave Narberth, PA 19072
Point of Contact (if applicable), Phone and Email address: Mary Lazzeri, (301) 204-0422, mary@bloomworks.digital
Statement of intent to supply a proposal on any future solicitation related to this Requirement: Bloom Works intends to respond to an RFP for improving the OPTN procurement competition and potentially for technology modernization.

Responses to Questions A and E

Introduction
Bloom Works is a woman-owned digital services company that helps organizations serve people better. Digital services are part of everyday life — we use them for everything from accessing information online to figuring out which public services we qualify for. At Bloom, we work with governments and nonprofits to meet those digital service needs -- and create products that are beautiful and easy to use.

The Bloom Works organ donation team included alumni of the United States Digital Service as well as other public interest technologists, researchers, and designers. Our work was supported by leading philanthropists (Arnold Ventures and Schmidt Futures) and nonprofits (Organize and the Federation of American Scientists). All five past Chief Technology Officers of the Department of Health and Human Services (HHS) - three who served under President Obama and two who served under President Trump - supported these data-driven findings of Bloom Works, writing:

> *"The results of this discovery sprint make clear that reforms to governance, process, and technology can help thousands more patients receive life-saving organ transplants each year. Patients deserve the very best both from their government and from the government contractors tasked with managing the organ donation system.*
>
> *"To realize that basic errors in process (e.g., contractors never showing up to donor hospitals) and technology (e.g., organ offers going to deceased patients) are preventing tens of thousands of patients from receiving transplants, highlights exactly where we should focus… As a patient care issue, an equity issue, and an issue of the best use of taxpayer dollars, policymakers have every reason to get this right. With this thoughtful set of recommendations, there is a clear path forward that will save lives."*

We note that no government contractor - either organ procurement organizations (OPOs) or the organ procurement transplantation network (OPTN) - has ever lost a government contract despite clear failures to perform critical services, resulting in thousands of unnecessary deaths each year.

Recommendations
In order to answer questions from CMS on equity, improved services, and lifesaving OPO competition to replace failing OPOs, we offer the following policy recommendations.

We implore the U.S. government to take steps to reform the OPTN and make contractors more accountable, as part of its commitment to the [Executive Order on Advancing Racial Equity](#) and [Executive Order on Equitable Pandemic Response](#).

Every time that a kidney is left at the airport or a liver goes unplaced because of inadequate processes and technology, someone dies on the organ waitlist. These deaths rarely generate action from oversight bodies, but they are devastating to families and loved ones. There are more than 100,000 people currently languishing on the organ transplant waitlist, and they deserve an organ donation system that is optimized and held accountable.

Review Existing Research
We therefore respectfully submit the following research chapters as a formal response to the Request for Information from the Health Resources Services Administration (HRSA) on [“Request for Information on Ways to Strengthen and Improve the Organ Procurement and Transplantation Network”](#).

(1) [The Costly Effects of an Outdated Organ Donation System](#)
- [Foreword](#) by all five past bipartisan Chief Technology Officers of the Department of Health and Human Services
- [Summary of Findings](#)
- [Inequity in Organ Donation](#)
- [OPO Best Practices](#)
- [Technology Recommendations](#)
- [Strategy for Buying OPTN Tech](#)
- [Oversight Gaps and Conflicts](#)
- [COVID-19 Impact on Organs](#)
- [Maps & Charts](#)
- [Visualization of HHS data](#) to show organ recovery performance - including with cuts based on race/ethnicity - around the country

This research has been cited by the bipartisan [Senate Finance Committee](#) investigation as well as the bipartisan [House Oversight Committee](#) investigation. As noted - the result of interviews with experts as well as a collection of relevant peer-reviewed research in this space.

Reduce disparities in organ transplantation
The most effective way to reduce disparities in organ transplantation is to:
(1) Implement the OPO final rule as soon as possible (including before 2026);
(2) Make all OPTN data (including data from contractors) publicly available to ensure evidence of equitable treatment of donor patients/families (e.g., in response rates/times)

given that [research has clearly shown](#) that lower donation rates in communities of color result from inferior service OPOs provide donors and donor families of color.

Structure a modern digital services procurement
Additionally, we note opportunities to modernize and remove conflicts from the governance structure of the federal organ donation contractors overall - including the OPTN:

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

Our research indicates the OPTN vendor maintains an antiquated technology and limited technical acumen, which contributes to high rates of organ discards. The current procurement processes in place hamper the government's ability to truly support organ donation reform and do not reflect procurement best practices. Our research uncovered a number of problems with the current and previous OPTN procurements, including:

- Wrong Objectives: The objectives from the existing contract do not support doing the most good for the most amount of people (in the organ transplant space)
- Short Proposal Window: The 31 days to submit a complete proposal has been inadequate for vendors to compete well (except for the incumbent)
- Technology Poverty: The technology is characterized by slow delivery of new features and lackluster security
- Unempowered End Users: End users have small voices when it comes to communicating problems to those who can best solve those problems
- Government's poor leverage: Existing technology is proprietary and therefore difficult for non-incumbents to improve upon
- Non-Profits Only Awarded: 42 US 274 prescribes awarding to a non-profit
- Past Performance / Corporate Experience: 42 USC 274 indicates that the vendor shall have *expertise in organ procurement and transplantation.*

Since the advent of the [agile manifesto](#), modern technology development approaches have significantly advanced. This involves incremental approaches to developing software in rapid agile cycles while gaining frequent feedback from end users. Only a non-traditional procurement approach can effectively support and leverage the benefits of modern technology practices. Done poorly, a contracting approach can easily block the delivery of digital services. Done well, a digital service contracting approach facilitates both (1) awarding to a modern technology vendor and (2) providing appropriate flexibility and incentives in the contract that enable — not strangle — innovative approaches to solving problems using digital services.

Opportunities for improved technology in organ donation include:

- Ensure future OPTN contractors use open-source, cloud-based technology. Open-source is essential so the government has flexibility to access and refresh all parts of the technology stack.
- Create or require a central data warehouse that enables data-driven decision making and more transparent public-facing data, with standardized metrics.
- Improve organ offer technology to ensure all organs find a suitable recipient. This improved technology should ensure no offers go to deceased patients. It could also include assisted clinical decision making to help transplant centers quickly decide whether to accept. (See Technology Recommendations.)

Thank you for the opportunity to respond to this request for information. We look forward to your upcoming request for proposal. If we can answer any questions regarding our prior research on the technology and processes that surround organ donation, or this RFI response, please contact:

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RESPONSE TO RFI re: ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Agency/Office: HHS/HRSA/OAMP
Contracting Office Location: 5600 Fishers Lane, Rockville, MD
Title: Organ Procurement and Transplantation Network (OPTN)
NAICS Code: 541611

As physicians and nurses involved in the care and support of patients amidst the COVID-19 pandemic, we are writing to respond to this Request for Information on the urgent need for accountability and oversight for the organ procurement transplantation network (OPTN) contractor in the organ donation, allocation, procurement, and transplantation process. Increased oversight and reform of the OPTN is critical to address equity, access and transparency issues that result in 33 Americans - disproportionately patients of color - dying on waiting lists every day.

Each of us have treated patients grappling with the debilitating effects of organ failure, and the iniquitous ways that thousands of Americans are left to languish on the organ waiting list.

As physicians and nurses, it is horrifying to know that thousands of these patients each year could receive life saving transplants, however those precious opportunities are not currently available because of basic failures of accountability amongst organ procurement organizations (OPOs).

The OPTN is charged with managing the nation's network of 57 organ procurement organizations (OPOs). According to new data from CMS, the majority of OPOs are failing tier 1 objective performance standards. CMS has quantified those failures as costing thousands of lives each year who are more likely to need an organ transplant. As the New York Times editorial board wrote: *"an astounding lack of accountability and oversight in the nation's creaking, monopolistic organ transplant system is allowing hundreds of thousands of potential organ donations to fall through the cracks… [and HHS should] revisit the UNOS monopoly."*

More than 107,000 Americans remain on the transplant waiting list and dying due to the lack of available organs. Apologists for the status quo have tried to blame Americans themselves for an unwillingness for people to donate based on education, cultural or demographic reasons, while ignoring the root-cause of the near 400% disparity in organ donations by OPOs around the country. The reason can be linked to the continuous, near-systemic failure of the OPTN and OPO system.

Further, OPOs and OPTN have recently begun to falsely claim performance improvements that are actually due to the overall rise in organ donations. Peer-reviewed research shows that "it is indisputable that nationally the increased number of donors is almost wholly attributable to the

drug epidemic, and reflects the byproduct of a national tragedy, rather than an improved system to be celebrated."

The US has experienced a jaw-dropping [50%](link) increase in overdose deaths from October 2020 to October 2021; it is plain wrong to hide behind the opioid crisis and to cynically and knowingly misrepresent the data.

The OPTN is designed to serve a critical function in our healthcare system. However, the OPTN contractor - UNOS - is under [bipartisan investigation](link) from the Senate Finance Committee for failures in technology and overseeing OPOs, the majority of which continue to fail in their basic responsibilities. How can we allow these failures to continue? Per the [Senate Finance Committee investigation](link), the OPTN contracting cycle has never - not once - been competitive. Further, no OPO contractor has ever been decertified, replaced or faced any accountability. Under the current rule, OPOs known to be failing will not be replaced by a higher-performing OPO until [2026](link), by which time [60,000](link) patients are projected to have died waiting for transplants.

We also note that [COVID-19](link) damages organs and that the demand for organ transplants is estimated to increase dramatically, and, as [bipartisan Congressional leaders](link) have highlighted, increases the urgency of OPTN and OPO reform. As Senators and House Representatives [jointly wrote](link) in July 2021: "The COVID-19 pandemic is exacerbating the need for organs now and creating an urgent health equity issue, as communities of color are disproportionately impacted by the failures of the current organ donation system and the effects of COVID-19."

Through the requirements specified in the RFP for the next OPTN contractor, HRSA can deliver on the [Executive Order On Advancing Racial Equity](link) and the [Executive Order on Ensuring an Equitable Pandemic Response and Recovery](link) by rejecting OPTN and OPO calls to lower standards of service for minority patient populations via a "race-based adjustment", which [Congresswoman Ayanna Pressley](link) characterized as a "racist request", and which [past NAACP President Ben Jealous](link) argued would "codify inequity into the health care system".

Given these facts and the current failures rampant throughout the organ procurement system, we ask that HRSA proceed with drafting the RFP with the following common-sense and patient-centered considerations:

- **Subdivide the OPTN contract, including separating out IT:** Multiple reports - including from NASEM, as cited in this RFI - recommend that HHS should subdivide the OPTN contract into core competencies, such as policymaking and IT. To that end, HRSA should also apply for immediate support from the Tech Modernization Fund (TMF) to open and best use OPTN data given noted [failings](link) of the current OPTN tech contractor, UNOS.

- **Promote competition**: The OPTN contract has only ever been held by UNOS, including because HRSA has previously included overly restrictive contracting requirements which

unnecessarily limited the field. HHS should aggressively promote competition for this contract, making clear to all potential bidders that, unlike in previous cycles, HHS is seriously considering better alternatives.

- **Governance**: The OPTN is riddled with conflicts of interest, including that the OPTN and UNOS - despite an explicit mandate from HRSA in 2018, and reaffirmed by the Government Accountability Office - have the exact same boards. HRSA should enforce its 2018 mandate, as well as ensure that all financial conflicts for OPTN board members are published openly.

- **Reabsorb OPO oversight:** Despite previously stating that it performs OPO oversight, after coming under bipartisan investigation from the Senate Finance Committee for OPO protectionism, UNOS subsequently changed its website and talking points to indicate it does not, in fact, consider itself to have any role in OPO oversight. Given then, HHS needs to immediately reabsorb all OPO oversight functions into government, given the now-stated position of the OPTN that OPO oversight belongs to HHS only.

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HSB115C1031, Organ Procurement and Transplantation Network (OPTN) RFI, May 05, 2022

Request for Information on Ways to Strengthen and Improve the Organ Procurement and
Transplantation Network
Submitted by
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My husband, Clinton W. Smith, Jr. was diagnosed with Chronic Kidney Disease in 1992 at the
age of 33 years old. After many years of efforts to control his recalcitrant malignant hypertension
it became clear that his declining renal function would require dialysis and/or a kidney transplant
in 2004. Many family members were tested to become Clint's living donor and MY sister
emerged as the best match. This gift of life sustained Clint for seven wonderful years before we
found ourselves once again facing dialysis and the hope for a transplant. Clint's Morehouse
College classmate and friend stepped forward and became his living kidney donor in December
2012. Clint is doing great and living a full life as a Juvenile Court Judge, husband, son, brother,
father, grandfather and friend. We became active very early on in the organ donation and
transplantation ecosystem as an organ recipient and caregiver and began sharing Clint's story.
We both volunteer with our local organ procurement organization, Louisiana Organ Procurement
Agency, the Legacy Donor Foundation and the National Kidney Foundation of Louisiana.

As a physician, I have cared for many renal failure patients on dialysis who were unaware and
felt uninformed about their options for potential transplantation. There is a great need for
appropriate education and communication for patients and families including avenues to
empower and encourage advocacy. It is not uncommon to see patients from our communities
unfairly deemed inappropriate transplant candidates largely as a result of implicit biases, based
on race, educational level, income and other social parameters.

I am also a committee member of Linkages to Life, a Signature Program of The Links,
Incorporated. The Links, Incorporated is an international, not-for-profit corporation, established
in 1946. The membership consists of more than 16,000 professional women of African descent
in 299 chapters located in 41 states, the District of Columbia, the Commonwealth of the
Bahamas, and the United Kingdom. It is one of the nation's oldest and largest volunteer service
organizations of extraordinary women who are committed to enriching, sustaining and ensuring
the culture and economic survival of African Americans and other persons of African ancestry.

The Links, Incorporated focuses on five facets for our service and programming, including
health. Specifically, the Health and Human Services Facet was established in response to the
chronic health disparities that persist in black communities and result in the decreased life
expectancy of African Americans and other people of African ancestry. Through education,
advocacy, and outreach, The Links, Incorporated initiates and supports programs that support the
maintenance of good health and the elimination of chronic health disparities in communities of
color. The Organ, Tissue and Bone Marrow Donation Awareness Signature Program, "Linkages

to Life" was established in response to the health disparities in organ, eye, and tissue (including bone marrow) transplantation. The goal of Linkages to Life is to decrease disparities in donor registration and transplantation in the African American community. Our members work to increase the number of registered donors through community-based events and multi-media awareness campaigns. In partnership with the national organization Donate Life America, we strive to register hundreds of donors each year through a Links, Incorporated and Donate Life America co-branded national donor registration page.

I have collaborated with both Linkages to Life National Program committee members and my colleagues in the medical profession on this important issue. Based on my experiences serving in this ecosystem, I offer the following comments in response to the Request for Information and hope it will be valuable in determining the final policy.

In response to E.4. Increasing Organ Donation and Improving Procurement: How can HRSA best incorporate the NASEM report's recommendations on increasing equitable access to transplants?

Leveraging trusted networks to emphasize organ donation and transplant opportunities. There are many ways to connect members of the African American community to sources of information and knowledge related to organ and tissue transplantation. African American physicians are an excellent source for connecting with members of the African American community on this topic. Regardless of the physician's specialty, African American physicians as well as those serving African American patients should emphasize the benefits of organ and tissue transplantation. As discussed by MOTTEP Founder, Dr. Clive Callender at NASEM, the historically Black medical schools are a tremendous resource for instilling this message into minority and minority-serving physicians. The HBCU Medical Schools Collaborative and the Links, Incorporated are each positioned to underscore the need for improved equity in the field of organ donation and transplantation.

Some suggested ways to increase outreach include:
- Career exposure to STEM, medicine, health professions, and specifically inclusion of transplantation.
- Cultural and linguistically tailored materials geared to educate minority individuals about transplantation for those receiving dialysis.
- Augmented programming with HBCUs, medical schools, and schools of nursing, public health, healthcare administration, and allied health professions.
- Presence at health fairs and organ donor drives, distributing said materials focused on living and deceased organ donation; and
- Continued collaboration with service organizations, faith-based congregations, and community influencers around organ donations.

Members of the Links, Incorporated through local and national Linkages to Life programming have been engaging in several of these activities. There are numerous opportunities to expand this programming by integrating with the Services to Youth Facet that includes the Links – STEMReady Signature Program and the National HBCU Initiative to encourage youth to pursue careers in the STEM fields. Additionally, I have served with

members of the Links, Incorporated who either work as clinical or healthcare professionals, are employed by an HBCU or both.

Recognizing the multiplying impact of poverty on social determinants of health on treatment access. Patients who are poor and African American are often rejected for surgery because transplanting them will decrease transplant outcomes. This, in turn may result in the transplant centers becoming decertified. A system must be put in place that does not penalize a transplant center for transplanting such high-risk patients. This phenomenon is important but never discussed. This practice is a form of institutionalized racism and bias that keeps socio-economically deprived patients from accessing organ and tissue transplants at rates proportionate to the prevalence of end-stage organ disease or other related injury. National and regional paired donations are performed but they rarely benefit people of color, in the way that local paired donations do. Encouraging local paired donations is more beneficial to people of color; and is an option that should be incentivized and encouraged.

G.1. OPTN Operations and Policy Development Improvements: 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.

Staffing for cultural sensitivity and to minimize biases is an area of opportunity. Representation of culturally sensitive individuals and organizations at every level of OPTN operations and policy development is necessary to transform the current system for attaining health equity. Specifically, priority in notification should be given to organizations of color including Historically Black Colleges and Universities, Black Greek letter sororities and fraternities, and other Black services organizations and programs. Priority in funding should be given to such organizations as well as programs led by people of color. Additionally, specific minimum allocations of funding proportional to the need for transplantation (or the incidence of end-stage disease and organ failure) should be allocated in each area related to organ transplantation. Input from these individuals and organizations must also be integrated in the writing of RFPs and the review of RFP submissions.

Incentivizing equitable outcomes through oversight. Individuals from diverse backgrounds must have a seat at the table to participate in the authority, finance and control of OPTN operations and policy development, to change the paradigm from health disparity to true health equity. This means there must be more oversight of the OPOs to require the presence of diverse representation at the highest administrative levels. When negotiating collaborations between the Links, Incorporated and potential partner health organizations, we strive to leverage greater representation on their decision-making boards. This strategy has been met with varying results. OPO compliance in this regard must be monitored. In addition, there must be mentoring, opportunities and funding for education, training and fellowships to allow for the advancement of persons of color to these positions.

G. 4. OPTN Operations and Policy Development Improvements: What other improvements to OPTN operations and policy development processes can and/or should be incorporated into the OPTN contact?

Increasing the ethnic diversity of OPO executive leadership is an opportunity. There are 57 OPOs very few of these OPOs have persons of color at the highest administrative level (CEO or Chairperson of the Board of Directors). It is important therefore to increase the number of CEOs and Board Chairs who are people of color (African American, Hispanic or Latino, Asian, Pacific Islander or Native American). Nearly 60% of people waiting for transplant are people of color. Systems should be put in place to eradicate explicit and implicit exclusionary hiring practices and monitor OPO compliance. Increasing the proportion of individuals from diverse backgrounds in leadership positions to better reflect the ethnic diversity of the community of patients being served by the OPO is paramount. Currently, oversight to combat against the current level of executive disparity is completely lacking and desperately needed as indicated by the statistics previously cited.

Living donation policy is an area of opportunity for African Americans. We know the living donations among African Americans are significantly below that of whites, underscoring the need for augmented education of living donation opportunities. In 2020, 16.4 percent of blacks were living donors as compared to 33.4 percent of white living donors. Instances of African Americans who receive a "second chance at life" through organ donation are celebrated in our community in churches, at family gatherings, in the workplace, and in our social and service organizations. It is important to peel back the crucial steps to allow these donations and transplants to happen, which begins with increasing the education outreach to minority communities about the benefits of living donation and simultaneously speaking to the fears, myths, and hesitancy associated with being a living donor. Overcoming this obstacle is best addressed with recipients and trusted community-based organizations delivering the information, not the transplant centers and organ procurement organizations. The education should be multi-generational and culturally tailored, addressing the most pressing concerns and highlighting the successes in minority communities. The Linkages to Life National Program Committee has increased its awareness and advocacy specifically around living donation in the 2021-2022 program year with several recorded webinars on the topic. These efforts by The Links, Incorporated or other historically Black service and civic organizations may often be superior to those of the transplant centers and OPOs to address this need. The Links, Incorporated was able to produce culturally sensitive content to meet patients in their communities. The data also shows that non-whites have lower rates of pre-emptive kidney transplantation, especially for living donation. It is important to highlight these disparities and use fund opportunities to educate our communities of color. While serving as National Chair for Linkages to Life, I've learned that people cannot properly advocate for themselves if they lack awareness of all treatment options available. Our campaigns work to increase this awareness.

H.2-3 Stakeholder Engagement: 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. How can and/or should the contract incorporate new or better approaches for including stakeholders in a shared decision model for organ acceptance?

Bringing diverse voices to the table early and through the organ procurement process is a tremendous opportunity for system improvement. Stakeholders including transplant recipients, prior living donors and family members of deceased donors should be engaged early,

often and meaningfully. Stakeholders from ethnically diverse backgrounds should be included in the oversight bodies referenced earlier in these comments. Executive search committees or contracted executive search firms should either include stakeholders from ethnically diverse backgrounds or specialize in diversity, equity and inclusion. Finally, through past experiences serving on stakeholder advisory boards for research funded by Patient Centered Outcomes Research Institute (PCORI), I consider them to have a portfolio of best practices in engagement strategies. There is significant value in OPTN members together with a more diverse cross-section of stakeholders examine these engagement techniques and employ them at numerous levels of planning, policymaking and operations, including the development of a shared decision-making model for organ acceptance. If serving patients in need of organ and tissue transplantation is the goal, OPTN members will transform stakeholder engagement practices and where appropriate will hone engagement relationships to meaningful collaboration and shared leadership to attain more inclusive health outcomes.

Each of these areas of increased emphasis must be met with thoughtful planning and financial resources. Critical to the proper planning is the involvement of organizations and individuals such as ours.

Thank you for considering this feedback.

Donor Network of Arizona (DNA) appreciates the opportunity to provide comment in response to the Request for Information (RFI); Organ Procurement and Transplantation Network (OPTN). We share the goal of strengthening equity, access and transparency in the organ donation, allocation, procurement, and transplantation process.

Donor Network of Arizona (DNA) is the non-profit federally designated Independent Organ Procurement Organization (IOPO) serving the state of Arizona. We work every day with our 129 donor hospitals to facilitate the gift of donation for the 106,648 people who are waiting for an organ transplant in the United States. Our vision, to realize Arizona's potential to save and heal lives, has driven DNA, our transplant centers, and donor hospitals to significant improvement. In the past 20 years, DNA has facilitated a 400% increase in organ donors resulting in thousands of lives saved through organ transplantation. We are pleased to report that in 2021, due to the generosity of donors and their families and the work of our dedicated healthcare partners and transplant centers, we recovered organs from more deceased organ donors than in any previous year.

The improvement that has taken place over the past 20 years gives us insight into the systems and measures needed to drive improvement working with recovery and transplant hospitals who are our partners in donation. The system works because we recognize that it is strongest when all stakeholders participate and are accountable. Together, we work every day to secure the trust of the donors and donor families who voluntarily agree to participate in the donation system.

We have long recognized the importance of improving equity in the donation and transplantation process, particularly related to working with our multicultural communities. This improvement has been bolstered by efforts of the federal government to increase the number of organs transplanted and lives saved through organ donation. These efforts include the HRSA Breakthrough Collaborative for Organ Donation and Transplantation and the HRSA Organ Donation grant programs. Our participation in the grant programs, helped us to significantly increase donation from our Hispanic community. It is with this experience in mind that we offer the following written response to several of HRSA's questions posed in the RFI.

We look forward to continuing to collaborate with HRSA and our fellow donation and transplantation stakeholders in efforts to continue to improve organ donation and transplantation.

Responses to Questions

Section B – Data Collection Activities

DNA supports greater transparency that can be derived from publishing standardized metrics to track performance and evaluate results in the U.S. organ transplantation system as recommended in the National Academies of Sciences, Engineering and Medicine (NASEM) report and would emphasize the following:

B.1. Describe the ideal process for developing superior performance metrics and benchmarks, including consulting with experts, subcontractors, transplant candidates, recipients, organ donors, and their families. The OPTN vendor should work with CMS to establish a set of unified industry metrics with appropriate risk adjustment mechanisms that incentivize all stakeholders to expand donor pools and push the boundaries of organ transplantation to save more lives. OPOs and other stakeholders should not be discouraged or penalized for making every possible effort to place an organ and save a life because the chances of positive outcomes may be less favorable. Risk adjusting organs donated and the organ recipient would allow the organ donation and transplant community to work together to expand the pool of eligible donors and transplant more organs into more medically complex candidates and save more lives without individual programs risking penalizing their financial viability. This would be consistent with CMS' use of risk-adjustment protocols in other value-based reimbursement models.

B.2.b.d. Describe how data collection and reporting should be structured as it pertains to: b) OPTN member performance benchmarks; d) national, regional and local performance dashboards; and e) long-term patient outcomes and relevant factors.

DNA supports the ongoing national and local efforts to improve OPO performance, but there is still significant work to be done related to identifying a data source from which to determine the potential for organ donation used to measure that performance. Ideally, the OPTN and CMS would utilize hospital provided ICD10 data, and not state death certificate data, to increase transparency and accessibility for more timely performance improvement.

Section E Increasing Organ Donation and Improving Procurement

E.2. How could the OPTN facilitate OPO engagement in research protocols to improve procurement? The OPTN must support processes that allow organs to be offered electronically to research clearinghouses (e.g. NDRI, IIAM). These agencies serve a critical role in providing organs for researchers.

E.3. What additional research could contribute to improving organ procurement? How could the OPTN facilitate OPO engagement in research to improve procurement? The OPTN could help establish guidelines for multicenter trials in donation research. Currently these are just beginning, and while the concept is proven, the OPTN could help facilitate information

sharing among these trials as well as develop agreed-upon frameworks for OPOs, donor hospitals, and transplant centers to design and participate in future trials.

E.4. How can HRSA best incorporate the NASEM report's recommendations on increasing equitable access to transplants? The NASEM Report recommends that HHS conduct ongoing culturally targeted public education campaigns to convey the need for organ donation to save lives, to eliminate misconceptions about organ donation and transplantation and to increase the trustworthiness of the transplantation system. This may best be achieved by funding updated research on the barriers to donation and most effective methods and messages to increase donor registration in multicultural communities followed by culturally targeted campaigns based upon that research.

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. The authors of the NASEM report rightly state that "too many donated organs are not transplanted each year" and "it is too easy for transplant centers to decline usable organs." But DNA's experience is that zero organ donors (donors from whom organs are recovered with the intent of transplantation, but from whom no organs are transplanted) can also be an indicator of an aggressive OPO program. Zero organ donors are the result of aggressively pursuing every donation opportunity. Since 2014, our increase of 99% in recovered organ donors, from 158 to 315 in 2021, also saw an increase in zero organ donors, from 9 (5.6%) to 26 (8.2%). Each organ recovery represents a critical dimension of a successful donation system which necessarily includes OPO response, authorization, hospital support and successful donor management. To ensure every suitable organ is recovered, the system must value and support zero organ donors. DNA's success is linked directly to our focus on every organ, every donor, every time. Our efforts focus on ruling donors in (rather than ruling them out) and looking for any piece of clinical data that might indicate an organ may have a chance to be accepted by a transplant center and transplanted, saving a life. In some cases, this results in zero-organ donors, but in many cases, it results in organs recovered from donors who initially may have looked like they had no organs suitable for transplantation. Performance metrics for OPOs, and other stakeholders should not be penalized for pursuing every possible organ transplant opportunity. Disincentivizing zero-organ donors will directly affect all OPOs' ability to pursue marginal donors and potentially reduce the number of organs available for transplant.

The OPTN should work with stakeholders to capture detailed information pertaining to zero organ donors to better understand why certain organs are not recovered or recovered but not transplanted. They should monitor this information and develop potential solutions, including but not limited to appropriate oversight for transplant programs that routinely engage in behaviors such as avoidable late organ offer turndowns that result in organ discard. In the interest of transparency and accuracy, each transplant program and OPO entity should be able to enter their

own explanation why an organ was not transplanted, and those reasons should not be later amended by another party.

Section H - Stakeholder Engagement

H.1. Describe how to support the OPTN by incorporating the NASEM report's recommendations to improve stakeholder engagement efforts and activities, including whether and how to improve patient awareness of all organs offered and by monitoring their changing health and attitudes impacting organ acceptance decisions. DNA supports the concept of increased candidate awareness of organ offers, but we do have some concerns about how this would be implemented. The confidentiality of donor information must be preserved. Perhaps the candidates could receive a periodic summary of organs offered and declined, but it's not clear how this would provide useful information without compromising donor confidentiality.

DNA is also concerned about the use of scarce OPTN information technology resources on a comparatively less-important project. Many valuable projects go unfulfilled because of a paucity of available IT development time. DNA recommends that OPTN focus on items that directly move the system closer to donation.

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? DNA recognizes the value of collaborative input into OPTN policies and actions. The current board of directors' structure is large, unwieldy, and focused more on transplant center interests than on other stakeholders. We would recommend separating the vice president for patient/donor affairs into two positions, one of whom is a waiting transplant candidate, and the other a family member of a deceased organ donor. We recommend that there be no fewer than three at-large positions assigned to OPO professionals. Finally, we believe that the public comment periods should be shortened, and that committees and the board of directors should take more decisive action without excessive concern about complaints from non-participatory commenters.

May 23, 2022

From: Duke Health System, DUMC 3512, Durham, NC 207710
Point of Contact: Stuart J. Knechtle, Phone: 919-613-9687
Email : stuart.knechtle@duke.edu

Re: Notice ID: HSB115C1031, Organ Procurement and Transplantation Network (OPTN) RFI,
April 8, 2022

Statement of Intent:

The Duke Health System, located in Durham, NC has considered the RFI referenced below and hereby
submits our responses to the questions posed. We wish to express our interest in supplying a proposal
related to future solicitation by HRSA for a bid to manage the OPTN. A proposal would be submitted by
a distinct entity created expressly for the purpose of responding to the solicitation and would be linked to
Duke academic departments including the Duke Center for Clinical Research (DCRI) that are related to
transplantation either through policy expertise, data management, or other affiliation and include external
collaborative partners.

Our responses to the questions posed in the RFI are shown below, referencing the question number.

A. OPTN Technology – IT System

A.1.a. Transformational Approach to OPTN Technology: Overview

Currently the technology infrastructure, UNet, of the OPTN is linear and process centric as
represented on their website in Figure 1(1).   This type of architecture is typical of incremental
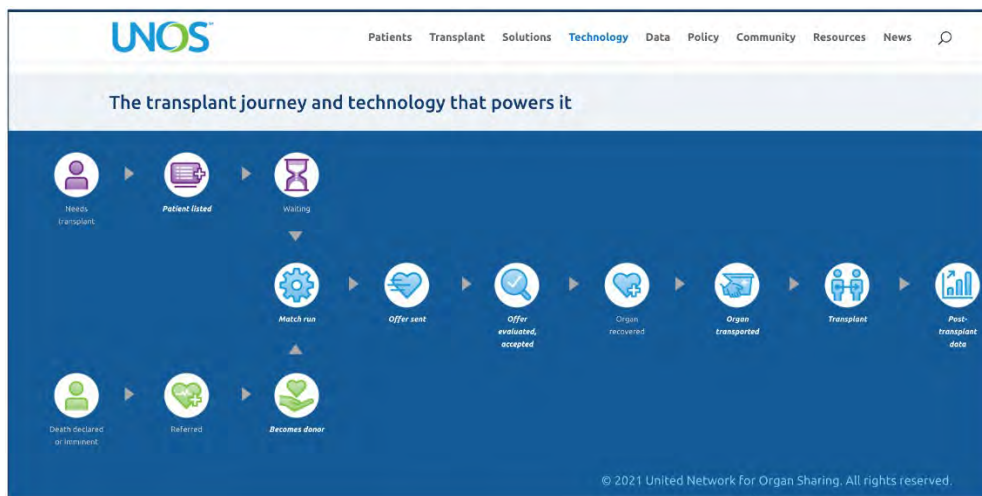
Technology development where business processes are automated/digitized one at a time. While

this is typical of technology evolution over time, it does not provide opportunity for reinvention. We propose a complete re-thinking of the OPTN technology infrastructure as an omnichannel network that places the donors and recipients at the center via a centralized data-centric architecture as shown in Figure 2. In e-commerce, an omnichannel experience is an approach that seeks to provide customers with a seamless experience, whether they're interacting online from a desktop or mobile device, by telephone, or in a brick-and-mortar store[1].

In the architecture of Figure 2, the donor and recipient are in the center as are all the data about them. Today, data is fragmented across various systems and processes. In this architecture all data about recipients and donors exist in one single longitudinal record for every application, and process utilizes those core records. When a change occurs, it happens in that single place and is automatically available to all applications. Also centralized are matching and other essential algorithms, which exist in a library of options that enable traditional matching but, also, transparent up-to-date reporting, metrics and simulations.

Connected to the data and algorithms layers are application programming interfaces (APIs) that enable workflow, data entry and all other OPTN technology applications.
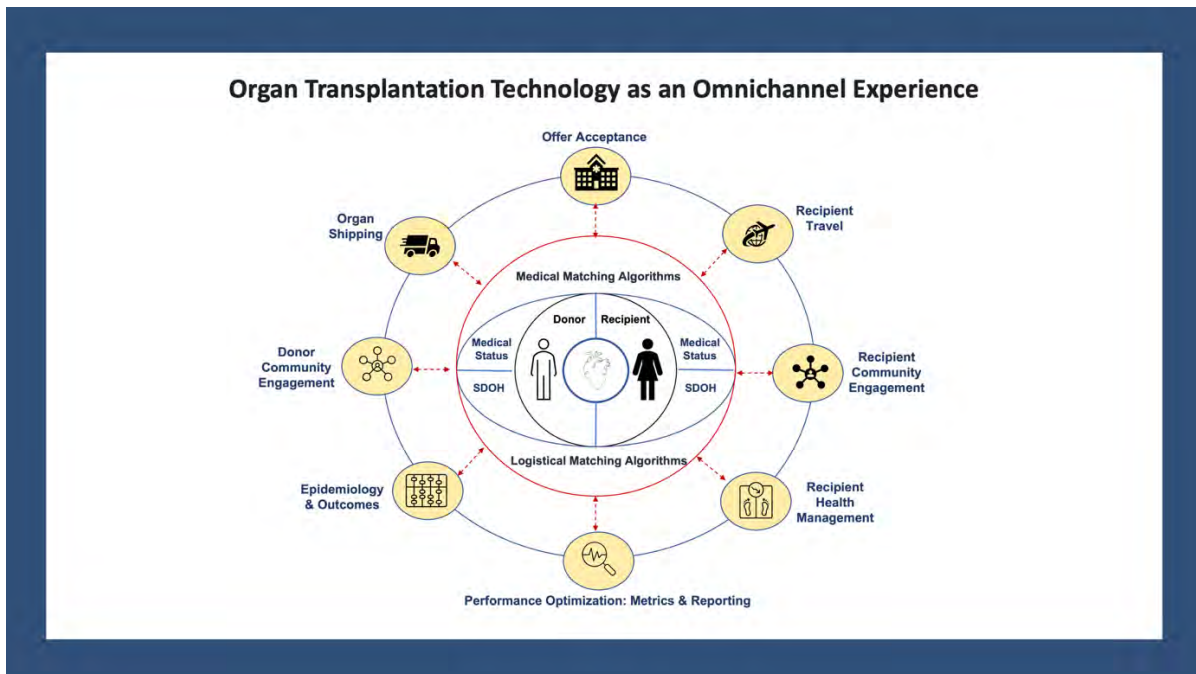
It is important to note that this approach would be the most time and cost effective as any current UNet applications that should be preserved can be re-tooled to connect to the API layer, removing the unnecessary waste of having to rebuild apps that currently meet the needs of the transplant community. This approach is both agile and modular by nature and allows the entirety of OPTN technology to be modernized over time in increments of 6-month intervals.

This proposed approach is inherently cloud native and could be made extremely secure if

implemented in a gov-cloud architecture or private equivalent[3]. Specifically, we recommend a cybersecurity stature of Federal Information Security Management ACT (FISMA) moderate for this network with the FISMA boundary securely managed around the OPTN technologies but not applicable to transplant centers or similar collaborators[4]. This approach built upon a model that completely centralizes the most high-risk data, will greatly diminish the current cybersecurity risk via significant reduction in attack surface[5,6.]

A.1.b.
By centralizing all data about donors and recipients including medical data, socioeconomic data, logistics information and geographical data into unique single unique records and connecting those records via APIs (as already described) with the external stakeholders, EHR and other data is fully available to current and future needs.

A.1.c.

The omnichannel is designed to provide a single, unified experience to all stakeholders based upon the centralized data strategy. This hub-and-spokes approach is far faster than current systems where data is not centrally available. In this model the single source of truth enables rapid application development and improvement in ways that the current architecture simply cannot deliver. For example, every app connected via this system will be viewing the exact same data records enabling seamless transparency and decision making across OPTN processes.

A.1.d.
Similarly, the centralized 'data-first' approach enables dashboards and reports that are real-time without the errors caused by data latency from linked or integrated systems. The single algorithm layer enables real-time exploration of all dimensions of data. Further, by building in external data sources, such as the CDC Vulnerability Index data, health disparities can be modeled in real time versus manual data aggregation[7].

A.1.e. All of the above will improve data timelines, accuracy and fidelity in ways that will minimize errors and save precious time for all stakeholders of the OPTN.

A.2. There is little peer-reviewed data on what expectations should be for uptime of critical systems. Amazon Web Services, which hosts most gov-cloud applications, guarantees 99.99% uptime for contracted infrastructure[11]. Rule of thumb for electronic medical records is 99%. Based upon these metrics, 99.5% is likely adequate but 99.99% is achievable is HRSA wishes.

A.3. Today, data is split between applications and replicated where needed which can propagate uncertainty and error. By re-architecting the OPTN technology infrastructure to put data first and data in the center of the design, timeliness and accuracy of data are improved greatly as there will be only one trusted source for data elements on donors and recipients. Further, by including social determinants of health and geographical data with medical and diagnostic data in one place, multiple models can be run simultaneously to model and confirm matching across many dimensions.

A.4. As per the previous overview, we would apply FISMA moderate procedural and technical controls across all core OPTN systems with a FISMA-light approach to network partners. The NIST 800-53 control family would be used as part of a risk-based approach to ensuring the security, availability and confidentiality of OPTN data[12].

A.5. System design and build can only bring an organization so far. Technology changes quickly, as do security threats. We would establish a technology oversight advisory to assist in the design, build and steady-state operation of all OPTN technology. This group would include current stakeholder delegates but also delegates from industry and government to ensure truly best practices. Further, the use of constantly evolving standards and guidances, such as the NIST 800-53 controls and the Cybersecurity and Infrastructure Security Agency (CISA) real-time cyber alert intelligence[13].

B. Data Collection Activities

B.1. In modern computing architectures, it is best practice to assume that data is the asset and technology is an expense. By placing all the data in single, central records available through APIs, metrics and reporting can become instantaneous, although a short lag for quality control and/or random sampling is also best practice. The same is true for engagement with transplant candidates that can be given access and administration privileges over their own records saving time and eliminating the redundancy of patients having to supply duplicate information to varying parties throughout the process. Done properly, the tedious and error-prone habit of using data calls to generate reporting can be eliminated.

B.2.a. Data collection would be handled via APIs, for directly integrated systems within the FISMA security barrier and via dedicated portals and apps for data collection processes outside the FISMA moderate security boundary. Manual processes would be reserved for establishing new interfaces with new entities. The interfaces will be fully logged with complete audit trails that can be used to metric performance and ensure proper and transparent records management.

B.2.b. OPTN member performance benchmarks will be derived primarily via data from the real-time applications and centralized data store. Reports will be highly automated ensuring objectivity across the OPTN network.

B.2.c. To ensure patient privacy and autonomy, data collection will be fully consented directly from the donor and patient registration process. The responsibility will start with the recipient candidates but will be greatly enhanced via a social determinants of health (SDOH) database as well as the CDC social vulnerability index. Unconsented patient linking technologies will not be used but privacy-preserving record linkage technologies will be used but only under full consent.

B.2.d. Dashboards will be automated and will be connected and pulling data directly from the centralized cloud data file system. Best of breed commercial technologies, such as Tableau will be utilized as standards that can be adopted across OPTN to drive efficiencies as well as the accuracy and speed of reporting.

B.2.e. Long-term patient outcomes will be collected over time via record linkage, surveys and monitoring of publicly available repositories, such as the social security death index[14]. Ideally, a novel app would be created to serve as a perpetual patient diary. Further, family members will be provided the opportunity to participate in the NIH All of Us study to enable cross-study between the OPTN and the largest registry of 'healthy normals' in the United States[15]

C. OPTN Finances

C.1.a. Fees would be invoiced separately by the OPTN contractor committee leading the oversight of the work done. The committee is separate from OPTN contract-supported functions.

C.1.b. Per above, fees would be aligned to OPTN contractor committees vs. non-OPTN contractor committees.

C.1.c. Per above, fees would be aligned to OPTN contractor committees vs. non OPTN contractor committees. Non OPTN contractor committees would be deemed as non-mandatory for transplant centers/organ procurement organizations.

C.1.d. Per above, non OPTN contractor committees would be titled as such.

D. OPTN Governance

D.1. Implement an HRSA five-person tribunal or audit committee, not a board of directors. It would be funded by registration fees, and it would provide oversight of the OPTN operational contractor's board of directors.

The current slow pace of policy development and implementation is the direct result of the current committee structure and policy development process within the OPTN. Organ specific (or other) committees develop concepts for policy change, move them up through the Policy Oversight Committee and then on to the Board, with the potential for a number of iterative movements up and down through this structure followed by periods of public comment. Alternatively, the Board may direct the committees to work on specific projects to advance the strategic goals of the OPTN, which then results in similar up and downward movement of policy through the cumbersome committee structure. In the current structure, by the time a policy is fully developed, most, or all, of the Committee members and Board members involved in the policy development have rotated away from their committee assignments, further clouding the policy development process. It is hypothesized that the current OPTN structure is overly inclusive, with many more participants involved through the policy development structure than necessary from a scientific perspective. A number of these participants may have limited knowledge regarding the details of the policy, and limited time for self-education, given the volunteer nature of their commitment to their committee or Board assignment. It is suggested that the entire structure of the OPTN with regards to policy development be re-examined, that the policy development process be streamlined and membership of committees be limited to those with expertise in the arena, rather than simple personal experience in the field. Consideration of the abandonment of Regional elections for committee membership (and for that matter, OPTN Board membership) should be undertaken, as committee members that are elected may not have the desired subject expertise, nor leadership skills needed for the pragmatic business management of the OPTN. Consideration should be given to longer term appointments to the policy making process such that greater continuity is present within the policy development structure. Stipends/contracts for participants in the policy development process should be considered to remove the volunteer nature of the positions, and garner added commitment to rapid turn-around, and mitigate the impact of longer-term appointments. The size of the Board of Directors must be re-assessed; the current size is unwieldy, leads to delays in policy implementation, and the Board membership in its current composition yields members that are not truly subject experts. The expectations of the Board should be re-imagined, such that the Board functions like that of a for-profit

corporation, with membership based on business acumen (with the business reflecting efficient management of the organ transplant system), and that sub-committees of the Board drive the business and its policies forward.

D.3. A single reporting mechanism would be the national number of organs procured and transplanted by organ type. A sliding scale of contract payment would be based on meeting predetermined targets.

D.4. Oversight by HHS, possibly by a newly created department within HHS that promotes an integrated transplantation ecosystem.

E. Increasing Organ Donation and Improving Procurement

E.1. and E.4.   The system of organ procurement via the OPOs has been little altered over the past 25 years. Performance has been largely self-reported, and OPTN interventions to enhance organ procurement largely limited to the most seriously underperforming OPOs. It is felt that this is largely related to the monopolistic nature of the current OPO geographic assignments, and the absence of either considerable incentives to do more, or penalties for performing at levels below expected. There seems to have been a historical bias toward doing a little better each year, but little drive for profound alteration in activities. This might be best summarized by a conversation that took place with an OPO Executive Director several years ago, when it was proposed that the system be altered such that OPOs generate incremental revenue for over-performance with regard to organ acquisition. The Executive Director's reply highlights the flaws in the current system, "I would not know what to do with the extra revenue".

The expectations related to OPO performance need to be completely redesigned, such that OPOs are incentivized to develop new and aggressive approaches to increasing the supply of transplantable organs, and penalized (as with removal of exclusive rights to serve a geographic population) when underperforming. New geographic territories would be granted to high performing OPOs who wish to expand their successful businesses, with the definition of high performance being based on volume of transplanted organs, and demonstrated functioning formal partnerships with local transplant centers to minimize discards. Development and implementation of innovative protocols to drive organ procurement would be a requirement for every OPO, and considered at the time of re-assessment of their contract renewal. The need for 57 independently functioning OPOs is not based on any business model, but the result of historical anachronism. It can well be imagined that ten high functioning OPOs that cover the country can yield efficiencies of scale, and employ best practices that merit their continued functioning in the US transplant system.

Oversight of OPO performance needs to be shifted away from the OPO community and again be vested in an OPTN Board, the members of which demonstrate fiduciary responsibility to the functioning of the transplant system, and not their own organization or historical UNOS Region. Professionals, whose allegiance is to the OPTN Board and performance of the system, can then direct rapid change, and process improvement.

F. Organ Usage

F.1. We propose to use metrics including discard rate to evaluate OPOs and have their exclusive contract to cover a DSA dependent on discard rate among other metrics (# of donors/population, # transplanted organs/population). We suggest rapidly incorporating new methods of organ perfusion that extend the preservation time greatly, thus reducing the discard rate (based on current research).

F.2. The time allocated/allowed for centers to accept an organ should be decreased, resulting in faster allocation of organs (and by better/faster electronic algorithms) and hence reduce cold ischemic time on kidneys. A common reason "marginal" kidneys are not transplanted is that too much cold ischemic time has accumulated by the time they are offered to centers that would otherwise use them. Reliance on modern electronic communication by algorithm-tree rather than a decision tree of multiple telephone calls would facilitate the speed of allocation.

F.3. See response B.2.d. and B.2.e.

G. OPTN Operations and Policy Development Improvements

G.1. HHS should require OPTN and HRSA to conduct a full audit of prior members of the boards and committees responsible for developing OPTN policies over the past 10 years. Data collected should include at minimum race, ethnicity, sex, gender, sexual orientation, profession, and years of experience. Using this data, combined with transplant workforce and patient data, OPTN should establish benchmarks for racial, ethnic, professional and gender diversity on the boards and committees. Special attention should also be given to ensuring institutional diversity within and across committees. Additional stakeholder groups such as donor families and organ transplant recipients should also be considered. OPTN should work with professional societies (AST, ASTS, IHLTS, AOPO) and advocacy groups to ensure validity of their auditing data.

G.2. OPTN should engage the national quality forum (NQF) to assist in increasing the efficiency of the policy making process. Under a consolidated system inspired by the Measure Applications Partnership (MAP), the OPTN board of directors and executive committee should adjust the responsibilities and role of the policy oversight committee.

      The Policy Oversight Committee currently advises the OPTN Board of Directors and Executive Committee in the development of strategic policy priorities, prioritization and coordination of policy and committee projects. Some of these activities should continue, including assessment of the impact of proposed policies, and ensuring compliance with policy development requirements prior to public comment. However, rather than a lengthy public comment period and review by multiple committees, the policy oversight committee should serve as a means of gathering and integrating stakeholder feedback on proposed policy changes. Public comment periods should run concurrent with any review by OPTN committees and be limited to 2 weeks in duration. Health equity and allocation/distribution may be initial specialized forums, comprised of internal and external stakeholders with subject matter expertise. Additional specialized forums may be created when the need arises. These forums, along with stakeholder groups, can serve as vehicles for collection of feedback during

implementation of new policies.

The Policy Oversight Committee should review feedback primarily to ensure compliance, but also to summarize comments in report to the Board of Directors and Executive Committee. This will allow adequate representation but remove the consensus-driven nature of the OPTN policy development process*(see #4 below for additional suggestions).

Vendors should also engage an independent entity to review data models that inform policies for algorithmic bias. A systematic approach to continuous management should be employed that includes easily understandable frameworks and toolkits as well as common definitions and controls. Algorithms informing new policy initiatives should be reviewed for bias at each stage of development, with a summary provided with any policy moving towards stakeholder feedback and public reporting of findings at the time of policy implementation and review.

G.3. A mission to ensure the responsible use of data for the purpose of generating knowledge, including the following principles:

a. Acknowledgement of the complexity of the transplant system and recognition of the need for continuous improvement
b. Adherence to algorithmic fairness and transparency in operations and model development
c. Engagement in education and training in the principles of health equity and equitable macro and micro policies that influence health outcomes
d. Respect for donor and recipient autonomy and commitment to data transparency and the use of data for continuous improvement in informed consent and shared decision making
e. A commitment to balanced representation of the various stakeholders including the listed groups below. Each of these may focus on a specific aspect of the transplant system, either due to narrow experience or regulatory burden. While on the surface these groups may at times seem opposed, ultimately, they all serve the larger mission of the full system of transplant.
    i. Transplant centers
    ii. OPOs
    iii. Clinicians
    iv. Patients with organ disease
    v. Donors

G.4. Multi-stakeholder consensus is a time intensive process that has resulted in significant delays in policy actualization and can be modernized. The Proposed OPTN stakeholder integration and policy workflow above provides a framework to allow integration of feedback from a diverse assortment of stakeholders through a central policy committee. Each forum and stakeholder group can facilitate collection and organization of constituent feedback and use of procedures like nominal group technique and online public surveys can improve expediency. Regional consultations and focus groups can ensure adequate representation of under-represented groups and geographic areas. The United Nations High-Level Political Forum (https://sustainabledevelopment.un.org/hlpf) is an example of how a committee can assimilate the views of various stakeholder groups and prepare them for executive committee review (https://www.unescap.org/sites/default/files/Final.Effective Stakeholder Engagement for the 2030 Agenda rev.pdf). The ICANN multistakeholder policy development process illustrates how this approach can vary by purpose and policy initiative: https://www.icann.org/en/system/files/files/multistakeholder-advice-development-30apr21-en.pdf

H.Stakeholder Engagement

H.1. The methodologies described in sections A and B with cloud-based, patient-centric data platforms inherently lend themselves to making data available to patients and families regarding organ offers and allows patients opportunity to update their health status and changes in their attitudes affecting organ acceptance.

H.2. Compliance with modified policies governing organ allocation and data submission would be audited and enforced as a condition of participation.

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Please submit your responses **by 1:00 pm ET, May 23, 2022, to NInazawa@hrsa.gov**

Response to:

Notice ID: HSB115C1031

Department: Health and Human Services, Health Resources and Services Administration

Title: Organ Procurement and Transplantation Network (OPTN) RFI

Date of issuance: April 8, 2022

Respondent point of contact:

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Statement of intent to supply a proposal to any future solicitation:

The respondents do not have an intent to reply to a request for proposals related to this requirement.

Carole Johnson
Administrator
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Administrator Johnson,

We are grateful for the opportunity to comment on urgently needed improvements to the Organ Procurement and Transplantation Network (OPTN) contract. As a group, we represent a spectrum of experience and perspectives including patient care, health services research, and policy advocacy, and we share a common goal of reliable and fair access to organ procurement care, and transplant care, for all Americans. We will provide responses specific to prompts within the Request for Information (RFI) below, but frame our comment with four themes:

1. [In response to RFI sections B.1-2, E.1-4] The stated aims of the RFI to increase accountability and strengthen equity in the system can best be accomplished through a unified and consistent approach to both organ procurement and transplantation as patient care. ***Both organ procurement organizations (OPOs) and transplant centers, which are regulated by the OPTN, are providers of clinical care within the larger population****. The OPTN contract must require the collection of transparent and complete records of clinical practice and processes for all patients <u>referred to</u> OPOs and transplant centers for care. Collection of these data would remediate a critical lack of patient-level information that hinders quality improvement and patient safety monitoring, particularly at OPOs and OPO-owned surgical organ recovery facilities.*

2. [In response to RFI sections A.3-5, E.2-4, G.4] Maximizing the recovery and utilization of deceased donor organs depends on mutually supporting policies, practices, and technologies. *The OPTN must define and enforce policies that support OPOs and transplant centers in the adoption of clinical processes and technology that improve access to and utilization of all potentially lifesaving organs. **To achieve this goal, HRSA should subdivide the OPTN contract to separate all IT functions.***

3. [In response to RFI sections D.1-4, H.2] Governance of the OPTN should be divided to avoid structural conflicts of interest as are present in the current environment. *Separating data collection and reporting from the enforcement entity of the contract promotes independent research and assessment of policy efficacy. **The current OPTN contractor is highly inconsistent and inadequate in the oversight function; all oversight functions should be reabsorbed by HHS.***

4. [In response to RFI sections C.2, D.1-4] The current OPTN contractor exerts improper influence on the governance and logistics of the HRSA contract; clear, decisive action must be taken by HHS to ensure that agency capture does not continue to undermine trust, transparency, and reliability of the US transplant system. *HRSA cannot allow the current OPTN contractor, nor any future contractors, to influence and frame for HRSA the terms of the contract, the governance of the OPTN, nor the policy goals of the US transplant system.*

HHS must take immediate steps to reverse the process of agency capture through critical reassessment of the HRSA-OPTN contractor relationship, and changes to the OPTN contract structure.

We will now describe in depth the four themes, with specific responses to the RFI for revisions to the OPTN contract contained within.

1. [In response to RFI sections B.1-2, E.1-4] **Improve equity and transparency in provision of care by reporting all patient and patient health record interactions, starting at the point of first contact with regulated entities (OPOs and transplant centers). Ensure that providers (OPOs and transplant centers) report patient-level data (analogous to current reporting by healthcare organizations like hospitals and hospices) to remediate deficiencies in data collection that pose a barrier to system improvement and a threat to patient safety.**

Currently, OPOs and transplant centers report data to the OPTN on only a portion of the patients referred to their organizations, and for whom they choose to provide clinical care.

HRSA should consider that OPOs are currently exempt from reporting data on patient care, even though OPOs routinely provide:
- off-site evaluation of patient EMRs via hospital record access
- in-hospital evaluation of patients and EMRs
- physical evaluation of patients
- consultation and coordination of care with patient providers
- order sets for patients
- transport of patients to private surgical facilities
- ICU and operative care in private surgical facilities.

It is important to note that OPOs provide much of this care for patients who are not yet, or will not be, declared brain dead. OPOs routinely care for living patients believed to be imminently deceased. **These patients deserve respectful, safe, high-quality care, just as palliative and hospice patients do**. As donation after circulatory death (DCD) continues to grow in importance, OPOs will interact with an even larger number of living patients. Even for those patients who are declared brain dead, the OPO care they receive prior to and after declaration still constitutes important information on the clinical management of potential donors, and the care itself should be measured and validated to be of highest quality.

Additionally, OPOs employ nurses, EMTs, paramedics, physicians, social workers, and advanced practice professionals, all of whom engage in direct patient care. It is illogical that OPOs should be exempt, under the current OPTN structure, from reporting patient-level data that all other healthcare providers receiving CMS reimbursement (such as hospices, hospitals, and ambulatory surgical centers) are mandated to report to protect patient safety, ensure quality care, and remain in good standing with CMS.

HRSA has allowed the current OPTN contractor to limit what is known about the quality of patient care provided by OPOs; the current contractor has done this through drastically limiting

data collection. HRSA can remediate this deficiency through improvements to the OPTN contract requirements for data collection, which we will describe. A similar restriction of data collection is present on the transplant center side as well, and we detail remedies for both.

As shown below, current OPTN identifiers are limited to a UNOS ID for the donor and a patient code for candidates and recipients. Data for the donor are provided by the OPO, while candidate/recipient data are submitted by the transplant center.[1]
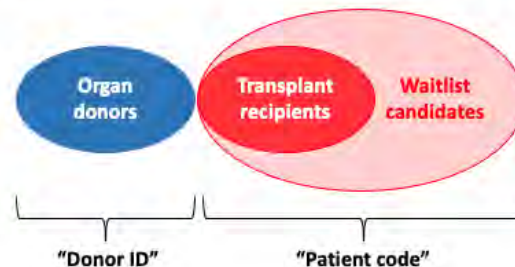
The incomplete reporting of all points of patient or patient EMR contact introduces bias into OPTN contractor assessments of both current clinical practices and the impact of future policy changes. Across both organ procurement and solid organ transplant, it is established that access to the patient pools on which the OPTN currently collects and reports data is inequitable.[2]

For patients who are potential deceased donors, the relative likelihood of successful organ procurement has been shown to be lower for minority populations, those living in rural and remote locations, and those receiving care in specific hospital settings.[3-6] Importantly, existing evidence shows large variation in the degree to which each of these population level disparities are experienced across the relevant OPTN member organizations — OPOs.[3,5]

For potential waitlist candidates, it has been well-established that access to the list represents a greater source of disparity for racial and ethnic minority patients, as well as those of lesser sociodemographic privilege, than is access from the waitlist.[7-9] As with procurement, there is evidence that some of these effects are modifiable at the center level.[10,11]

For both potential donor patients and recipient patients, judging supply of and demand for lifesaving organs on the populations who are those already best served by the system necessarily distorts any conclusions about need and equity through selection bias. This selection bias can and must be remediated through improved data collection.
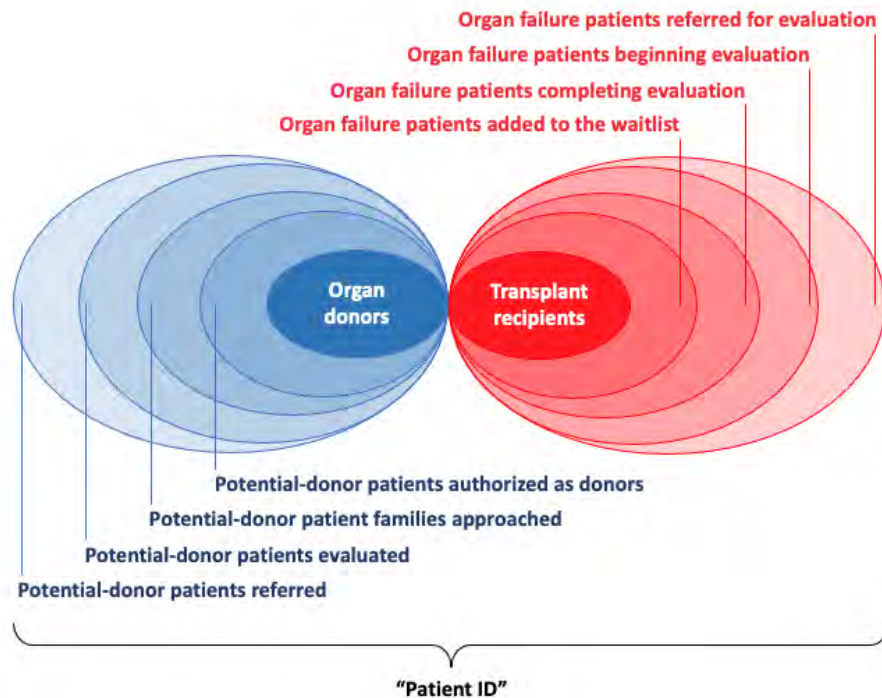
In addition, the current OPTN contractor has taken an inconsistent approach to assessing reference populations for transplant patients, both acknowledging inequity in waitlist access for end stage renal disease (ESRD) patients and actively excluding these concerns from policy formulation for liver disease patients.[12-15] The reasons for this conflicting approach remain obscure, but while the current contractor has publicly stated "*for us and everyone else in the transplant community, the ultimate form of equity means providing a transplant for every single patient that needs one,*" in more candid conversations, they have derided concern over waitlist

access as "*this isn't a "give txs to poor people" argument, it's a "give tx to those of us who have to live near poor people" argument.*"[16,17]

Recent revelations of inaccurate reporting of candidate and recipient deaths compounds concerns over the current contractor's fitness to manage an equitable system, as 17% of deaths were found to be misclassified, with incomplete data being "*differential by time since listing or transplant, age, race/ethnicity and state of residence.*"[18,19] It is vital that the attitudes and actions of the OPTN contractor reflect a measurably effective, and ethically honest, commitment to equity. High quality data will be central to this effort.

We propose that HRSA change the OPTN contract to ensure complete reporting of data for all patients referred to OPTN members for care (i.e., OPOs and transplant centers). **Under this conceptual framing, all patients <u>referred into</u> the system, whether as potential deceased organ donor patients or potential transplant candidates, would be recorded by the health care organization receiving the referral – either an OPO for potential donor patients or a transplant center for potential candidates.**[20,21] Each referred patient would be assigned a unique identifier within OPTN contractor database analogous to that already in use by OPOs in their own electronic medical records (see figure).[22]

Improved OPTN paradigm for measuring equity in provision of procurement and transplant care

Organ failure patients referred for evaluation
Organ failure patients beginning evaluation
Organ failure patients completing evaluation
Organ failure patients added to the waitlist

Organ donors

Transplant recipients

Potential-donor patients authorized as donors
Potential-donor patient families approached
Potential-donor patients evaluated
Potential-donor patients referred

"Patient ID"

The OPTN contractor, per HRSA requirement, should collect data from the responsible OPO or transplant center that documents date- and time-stamped data for processes of care until the ultimate disposition of the referred patient.

In the case of a potential organ donor patient, this would include:
- the OPO evaluation of the patient for potential for procurement,
- specific criteria for rule in or rule out decision pertaining to whether the OPO will provide patient care after referral,
- assignment of OPO staff to patient care,
- timing, assignment, and outcome of donation approach to family,
- performance and result of brain death testing,
- attainment of donor management goals,
- location, manner, and outcome of surgical organ recovery
- date- and time-stamped data on location and specialty of referring entity,
- dates and setting (inpatient/outpatient) of beginning and completing the evaluation process would be provided.[20]

Additional data related to procurement logistics would also be gathered, including the origin of the recovering surgical team and the means of travel for all teams and organs involved.

It is important to note that as the share of deceased organ donor patients procured after circulatory death increases, the current OPTN contractor does not adequately collect important data on the quality of clinical practice, nor the relevant training, credentialling, or licensure of the OPO providers who are engaged in the care of living patients. HRSA must immediately increase the requirements for collection of data from OPOs in order to ensure patient safety, and allow regulators and researchers to identify:

A. Differences in the quality of clinical care provided between OPOs and providers employed by OPOs,
B. How these differences in quality of care constitute unwarranted practice variation in clinical care as delivered by OPOs,
C. In what ways unwarranted practice variation may lead to inequitable health outcomes for marginalized patient populations, in both potential donor patients and potential recipients,
D. Type and frequency of critical patient safety events involving potential organ donor patients, OPOs, and hospitals.

This inclusive and detailed reporting of all patients referred to procurement and transplant system providers would serve as a necessary adjunct to existing population level data sources.

We are uniquely positioned to provide commentary on this topic, as we have previously published about OPO-collected process data that allows insight into specific practice deficiencies.[22] Many in the transplant system have called for quality improvement efforts for OPOs, yet we are among the few academic researchers involved in evaluating OPO clinical practice at the level of patient data supplied from the OPO. Within this group, we alone have validated patient-level OPO records against an objective, validated metric of performance.[23]

The performance improvement intervention we designed was made possible through study of patient-level data from an OPO that allowed close examination of clinical practice characteristics. The current OPTN contract does not provide for adequate data collection for

providers (OPOs and transplant centers) that permits intervention and the study of evidence on which to base clinical practice. Because of this deficiency, OPOs and centers are often unaware when their clinical practice is suboptimal, outdated, or unnecessarily risky (or risk-averse).

The OPO with which we partnered for study and intervention was improperly limiting care of potential organ donor patients over age 50 through suboptimal clinical evaluation and case management. **This constituted inequitable care for older patients within the OPO's DSA; should HRSA seek to engage in effective, measurable remediation of inequitable care provided by OPOs, HRSA must measure where inequities in provision or practice of care exist using patient-level data provided by all OPOs.**

HRSA and CMS understand that quality improvement in the procurement and transplant system is urgently needed and entirely possible, yet without requiring basic patient-level data collection, the OPOs, transplant centers, researchers, regulators, and any future OPTN contractor are without critical information to drive and sustain quality improvement.

For organ procurement, the cause, age, and location-consistent (CALC) deaths used in the metric outlined in the 2021 changes to the CMS Conditions for Coverage approximate the maximal donor potential in a given area.[24] For organ failure patients, only kidney disease has a detailed denominator in the form of the United States Renal Data Systems (USRDS) database.[25] The key difference between these existing data sources and the proposed full reporting of procurement and transplant data is that OPTN-regulated stakeholders directly engage in the care of referred patients. The mechanism for reporting could be analogous to the existing CMS 2728 form collected in ESRD patients, with demographic, medical, and provider data appropriate to both potential donor patient and potential recipient groups.[26]

We propose that there be no direct cost associated with reporting referred transplant center patients, and instead, support maintaining the payment of a 'listing fee' at the point when organ failure patients are entered into a waitlist. This would prevent any financial disincentive to reporting of pre-listing patients.

2. [In response to RFI sections A.3-5, E.2-4, G.4] **Promote access to listing and transplantation for organ failure patients with policies that support optimal center and OPO practices and innovative procedures. Subdivide the next OPTN contract to separate all IT functions and return technology ownership to HHS.**

Current OPTN policies provide limited performance feedback to stakeholders. While the 2021 changes to OPO Conditions for Coverage represent a major step forward in objective and reproducible assessment of donor and organ recovery, the three-tier system does not identify specific areas of strength and weakness in OPO clinical practice as delivered to patients. Similarly, center metrics provide limited assessments of pre-transplant and post-transplant survival, with some previous initiatives having failed due to misaligned aims and inconsistent values.[27,28]

Maximizing equity and utility of the procurement and transplantation system requires work on many fronts by a diverse group of stakeholders. The OPTN contractor's role in overseeing such a

system should be create policies that incentivize OPOs and transplant centers to broaden and grow their clinical practices. Members organization must be supported in organizational and logistical innovation.[29,30] In turn, these efforts will benefit from integration of technologic adjuncts such as organ perfusion. [31,32]

For the OPTN contractor to create and maintain a policy environment that prioritizes equitable and maximal access to procurement and transplantation, key organizational attributes will include:

A. Collection of detailed and reliable patient-level data that allows identification of individuals and centers/OPOs involved in novel processes or technologic initiatives,
B. Flexibility to identify and delegate authority for correcting missed opportunities in procurement and transplantation practice,
C. Rolling assessment of policy effectiveness and barriers and facilitators to OPO and center-driven initiatives to improve patient care.

We strongly support HRSA changing the structure of the current OPTN contract, as per the recent National Academies of Sciences, Engineering and Medicine (NASEM) report, to separate IT function and ownership.[33] The current OPTN contractor has shown serious deficiencies in the ability to adequately design, implement, and update technology to support the transplant system. These deficiencies constitute a danger to patients, a threat to quality improvement, and diminished ability of OPO and transplant center providers to prevent errors, adequately collect and protect necessary patient-level data, and ensure patient safety. HHS <u>must</u> own the technology critical for the function of the US transplant system, so that any one contractor may not hold HRSA and American patients effectively hostage through ownership of even the current antiquated, inadequate, inferior—and uniquely held by UNOS—technology.

3. [In response to RFI sections D.1-4, H.2] **Separate system evaluation from enforcement entities to ensure objective and independent assessment of policy efficacy. Absorb transplant system oversight into HHS.**

The current structure of the OPTN is unparalleled in American healthcare. A single government contractor ordains strategic priorities, designs and implements policy changes, and evaluates its own work in official and academic publications. By virtue of its central role in policy development, the OPTN contractor enjoys unrivalled and unquestioned access to virtually all academic and society discussions of problems and opportunities in the field. Even under ideal circumstances, a monolithic regulatory structure of this type has notable limitations. Consideration of outside perspectives cannot be guaranteed, and there is a risk of 'echo chamber' phenomena, where unproven hypotheses are reiterated into dogmatic truths about the scope and aims of the policymaking body. As has been shown by recent oversight investigations and legal discoveries, however, the current OPTN contractor has significant lapses in transparent and impartial policymaking.[13]

We urge HRSA and HHS to reabsorb all oversight of OPTN membership organizations as the current OPTN contractor has shown an inability and unwillingness to adequately oversee the very healthcare organizations it audits, convenes, confers membership, and reviews for

adherence to professional standards. **The current OPTN contractor has created an environment in which there are no significant consequences to OPOs for low quality or unsafe procurement practice, and in doing so, has instead asked patients to endure the effects of such underperformance through longer wait times and increased waitlist mortality, and for potential donor patients, unsafe attempts at organ procurement.** HRSA can and should protect both patients through returning oversight to HHS.

4. [In response to RFI sections C.2, D.1-4] **Preserve agency authority over contractor.**

The attitudes and actions of UNOS, the current OPTN contractor, put them at odds with HRSA's central mission: "*to provide equitable health care to people who are geographically isolated and economically or medically vulnerable.*"[34] The OPTN's role is described by this RFI as "*to increase the availability, and access to, donor organs for patients with end-stage organ failure.*" UNOS's own vision statement, "*our vision is a lifesaving transplant for everyone in need,*" sounds consistent with these values and priorities.[35] In practice, however, UNOS policymaking has often been marked by intractable pursuit of policies in the face of clear evidence of harm.[15] By their own admission, UNOS leaders have succeeded in these efforts by publicly leveraging HRSA authority while privately maneuvering HRSA staff into consenting to their aims.[17]

The advancement of harmful policies has been carried out in part by manipulation of policymaking committees to avoid or confound discussion of risk to vulnerable populations, as when the Board of Directors Executive Committee met to discuss broadening the charge of the Liver and Intestine Committee from "*liver candidates*" to "*liver failure patients.*"[36] While verbalizing concern for underserved groups, HRSA attendees stated that their understanding of HRSA's position was that only access within a waitlist, rather than to a waitlist, was within the OPTN's purview to assess. The origin of this belief within HRSA is unknown, but several other examples of UNOS leadership using HRSA in a fallacious 'appeal from authority' role exist.

In 2017, a common warning from UNOS was that if the transplant community did not agree to broader distribution of donor livers by the end of the year, that HRSA would intervene and wrestle control of policymaking from medical professionals. On questioning in an OPTN meeting in October of 2017, however, UNOS chief executive officer Brian Shepard admitted that no such threat from HRSA existed, but that this was being said by UNOS to create pressure on the community.[37] In private emails in June of the next year, Mr. Shepard and a board member and OPO CEO, Ms. Alexandra Glazier, joked about shaping HRSA's directions to them in regard to organ allocation policy. Ms. Glazier's statement "*I believe that idea (to create comm that would develop principles) was hatched by us :)*" was answered by Mr. Shepard's response "*Oh yeah? Read the next one . . .*"[17]

These instances typify a larger concerning picture within the OPTN policymaking environment. <u>By its own admission, UNOS obviates official procedures for policy design by concentrating power within a small group of individuals regardless of any formal role</u>: "*and if that were not enough, on the day after she officially left the OPTN Board, UNOS's CEO asked to keep Ms. Glazier involved in discussions regarding liver allocation policy because he said it was helpful to him and other members of the OPTN Board to hear Ms. Glazier's perspective, including on legal matters.*"[38] This group then limits the collection or presentation of data that shows adverse

effects of their work, including matters of equity and logistical complexity and financial waste.[36,39] In these discussions, selective quoting of statutory guidelines is frequently used to make the OPTN Final Rule and HRSA the apparent origin of these strategic aims.[40]

This is a well-understood means of bureaucratic manipulation known as regulatory capture – *"description is prescription. If you can get people to see the world as you do, you have unwittingly framed every subsequent choice . . . But the risk is that the agency fails to reframe the case to focus on its public interest mission."*[41]

The risk of regulatory capture is that HRSA, as the governing agency, fails to critically parse the contractor's preferred course of action from its own obligation to increase *"availability of, and access to, donor organs for patients with end-stage organ failure"* as described above. The possibility of regulatory capture in the OPTN contract exists in part because of the nature of OPTN's board, which has industry stakeholder involvement that creates structural conflicts of interest. A second feature of the contract, that the vendor has contract experience in the area, has perpetuated an effective monopoly for UNOS. Together, these characteristics create an environment where a continued stream of successes is lauded without significant moves to define or address deeper problems within the system, including persistent deficits in both organ failure patient access to care and OPO procurement of donor organs.[2,33,42,43]

The solution to regulatory capture is for HRSA to reassert control over the OPTN contract and contractor in monitoring, and to reabsorb governance and oversight functions into HHS. Specific recommendations include:

A. Separate and independent boards of directors for the OPTN and the contracting entity
B. Separation of data collection and distribution from the policymaking arm of the contract to prioritize independent access for policy analysis
C. Complete reporting of patient-level data from OPOs and transplant centers to allow transparent and accurate assessment of equity, utility, and efficiency
D. Specific inclusion of board and committee members with perspectives reflective of barriers in access to both procurement and transplant care (including current unrepresented patient and family representatives of individuals not procured as donors or not listed for transplant prior to illness or death)
E. Specific inclusion of board members from <u>outside</u> the OPO and transplant system who are skilled in public health, epidemiology, logistics, technology, and quality improvement
F. Complete reporting of conflict of interests for OPTN members, and contractor employees or committee members, in a manner consistent with other government contracts, to include personal/family financial or structural conflicts related to procurement, transplantation, and organ transport logistics
G. Thorough assessment of policy and implementation outcomes by HHS on a periodic basis

In summary, the current OPTN contract has significant limitations which must be addressed. Correcting these deficiencies will facilitate the work of the dedicated procurement and transplantation providers who administer this care nationwide, and will guarantee the strategic mission of HRSA to *"improve health outcomes and achieve health equity."* In doing so, we will

honor our commitment not only to those with organ failure, but also to those individuals who trust that they will receive diligent and respectful care as patients served by OPOs.

Sincerely,

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23 May 2022

To Whom It May Concern:

I submitted a joint response to the OPTN RFI with other former staffers.

Responses below provide answers to specific questions posed by the RFI, in the hopes to put known problems - and suggested solutions - on the record.

Yours sincerely,

Jennifer Erickson
Senior Fellow, Federation of American Scientists
White House Office of Science and Technology Policy, 2015 - 2017

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A. OPTN Technology - IT System The NASEM report recommends that the OPTN use a state-of the art information technology infrastructure that optimizes the use of new and evolving technologies to support the needs and future directions of the organ transplantation system. HRSA received similar feedback from the U.S. Digital Service as part of HRSA's 2019 market research. Additionally, organ procurement organizations and transplant programs currently do not submit data to the OPTN IT system in real time. HRSA seeks to enhance the usability and performance of the OPTN IT system and related tools, as well as ensure the OPTN IT system is protected from emerging and evolving security threats. HRSA is seeking feedback on the following questions:

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

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.

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.

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.

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

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

[Alumni of the USDS](#) found alarming failures and ["technology poverty"](#) of the current OPTN contractor, including the following analysis:

"While investigating UNet℠ and the organ transplant ecosystem as a whole, we identified a number of shortcomings and opportunities.

- *"Technical Seams" Or Opportunities For User Error And Incorrect Data Entry*
  Technical seams are places between automated APIs, or computer-to-computer communication, where information tends to get lost or corrupted. When there are unnecessary, human-powered technical seams between computer systems, we create risk for lost or corrupted data.

- *Closed And Proprietary Systems Block Innovation*
  Under the current structure, the black box of UNet℠ provides no opportunity for collaboration or outside competition to drive innovation. In this context, the system owner (UNOS, whose funding results from a government monopoly contract) effectively keeps the United States government beholden to them as contractors with their proprietary tech, against the best interests of taxpayers, physicians, and patients.

- *Siloed Systems Prevent Thorough Data Analysis*
  The current "transplant tech ecosystem" contains many disparate systems that each handle their own data. In systems where there are numerous stakeholders, whoever speaks the loudest often gets to determine the next feature built. In more mature technical organizations, to overcome this human political bias, all decisions on what to build next are validated with central data to ensure the expected outcome is achievable.

- *Too Much Focus On "Feature Releases" Instead Of Iterations*
  Users we talked to described upgrades specifically on UNet℠ as patch fixes. They described frequent "feature releases," built up with PR campaigns that illustrate the lack of a more modernized approach. The more modern approach, iterative development, involves small changes to a small subset of users. When those changes are effective, then a wider release occurs.

- *Lost Organs From Transportation Issues & Lack Of Tracking*
  Hundreds of recovered organs have not been transplanted because they were lost or damaged in transit. With the vast improvements in logistics and transportation within the private sector, organs should not be getting lost this way."

This analysis leads to two clear conclusions: (1) the incumbent OPTN contractor has proven incapable of implementing the modern IT infrastructure that the RFI seeks, and which patients

urgently require; and (2) HRSA should work with USDS procurement experts on an agile system of purchasing and deploying technology in the national interest as outlined in this Bloom Works research chapter and this draft RFP.

It is also critical that anti-competitive contracting practices that have been used in the past not be perpetuated in the upcoming RFP cycle. For example, the 2018 HRSA RFP requirement that a vendor have three years' experience effectively locked out all other potential respondents given the incumbent OPTN contractor is the only organization that has that track record as it is a national monopoly.

See findings from Bloom Works (USDS alumni):

"The 2018 RFP specified that vendors would be evaluated on, "The Vendor (organization) experience… in the field of organ transplantation based on a minimum of 3 years of corporate experience in managing projects of similar scope and complexity in the field of organ transplantation."

"We had difficulty identifying leading technology vendors in the organ transplantation space that managed similar scope and complexity to the scope of the requirement/contract. This requirement has contributed to HRSA's lack of meaningful competition. In addition, modern technology vendors have the ability to coordinate highly complex situations including organ donation transplantation. We recommend the following changes:

- *Eliminate the minimum amount of years of corporate experience in the specific organ transplantation field*
- *Indicate that vendors with no experience in the field of organ transplantation receive a neutral score for past performance*
- *Structure the past performance technical factor as far less important than any other Technical Factor"*

Additionally, given the "technology poverty" of the incumbent OPTN contractor cited by USDS alumni, there are urgent questions HRSA and OMB need to answer about the security of the current system. It is hard to imagine that a contractor that is responsible for hundreds of lost/damaged organs in transit is capable of adhering to the latest best practices for IT security infrastructure, practices, and standards.

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?

99.999% uptime is reasonable and achievable. If the current OPTN contractor has not achieved this standard, it is an indictment of its technological capabilities. System downtown translates to lives lost, and is unacceptable.

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

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

Given the "technology poverty" of the incumbent OPTN contractor cited by USDS alumni, there are urgent questions HRSA and OMB need to answer about the security of the current system. It is hard to imagine that a contractor that is responsible for hundreds of lost/damaged organs in transit is capable of adhering to the latest best practices for IT security infrastructure, practices, and standards.

B. Data Collection Activities The NASEM report recommends the creation of a dashboard of metrics to track performance and evaluate results, and modernize the data collection for deceased donor organ procurement, allocation, distribution, and transplantation. Enhancing OPTN data collection and dissemination could improve performance assessment, reduce practice variation, and support quality improvement and innovation. HRSA is seeking feedback on the following questions:

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.

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

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

b. To establish OPTN member performance benchmarks.

For procurement performance metrics, CMS has already set the performance metrics for OPOs. Data released in April 2022 show the majority of OPOs are failing tier 1 standards, costing thousands of patients' lives.

This is also an indictment of the current OPTN contractor. See the Senate Finance Committee: *"We have serious concerns related to UNOS' role in overseeing our nation's OPOs, which have been severely underperforming for decades. Our review has shed light on the improper use of*

Medicare funds, conflicts of interest and gaps in oversight. UNOS has served as the federal government's contractor, without competition, since 1986, and is responsible for overseeing the Organ Procurement and Transplantation Network established by Congress."

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

The current OPTN contractor seems to have no interest (or no capability) in making user-friendly dashboards. For example, if you use the OPTN website to access a cut of data analysis, the page/results displayed is not capable of being copied and emailed to someone else.

C. OPTN Finances Currently, the OPTN contractor charges additional fees (outside of OPTN registration fees) to provide services to the donation and transplantation community. Although no OPTN member is required to pay such fees in order to participate in the OPTN, in practice, many OPTN members may view them as necessary to receive the services they need from the OPTN contractor. HRSA seeks to increase accountability and transparency in OPTN financial structures. HRSA is seeking feedback on the following questions:

1. 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.

Per the [October 2020 Senate Finance letter to HHS,](#) it is deeply concerning that there appears to be a clear [double charging of Medicare by the OPTN contractor](#) - billing Medicare once for each waitlisted patient as the OPTN and a second time as the OPTN contractor (UNOS). This should not be allowed.

Additionally, paying for the waitlisting of patients does not preference for the outcome that best serves patients, as it does not account for whether they are actually transplanted. HRSA should work with Congress to reform the [financing structure of the OPTN](#) and any related contractors in a way that clearly better serves patients and taxpayers.

Transparency and a lack of conflicts should be at the core of such reforms. For example, the current OPTN contractor spends large sums marketing for itself (e.g., UNOS placed a full color Magazine insert in USA Today in December 2021 to promote misleading information obscenely claiming credit for deaths caused by the tragic opioid epidemic and COVID pandemic). It is in no way clear that such funds help patients.

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?

A central problem in the current financing of both the OPTN and the OPOs is that there is no financial pressure to perform for patients. In other words, OPTN/OPO budgets are set and largely exist irrespective of those contractors delivering on their charge to help patients receive lifesaving transplants. HRSA should work with Congress to amend NOTA to address structural flaws in OPTN financing - making clear the government itself owns the work product it is purchasing on behalf of patients and taxpayers, and re-aligning financial incentives to meaningfully correspond with performance - and HRSA should work closely with financial healthcare experts and OIG to ensure that it is not merely categories of expenditure that are approved, but a way to monitor that such expenditures are effective.

D. OPTN Governance HRSA seeks additional robust accountability and oversight measures regarding the OPTN. Today, the same individuals concurrently serve as members of the OPTN Board of Directors and the OPTN contractor's corporate board, which may hinder implementation of such accountability and oversight measures. HRSA is seeking feedback on the following questions:

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.

The OPTN board should clearly be entirely separate from any OPTN contractors. That said, accountability for the OPTN - and OPOs - must rest with HHS itself. To that end, OPO oversight must be reabsorbed by HHS. And to have appropriate oversight of all OPTN contractors, HRSA should publish its own dashboards of performance, including adverse event reporting, so that there is no regulatory capture/incentive to hide errors or gross negligence.

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

The OPTN board of directors - as well as directors of any OPTN contractors - should have to clearly and publicly disclose any conflicts of interest, including any relationships with other government contractors (e.g., OPOs) or trade associations (e.g., AOPO).

For example, that OPTN board members have publicly advocated against HHS reforms that can help patients, without disclosing such relationships.

Related: that Committee members for NASEM did not have to publicly disclose such conflicts is also concerning. See Washington Post.

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

Critical data such as organs transplanted and organs lost (e.g., never recovered; lost/damaged in transit; or discarded due to basic OPO errors) should be immediately publicly reported via HHS dashboards.

The government is well-placed to do adverse event reporting, and without such reporting, too many patients are dying due to errors that never become public, and are never addressed.

E. Increasing Organ Donation and Improving Procurement The NASEM report identifies concerns with organ donation rates, including geographic and demographic variations. HHS is actively taking steps to enhance the accountability of Organ Procurement Organizations (OPOs). HRSA is seeking feedback on the following questions regarding increasing the donation of organs and improving the procurement of organs.

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.

The OPTN - and all related contractors - should be opening all de-identified data in a timely way to the public/qualified researchers. HRSA/CMS/HHS should ensure these data are easy to access and understand, fitting into the Biden administration's commitment to data/equity/transparency.

For example, too often now data are either not available, available for purchase from the OPTN, or are available only in difficult-to-access-or-use formats.

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

Through open, timely, and easily-accessible data - for example on match runs.

Too often HHS defers to costly and unproven "best practice sharing" that is not grounded in data, and worse-still can suggest the problems are with certain communities (e.g., rural patients, or patients of color) versus with the treatment these communities receive from the government contractors themselves.

F. Organ Usage The NASEM report identifies concerns with the current high level of organ non-usage (discards), estimated at an unacceptable 25%. Over the past several years, the OPTN Collaborative Improvement and Innovation Network (COIIN) projects and the current CMS/HRSA End Stage Renal Disease Treatment Choices Learning Collaborative (ETCLC) have worked to build and share best practices models to aid the community in addressing variables that adversely impact organ usage. HRSA is seeking feedback related to the following questions on increasing organ usage and simultaneously decreasing organ non-usage (discards).

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.

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

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.

Current OPTN technology is not fit for purpose, resulting in difficulty of user experience (e.g., "antiquated technology", manual entry of information, paucity of workable APIs).

Additionally, there is no public adverse-event reporting. So when lifesaving organs are lost in transit or discarded due to OPO/OPTN error, it is not known to the public unless there is investigative reporting. Near real-time adverse event reporting is required.

G. OPTN Operations and Policy Development Improvements The NASEM report recommends making that the improvements to the OPTN policymaking process including increasing racial, ethnic, professional, and gender diversity on the board and committees responsible for developing OPTN policies. NASEM also recommended seeking engagement with external organizations, such as the National Quality Forum (NQF) or the National Academy of Public Administration, with expertise in guiding federal programs through unique challenges in leadership and stakeholder collaboration. HRSA is seeking feedback on the following questions: 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. 2. Describe how you would/vendors could engage with experts in quality improvement and stakeholder collaboration in executing OPTN deliverables.

HRSA/CMS/HHS should act on what it knows (e.g., move forward with open data, including with critical cuts based on patient demographics such as race/ethnicity and rural status; move forward with decertifying failing OPOs), and not wait for additional studies. Organ donation systems have been studied for decades - what has been missing is accountability. Given massive one-year improvements from contractors under the pressure of oversight, it is simply not true that the system is so complex or the solutions so mysterious that they cannot be achieved through an acceleration of oversight and accountability.

See [Bloom Works](#) (emphasis added) example below about an OPO, though the principle applies to the OPTN as well:

*"**We've seen promising evidence of OPOs turning around when they feel pressure from oversight bodies**. For example, in 2019, Senators Chuck Grassley (R-IA) and Todd Young (R-IN) sent an inquiry to the Inspector General about an OPO in Indiana – specifically asking if Indiana Donor Network charged taxpayers for private jet travel unrelated to organ recovery. In apparent response to this oversight pressure, the OPO engaged external consultants to improve its organ recovery operations. In the subsequent 12 months, the OPO increased donation rates by 44%; and it increased its ranking from 51st to 18th among the nation's 57 OPOs, underscoring vast underperformance at OPOs. Importantly, the increased donation rates seem to have resulted simply from the OPO exerting more effort; over this period of improvement, the OPO approached 57% more families for donation than it had over the previous 12 months. **This suggests that, in the absence of oversight, the OPO seems to have flagrantly ignored its mandate to pursue all possible donation opportunities, and it is entirely likely that hundreds of additional lives have been saved over the past year as the direct result of Senators Grassley and Young simply asking oversight questions**. This is an encouraging example of how elected officials can best serve their constituents. However, without more and sustained Congressional oversight and regulatory pressure, shadow deaths will remain high, and even OPOs that have improved amidst heightened scrutiny could backslide into previous practices. For this reason, **we implore the U.S. government to take steps to hold OPOs and UNOS more accountable and heed these important recommendations**."*

23 May 2022

Carole Johnson
Administrator, Health Resources Services Administration
5600 Fishers Lane
Rockville, MD 20852

Re: "Request for Information on Ways to Strengthen and Improve the Organ Procurement and Transplantation Network"

Dear Administrator Johnson:

We are writing to support reforms to the nation's organ transplantation system. We appreciate reforms that are already underway, and believe that accountability for the governments' contractors is critical to reducing disparities in organ transplantation and saving more lives through organ transplantation.

Because of the monopolistic nature of existing government contracts, we believe that bipartisan, bicameral Congressional leaders were correct to identify the need to accelerate reforms of organ procurement organizations (OPOs) as an "urgent health equity issue", and that both the Senate Finance Committee and the House Appropriations Committee have appropriately highlighted the need for reform of the organ procurement transplantation network (OPTN).

The recommendations below call for removing barriers and conflicts, increasing transparency, and following basic principles of good governance and federal contracting.

We recommend that HRSA and the Department of Health and Human Services (HHS) work to ensure a first-ever competitive OPTN contract in line with calls from the House Appropriations Committee and consistent with standard government contracting policies.

For too long, HHS procurement policies regarding the OPTN have had the effect of preferencing incumbency at the expense of patients' lives, and the monopolistic structure of the OPTN has undermined systemic pressures to improve, while patients are left to languish.

The OPTN contractor (UNOS) performs three key functions: policymaking, technology delivery, and OPTN member compliance. Its functions in all three have drawn criticism from Congressional oversight, the media, and external stakeholders. Per a recent report from alumni of the U.S. Digital Service (USDS) endorsed by all 5 past HHS Chief Technology Officers: *"The OPTN contractor has devolved into a hostage-taking situation, where it has convinced the government that no one else can do what it does, but it doesn't perform its functions particularly well."* Examples:

- Policymaking has been divisive, drawing criticism across administrations and eroding public trust. Examples:
  - In 1998, HHS Secretary Shalala cited UNOS misinformation seven times: *"I have received numerous letters from Members of Congress, transplant professionals, patients, and the public that reflect inaccuracies published by UNOS. I am especially distressed that UNOS is needlessly frightening transplant patients."*
  - In 2021, a federal judge unsealed emails with incendiary statements further eroding trust and prompting Congressional concern about how policies are decided, pitting states against each other. See email from UNOS board member to the UNOS CEO, emphasis added: "*The fact that some states do better than others in preventing preventable deaths and providing health care insurance coverage and access means you're a **dumb fuck** for living there."* In fact, the Washington Post characterized UNOS's handling of this policy process as *"spark[ing] open conflict among transplant centers."*
  - Note: The above is not meant to relitigate any individual policy, but speaks to a lack of care and conflicts in how UNOS functions as the OPTN.
- Technology: USDS alumni cited the "technology poverty" of the current system e.g.,
  - UNOS tech is so dated that 17% of kidney offers go to dead people.
  - Kaiser Health News noted that *"a startling number of lifesaving organs are lost or delayed after being shipped on commercial flights… [because UNOS] typically tracks [them] with a primitive system of phone calls and paper manifests."*
  - The American Society of Nephrology highlighted that UNOS is 15 times more likely to lose an organ in transit than an airline is luggage.
- OPTN member compliance: per the Senate Finance Committee, "*We have serious concerns related to UNOS' role in overseeing our nation's OPOs. Our review has shed light on the improper use of Medicare funds, conflicts of interest and gaps in oversight."*
  - The Committee is investigating deadly patient safety issues, wasted taxpayer dollars, criminality, or for the failure to recover organs.

To address the above failings, and to best serve patients with a first-ever competitive contracting OPTN contracting cycle, HRSA should:

- **Reform the governance of the OPTN** so that there is an OPTN board solely focused on the interests of patients and a high-functioning national organ donation and transplantation system separate from the interests of any OPTN-related contractor(s).
  - *Note: HRSA proposed a separation of OPTN and contractor boards in 2018, and the Government Accountability Office reinforced this position; however HRSA has not required compliance with this position from the current OPTN contractor leading to ongoing conflicts of interest.*
- **Subdivide the OPTN contract into policy and technology**, given the fundamentally different core competencies of these two areas.

- ○ *Note: this recommendation has been endorsed by the [National Academies of Science, Engineering, and Medicine](#) (NASEM), as well as by leaders of the [American Society of Nephrology (ASN), Global Liver Institute (GLI), and Organize](#), as well as [USDS alumni](#).*
- **Make the technology component open to all bidders, working with USDS procurement experts so that HHS can choose from the best vendors to serve patients**.
  - ○ *Note: this recommendation has been endorsed by [USDS alumni](#) who included a damning indictment of the capabilities of the current contractor (UNOS): "The technology scope of the OPTN contract has been fulfilled by one vendor. Our research indicates the vendor maintains an antiquated technology and limited technical acumen."*
- **Make all de-identified OPTN data publicly available** as the practical way to show evidence of equitable and effective treatment of donor families and patients - something noticeably absent from the status quo.
  - ○ *Note: data transparency is critical to achieving the aims of the [Executive Order on Advancing American Kidney Health](#) (2019) and addressing equity failures in the system, and also relates to the [Executive Orders for Equity](#) (2021) and [Equitable Pandemic Response](#) (2021). Additionally, as the OPTN operates as a quasi-governmental body, data transparency is in line with the spirit of the [Executive Order on Open Data](#) (2013).*
- **Streamline organ donation policymaking through an elevated Office of Organ Policy, as advocated for by the House Appropriations Committee, including addressing what the Senate Finance Committee has identified as [“conflicts of interest and gaps in oversight”](#) from the OPTN.**
  - ○ *Note: elevating and streamlining organ policy has had the support of bipartisan political leaders, including a January 2021 HHS proposal to Congress that the [House Appropriations Committee](#) and [Members of Congress](#) supported in the same year, as well as patient groups such as [ASN, GLI, and Organize](#) in 2022.*
  - ○ *As one of us (Mande, who served as the primary staff person who drafted the legislation for Representative Al Gore and the cosponsors, including former Senator Hatch) [wrote](#) in a 2019 letter to HHS of the status quo: "The result has been ineffective organ donation oversight, with jurisdiction splintered across various bodies. Far from enabling more oversight, this dynamic has allowed federal oversight to slip through the cracks... When we passed NOTA, we had hoped that organ donation responsibilities would be consolidated within the Office of the Secretary. We were disappointed by the decision to place the Division of Transplantation within HRSA which, given its many and varied mandates, has seemed unable to make transplantation a priority."*

Additionally, we encourage HRSA/HHS to work with Congress to reform the National Organ Transplantation Act (NOTA) in a way that better serves patients with any necessary structural changes to the OPTN, including updating how the OPTN is financed and governed, ensuring HHS has the leverage and transparency it needs to act on patients' behalf.

Ike Brannon
White House Office of Information and Regulatory Affairs, 2001 - 2002; Senate Finance Committee, 2005 - 2007; U.S. Treasury, 2007 - 2008; House Energy and Commerce Committee, 2009-2011

Jennifer Erickson
White House Office of Science and Technology Policy, 2015 - 2017

Jerold Mande
Staff author of the National Organ Transplant Act of 1984, Al Gore, 1982 - 1991; White House Office of Science and Technology Policy, 1997 - 1998

Jim Parker
U.S. Department of Health and Human Services, 2018 - 2021

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White House National Economic Council and Domestic Policy Council, 2017 - 2019

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To:	Inazawa, Naomi (HRSA)
Cc:	'Garrett Erdle'
Subject:	[EXTERNAL] RFI response

Dear Naomi,

We are coming upon my one-year anniversary as Chairman of OPTN Patient Affairs Committee (PAC) and the beginning of my seventh year associated with PAC. I am reaching out today to share what I observed and heard from our patient members over the past year.

Following the precedent first established by my predecessors Kristie Lemmon and Darnell Waun, we assembled a diverse team of volunteers who are called to offer their own personal and professional skills, plus experiences, to assist transplant practitioners and professionals learn and understand the concerns of the patient community and offer suggestions for improvement to the transplantation system.

Our current PAC roster includes a health care executive, tailor, engineer, attorney, financial analyst, OPO employee, Army colonel, nurse and professor. Our members have real world management skills, P&L responsibilities and technology/process improvement experience in the private sector. Each of our members also navigated either the transplant or donor experience at many of the US's top hospitals and have seen firsthand the excellence, and shortcomings they aspire to change, as a way to demonstrate the gratitude for their own gifts of life, and to make it better for the next transplant patient who comes behind them. With this higher level of sophistication and experience comes a higher level of expectation they have of the OPTN/UNOS organization.

From a powerful team comes powerful expectations, and I want you to be aware of these conversations. Like never before, our patient members are leaning in and asking probing questions about long standing policies and practices and what's more, they are not just accepting the given answer but going farther to better understand the issues to come back with new, innovative ideas grounded in the desire to save lives. Their real-world experience in the for-profit world lends them a mindset to question the actual accountability of peer-to-peer measurement of transplant center performance, knowing full well the entwined relationships and priorities of the transplant professionals in review. When the topic of tracking organs as they move from donor to recipient is discussed, there is little acceptance of cost or adoption as blockers. Instead, this team wonders if resistance is due in some part to the added accountability that will certainly come when each party has clear visibility into the location of an organ. And finally, there is an absolute rebuke of any narrative of classic policy draft and review being the only way to enforce or ignite change, whether in terms of making immediate change to the eGFR consideration or, to enabling a patient to have an open conversation with their doctor regarding which risk factors may be acceptable to increase the chances of getting an organ. While the practice of medicine is still an elite niche, the business of medicine is not and, in many ways, this committee represents the customers of transplant. This is a team who will invest heavily to drive change that will save lives, and it is not a team who will accept the status quo. Be it real or perceived, UNOS is the head of organ transplantation for the US. PAC believes leadership must be the force which drives the needed change to and through the Centers and OPOs.

Our group observed that we appear to make progress as an organization when we are on the receiving end of a lawsuit, in a contract renewal period or most recently, the subject of a congressional investigation. Let's command that leadership role by getting out front and making tough decisions that will immediately benefit the patient community. Let's start by asking our patients what worked and didn't work during their journey through transplantation. Let's identify which OPOs, Centers and doctors are our top performers, document their processes and technology, and require all members to use the same processes and metrics. Let's press for initiatives which allow us to partner with technology and logistics companies who have proven themselves successful at tackling the issues where we seem to struggle. While this may be a multi-year journey, it will enable us to inform our candidates, patients, and constituencies that we are making needed improvements to the system to save lives.

Sincerely,

Garrett

Garrett Erdle
703-625-3674

Request for Information (RFI) seeking input on ways to strengthen and improve the Organ Procurement and Transplantation Network (OPTN) through the upcoming Fiscal Year 2023 Request for Proposal (RFP)

Response from the GW Transplant Institute
J. Keith Melancon, MD
Transplant Surgeon and Medical Director, Ron and Joy Paul Transplant Center,
The George Washington School of Medicine
Naoru Koizumi, PhD
Professor of Public Policy and Associate Dean of Research and Grants, Schar School of Policy and Government, The George Mason University

This response is to Sections E and B of HRSA's recent RFI seeking to *strengthen equity, access, and transparency in the organ donation, allocation, procurement, and transplantation process in the contract arrangement that results from the forthcoming RFP* [1]

Under B2. (c) <u>Describe how you would/how vendors could structure data collection and reporting mechanisms for the system:</u>

It is well documented that African American patients have higher chances of developing kidney disease than any other race and tend to suffer from numerous comorbidities[2]. Despite that, non-Hispanic African American chronic kidney disease (CKD) patients are up to 70% less likely to get transplanted[3]. Among the contributing factors to lower transplantation access is socioeconomic status (SES), and the factors associated with it such as travel, education, and insurance limitations[4]. Consequently, the elevated health risks associated with lower SES patients as well as the current scoring system, have prompted transplant centers to avoid treating those patients. We believe that because of the barriers lower SES patients face in trying to access renal care, their chances of survival will be much higher when transplanted than when staying on dialysis. Thus, we highly recommend that SES becomes much more emphasized on two levels, including the following:

1. Program scoring. The transplant outcome risk adjustment model should highlight socioeconomic status for vulnerable populations as an evaluating factor of the overall program outcomes. Penalties put on transplant programs based on their outcomes have discouraged centers from performing transplants on poorer and higher risk patients and thus should be eliminated. In addition to correcting for comorbidities, SES should be corrected for in the risk adjustment model due to its detrimental effects on transplant outcomes.

2. Patient selection and evaluation. Transplant centers should be incentivized to treat those patients due to the stark difference in life expectancy between transplant vs. dialysis outcomes, specifically in lower income and higher risk patient populations.

We encourage the OPTN committee to take the hospital risk adjustment framework, which highlights SES for Medicaid patients who are admitted for kidney transplants, as an exemplary model. Correcting the risk adjustment model to include SES as a main factor in the reimbursement of hospital costs for transplant patients has incentivized hospitals to take on more disadvantaged patients and thus contributed to increasing access for minorities.

<u>Under E. Increasing Organ Donation and Improving Procurement, we would like to point out the importance of further programs to facilitate donation at the national level.</u>

Similarly, further programs to facilitate deceased donation at the national level could include:
1. An opt-out, instead of the current opt-in, policy for deceased donation akin to the policy in many European countries.
2. Financial incentives including tax credits or discounts on insurance premiums for live kidney donors.
3. Special college scholarships, financial aid and/or stipends that could be awarded to living kidney donors, as well as retrospectively, to past live kidney donors.

References:

[1] https://www.hrsa.gov/about/news/press-releases/hrsa-releases-organ-procurement-transplantation-network-rfi

[2] Kovesdy, C.P., 2022. Epidemiology of chronic kidney disease: an update 2022. *Kidney International Supplements*, *12*(1), pp.7-11. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9073222/

[3] Wilk, A.S., Cummings, J.R., Plantinga, L.C., Franch, H.A., Lea, J.P. and Patzer, R.E., 2022. Racial and ethnic disparities in kidney replacement therapies among adults with kidney failure: an observational study of variation by patient age. American Journal of Kidney Diseases. https://doi.org/10.1053/j.ajkd.2021.12.012

[4] Ross-Driscoll, K., Gunasti, J., Lynch, R.J., Massie, A., Segev, D.L., Snyder, J., Axelrod, D. and Patzer, R.E., 2022. Listing at non-local transplant centers is associated with increased access to deceased donor kidney transplantation. *American Journal of Transplantation*. https://doi.org/10.1111/ajt.1704.

May 23, 2022

HHS Health Resources & Services Administration
5600 Fishers Lane
Rockville, MD 20852

RE: Organ Procurement and Transplantation Network (OPTN), NAICS Code: 541611

Sent via email to: NInazawa@hrsa.gov

Dear HRSA,

On behalf of HonorBridge, thank you for the opportunity to provide feedback regarding methods to strengthen and improve components of the OPTN contract including its governance, finance, IT, data collection, policy, and operational components, as well as ways to incorporate the findings and recommendations of the February 2022 National Academies of Science, Engineering, and Medicine (NASEM) report titled, "Realizing the Promise of Equity in the Organ Transplantation System".

HonorBridge is the federally designated organ procurement organization (OPO) serving 7.5 million people in 77 counties in North Carolina, along with Pittsylvania County in Virginia. Our service area includes over 100 hospitals and four transplant centers that perform heart, lung, liver, kidney, pancreas and intestine transplants. As a member of the Association of Organ Procurement Organizations (AOPO), HonorBridge fully endorses the detailed comments submitted by AOPO in response to this solicitation, but we would like to emphasize areas that are of particular interest to us.

A: OPTN Technology – IT System

A.1.b: Describe how to 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.

As AOPO indicated, electronic referrals show great promise in creating greater efficiency in the donation process by helping to ensure that no donor is inadvertently missed and facilitating data collection that helps inform predictive analyses to increase the speed and accuracy of future organ matching. Similarly, APIs allow for seamless clinical integration, which helps automate the potential donor screening process and leads to earlier and more effectively managed donor referrals. Despite their great potential to drastically improve the donor hospital referral process and save lives, these technologies can be expensive, which has limited their adoption across system stakeholders to date. We strongly encourage OPTN to leverage APIs, but it will only be as useful as the degree to which all components of the organ donation and transplant system industry adopts them. Past CMS programs such as the EHR Incentive Program have proven successful at driving the rapid implementation of promising new technologies. We believe HHS should build off these past successes to drive the adoption of electronic referrals and APIs in organ referrals through a similar nationwide incentive program, if not through grants or supplemental funding initiatives. Equally important- **these systems must all be interconnected, including donor hospital EHRs** to truly leverage these abilities to assess donation potential more rapidly in real-time. The OPTN

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could be the coordinating entity for a robust data warehouse for this information exchange. This could be the foundational building blocks for a better more accurate and timelier dataset to calculate a denominator for OPO metrics.

A.1.c: Describe how to enhance real-time tracking of donated organs to allocate organs more efficiently and support increased transplant center engagement with patients in organ acceptance decisions.

System efficiency in offering organs in a manner that minimizes time between the "offer and acceptance" as well as the most expeditious method of transportation of these accepted organs is needed. Decreasing critical hours between identifying a donated organ with potential matches will allow increased flexibility for patients to be more actively engaged in organ acceptance decisions.

Several promising tools have been piloted and tested both within the OPTN framework and independently. The results of these pilot tests should drive the adoption of new technologies and innovated processes across the entire system. Standardization of process, data metrics and interoperability of various technology platforms is <u>critical</u> for this to work effectively. Currently, different OPOs utilize different platforms that collect different data points that are not integrated with the OPTN's system (UNet). Identical data sets are imperative for an accurate understanding of the time-process flow. Cost may be a barrier to implementing these new technologies, particularly for smaller OPOs and other stakeholders. We urge HHS and OPTN to work with stakeholders to finalize the development of these new systems and technologies as well as provide the necessary resources and support to ***all*** OPTN members to ensure the implementation and rollout of a coordinated interoperable system.

A.1.d: Describe how to produce public performance dashboards and actionable data to identify opportunities for program improvement, reduce inequities, and benchmark performance.

HonorBridge strongly supports the collection and dissemination of actionable data. OPOs and all transplant system stakeholders can leverage this data to find innovative ways to drive system-wide performance improvements and efficiencies and save more lives. We believe HRSA and OPTN should design dashboards with the specific audience and intended user in mind. For example, any information available to the public should be provided with proper context so that a layperson can understand what the metric means. It should also be provided in a user-friendly format that does not overwhelm the average consumer so that the information can be useful to them. Notably, HHS needs to ensure all data, but particularly any that is made available to the public and/or used to compare performance, is sufficiently risk-adjusted including accounting for population demographics, social determinants, or other factors. It is critically important to do this in such a way that does not create separate standards in the system for different patient populations but also that does not unduly penalize OPOs, transplant centers, and other stakeholders that are attempting to engage historically underserved patient populations. At the same time, public reporting of clearly defined, appropriately risk-adjusted metrics broken down by race or other demographic factors can be a powerful way to shed light on true system performance, monitor which interventions are most effective, and track progress on addressing inequities. In addition, a better understanding of the circumstances and reasoning behind organ discharges may help facilitate data driven solutions to reducing discards in the future. HonorBridge believes this commitment to transparency will

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help enhance trust in the organ donation and transplantation system and improve both donation and transplant rates. HonorBridge is fully committed to supporting OPTN in these efforts.

For purposes of performance reports for individual OPOs or other system actors, it would be helpful to provide a more detailed breakdown of system-wide data. For instance, the ability to disaggregate data by race and other sociodemographic factors is important, as well as the ability to compare prospective benchmarks and other detailed information so that all stakeholders (ie, OPOs, donor and transplant hospitals, and others) have a way to assess their relative performance and potential for improvement to similar entities. Regardless of the method of collecting or sharing this data, it is critical to ensure it is transparently and consistently defined as well as properly risk- adjusted.

A.1.e: Describe how to maximize these and other tools to help ensure data collection is relevant, accurate, timely, and streamlined to save critical time in the organ allocation process, minimize errors, and improve patient outcomes.

APIs, EHRs, GPS tracking, and artificial intelligence algorithms all have the potential to facilitate a faster, if not real-time, sharing of information that can significantly speed the process of sharing and comparing relevant clinical information to determine which organ and recipient would yield the best outcome. However, we come back to the same core themes of giving industry stakeholders the necessary resources and tools to implement these often-costly new technologies, as well as ensuring from the outset that these technologies are deployed as part of a coordinated implementation strategy and that each segment of this information sharing chain can appropriately relay information across technology platforms. This will require a joint effort from HHS, OPTN, OPOs, and other industry stakeholders.

B: Data Collection Activities

B.1: Describe the ideal process for developing superior performance metrics and benchmarks, including consulting with experts, subcontractors, transplant candidates, recipients, organ donors, and their families.

Metrics should be consistent across stakeholders. To reach this end goal, the critical piece is engaging stakeholders throughout the process. Importantly, this group should be broadly inclusive and not over or underrepresent the voice of any particular stakeholder. It is also critically important to engage patients and other stakeholders from diverse backgrounds so that the industry can collectively better understand and improve any systemic inequities that exist throughout the organ donation and transplantation system. The National Qualify Forum may be helpful in this regard.

B.2.a.b.c.d.e: Describe how data collection and reporting should be structured as it pertains to: a) process, outcome, and patient engagement measures; b) OPTN member performance benchmarks; c) patient and donor demographics, including race, ethnicity, language, and socioeconomic factors; d) national, regional and local performance dashboards; and e) long- term patient outcomes and relevant factors.

As with any data collection and sharing effort, alignment and consistency across the system is critical to meet a common goal. To this end, we encourage HRSA and CMS to align their metrics with OPTN metrics. For example, CMS eliminated outcomes metrics as a condition of recertification of transplant

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centers to remove disincentives to utilize organs at risk of discard, which AOPO and HonorBridge applauds. However, performance standards used by the OPTN to evaluate transplant centers for continued OPTN membership and SRTR-calculated public "star ratings" used by private payers to determine transplant center participation in payer networks, unfortunately, both continue to disincentivize increased organ acceptance or risk-taking for expanded criteria donors.

HHS should replace or modify existing metrics across agencies that may discourage its own goal of encouraging all stakeholders to work together towards maximizing every possible organ. For example, OPOs and other stakeholders should not be penalized for pursuing every potential organ with metrics that focus on unused organs or that exclude from the donor count a donor whose organs were recovered and declined by transplant centers. Ongoing development of innovative technologies (e.g. perfusion devices) that could meaningfully and rapidly change what organs are suitable for transplantation warrants collaboration to safely push boundaries rather than failing to recognize OPOs who follow CMS' directive to pursue all possible organs. CMS could achieve this by recognizing recovered organs later deemed unusable by counting them towards Medicare's organ count or separately accounting for them in some other way, provided they have a valid clinical reason that could not have been known before surgically removing the organ.

Another specific way CMS or OPTN could improve the data collection and reporting to drive improvement in the organ donation and transplantation system would be to require transplant programs to **make organ acceptance criteria publicly available**. Availability of transplant center acceptance criteria related to perfusion and other technologies that allow for repair of previously non-transplantable organs will create efficiencies and facilitate allocation of organs directly to transplant centers that have embraced the new technologies to repair previously non- transplantable organs.

Finally, it will be essential to collect information on and disaggregate outcomes data by racial, economic, and other social demographic factors with any data collection moving forward. This is the only way to understand better and address sources of inequities in the donation and transplantation system. We would particularly urge HHS and OPTN to collect demographic information for referred but not listed transplant patients. We understand that these patients face disproportionate barriers to completing the numerous screenings and meeting other criteria required for transplant. Designing interventions at this part of the transplantation process could significantly help reduce system-wide inequities. We also believe that transparently posting disaggregated outcomes data could help to build trust in the system and encourage higher donation rates among groups with hesitancies.

E. Increasing Organ Donation and Improving Procurement

The NASEM report identifies concerns with organ donation rates, including geographic and demographic variations. HHS is actively taking steps to enhance the accountability of OPOs.

E.1: Describe how changes in OPTN policies/requirements for OPOs could help reduce variations in practices and procedures, facilitate increased organ donation and improve procurement, and otherwise improve OPO performance.

As explained in detail in responses to previous questions, creating a data collection and sharing system that is transparent, consistent across all stakeholders and agencies, and one that is appropriately risk-adjusted and disaggregated by sociodemographic information is one of the most effective ways OPTN and HHS can drive system-wide improvement as well as reduce inequities.

Specifically, we would urge HHS to replace or modify metrics that dissuade OPOs or any entity from pursuing every possible organ and transplantation opportunity, provided they have appropriate documentation to support their decision-making. We also emphasize the need for metrics to be aligned within the system such that incentives for OPOs to recover organs from more complex donors are paired with metrics that incentivize programs to use these organs. HonorBridge strongly supports the OPTN's recent passage of transplant center metrics that will increase transplant center accountability for organ utilization through metrics such as organ offers acceptance rates. HonorBridge supports the OPTN developing appropriate patient waitlist metrics to address NASEM's observation that many patients receive organ offers that are declined on their behalf without their knowledge.

E.3: What additional research could contribute to improving organ procurement? How could the OPTN facilitate OPO engagement in research to improve procurement?

Right now, there are exciting, groundbreaking innovations that can turn previously unusable organs into ones that can be safely transplanted and save lives. For example, many previously unusable lungs could be rehabilitated and transplanted thanks to new advances in perfusion technology, which is an exciting possibility considering only 20-25% of donated lungs are currently transplantable. However, these new technologies can be expensive. Certain perfusion technologies can reach upwards of $70,000 per lung. Similarly, APIs, EHRs, GPS tracking, and AI algorithms can rapidly improve the speed and accuracy of data sharing that could improve organ matching. OPTN and HHS must build metrics and policies that work not just for now but that support continued growth and innovation. Beyond OPTN supporting industry-wide metrics that encourage innovation, OPTN and HRSA could work together to coordinate implementation so that these various systems can communicate with one another and facilitate cost-effective ways to speed more widespread adoption. HHS should ensure this commitment to continued innovation is shared across its agencies. This might include CMS revising its standard acquisition charge (SAC) policies to accommodate new technologies that, while expensive, could be the difference between a life saved or lost. While we believe this benefit is worth the cost, it may be more feasible to address these added costs on an ad hoc basis, particularly for less frequently transplanted organs, to ensure the system can withstand and support innovations, provided their use is appropriately justified and documented. This type of approach would allow the industry to have more stable SACs while still retaining the ability for singular cases to leverage all the tools at their disposal to pursue a lifesaving transplant.

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

Increasing equitable access is a critical component of advancing overall system improvement. Data collection, disaggregation, and transparency are vital ways to address system inequities and foster trust. In particular, we would encourage HHS and OPTN to explore potential barriers to patients in need of transplant being referred and subsequently listed for transplant, which based on our experiences and

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communications with other industry stakeholders, can disproportionately affect minority and other underserved populations as identified by NASEM and can be a substantial driver of downstream inequities across the system. In other words, if we devote resources to addressing what in some ways can be described as the root of the problem, we believe this will yield exponential positive downstream benefits.

F: Organ Usage

F.1: Describe how to support OPO performance improvement activities to decrease discarded organs and further increase the use of organs.

Aligning incentives for all stakeholders and agencies, including performance metrics, is an important way to drive system-wide improvement, including collecting data on and incentivizing improvements in addressing system inequities. For example, HHS and OPTN could recognize organs that went through all the steps of being procured but were ultimately deemed unusable provided an OPO can document that they made all the appropriate efforts to place the organ for transplant. At a minimum, performance metrics for OPOs (and other stakeholders) should not be penalized for pursuing every possible organ and transplant opportunity. HHS and OPTN should pursue reimbursement models that encourage innovation, including new technologies to recover organs previously deemed unusable, new IT infrastructure to support information flow, and real-time matching to improve the efficiency of organ matching and organ tracking. This should be complimented by reimbursement systems that keep costs low overall while retaining the ability to be dynamic and leverage technological advances. As noted previously- one such approach could be to allow OPOs to charge certain add-on fees in addition to standard acquisition charges in cases where a specific new technology or transport could result in an organ being placed and a life saved, provided appropriate documentation is provided.

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

The primary focus of the OPTN should be to reduce the use of "provisional yes" in a manner that results in late turn downs. HonorBridge strongly supports the OPTN's current work to change policies and procedures around transplant program use of "provisional yes" and the ability to turn down previously accepted organs late in the process without penalty – which often results in non-usage of organs. HonorBridge believes technology advancements, including APIs, EHRs, and AI algorithms, when used collectively, have the potential to drive rapid and meaningful improvements in the efficiency and effectiveness of organ matching. As stated previously, widespread adoption and successful implementation will rely on a coordinated approach in which the different systems can communicate and will also require the necessary investment to facilitate their widespread adoption.

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.

HonorBridge strongly supports the public reporting of data that the average consumer can reasonably understand, is provided with appropriate explanation and context, and is appropriately risk- adjusted. In particular, collecting and disaggregating outcomes data by race and sharing this information could be an

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effective way to create transparency and possibly engender trust from groups with a historical distrust of the donation or medical system. HonorBridge believes transparency at every stage of the organ donation and transplantation process is critical but would encourage more data around discrepancies in patients referred for transplant compared to those listed to assess the barriers disproportionately experienced by minority and other underserved communities.

H. Stakeholder Engagement

The NASEM report outlines how transplant centers should be required to improve their stakeholder engagement efforts and activities, specifically by making transplant candidates, transplant recipients, other affected patients, and family members aware of all organs they have been offered and by monitoring their changing health and attitudes impacting organ acceptance decisions. HRSA is soliciting feedback related to the following questions:

H.1: Describe how to support the OPTN by incorporating the NASEM report's recommendations to improve stakeholder engagement efforts and activities, including whether and how to improve patient awareness of all organs offered and by monitoring their changing health and attitudes impacting organ acceptance decisions.

HonorBridge fully supports efforts by OPTN and others to engage patients in organ acceptance decisions more effectively and introduce more transparency in the process, including monitoring and publicly posting transplant program acceptance criteria and rates. We agree that being transparent with patients throughout the process, including having difficult conversations in which they may not be the most appropriate candidate, provides transparency and builds trust within the process. We believe new technologies such as EHR integration, APIs, and AI algorithms could facilitate rapid sharing of information that would allow critical time for physicians to routinely engage patients in these decisions.

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.

HonorBridge offers our total commitment to do our part to support these efforts. An important place to start is to continue engaging a diverse group of stakeholders, including patients, in OPTN policy development and standardizing metrics across stakeholders and agencies to work in unison towards shared goals. Also important is modifying or replacing metrics that could be discouraging stakeholders from pursuing every possible organ or transplant opportunity.

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?

OPTN does a good job of engaging stakeholders but should ensure there is diversity of opinions represented in patients and donor families and confirm that the various stakeholder voices are appropriately balanced, and that one particular group is not over or under-represented. This may require targeted outreach to groups that have been less engaged in the past or are less familiar with the process, including patients, but we believe these perspectives are critical.

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We appreciate HRSA's consideration of our perspective on these important questions. Please feel free to contact me via email at dneidfeldt@honorbridge.org or at the phone number listed below. HonorBridge would welcome additional dialogue on any information provided in this Request for Information (RFI) with HRSA.

Respectfully Submitted,

Danielle Niedfeldt, RN,JD

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Ways to Strengthen and Improve the OPTN
Notice ID: HSB115C1031
Date of Issuance: April 08, 2022
Jennifer Dillon
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Jennifer Dillon

Overview

I am pleased to submit this request for information to the United States Department of Health and Human Services in support of strengthening and improving the current system of organ donation and transplantation. I first conceived of the idea of a non-profit entity that could focus on applying modern IT infrastructure and analytics to this field while I was working in an OPO. I recognized the vast opportunity for improvement in this critical segment of the healthcare landscape. I was thrilled to read the NASEM report and believe strongly in the work that needs to be undertaken to redefine the way organ procurement and transplant occurs in the Unites States. I spent almost two decades working in the field and was consistently surprised by the juxtaposition of highly complex evaluations, surgeries, and pharmacotherapies, against a backdrop of a largely manual system that included a lot of room for error, different interpretations, and lack of transparency. I witnessed several intended donations that were unable to be realized, because of human error and/or the inability of the current system to adequately store and share critical information with all stakeholders.

The intricate work required for safely procuring and transplanting an organ typically includes much more data and many more stakeholders than the average hospitalization, making the case for an equally sophisticated tool to help us manage that complexity. An additional and highly significant benefit is that it also has the potential to provide an incredible amount of data that can be used to rapidly develop evidence-based guidelines and best practices from a broader foundation of information. Transparency is required for equity and so, in order to ensure transparency in a process as complex as donation and transplantation, a network should be designed to capture every single data point. It is only through the analysis of the whole process that we can truly address all domains of equity, rigorous governance, and the development of modern operational systems.

The scale and design of the current OPTN infrastructure does not come close to leveraging today's available technology. It is fragmentary, and there are currently several independent donation and transplantation SaaS applications, some of which are beginning integrations to connect different steps in the system. However, to truly maximize the way procurement and transplant care is delivered and extract meaningful data in a secure way, an end-to-end system that connects all stakeholders and process points is required. Utilizing this approach is the most rapid route to providing equitable access to transplant as well as tracking the successes and challenges of this initiative. This is a life-cycle approach for collection of the transplant patient data, yielding information about their clinical pathway, outcomes and the graft function trends that emerge from donor characteristics that we have never previously collected. *While the information I am providing herein focuses heavily on the IT market research questions, it's clear*

that a committed investment in automation will impact every area you are seeking improvement information on.

A. **OPTN Technology - IT System**

A.1. There is no question that the complexities and safety requirements of donation and transplant require accurate data collection and thorough review. The opportunity exists to build an end-to-end technical infrastructure for the donation and transplant work in the United States via the OPTN. In today's tech environment, the best solution would be a highly available and secure cloud architecture.

A.1.a. The amount of data that a system of this kind could collect would provide unprecedented evidence of areas of success, opportunity, helping to generate practice guidelines. The modern technical solution is the creation a highly available and secure cloud-based platform using modular architecture. Modular platform architecture and agile development are crucial in the ever-evolving arena of healthcare because by its nature, agile expects changes and modularity allows easy changes. The different pieces of the donation and transplant process lend themselves perfectly to a modular approach because regulatory or clinical updates that are required by one stakeholder but not by others can easily be addressed; in addition, the efficiency that is afforded by modularity allows for parallel development, building more productivity into development work.

A.1.b. Currently, there are in-patient EMRs, EDRs that include allocation records and newer connections that are allowing for referral from hospital EHR to the OPO. A better solution is to build one platform that can deliver and receive information across the continuum of donation and transplant care. This is achievable through the development of APIs that can act as bridges between different systems (e.g., an OPTN enterprise platform and a donor hospital's EMR). Those API's will transmit data to the cloud based platform, where it can be stored in perpetuity as part of the record of the donation and resulting transplant.

A.1.c. The platform needs to access and share every point in the process beginning with facilitating automatic electronic referral of both potential donor to OPO as well as potential transplant candidates and the listing of candidates. By virtue of a unique identifier that each patient retains, the organs can be tracked through the donor management, allocation, procurement, transport, transplant, and post-transplant care for the life of the graft. The platform would have several portals for the following stakeholders:

- Providers treating patients in the community with imminent or actual end stage organ failure to "register" them as being potential transplant recipients. These referrals should be forwarded to a centralized office which can provide information on transplant and address barriers to that care, as well as track the outcomes for every referred potential

recipient. Once the patient is evaluated, the center(s) providing the evaluation will enter data on the decision and eventual path. Data around factors determining eligibility will then be available via this portal into the platform.

- Providers who have a potential donor meeting clinical triggers, who require the ability for automatic electronic referral of potential donor to OPO. This portal is meant to address referral, donor management (providing real time data to the OPO and guidance back to the referring physician). A prime example of one of the highest risk areas is the communication between acute care provider for the donor and the OPO employees regarding the donor history and status (lab values, radiologic results, medications). A platform with an API connecting to the patient's EMR would seamlessly transmit this and save time for the OPO and the provider. In addition, an analytics feature can provide graphic representation on trends in the donor's clinical status, making for fast decision making on acceptance of organs.

- Transplant providers would receive early notification, and all offers, response times, and decisions could be tracked for each center, allowing for great transparency on utilization characteristics for each center, provider, and region. The transplant providers would also enjoy access to real time tracking of the donor's status, the ability to look at various analytics around the donor and compare donor characteristics and their relation to graft function much more rapidly than they are able to currently do. At the population health level, the data collected by an end-to-end system would ultimately also provide much longer-term data on outcomes post-transplant, which can also be used to analyze the impact of donor hospital performance, clinical donation pathway, and donor characteristics on the outcomes.

- Patients who are potential recipients would access the platform via another portal when they are first referred following an imminent end-stage diagnosis and entry into the system by their provider (detailed in first bullet). Upon entry, they could be given information and resources to eliminate barriers to being listed. In addition, once listed, their clinical status while waiting would yield more data that would be contained within the same system as their donor. This offers the opportunity to develop additional future algorithms that can expand utilization. The addition of a patient portal allows for centers to rapidly deploy information on organ offers and include the patient in the decision around what is accepted on their behalf.

A.1.d. This perpetual tracking mentioned in A.1.c allows for unprecedented outcome tracking as well as the ability to retroactively link everything from referral to transplant program time and donor management techniques to recipient outcomes. An analytic platform feature can produce trending reports and allow for performance improvement areas.

A.1.e. This data can be shared for policy evaluation, interventions, and development of best practice across the field of donation and transplant. The idea of tracking both recipients and

donors on the same platform allows for a new perspective on the best areas to focus for rapid change.

A.2. A system that relies on 24/7 patient care requires the highest level of uptime achievable, thus the HRSA goal of 99.999% is achievable today. This is equal to just over 5 minutes of down time per year. The complexity of an end-to-end system does make it more challenging to achieve high availability, but it possible through certain design choices such as eliminating any potential single points of failure, building in redundancies, and having multiple instances, with replication for synching databases.

A.3. An enterprise platform that is utilized nationally and as an end-to-end system will have the natural consequences of speeding up organ allocation, allowing for real time back up offers, and tracking compliance with regulations around these behaviors. It also provides the opportunity to collect and analyze a trove of data around acceptance behaviors, and factors influencing graft function. The utilization of one system that is integrated with the EHR of the donor hospital will eliminate potential the potential errors that currently occur when a donor coordinator is entering information from the EMR into the EDR, allowing for better risk analysis and matching.

A.4. Understanding the possible points of vulnerability are important to build into the development of an OPTN platform so that any potential areas of weaknesses are fixed before they can be exploited. Integrating security into the development process instead of considering it following development is a newer best practice and critical in today's cyber environment. A solid cyber-security program incorporates the elements of risk assessment, risk mitigation and risk transferal.

A.5. Best practices suggested would include:

- CSIO (Chief Information Security Officer) is an important role that can oversee that strategic approach to development that considers security as well as the ongoing governance of risk, intelligence, investigation, policies, and programs for the system. This position should be responsible for HIPAA rules at all times and ensure the integrity of those with the system.
- The network should consider wide geographic distribution of servers to lessen the impact of downtime in one area, especially in the event of weather emergencies.
- All data should be encrypted, whether it is in transit or at rest.
- Regular risk assessments and audits should be conducted.
- A 24/7 cyber security office should be staffed by OPTN or contracted vendor.

Intent

It is my intent to supply a proposal for any project similar to what is outlined above if there is future solicitation for such work. If you have any questions regarding this information, please

reach out to Jennifer Dillon at your convenience by email at jendmph@gmail.com or by phone at (845)-554-7551.

Thank you for your consideration,

Jennifer A. Dillon

23 May 2022

Dear Administrator Johnson -

We are writing as patients in response to the [Request for Information about the nation's Organ Procurement Transplantation Network](#) with two urgent pleas:

1) Be the first Administration that runs a competitive process for the OPTN - subdividing its functions into policy and technology, with oversight reabsorbed into government; and
2) As part of that competitive process, be the first Administration to ensure that all OPTN contractors that are awarded that critical public trust are judged to be capable of acting in the patients' interests, using exceptional processes and technology to help more patients receive lifesaving organ transplants, fixing a major health inequity.

All previous HRSA-led OPTN contracting cycles have failed this standard, leading to an OPTN contractor (UNOS) that has proven to be a deeply flawed and incapable organization responsible for unconscionable patient deaths and demonstrable inequity due to gross negligence. As [Forbes](#) wrote in (1999): *"[UNOS is a] cartel"* and *"the federal monopoly that's chilling the supply of transplantable organs and letting Americans who need them die needlessly."*

For decades HRSA - and HHS more broadly - have had the risk calculus exactly wrong: assuming that patients would be harmed by a disruption of the status quo while ignoring that the status quo failures of the current OPTN contractor, and the organ procurement organizations (OPOs) it is supposed to oversee, are killing patients.

[Thirty-three Americans](#) - [disproportionately people of color](#) - are dying each day due to an unnecessary organ shortage, which is fueled by complacency and incompetence.

Imagine being a patient, or the loved one to a patient, and knowing that UNOS is [15 times](#) more likely to lose or damage an organ in transit than an airline is a suitcase.

Imagine being a patient, or the loved one to a patient, while reading that Black patients are routinely ignored for organ donation, and that OPO recovery of Black donors varies by [10-fold](#) around the country, while UNOS has done nothing to address it.

Imagine being a patient, or the loved one to a patient, and seeing that UNOS wastes resources on full-color advertisements in national press, disseminating misinformation to praise its success, while [data show](#) that rising organ donation is the result of public health tragedies such as the opioid epidemic while organ recovery rates are dismal.

Imagine being a patient, or the loved one to a patient, and knowing that while HHS has called out the [majority](#) of OPOs as [failing](#) basic standards, and the [Department of Justice and Federal Bureau of Investigations](#), the [Office of Inspector General](#), the [Senate Finance Committee](#), and [House Oversight Committee](#) have found glaring problems such as [patient deaths due to basic safety oversights](#), [misuse of Medicare dollars](#), and [outright fraud](#), [UNOS has only ever listed two OPOs as members not in good standing of the OPTN](#), and - even then - there has been no meaningful consequence.

Imagine being a patient, or the loved one to a patient, and reading unsealed emails from UNOS executives calling referring to patients as *["dumb fuck[s]"](#)* and the CEO of UNOS acknowledging that *["we [UNOS] don't have a real board"](#)*.

Now, please imagine being an Administration who ignores all of those things - all of that death and inequity - and gives the upcoming OPTN contract to the same contractor who has presided over this failing system for decades. That would be unconscionable.

We are counting on you. Please lead.

Specific answer to *RFI questions* below.

"1. Solicit feedback on ways to strengthen and improve components of the OPTN contract, including but not limited to its governance, finance, IT, data collection, policy, and operational components"

Subdivide the OPTN contract into component parts of policy and technology; open to all innovators; reabsorb OPO oversight entirely into HHS, given the failures of the OPTN to oversee other contractors.

"2. Solicit feedback on ways to incorporate the findings and recommendations of the February 2022 National Academies of Science, Engineering, and Medicine (NASEM) report titled, "Realizing the Promise of Equity in the Organ Transplantation System"

Open all OPO and OPTN contractor data to the public to ensure evidence of effective and equitable service, regardless of race/ethnicity/gender/urban-or-rural status of donors or transplant patients.

"3. Solicit feedback on incorporating lessons learned from HRSA's 2019 market research, conducted in partnership with the U.S. Digital Service, on ways the OPTN IT system should utilize modern IT architecture, such as adopting a "cloud-native," agile, and modular approach

to IT development, security, and maintenance and prioritizing 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 in order to save critical time in the organ allocation process, minimize errors, and improve patient outcomes"

Acknowledge that other organizations are much better positioned to deliver IT services on behalf of patients than UNOS; follow the [recommendations of alumni of the United States Digital Service](#) (USDS) - endorsed by [all five past Chief Technology Officers of the U.S. Department of Health and Human Services](#) - and separate out IT from the rest of the OPTN contract, opening to all innovators, and removing conflicts.

"4. Gauge interest in the upcoming RFP opportunity and feasibility of the requirements via statements of intent from prospective offerors."

Regardless of the response of this RFI, we are counting on HRSA leadership to run an extended and extensive RFP process, open via true competition to the best innovators across the country. High-functioning OPTN contractors are a national imperative, so engaging USDS procurement experts to run the process is critical for success, and for saving patients' lives.

Respectfully submitted,

Kendall Ciesemeier, liver recipient

LaQuayia Goldring, kidney recipient and kidney waiting list patient

Tonya Ingram, kidney waiting list patient

Michael Kutcher, heart recipient

Sergio Rosas, kidney recipient

Erica Sivertson, patient family member

Quin Taylor, kidney recipient

HSB115C1031, Organ Procurement and Transplantation Network (OPTN) RFI, May 05, 2022

Request for Information on Ways to Strengthen and Improve the Organ Procurement and
Transplantation Network[1] [2]
Submitted by
Monica Fox
Kidney Transplant Recipient
1222 Western Ave. Flossmoor, IL 60422

In November of 2013, I was suddenly diagnosed with End Stage Renal Disease, among other
cardiac and respiratory issues and I was immediately placed on emergency hemodialysis. As I
learned about my options, I understood that transplant was the best for me but the wait in Illinois
for a deceased donor transplant was 5 to 7 years. So, I began volunteering for Gift of Hope, my
local Organ Procurement Organization and was eventually appointed to their Advisory Council
in 2017, I still maintain that role today. In November of 2016 I received the gift of a directed
deceased donor kidney. This gift made me even more passionate and committed to raising
awareness and educating others about kidney disease, transplantation, and organ donation. I now
continue my work as the Director of Outreach and Government Relations for a local non-profit
kidney organization.

I am also the National Co-Chair of Linkages to Life, a Signature Program of The Links,
Incorporated. The Links, Incorporated is an international, not-for-profit corporation, established
in 1946. The membership consists of more than 16,000 professional women of African descent
in 299 chapters located in 41 states, the District of Columbia, the Commonwealth of the
Bahamas, and the United Kingdom.[3] It is one of the nation's oldest and largest volunteer service
organizations of extraordinary women who are committed to enriching, sustaining, and ensuring
the culture and economic survival of African Americans and other persons of African ancestry.

The Links, Incorporated focuses five facets for our service and programming, including health.
Specifically, the Health and Human Services[4] facet was established in response to the chronic
health disparities that persist in black communities and result in the decreased life expectancy of
African Americans and other people of African ancestry. Through education, advocacy, and
outreach, The Links, Incorporated initiates and supports programs that support the maintenance
of good health and the elimination of chronic health disparities in communities of color. The
Organ, Tissue and Bone Marrow Donation Awareness Signature Program, "Linkages to Life"
was established in response to the health disparities in organ, eye, and tissue (including bone
marrow) transplantation. The goal of Linkages to Life is to decrease disparities in donor
registration and transplantation in the African American community. Our members work to
increase the number of registered donors through community-based events and multi-media
awareness campaigns. In partnership with the national organization Donate Life America, we

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[1] https://www.hrsa.gov/about/news/press-releases/hrsa-releases-organ-procurement-transplantation-network-rfi, Accessed on
May 8, 2022
[2] https://sam.gov/opp/005656500e5741538ce72d57b9b3d558/view, Accessed on May 9, 2022
[3] https://linksinc.org/the-links-incorporated/, Accessed on May 19,2022
[4] https://linksinc.org/health-and-human-services/, Accessed on May 9, 2022

strive to register hundreds of donors each year through a Links, Incorporated and Donate Life America co-branded national donor registration page.

I have collaborated with both Linkages to Life National Program committee members and members of The National Minority Organ Tissue Transplant Education Program (MOTTEP)[5] on this important issue. Based on my experiences serving in this ecosystem, I offer the following comments in response to the Request for Information and hope it will be valuable in determining the final policy.

In response to E.4.[6] Increasing Organ Donation and Improving Procurement: How can HRSA best incorporate the NASEM report's recommendations on increasing equitable access to transplants?

Leveraging trusted networks to emphasize organ donation and transplant opportunities. There are many ways to connect members of the African American community to sources of information and knowledge related to organ and tissue transplantation. African American physicians are an excellent source for connecting with members of the African American community on this topic. Regardless of the physician's specialty, African American physicians as well as those serving African American patients should emphasize the benefits of organ and tissue transplantation. As discussed by MOTTEP Founder, Dr. Clive Callender at NASEM[7], the historically Black medical schools are a tremendous resource for instilling this message into minority and minority-serving physicians. The HBCU Medical Schools Collaborative and the Links, Incorporated are each positioned to underscore the need for improved equity in the field of organ donation and transplantation.

Some suggested ways to increase outreach include:
- Career exposure to STEM, medicine, health professions, and specifically inclusion of transplantation.
- Cultural and linguistically tailored materials geared to educate minority individuals about transplantation for those receiving dialysis.
- Augmented programming with HBCUs, medical schools, and schools of nursing, public health, healthcare administration, and allied health professions.
- Presence at health fairs and organ donor drives, distributing said materials focused on living and deceased organ donation; and
- Continued collaboration with service organizations, faith-based congregations, and community influencers around organ donations.

Members of the Links, Incorporated through local and national Linkages to Life programming have been engaging in several of these activities. There are numerous opportunities to expand this programming by integrating with the Services to Youth Facet[8] that includes the Links – STEMReady Signature Program and the National HBCU Initiative to encourage youth to pursue careers in the STEM fields. Additionally, I have served with

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[5] https://www.natlmottep.org/, Accessed on May 19, 2022
[6] https://sam.gov/opp/005656500e5741538ce72d57b9b3d558/view, Accessed on May 19, 2022
[7] https://www.nationalacademies.org/event/07-15-2021/a-fairer-and-more-equitable-cost-effective-and-transparent-system-of-donor-organ-procurement-allocation-and-distribution-virtual-public-listening-session, Accessed on May 19, 2022
[8] https://linksinc.org/services-to-youth/, Accessed on May 19

members of the Links, Incorporated who either work as clinical or healthcare professionals, are employed by an HBCU or both.

Recognizing the multiplying impact of poverty on social determinants of health on treatment access. Patients who are poor and African American are often rejected for surgery because transplanting them will decrease transplant outcomes. This, in turn may result in the transplant centers becoming decertified. A system must be put in place that does not penalize a transplant center for transplanting such high-risk patients. This phenomenon is important but never discussed. This practice is a form of institutionalized racism and bias that keeps socio-economically deprived patients from accessing organ and tissue transplants at rates proportionate to the prevalence of end-stage organ disease or other related injury. National and regional paired donations are performed but they rarely benefit people of color, in the way that local paired donations do. Encouraging local paired donations is more beneficial to people of color; and is an option that should be incentivized and encourage.

G.1. OPTN Operations and Policy Development Improvements: 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.

Staffing for cultural sensitivity and to minimize biases is an area of opportunity. Representation of culturally sensitive individuals and organizations at every level of OPTN operations and policy development is necessary to transform the current system for attaining health equity. Specifically, priority in notification should be given to organizations of color including Historically Black Colleges and Universities, Black Greek letter sororities and fraternities, and other Black services organizations and programs. Priority in funding should be given to such organizations as well as programs led by people of color. Additionally, specific minimum allocations of funding proportional to the need for transplantation (or the incidence of end-stage disease and organ failure) should be allocated in each area related to organ transplantation. Input from these individuals and organizations must also be integrated in the writing of RFPs and the review of RFP submissions.

Incentivizing equitable outcomes through oversight. Individuals from diverse backgrounds must have a seat at the table to participate in the authority, finance, and control of OPTN operations and policy development, to change the paradigm from health disparity to true health equity. This means there must be more oversight of the OPOs to require the presence of diverse representation at the highest administrative levels. When negotiating collaborations between the Links, Incorporated and potential partner health organizations, we strive to leverage greater representation on their decision-making boards. This strategy has been met with varying results. OPO compliance in this regard must be monitored. In addition, there must be mentoring, opportunities and funding for education, training, and fellowships to allow for the advancement of persons of color to these positions.

G. 4. OPTN Operations and Policy Development Improvements: What other improvements to OPTN operations and policy development processes can and/or should be incorporated into the OPTN contact?

Increasing the ethnic diversity of OPO executive leadership is an opportunity. There are 57 OPOs very few of these OPOs have persons of color at the highest administrative level (CEO or Chairperson of the Board of Directors)[9]. It is important therefore to increase the number of CEOs and Board Chairs who are people of color (African American, Hispanic or Latino, Asian, Pacific Islander or Native American). Nearly 60% of people waiting for transplant are people of color. Systems should be put in place to eradicate explicit and implicit exclusionary hiring practices and monitor OPO compliance. Increasing the proportion of individuals from diverse backgrounds in leadership positions to better reflect the ethnic diversity of the community of patients being served by the OPO is paramount. Currently, oversight to combat against the current level of executive disparity is completely lacking and desperately needed as indicated by the statistics previously cited.

Living donation policy is an area of opportunity for African Americans. We know the living donations among African Americans are significantly below that of whites, underscoring the need for augmented education of living donation opportunities. In 2020, 16.4 percent of blacks were living donors as compared to 33.4 percent of white living donors[10]. Instances of African Americans who receive a "second chance at life" through organ donation are celebrated in our community in churches, at family gatherings, in the workplace, and in our social and service organizations. It is important to peel back the crucial steps to allow these donations and transplants to happen, which begins with increasing the education outreach to minority communities about the benefits of living donation and simultaneously speaking to the fears, myths, and hesitancy associated with being a living donor. Overcoming this obstacle is best addressed with recipients and trusted community-based organizations delivering the information, not the transplant centers and organ procurement organizations. The education should be multi-generational and culturally tailored, addressing the most pressing concerns and highlighting the successes in minority communities. The Linkages to Life National Program Committee has increased its awareness and advocacy specifically around living donation in the 2021-2022 program year with several recorded webinars on the topic. These efforts by The Links, Incorporated or other historically Black service and civic organizations may often be superior to those of the transplant centers and OPOs to address this need. The Links, Incorporated was able to produce culturally sensitive content to meet patients in their communities. The data also shows that non-whites have lower rates of pre-emptive kidney transplantation, especially for living donation. It is important to highlight these disparities and use fund opportunities to educate our communities of color. While serving as National Co-Chair for Linkages to Life, I've learned that people cannot properly advocate for themselves if they lack awareness of all treatment options available. Our campaigns work to increase this awareness.

H.1. 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

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[9] https://aopo.org/find-your-opo/, Accessed May 19, 2022
[10] https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=27, Accessed May 19, 2022

organs they have been offered and by monitoring their changing health and attitudes impacting organ acceptance decisions.

I believe that education while patients are waiting is significantly important. If patients are better educated about the options that may be presented to them, the pros and cons of the offers, then they will be prepared to make educated versus emotional decisions when the call comes.

H.2-3 Stakeholder Engagement: 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. How can and/or should the contract incorporate new or better approaches for including stakeholders in a shared decision model for organ acceptance?

Bringing diverse voices to the table early and through the organ procurement process is a tremendous opportunity for system improvement. Stakeholders including transplant recipients, prior living donors and families members of deceased donors should be engaged early, often and meaningfully. Stakeholders from ethnically diverse backgrounds should be included in the oversight bodies referenced earlier in these comments. Executive search committees or contracted executive search firms should either include stakeholders from ethnically diverse backgrounds or specialize in diversity, equity and inclusion. Finally, through past experiences serving on stakeholder advisory boards for research funded by Patient Centered Outcomes Research Institute (PCORI), I consider them to have a portfolio of best practices[11] in engagement strategies. There is significant value in OPTN members together with a more diverse cross-section of stakeholders examine these engagement techniques and employ them at numerous levels of planning, policymaking and operations, including the development of a shared decision-making model for organ acceptance. If serving patients in need of organ and tissue transplantation is the goal, OPTN members will transform stakeholder engagement practices and where appropriate will hone engagement relationships to meaningful collaboration and shared leadership to attain more inclusive health outcomes.

Each of these areas of increased emphasis must be met with thoughtful planning and financial resources. Critical to the proper planning is the involvement of organizations and individuals such as ours.

Thank you for considering this feedback.

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[11] https://www.pcori.org/engagement/value-engagement, Accessed May 19, 2022

Health Resources and Services Administration [HRSA] Request for Information

HHS/HRSA/OAMP
5600 Fishers Lane
Rockville, Maryland 20857-5600
Title: Organ Procurement and Transplantation Network (OPTN)
NAICS Code: 541611
Incumbent: United Network for Organ Sharing (UNOS)
Date of Issuance: April 8, 2022
Point of Contact: NInazawa@hrsa.gov

National Kidney Foundation
30 E. 33rd Street
New York, NY 10016
Point of Contact: Morgan Reid, Director, Transplant Policy & Strategy
Email: Morgan.Reid@Kidney.org
Phone: 908-247-5238

![National Kidney Foundation logo](NATIONAL KIDNEY FOUNDATION®)

May 23, 2022

The Honorable Carole Johnson
Administrator
Health Resources and Health Administration (HRSA)
5600 Fishers Lane
Rockville, Maryland 20857-5600

Dear Administrator Johnson,

The National Kidney Foundation (NKF) appreciates the opportunity to comment on the Health Resources and Services Administration (HRSA) Request for Information (RFI) regarding the Organ Procurement and Transplant Network (OPTN).

We respectfully submit our comments on behalf of the 37 million individuals, 1 in 7 adults, in the United States estimated to have chronic kidney disease (CKD).[1] The prevalence of kidney failure is expected to increase dramatically, possibly exceeding one million people who may need access to the transplant waitlist by 2030.[2] There are not enough deceased or living donor organs to meet current or future needs creating a public health emergency in need of immediate attention. Although 24,669 people received a kidney transplant in 2021, far too many are still waiting, never access the transplant waitlist, or never learn that a transplant is an option.

NKF appreciates HRSA's efforts to improve the organ and transplant system and optimize the OPTN contract to ensure that each component maximizes organ donation and transplantation. We champion the primary objectives outlined in the RFI for the improvement of the OPTN contract:

1. Increase accountability in OPTN operations, including board governance, financial structures, data quality transparency, and policy development;
2. Enhance the usability and performance of the OPTN IT system and related tools; and
3. Strengthen equity, access, and transparency in the organ donation, allocation, procurement, and transplantation process.

Our comments follow the suggested format requested in the RFI.

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[1] Centers for Disease Control and Prevention. *Chronic Kidney Disease in the United States, 2021*. Centers for Disease Control and Prevention; 2021.

[2] McCullough KP, Morgenstern H, Saran R, Herman WH, Robinson BM. Projecting ESRD Incidence and Prevalence in the United States through 2030. J Am Soc Nephrol. 2019 Jan;30(1):127-135. doi: 10.1681/ASN.2018050531. Epub 2018 Dec 17. PMID: 30559143; PMCID: PMC6317596.

Comments:

A. OPTN Technology—IT System

1a. We believe that HRSA should create two separate contracts for the Information Technology (IT) Infrastructure and one for other OPTN priorities. The current IT architecture is outdated and fraught with inefficiencies that impair organ donation and transplantation. The OPTN contractor should not own any technology associated with the organ donation process, including donor management and allocating organs for transplant. Separating the two contracts allows OPTN to leverage significant improvements in information technology and mitigate the risk of disruption to the donation and transplant process. Consultation with IT experts is germane to enhance data collection, organ allocation, transplantation, and usability.

1b. We strongly support the need for data transparency and implementation of information technology that facilitates these changes, such as application programming interfaces. The current OPTN contractor has not kept pace with the rapid changes in healthcare IT standards, including implementing fast healthcare information resources (FHIR) across EMRs, standard data models, or a robust and transparent data dictionary for the data captured from transplant centers or OPOs.

1d. We believe that it is critical to establish meaningful collaborations with EMR providers, clinical informaticians, and transplant experts to identify performance improvement areas for data collecting and reporting and reduce inequities within the transplant ecosystem.

3. We believe that data transparency of organ donor hospitals, OPOs, and transplant centers must be priotitized in order to improve organ allocation processes. The lack of data transparency creates significant barriers to care and inequities for the entire population that could benefit from transplantation. Data collected from OPOs and transplant centers are out of date, unaudited, incomplete, and self-reported, making it impossible to develop modern quality measures, specifically for steps in the pre-transplant process. Patients need real-time data, or as close to real-time as possible, to make informed decisions about transplantation. The current delay in data does not accurately portray the current state of organ donation and transplantation.

The transplant waitlist is poorly maintained because of inconsistent communication between transplant centers, dialysis facilities, and patients or caregivers due to the current antiquated IT architecture. Patients on the waitlist are frequently unaware of their waitlist status—active or inactive-- and receive little or no information from the transplant centers. This absence of communication among patients, their dialysis facilities, and transplant centers represents a failure of the OPTN to improve communication between various stakeholders in transplantation, resulting in inefficiencies of allocation and the perpetuation of silos of care. Patients face life-threatening consequences because the IT infrastructure stymies efficient

allocation. For example, nearly one in five kidneys is offered to a deceased person still on the waitlist because the transplant center is unaware that the patient has died, and deceased candidates receive a median of 4 organ offers before being removed from the waitlist.[3]

HRSA should also require the OPTN contractor to inform patients of the criteria used by transplant centers for accepting offered organs. Transplant centers do not share these criteria with patients. Educating patients on this information would empower patients to choose which center would suit them best. Bypass filters are used by transplant centers to automatically screen-out offered kidneys from donors with specific clinical characteristics. For example, donor age criteria can be set such that centers do not receive national organ offers from donors above a pre-specified age. While these filters were initially designed to help accelerate allocation, their use needs to be monitored and researched by CMS to determine the impact.[4] These bypass criteria often can result in dramatic changes in the probability of transplantation because it shrinks the pool of donor organs to which patients at a given transplant center have access.

Prioritize quality assurance efforts and utilize an IT platform that fosters improved data collection for better patient outcomes. Practices such as out-of-sequence placements, list diving, and the decline of many organ offers also contribute to inefficiency and exacerbate inequities in the transplant system. HRSA must ensure that prospective contractors construct algorithms to combat these practices and provide a more efficient and equitable system in future contracts.

Finally, we were deeply troubled by OPTN's recent announcement about the addition of 35,000 verified deaths to the standard analytical files. This adjustment illustrates the failure of the current system to capture data from a range of sources and cross-reference it to ensure maximum efficiency. Further, OPTN's announcement lacked urgency or even recognition of the gravity of data inconsistencies and their implications for transplantation-related research. This incident reinforces the critical need for transparency and the need to separate the IT contract from other OPTN requirements to ensure that patients and the system benefit from the cutting-edge technologies that can eliminate these inconsistencies and inefficiencies. HRSA must also determine how death data is collected and verified with the OPTN contractor and CMS to mitigate an error of this magnitude in the future.

B. Data Collection Activities

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[3] Husain SA, Winterhalter FS, Mohan S. Kidney transplant offers to deceased candidates. Am J Transplant. 2018 Nov;18(11):2836-2837.
[4] King KL, Husain SA, Mohan S. Trends in Transplantation Center Use of Kidneys From Deceased Donors With Positive Hepatitis C Virus Nucleic Acid Testing. Am J Kidney Dis. 2020 Nov;76(5):743-746.

1. We support HRSA's goal to develop performance metrics and standards for organ donation, allocation, recovery, and transplant. We applaud HRSA in its desire to engage with patients and donor families to learn about the measures they value and firmly advocate for the inclusion of patient and donor family voices in each data development phase. It cannot be stressed enough: data transparency needs to be enforced among donor hospitals, organ procurement organizations, and transplant centers. Without honest data-sharing compliance from the stakeholders within the transplant ecosystem, the process remains fractured, and patients suffer. An innovative information technology infrastructure would facilitate seamless data collection, sharing, and reporting across different platforms used by donor hospitals, OPOs, and transplant centers.

Patients treasure the opportunity to receive a transplant and often inquire about the efficiency and effectiveness of the process itself. Unfortunately, current data collection from transplant centers is insufficient to address patients' concerns. We encourage the OPTN contractor to collect information that is most relevant to patients, including the following data points:

- Percentage of referrals who receive an evaluation after referral
- Time from evaluation to listing
- 1-year health-related quality of life post-transplant
- Long-term graft survival

Improved data collection is a critical component of meaningful measurement. Lastly, performance standards should align with financial incentives across all stakeholders overseeing and regulating the transplant system to encourage more patients to transplant.

2a. Current data capture systems are antiquated and need to be updated. These data systems do not currently facilitate data validation, quality checks, meaningful feedback, or avoid duplication. There is also a need for a robust and well-maintained data dictionary.

Additionally, require the OPTN contractor to establish and monitor process and outcome measures. The current inability of the MPSC to be able to generate meaningful reports on the number of out-of-sequence exceptions and other violations/exceptions is a concerning example of the limitations of the current vendor's oversight capabilities.

2d. Data reports, summaries, and infographics need to be formatted to be consumer-friendly. Data reporting should be patient-centered and simple, omitting medical or statistical jargon so that patients can easily make informed decisions about a transplant as the next possible phase in their care. Patients should not have to decipher the same data as clinicians and statisticians to decide if a transplant is the best treatment.

2e. The OPTN contractor should collect data on social determinants of health and data on patients denied an opportunity to be waitlisted, along with the reason, to better understand and determine the need. The contractor can collect this data by using links to other public and

proprietary datasets to monitor the OPTN. These data linkages need to be robust, recurrent and used to develop policies that would support equity in the allocation system and the development of interventions necessary to improve access to transplantation.

C. OPTN Finances

1b. Access to data is critical to maximizing every organ donation and transplant opportunity. Currently, the OPTN contractor charges a fee for specific data reports and visualizations needed by transplant centers and OPOs to understand the impact of the allocation system on organ offers, organ acceptance, and bypass filters. Requiring payment to access process data measures is a significant hindrance to transplantation and should be prohibited.

1c. The OPTN data portal is challenging because it is difficult to understand and identify actionable information, and as previously noted, the OPTN contractor assesses a fee to access this data. We would urge the contractor to create data reports that are easy to decipher and at no cost to clinical stakeholders who need to access this information to optimize patient care.

1d. The introduction of quality measures that encourage transplant referral and waitlisting at the dialysis facility level will likely increase the number of patients referred to transplant centers. An unintended consequence is a potential change in transplant waitlisting behavior and a drastic increase in the number of individuals listed as inactive. The conflict that arises with this process is thousands of patients become waitlisted without the hope of being evaluated promptly, all while OPTN continues to receive waitlist fees. NKF would urge HRSA to monitor this situation closely and intervene quickly to address and resolve this practice if it occurs.

2. Any entity that holds the OPTN contract must create, maintain and produce a detailed accounting record of all funds received and their use. Develop public confidence by transparently sharing all money received and its use to operate with accountability.

D. OPTN Governance

1. NKF recommends decoupling the OPTN board from the UNOS board. These two entities should be separate and members of one board should be prohibited from serving on another. We also recommend that OPTN increase racial, ethnic, professional, and gender diversity on the boards and committees responsible for developing policies and making these voices heard. HRSA should survey the OPTN board and committee members on their experience serving OPTN to assess performance and identify opportunities to ensure that the boards are representative, effective, and high functioning.

Member selection for the OPTN board, the board of the OPTN contractor, and committees should be transparent and ensure that prospective members have the requisite expertise and continuous participation engagement. Consider including external voices on the board and various OPTN committees. Public health experts with experience in bioinformatics and

epidemiology, patient safety specialists, and other healthcare professional thought leaders may offer innovative solutions and changes to improve the organ procurement and transplant system.

2. We believe that a commitment to transparency dictates that all board and committee members must disclose any paid conflict of interest, such as physicians paid as medical directors for their local OPO and examples of the like. Further, the contractor must have a process to ensure that members are not involved in conflicting relationships. Members must recuse themselves when voting on issues with a conflict of interest.

3. The current OPTN regions would be equitable either in terms of patients served, population served, or volume of transplants and should no longer be used to estimate representation.

4. We reiterate our request that the contract requires the vendor to share its process for determining how volunteers are selected and assigned. The current governance of the OPTN contractor is opaque, with little clarity around the member selection process. There has been considerable turnover among UNOS staff, resulting in limited institutional memory and transparency and little desire to change the status quo. Most committees have limited relevant expertise to address the questions, often unaware of pressing issues. We strongly advise that members be vetted to assure they have the necessary knowledge and experience to serve on key committees and boards. Lastly, seek external expertise when it is not available in the committee.

E. <u>Increasing Organ Donation and Improving Procurement</u>

1a. Organ Procurement Organizations are the only stakeholders responsible for recovering deceased organs in the transplant ecosystem. The OPTN contractor should enforce strict oversight and accountability of OPOs to ensure every opportunity for organ donation is optimized. NKF recommends the following strategies to improve OPO performance:

Immediate data transparency—OPOs collect organ donation data that is inaccessible to the public. As an entity whose sole purpose is to serve the public, it is a disservice to patients in need of transplantation, organ donors, and donor families who make the selfless decision to donate their loved one's organs. The following metrics (at a minimum), currently captured by all OPOs, should be made readily available:

- Number of organ referrals
- Number of brain dead donors
- Number of DCD donors
- Missed organ referrals
- Conversion rate
- Approach rate

- Consent rate
- Percentage of first-person consent

Regulatory consequences for OPOs failing to respond timely to donor hospitals to evaluate potential organ donors – When donor hospitals make a referral for a patient who is not automatically clinically ruled out as an organ donor, the OPTN contractor should require OPOs to make every effort to elicit a timely onsite response for an evaluation.

Regulatory consequences for missed organ referrals – Donor hospitals should face repercussions for substandard missed referral rates. When a hospital fails to notify an OPO of a potential organ donor, critically ill patients continue to wait for a life-saving organ transplant. Further, families lose the opportunity to continue the legacy of their loved ones through the selfless gift of organ donation, and the wishes of the person who has designated their desire to donate their organs are unfairly forfeited.

Donor hospital EHR clinical trigger – Timely communication between the donor hospital and the OPO is crucial to the organ donation process. The OPTN contractor should ensure that donor hospitals deploy tools that maximize donation and facilitate prompt referral to the OPO, such as electronic clinical triggers in the EHR that prompt clinical staff to call the OPO when a provider documents specific patient criteria. For example, if a nurse charts that a patient is intubated and documents a loss of two cranial nerve reflexes or has a Glasgow Coma Scale of 5 or less, a prompt should appear notifying the nurse to call the OPO. The responsibility to refer the patient to the OPO lies with the hospital staff.

Staffing to reflect the DSA community—The OPTN contractor must call for OPOs to recruit, hire, and train staff representing the diverse racial, ethnic, and cultural communities they serve. Diversity, equity, and inclusion should be reflected across all departments within the OPO, including executive leadership, OPO professional staff, the clinical teams that interface with donor hospitals, and the teams that work with potential donor families.

2. We believe that the OPTN contractor should mandate OPO compliance with research efforts to examine and analyze practices that could improve donation, recovery, and allocation of organs. With the continuous growth of the transplant waitlist, research initiatives should include increasing the utilization of organs, decreasing organ discards, data transparency, and health equity. Please note the following suggestions for research to enhance the donation and transplant process:

Transportation: Organ transportation delays and inefficiencies have life-threatening consequences for patients on the waitlist. It is unacceptable that donated organs are discarded due to transportation inefficiencies after donors and donor families have made the selfless decision to donate organs. NKF implores HRSA, in collaboration with the OPTN contractor,

to examine challenges in the transportation system and identify policies, best practices, and strategies to mitigate cold ischemia time that results in organ discards.[5]

Equity: Reducing disparities and ensuring that each donor and their family are respectfully considered and supported during the donation process.[6]

Consent training: Strengthen the skills of OPO staff responsible for approaching families for organ donation, emphasizing donor family communication best practices, implicit bias, racial equity, and trauma-informed care.

Donor management: Assess and improve clinical knowledge to maximize organ recruitment and transplantation, including perfusing organs and donation outcomes after cardiac death (DCD) and brain dead (BD) donors and organs.

Data reporting: Optimize data collection and reporting for quality assurance and performance improvement to be shared transparently with the public.

4. Education and outreach are critical components of overcoming every challenge in kidney care, including racial and ethnic bias in organ donation. The OPTN contractor could implement a multipronged organ donation and transplantation education initiative, because it has a vital role in incentivizing OPOs to build trust and awareness in historically underserved populations and communities (including racially and ethnically diverse communities).

First, OPO staff must receive consistent education on cultural sensitivity, empathy, and consent training. Obtaining consent for donation is vital to increasing the number of organs available for transplantation. OPOs have a crucial role in educating the public on organ donation and reaching out to underserved populations to address concerns or misconceptions regarding organ donation. *NKF strongly opposes race-based adjustments to the OPO metrics, which perpetuate these inequities rather than encourage OPOs to improve their service to underserved communities.

Second, OPOs must engage in community outreach and build partnerships with stakeholders and religious leaders or hospital clergy to provide family support and spiritual guidance to potential donor families. Investing in relationships within the community and providing education on organ donation and transplantation could increase authorization rates and health literacy initiatives that educate underserved, rural, and diverse communities on organ donation, living donation, and transplantation.

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[5] Cooper M, Formica R, Friedewald J, et al. Report of National Kidney Foundation Consensus Conference to Decrease Kidney Discards. *Clin Transplant*. 2019;33(1):e13419. doi:10.1111/ctr.13419

[6] Guadagnoli, E., McNamara, P., Evanisko, M. J., Beasley, C., Callender, C. O., & Poretsky, A. (1999). The influence of race on approaching families for organ donation and their decision to donate. *American journal of public health*, *89*(2), 244–247. https://doi.org/10.2105/ajph.89.2.244

Third, the OPTN contractor should consider how regulatory policies can encourage OPOs to adopt best practices to overcome the effect of bias and prejudice on the ability of families to donate their loved one's organs. Examples include hiring staff representing the communities they serve and implementing frequent training on cultural sensitivity, diversity, and inclusion to improve conversations with non-White populations about donation. Prejudice and implicit bias are common elements of OPO practice. Beliefs that people of color will not donate perpetuate patterns where hospitals are less likely to refer prospective donors to the OPO. In studies, Black/African American families have declined organ donation because of insufficient time to process and discuss important issues and a lack of sensitivity and empathy during the approach process.[7] Research has also found that OPOs are more likely to approach White families over Black/African American families.[8]

Fourth, require transparent data sharing to understand how race, ethnicity, and disability impact the success of organ procurement and transplant. Transparent, verifiable, and publicly available process data, including approach, consent/authorization, and conversion rates, broken down into specific demographics (ethnicity, religion, age, location, etc.), are necessary to address and resolve disparities.

Lastly, decertify OPOs that consistently underperform, primarily due to a lack of engagement with communities of color. Donor families find organ donation to help with grief, knowing the legacy of their loved ones lives on through the selfless act of organ donation. Yet, this is often not afforded to Black families because OPOs approach them at lower rates than white families. Better data collection and reporting will reveal these inequities and incentivize performance improvement by OPOs.

F. Organ Use

1. NKF recommends a series of activities that will improve efficiency and minimize the number of organ discards:

Place urgent attention on the role of organ transportation in organ discards. Changes in the allocation system have resulted in more organs flying across the nation than ever. Dependence on commercial flights presents several challenges for transplantation that contribute to avoidable discards. Organ recovery usually occurs in the late hours when donor hospital operating rooms are less busy and when there are fewer commercial flights. Every hour a recovered organ waits to be transplanted, cold ischemia time (CIT) increases, decreasing the likelihood of transplantation. Federal regulations no longer allow organs to fly

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[7] Siminoff, L.A., Alolod, G.P., Gardiner, H.M. et al. A Comparison of the Content and Quality of Organ Donation Discussions with African American Families Who Authorize and Refuse Donation. J. Racial and Ethnic Health Disparities 8, 485–493 (2021). https://doi.org/10.1007/s40615-020-00806-7

[8] Siminoff, Laura A. PhD; Lawrence, Renee H. PhD; Arnold, Robert M. MD Comparison of black and white families' experiences and perceptions regarding organ donation requests, Critical Care Medicine: January 2003 - Volume 31 - Issue 1 - p 146-151

in the cockpit with the pilot, only as cargo, which exacerbates CIT. Kidneys with too much CIT are discarded and represent a potential life lost on the waitlist. Deceased kidneys are a scarce resource; inefficiencies in air travel should never be a reason for organ discard.

Improve the protracted process by which the current OPTN contractor commits resources to introduce changes in the IT systems. For example, the process of implementing new organ decline codes took nearly five years. This extensive delay caused by the lack of adequate IT resources highlights a problem that stems from the need to invest in modern IT infrastructure and the absence of a desire to invest proactively in the system. A state-of-the-art IT infrastructure is imperative to implement changes quickly to optimize an efficient organ allocation system.

Increase living donation and deceased donation to contribute to closing the gap between the supply of kidneys and the demand for them. NKF supports both the *Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs* and *Removing Financial Disincentives to Living Organ Donation* final rule as significant steps in increasing the organ supply. We encourage iterations on the OPO final rule through sub-regulatory guidance and further regulatory action to incentivize consistently high-quality organ procurement practices.

HRSA must also maximize its authority under the Reimbursement of Travel and Subsistence Expenses Incurred Toward Living Organ Donation Program, administered by the National Living Donor Assistance Center (NLDAC), to raise the income eligibility threshold for assistance to, at minimum, 500% of HHS Federal Poverty Guidelines.

Prioritize efforts on improving kidney paired donation (KPD) to address the organ shortage and maximize the benefit of each living donor organ. Relatively little has been done to facilitate KPD. At a minimum, further investment in evolution and policymaking around the UNOS Kidney Paired Donation Pilot Project is warranted.

2. The OPTN contractor should consider the extent to which regulation, quality, and payment policies, and quality improvement initiatives can incentivize OPO and transplant center practices that could reduce discards as recommended by NKF's 2019 Discard Consensus Conference:[9]

- Begin the organ allocation process earlier in the donor evaluation phase.
- Improve communication between OPO and transplant surgeons--The Kidney Allocation System relies on an electronic communication platform, DonorNet, that limits verbal communication between the OPO and transplant center. The exclusive use of DonorNet without collaborative conversations between the OPO and transplant center contributes to decreased organ utilization.

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[9] Cooper M, Formica R, Friedewald J, et al. Report of National Kidney Foundation Consensus Conference to Decrease Kidney Discards. *Clin Transplant*. 2019;33(1):e13419. doi:10.1111/ctr.13419

- Accelerate virtual crossmatching and send early prospective crossmatch samples.
- Require more frequent QAPI meetings with OPOs and transplant centers to review and analyze data and investigate root causes for low organ transplant rates.
- Secure "local backups" to mitigate the possibility of a kidney discard.
- Increased patient-centricity around organ offers may also contribute to reduced kidney discards.
- The OPTN contractor should consider creating an algorithm that recommends which patient group receives specific organ offers (ex., determine which patient group would benefit most from a particular organ offer to mitigate "list diving" and reduce organ discards)

Patients have an essential role in improving risk aversion and reducing discards by making their wishes clear to their care teams. Patients are often less risk-averse than their surgeons and centers. As they spend more time on the waitlist, they may accept an imperfect organ that still confers clinical value compared to dialysis. Transplant centers, nephrologists, and dialysis facilities must regularly consult patients to assess and refine their transplant goals. Increasing utilization is closely linked to reimbursement, transparency, and improved organ acceptance practices. However, it begins with a patient-centered approach to understanding the waitlisted patient's goals and preferences. Transplant programs should also promote shared decision-making with inactive waitlist patients.

3. NKF is troubled by the lack of transparency given to patients regarding organ offers declined on their behalf. Patients deserve to be active participants in their healthcare, with decision-making authority. While transplant centers are not the sole provider of direct patient care for waitlisted patients, they are responsible for communicating with patients, ensuring readiness for transplant, and educating patients about organ donation. Remaining active on the list and knowing activation status and their time on the waitlist is paramount for patients. We urge you to develop a measure that captures the percentage of waitlisted inactive patients and why they have become inactive. The following metrics are also performance standards that we would like OPTN to create to improve patient-centricity and equity in the transplant process:

- Percent of referred patients who completed the transplant evaluation
- Average time from referral to evaluation
- Average time from evaluation to listing
- Percent of patients placed on the transplant waitlist
- Breakdown of demographics and socioeconomic status of these data

The pre-transplant process is unclear; patients and providers currently have no insight into where patients are in the transplant process because communication from the transplant center to the referring provider is often slim or nonexistent. There is frequently no information on what is pending, the barriers patients face to complete an evaluation, or

why patients are accepted/denied waitlisting or inactivated/activated at any time point. We would urge HRSA to investigate this concern as it impedes patient-centricity and creates hurdles to transplant access.

G. OPTN Operations and Policy Development Improvements

1. We believe that it is imperative to increase diversity, equity, and inclusion in OPTN operations and governance. It is short-sighted of the OPTN to continue to hear from the same voices. Marginalized and underrepresented groups are left out of policymaking and decisions that impact their lives and well-being. In the same way that we recommend OPOs diversify their staff to reflect their communities, we implore the OPTN contractor to do the same for their board and committees. We also encourage the contractor to collaborate with the National Quality Forum (NQF) and the National Academy of Public Administration for their federal program leadership expertise and stakeholder collaboration.

H. Stakeholder Engagement

1. We ask HRSA to consider the following feedback from our patient advocates regarding their transplant experience that can affect awareness of organ offers/acceptance:

Improve communication – "Ensure that transplant centers have adequate resources and staff to support their patients with consistent and effective communication. Patients deserve to know when they are listed for transplant and the actions they can take to maintain optimal health on the waitlist. Centers must alert patients of their waitlist status when they become listed and made inactive or delisted. Physicians, Advanced Practice Providers, Nurses, Transplant Coordinators, Social Workers, and other transplant center staff that interface with patients should adequately and compassionately share the reasons for an inactive status with patients and why they have been delisted."

Include the Patient as Part of the Care Team – "Clear and timely communication between the transplant team and patients can promote shared decision-making should be afforded to each patient. Transplant centers have complained about patient compliance; if transplant centers want improved cooperation from patients, they should prioritize shared decision-making.

Promote Cultural Sensitivity – "Clinical and non-clinical transplant center staff must practice cultural sensitivity and inclusivity to decrease patients' risk of falling through the cracks due to language barriers and cultural misunderstandings. Transplant centers need appropriate communication strategies and mechanisms to relay messages with non-English speaking patients to prevent patient isolation and poor outcomes."

Address Patients' Mental and Emotional Well-being – "Organ failure is scary. Dialysis creates added stress and anxiety. Dialysis patients face a variety of challenges—healthcare complications, lethargy (too tired to participate in common daily activities), lack of social support, and depression, to name a few. There is a general fear that patients experience when faced with organ failure and the prospect of their mortality. Organ donation and transplant surgery are overwhelming to think about. Transplant centers could assuage these feelings by communicating with their patients in as close to real-time as possible about what to expect during the process (not just once, but reminders throughout would be helpful)."

2. The NASEM report recommends each stakeholder in the organ donation and transplant system be accountable for every patent in need of transplantation, including those on the waitlist and those who are not. NKF strongly agrees. Justice, fairness, equity, and transparency are values that our organ donation and transplant system need and patients deserve. The NASEM report highlights trustworthiness, which OPOs, the Organ Procurement and Transplant Network (OPTN), and federal agencies must uphold to influence public confidence in our organ donation and transplant system. Regardless of demographic characteristics or socioeconomic status, every person should have the right to access the national transplant waitlist. Organ failure patients desperately need an equitable transplant ecosystem.

3. We would reiterate the need to amplify patient-centricity. Prioritize providing adequate education to patients that allow informed decision-making about their health care, including creating and implementing aids and tools to facilitate increased organ donation and transplant understanding and patient-provider collaboration.

The National Kidney Foundation (NKF) would like to thank the Health Resources and Service Administration again for the opportunity to comment on the Request for Information regarding the Organ Procurement and Transplant Network. We welcome any questions about our recommendations and collaboration to improve the American organ donation and transplant system. Please contact Morgan Reid, Director of Transplant Policy and Strategy (morgan.reid@kidney.org). Sincerely,

Kevin Longino
CEO and transplant patient

Paul Palevsky, MD
President

COVER PAGE

1. NAICS Code: 541611
   Title: Organ Procurement and Transplantation Network (OPTN)
   Date of issuance: May 05, 2022 04:33 pm EDT

2. Name: Colleen O'Donnell Flores, MHA, Nabil Dagher, MD

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4. Point of Contact, Email address: Colleen Flores cflores6@northwell.edu

5. Agency/Office: HHS/HRSA/OAMP

Responses to Questions

Section H.1: Stakeholder Engagement

The Northwell Health Transplant Center supports the effort to improve patient awareness of all organs they have been offered via a patient portal, ideally within UNet. A transplant candidate, waiting for a lifesaving organ offer, should have the ability to login into a patient portal to access a patient report with relevant information about his/her status on the list. This report, if based within UNet, should be standardized, patient literate and accessible at all times and when convenient to the patient. The type of report could include, a candidate's listing date, organs offered, denial codes and/or anticipated wait time. A candidate should have accessed to this information at his/her convenience. In addition, patients could also receive an annual statement from the transplant center, indicating a summary of the patient's experience that year and/or next steps to achieve a match.

This design is akin to a banking customer who logs in to see their accounts on demand, but also receives a statement, annually, from the bank with a summary of activity. Programs may discuss the annual report with patients during their waitlist management update.

In addition to organs offered, candidates in a prolonged inactive phase should similarly be informed of their status. Candidates waiting for a transplant may be placed in a UNet 'inactive status' for any number of reasons including illness, financial reasons and/or while awaiting test results, to name a few. Candidates in this inactive status are unable to receive organ offers.

We believe candidates that have remained in inactive status for an extended period of time (i.e. greater than 120 days) should receive formal notification by the transplant programs and/or a UNet report - possibly via a patient portal. This data is readily available and patients have a right to formally know if they are not being considered for lifesaving organs over an extended period of time. There is currently no regulatory requirement to inform patients of a prolonged inactive status, other than in circumstances of prolonged programmatic closure.

Section H.2: Stakeholder Engagement

There are revisions within the OPTN that can be made to advance equity, access and transparency in organ transplantation. We know that the racial makeup of our current transplant waitlists do not match the racial makeup of the disease. We need additional ethnic/racial benchmarking data to help us identify gaps in waitlist distributions.

Transplant programs currently have semi-annual reports from the Scientific Registry of Transplant Recipients (SRTR) regarding the racial makeup of their waiting lists. This is found specifically in the Program Specific Report, ***Table B2 Demographic characteristics of waiting list candidates***. This data is benchmarked against the region and nation. However, these benchmarks <u>do not</u> incorporate the prevalence of the disease within specific communities.

The SRTR Program Specific Reports (PSR) could produce an 'expected' benchmark on what the racial makeup of the waitlists *should be*, based on the disease prevalence within the community.

Data presently utilized by the SRTR includes supplemental data by CMS and the Social Security Death Master File. The kidney disease prevalence by race and zip code is available within ESRD and could also be incorporated. While this type of data may not readily exist for non-renal organs, we do not believe it should hold back the system from incorporating this data to help kidney transplant candidates and programs, which makes up well over 80% of all candidates waiting for an organ.

The PSR report is updated semi-annually and carefully reviewed by transplant programs, the OPTN, payors and even patients. Transplant programs are experienced to monitoring program performance using an observed rate versus the expected rate. We have benchmarks on observed versus expected for transplant rates , pre-transplant waitlist deaths, 1-year and 3-year post transplant outcomes.

There are robust transplant QAPI programs that review SRTR program data routinely. Benchmarks are a key component to our performance review and monitoring. If transplant programs were provided with additional benchmarking data on race/ethnicity, then transplant programs could have the data necessary to increase equity in access to transplants and/or CMS or the OPTN would have benchmarks with which to hold programs accountable.

Without providing the expected rates, programs will continue to benchmark against an underperforming system with respect to equity and access.

Section H.2: Stakeholder Engagement

We support the NASEM Committee's principle to put the patient at the center of system improvement. To that aim, we encourage the production of OPTN transplant education materials in languages other than English.

Section H.3: Stakeholder Engagement

The new contract may incorporate better approaches. Regulations from the OPTN and CMS are important factors in helping to ensure the health and safety of candidates, recipients and living donors. One recent step in support of a better approach is the newly adopted transplant program performance measures adopted and finalized in December, 2021 by the OPTN.

Transplant programs have benefited from CMS and OPTN regulations. The regulations have helped to design and monitor program performance. Programs wish to remain in compliance of

regulations and optimize health for patients. We support a national dashboard and we encourage standardized definitions as proposed within the NASEM report. Moreover, CMS can further support program performance by:

1) finalizing the CMS Conditions of Participation from 2019.
2) engaging with the OPTN to routinely update the regulatory crosswalk.
3) attending and speaking at transplant professional conferences where we may engage and collaborate toward the goals set forth in the NASEM report.

May 23, 2022

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration
Office of Acquisition Management & Policy
5600 Fishers Lane
Rockville, MD 20857-5600

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Attached please find the response from the Pacific Northwest Transplant Bank (PNTB) to the
following Request for Information (RFI):

Notice Number: HSB115C1031
Notice Title: Organ Procurement and Transplantation Network (OPTN)
Original Date of Issuance: Friday, April 8, 2022
Updated: Saturday, May 7, 2022
Deadline: May 23, 2022 at 1 PM ET

Name: Pacific Northwest Transplant Bank (PNTB)
2611 SW Third Ave, Suite 320, Portland, OR 97201
Point of Contact: Craig Van De Walker
                      Executive Director
                      vandewac@ohsu.edu
                      503-494-2146

PNTB does not intend to supply a proposal on any future solicitation related to this requirement.

Responses to Questions

A. OPTN Technology – IT System

A.1.b) Describe how to 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. Electronic referrals show great promise in creating greater efficiency in the donation process by helping to ensure that no donor is inadvertently missed and facilitating data collection that helps inform predictive analyses to increase the speed and accuracy of future organ matching. Similarly, APIs allow for seamless clinical integration, which helps to automate the screening process and can lead to earlier and more effectively managed referrals. Despite their great potential to drastically improve the patient referral process and save lives, these technologies can be expensive, which has limited their uptake across industry stakeholders to date. We strongly encourage OPTN to leverage APIs, but it will only be as useful as the degree of which the rest of the industry adopts it. Past CMS programs such as the EHR Incentive Program have proven successful at driving the rapid implementation of promising new technologies. We believe CMS should build off these past successes to drive the adoption of electronic referrals and APIs in organ referrals through a similar nationwide incentive program, if not through grants or supplemental funding initiatives. Equally important- these systems must all be interconnected including with donor hospital EHRs to truly leverage these abilities to more rapidly assess donation potential in real time.

A.1.c: Describe how to enhance real-time tracking of donated organs to allocate organs more efficiently and support increased transplant center engagement with patients in organ acceptance decisions. Standardization of data metrics and interoperability of various technology platforms is critical for this to work effectively. We would urge HHS and OPTN to work with stakeholders to assess current systems in use and to encourage widespread adoption of affective and compatible monitoring systems in a coordinated fashion.

A.1.d: Describe how to produce public performance dashboards and actionable data to identify opportunities for program improvement, reduce inequities, and benchmark performance. We strongly support the collection and dissemination of actionable data so that OPOs and all transplant system partners can leverage this to find new innovative ways to drive system-wide performance improvements and efficiencies and save more lives. Like any performance data, we believe HRSA and OPTN should design dashboards with the specific audience and intended use in mind. For example, any information that is available to the public should be provided with proper context so that a layperson can understand what the metric means. It should also be provided in a user friendly format that does not overwhelm the average consumer so that the information can actually be useful to them. Importantly, HHS needs to ensure any data, but particularly any that is made available to the public and/or used to compare performance, is sufficiently risk-adjusted, including accounting for population demographics, social determinants, or other factors. We believe this commitment to transparency in and of itself will help to rebuild trust in the organ donation and transplantation system and potentially improve both donation and transplant rates and we are fully committed to supporting OPTN in these efforts.

A.1.f: Describe how to maximize these and other tools to help ensure data collection is relevant, accurate, timely and streamlined to save critical time in the organ allocation

process, minimize errors, and improve patient outcomes. APIs, EHRs, GPS tracking, and artificial intelligence algorithms all have untold potential to facilitate a faster if not real-time sharing of information that can greatly speed the process of sharing and comparing relevant clinical information to decide which recipient would yield the best outcome. However, we come back to the same core themes of giving industry stakeholders the necessary resources and tools to implement these often costly new technologies- as well as ensuring from the outset that these technologies are deployed as part of a coordinated implementation strategy and that each segment of this information sharing chain can appropriately relay information across technology platforms. This will require a coordinated effort on the part of HHS, OPTN, OPOs, and other industry stakeholders.

B. Data Collection

B.1: Describe the ideal process for developing superior performance metrics and benchmarks, including consulting with experts, subcontractors, transplant candidates, recipients, organ donors, and their families. The critical piece really is engaging stakeholders throughout the process. Importantly, this group should be broadly inclusive and not over or underrepresent the voice of any particular system actors. It is also critically important to engage patients and other stakeholders from a broad range of diverse backgrounds so that the industry can collectively better understand and improve any systemic inequities throughout the organ donation and transplantation system.

B.2.a: Describe how data collection and reporting should be structured as it pertains to: a) process, outcome, and patient engagement measures; b) OPTN member performance benchmarks; c) patient and donor demographics, including race, ethnicity, language, and socioeconomic factors; d) national, regional and local performance dashboards; and e) long-term patient outcomes and relevant factors. With any data collection and sharing, the critical item of importance is alignment and consistency across the system, including aligned goals. To this end, we encourage HRSA and CMS to align their metrics with OPTN metrics.

HHS should replace or modify existing metrics that may discourage its own goal of encouraging all stakeholders to work together towards maximizing every possible organ. For example, OPOs and other stakeholders should not be penalized for pursuing every possible organ in the form of metrics that measure unused organs. Especially with all of the exciting innovations such as perfusion technologies that could meaningfully and rapidly change what organs are suitable for transplantation, we should be encouraging actors to work together to push the boundaries of what organs can be used, not penalize entities who are following CMS' directive to pursue all possible organs. One way CMS could achieve this is by awarding partial credit or reimbursement for organs that are recovered but later deemed unusable, provided a valid clinical reason that could have not been known prior to surgically removing the organ. CMS could also separately count such organs that are subsequently donated for research purposes to encourage donation for scientific and medical research purposes.

E. Increasing Organ Donation and Improving Procurement

The NASEM report identifies concerns with organ donation rates, including geographic and demographic variations. HHS is actively taking steps to enhance the accountability of OPOs.

E.1: Describe how changes in OPTN policies/requirements for OPOs could help to reduce variations in practices and procedures, facilitate increased organ donation and improve procurement, and otherwise improve OPO performance. As explained in detail in responses to previous questions, creating a data collection and sharing system that is transparent, consistent across stakeholders and agencies, and one that is appropriately risk-adjusted and disaggregated by sociodemographic information is one of the most effective ways OPTN and HHS can drive system-wide improvement, including reducing inequities. Specifically, we would urge HHS to replace or modify metrics that dissuade OPOs or any entity from pursuing every possible organ and transplantation opportunity, provided they have appropriate documentation to support their decision making.

E.3: What additional research could contribute to improving organ procurement? How could the OPTN facilitate OPO engagement in research to improve procurement? Right now, there are exciting groundbreaking innovations that have the ability to turn previously unusable organs into ones that can be safety transplanted into waiting recipients and save lives. As an example, up to two-thirds of previously unusable lungs could be rehabilitated and transplanted thanks to new advances in perfusion technology, which is an exciting possibility considering only 20-25% of donated lungs are currently transplantable. However, these new technologies can be expensive. Certain perfusion technologies can reach upwards of $70,000 per lung. Similarly, APIs, EHRs, GPS tracking, and AI algorithms have the ability to rapidly improve the speed and accuracy of data sharing that could facilitate real-time organ matching in the not-so-distant future. It is important that HHS and OPTN build policies that work not just for now, but for continued growth and innovation. This includes supporting industry-wide metrics that encourage innovation, coordinating implementation so that these various systems can communicate with one another, and perhaps facilitate cost-effective ways to speed more widespread adoption. One specific example, HHS should consider how its current reimbursement policies can support continued innovation and pushing the boundaries of what is possible in transplantation. This might include revising its standard acquisition charge policies to accommodate new technologies that while expensive, could be the difference between a life saved. While we would argue is certainly worth the cost- it may make more sense to address these added costs on an ad hoc basis, particularly for less frequently transplanted organs, in order to ensure the system is able to withstand and support new innovations, provided their use is properly justified and documented. This type of approach would allow the industry to have more stable standard acquisition charges while still retaining the ability for singular cases to leverage all their tools at their disposal to pursue a lifesaving transplant.

E.4: How can HRSA best incorporate the NASEM report's recommendations on increasing equitable access to transplants? Increasing equitable access is a critical component of advancing overall system improvement. Data collection, disaggregation, and transparency are

key ways to better understand and address system inequities and foster trust in the process. In particular, we would encourage HHS and OPTN to explore potential barriers to referred patients being listed for transplant, which based on our experiences and communications with other industry stakeholders can disproportionately affect minority and other underserved populations and can be a driver of downstream inequities across the system. In other words, if we devote resources to addressing what in some ways can be described as the root of the problem, we believe this will yield exponential positive downstream benefits.

F. Organ Usage

F.1: Describe how to support OPO performance improvement activities to decrease discarded organs and further increase the use of organs. Aligning incentives including **transplant center performance metrics** is an important way to drive system-wide improvement, including collecting data on and incentivizing improvements in addressing system inequities. For example, HHS and OPTN could award partial credit for organs that were procured but later deemed unusable, provided proper documentation is provided, particularly those that are subsequently donated to research. At a minimum, OPOs (and other stakeholders) should not be penalized for pursuing every possible organ and transplant opportunity. HHS and OPTN should look for reimbursement models that encourage innovation, including new technologies to recover previously unusable organs, new IT infrastructure to support information flow and real-time matching to improve the efficiency of organ matching, and organ tracking. This includes building a reimbursement system that keeps costs low overall, while retaining the ability to be dynamic and leverage technological advances. As noted previously- one such approach could be to allow OPOs to charge certain add-on fees in addition to standard acquisition charges in cases where a specific new technology or transport could result in an organ being placed and a life saved, provided appropriate documentation is provided.

F.2: How can OPTN organ matching activities be modified to decrease non-usage (discards) of procured organs? Adoption of technology advancements including APIs, EHRs, and AI algorithms when used collectively have a potential to drive rapid and meaningful improvements in the efficiency and effectiveness of organ matching. As stated previously, widespread adoption and successful implementation will rely on a coordinated approach in which the different systems are able to communicate and will also require the necessary investment to facilitate their widespread adoption.

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. We support the public reporting of data that can be reasonably understood by the average consumer would greatly improve transparency. This data must be provided with appropriate explanation and context, and appropriately risk adjusted. In particular, collecting and disaggregating outcomes data by race and sharing this information could be an effective way to create transparency and possibly engender trust from groups with a historic distrust of the donation or medical system in general. Be believe transparency at every stage of the organ donation and transplantation system is critical but would particularly encourage more data around discrepancies in patients referred for verses listed for transplant, which as we understand minority and other underserved

communities can disproportionately experience barriers to being listed that has ripple effects throughout the organ donation and transplant system.

H. Stakeholder Engagement

The NASEM report outlines how transplant centers should be required to improve their stakeholder engagement efforts and activities, specifically by making transplant candidates, transplant recipients, other affected patients, organ donors and family members aware of all organs they have been offered and by monitoring their changing health and attitudes impacting organ acceptance decisions. HRSA is soliciting feedback related to the following questions:

H.1: Describe how to 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. We fully support efforts by OPTN and others to more effectively engage patients in organ acceptance decisions and introduce more transparency in the process, including monitoring and publicly posting transplant program acceptance criteria and rates. We agree that being transparent with patients throughout the process, including pro-actively, having difficult conversations in which they may not be the most appropriate candidate, helps to plant transparency and therefore trust within the process. We believe new technologies such as EHRs, APIs, and AI algorithms could facilitate the more rapid sharing of information that could buy some more critical time that might allow physicians to better engage patients in these decisions. However changes made must not delay placement efforts that result in the increased likelihood of organ discard.

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. We offer our full commitment to do our part to support these efforts. An important place to start we think is to continue engaging a diverse group of stakeholders, including patients, in OPTN policy development, as well as standardizing metrics across stakeholders and agencies so we can all work in unison towards shared goals. Also important is modifying or replacing metrics that could be discouraging stakeholders from pursuing every possible organ or transplant opportunity. OPOs should not necessarily be penalized for unused organs provided they can justify why the organ was not suitable for transplant.

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? We believe OPTN does a good job of engaging stakeholders. We suggest a targeted outreach to groups that have been less engaged in the past or are less familiar with the process, including patients, could further improve engagement.

23 May 2022

Dear Administrator Johnson -

We are writing as patients in response to the [Request for Information about the nation's Organ Procurement Transplantation Network](#) with two urgent pleas:

1) Be the first Administration that runs a competitive process for the OPTN - subdividing its functions into policy and technology, with oversight reabsorbed into government; and
2) As part of that competitive process, be the first Administration to ensure that all OPTN contractors that are awarded that critical public trust are judged to be capable of acting in the patients' interests, using exceptional processes and technology to help more patients receive lifesaving organ transplants, fixing a major health inequity.

All previous HRSA-led OPTN contracting cycles have failed this standard, leading to an OPTN contractor (UNOS) that has proven to be a deeply flawed and incapable organization responsible for unconscionable patient deaths and demonstrable inequity due to gross negligence. As [Forbes](#) wrote in (1999): *"[UNOS is a] cartel" and "the federal monopoly that's chilling the supply of transplantable organs and letting Americans who need them die needlessly."*

For decades HRSA - and HHS more broadly - have had the risk calculus exactly wrong: assuming that patients would be harmed by a disruption of the status quo while ignoring that the status quo failures of the current OPTN contractor, and the organ procurement organizations (OPOs) it is supposed to oversee, are killing patients.

[Thirty-three Americans](#) - [disproportionately people of color](#) - are dying each day due to an unnecessary organ shortage, which is fueled by complacency and incompetence.

Imagine being a patient, or the loved one to a patient, and knowing that UNOS is [15 times](#) more likely to lose or damage an organ in transit than an airline is a suitcase.

Imagine being a patient, or the loved one to a patient, while reading that Black patients are routinely ignored for organ donation, and that OPO recovery of Black donors varies by [10-fold](#) around the country, while UNOS has done nothing to address it.

Imagine being a patient, or the loved one to a patient, and seeing that UNOS wastes resources on full-color advertisements in national press, disseminating misinformation to praise its success, while [data show](#) that rising organ donation is the result of public health tragedies such as the opioid epidemic while organ recovery rates are dismal.

Imagine being a patient, or the loved one to a patient, and knowing that while HHS has called out the [majority](#) of OPOs as [failing](#) basic standards, and the [Department of Justice and Federal Bureau of Investigations](#), the [Office of Inspector General](#), the [Senate Finance Committee](#), and [House Oversight Committee](#) have found glaring problems such as [patient deaths due to basic safety oversights](#), [misuse of Medicare dollars](#), and [outright fraud](#), [UNOS has only ever listed two OPOs as members not in good standing of the OPTN](#), and - even then - there has been no meaningful consequence.

Imagine being a patient, or the loved one to a patient, and reading unsealed emails from UNOS executives calling referring to patients as *"dumb fuck[s]"* and the CEO of UNOS acknowledging that *"we [UNOS] don't have a real board"*.

Now, please imagine being an Administration who ignores all of those things - all of that death and inequity - and gives the upcoming OPTN contract to the same contractor who has presided over this failing system for decades. That would be unconscionable.

We are counting on you. Please lead.

Specific answer to *RFI questions* below.

"1. Solicit feedback on ways to strengthen and improve components of the OPTN contract, including but not limited to its governance, finance, IT, data collection, policy, and operational components"

Subdivide the OPTN contract into component parts of policy and technology; open to all innovators; reabsorb OPO oversight entirely into HHS, given the failures of the OPTN to oversee other contractors.

"2. Solicit feedback on ways to incorporate the findings and recommendations of the February 2022 National Academies of Science, Engineering, and Medicine (NASEM) report titled, "Realizing the Promise of Equity in the Organ Transplantation System"

Open all OPO and OPTN contractor data to the public to ensure evidence of effective and equitable service, regardless of race/ethnicity/gender/urban-or-rural status of donors or transplant patients.

"3. Solicit feedback on incorporating lessons learned from HRSA's 2019 market research, conducted in partnership with the U.S. Digital Service, on ways the OPTN IT system should utilize modern IT architecture, such as adopting a "cloud-native," agile, and modular approach

to IT development, security, and maintenance and prioritizing 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 in order to save critical time in the organ allocation process, minimize errors, and improve patient outcomes"

Acknowledge that other organizations are much better positioned to deliver IT services on behalf of patients than UNOS; follow the [recommendations of alumni of the United States Digital Service](#) (USDS) - endorsed by [all five past Chief Technology Officers of the U.S. Department of Health and Human Services](#) - and separate out IT from the rest of the OPTN contract, opening to all innovators, and removing conflicts.

"4. Gauge interest in the upcoming RFP opportunity and feasibility of the requirements via statements of intent from prospective offerors."

Regardless of the response of this RFI, we are counting on HRSA leadership to run an extended and extensive RFP process, open via true competition to the best innovators across the country. High-functioning OPTN contractors are a national imperative, so engaging USDS procurement experts to run the process is critical for success, and for saving patients' lives.

Respectfully submitted,

Kendall Ciesemeier, liver recipient

LaQuayia Goldring, kidney recipient and kidney waiting list patient

Tonya Ingram, kidney waiting list patient

Michael Kutcher, heart recipient

Sergio Rosas, kidney recipient

Erica Sivertson, patient family member

Quin Taylor, kidney recipient

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RE: Request for Information, Organ Procurement and Transplantation Network
Notice ID: HSB115C1031

Dear Sir/Madam:

We are pleased to submit our responses to the "Request for Information, Organ Procurement and Transplantation Network" (Notice ID: HSB115C1031). We and other researchers affiliated with RAND Health Care intend to supply proposals in response to future solicitations related to this notice.

RAND Health Care is a research division of the RAND Corporation, a nonprofit institution that helps improve policy and decisionmaking through research and analysis. The division possesses broad, deep, and longstanding expertise not only in health policy areas and key methodologies, but also topics such as systems engineering, acquisition, and software engineering.

The enclosed response focuses on conducting actionable, rigorous, and objective analysis that support HRSA's objectives in strengthening the organ procurement processes; enhancing the security of the OPTN IT system; and promoting accountability and broader stakeholder engagement. We welcome opportunities to leverage our expertise in various areas to develop frameworks and evidence-based recommendations for supporting the transplantation community.

Please contact me if you have any questions or comments about this RFI.

Sincerely,

Jeanne Ringel,
Senior Economist and Program Director
Health Care Access and Delivery, RAND Health Care

R. J. Briggs, Economist
Chad Heitzenrater, Senior Information Scientist
Vikram Kilambi, Operations Researcher
Zachary Predmore, Associate Policy Researcher

Responses to RFI, Organ Procurement and Transplantation Network
HSB 115C1031
R. J. Briggs, Chad Heitzenrater, Vikram Kilambi, and Zachary Predmore

RAND Health Care is pleased to contribute to this request for information (RFI). The market research questions included in HRSA's notice indicate priority areas for improving the performance and accountability of the Organ Procurement and Transplantation Network (OPTN). Many issues in these priority areas have been raised in the research literature, in the NASEM report referenced in the RFI, and in the wider transplantation community over the course of three decades. Sections E and F, respectively on "Increasing Organ Donation and Improving Procurement" and "Organ Usage", have received increased scrutiny in more recent years as allocation policies for solid organs changed, new OPO and transplant center evaluation regulations were proposed, and more procured organs were discarded. While these issues remain the most pressing for the sustainability of the OPTN and would always benefit from further work, some topics less studied by the transplantation research community also deserve attention. Topics discussed in Sections A, B, C, D, and H may have a less clinical focus, but also warrant systematic study: robust IT systems, reliable data, efficacious governance structures, and improved accountability systems undoubtedly strengthen organ procurement. Given the scale of the OPTN and its importance to the quality of life for thousands, prudence would require that evidence-based frameworks should be deployed for each of these priority areas.

Our responses to the market research questions are below. Table 1 reproduces all the questions in the notice and also indicates the questions to which we responded.

Table 1: Market Research Questions for which Responses are Included

Section	Market Research Question	Response Included
A: OPTN Technology, IT System	1. Describe how you would/a vendor would implement and utilize modern IT architecture	x
	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?	x
	3. How can the OPTN ensure data collection is relevant, accurate, timely and streamlined in order to improve organ allocation processes?	x
	4. How would you/a vendor ensure ongoing security enhancements to protect against emerging and evolving IT security threats?	x
	5. How would you/a vendor ensure adherence to the latest industry best practices for IT security infrastructure, practices, and standards?	x
B: Data Collection Activities	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,	x

	subcontracting, and engagement with transplant candidates, transplant recipients, organ donors and their families about the metrics they value.	
	2. Describe how you would/how vendors could structure data collection and reporting mechanisms for the system	x
C: OPTN Finances	1. Describe how you would/vendors could ensure that any fees, beyond OPTN registration fees, charged to transplant centers or others	Responded to C1a. and C1d.
	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?	x
D: OPTN Governance	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.	x
	2. Describe the conflict of interest policies you would/vendors could implement to ensure independence of the OPTN board of directors	x
	3. Describe the reporting mechanisms you would/vendors could utilize to hold operational contractors' accountable for system performance and outcomes.	x
	4. Describe the additional factors and process steps you would/vendors could take to ensure effective operations of such an independent board of directors	x
E: Increasing Organ Donation and Improving Procurement	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	x
	2. How could the OPTN facilitate OPO engagement in research protocols to improve procurement	x
	3. What additional research could contribute to improving organ procurement?	x
	4. How can HRSA best incorporate the NASEM report's recommendations on increasing equitable access to transplants?	x
F: Organ Usage	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.	x
	2. How can OPTN organ matching activities be modified to decrease non-usage (discards) of procured organs?	x
	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	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	

Development Improvements	boards and committees responsible for developing OPTN policies	
	2. Describe how you would/vendors could engage with experts in quality improvement and stakeholder collaboration in executing OPTN deliverables.	
	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	
	4. What other improvements to OPTN operations and policy development processes can and/or should be incorporated into the OPTN contact?	
H: Stakeholder Engagement	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	x
	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.	x
	3. How can and/or should the contract incorporate new or better approaches for including stakeholders in a shared decision model for organ acceptance?	x

A. OPTN Technology - IT System

The NASEM report recommends that the OPTN use a state-of the art information technology infrastructure that optimizes the use of new and evolving technologies to support the needs and future directions of the organ transplantation system. HRSA received similar feedback from the U.S. Digital Service as part of HRSA's 2019 market research. Additionally, organ procurement organizations and transplant programs currently do not submit data to the OPTN IT system in real time. HRSA seeks to enhance the usability and performance of the OPTN IT system and related tools, as well as ensure the OPTN IT system is protected from emerging and evolving security threats. HRSA is seeking feedback on the following questions:

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

    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.

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

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

Answer to A.1.a. – A.1.e.:

    An agile, cloud-native environment that provides maximal flexibility for development and operation must foremost also be secure. Striking the balance between security and usability is critical to meeting the accessibility, uptime, management, and performance goals of the OPTN. While many agile approaches purport to supply security, their emphasis on speed often overshadow sound security and engineering practice. RAND has long worked with military and homeland defense customers on security-first approaches to agile development, augmenting the speed of agile approaches with the security, modularity, and performance needs of critical systems. The interconnectivity of risks (such as external Application Programming Interfaces [APIs] and Electronic Health Record [EHR] integration) present in OPTN systems makes security-first approaches even more important and drives the need for robust analysis at design, test, and deployment throughout the lifecycle. Finally, OPTN system developers should be aware that security concerns extend beyond the deployment environment: risks are present in elements of the software supply chain, to include the environment for system development, supporting technology (for external interfaces, data connections, and linked libraries, as captured in a Software Bills of Materials or SBOM), and the development of secure policies and practices.

    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?

Answer to A.2:

    Critically, the drive for security cannot lose sight of the functional and performance requirements of the application. The ambitious goals for uptime and performance are achievable with modern managed services but are placed at risk when security is not considered from a systemic point of view. The process-oriented, lifecycle approach described above is specifically designed to offset the need for costly controls, which threaten system goals for timeliness, accuracy, and availability. While legal and regulatory requirements may drive the implementation of the cloud system toward either commercial or government-based services, any properly designed cloud environment will be operated by trained personnel in

closed environments supported by defined processes and incorporate best practices such as containerization, hypervisors, and managed services.

Secure management of these resources is commonly referred to as 'cyber hygiene' and represents the only the starting point for any security posture. To realize uptime goals and maximize lifesaving through transplant, these capabilities must be operational and free from interference, necessitating secure design and development approaches that incorporate multi-factor authentication (MFA), the employment of encryption (both 'at rest' within the cloud and 'in-motion' to/from endpoints), and measured application of detection technology. With the introduction of these critical technologies come system concerns. For example, poorly designed MFA mechanisms may impact system availability and undermine security; encryption requires well-considered key management and credential revocation services; the resource consumption and response rates for detectors can detract from performance and uptime goals while contributing little to prevention; and the processes for applying patches and updates to any controls can overwhelm available resources. Understanding how these aspects affect the attack surface, balance performance and security needs, and realize system goals in context are central to DHHS goals. RAND's expertise in secure software development practice spans research and analysis in each of these areas, supporting the development of sound policies and processes augmented by technology to establish and maintain robust and secure systems.

> 3. *How can the OPTN ensure data collection is relevant, accurate, timely and streamlined in order to improve organ allocation processes?*
>
> 4. *How would you/a vendor ensure ongoing security enhancements to protect against emerging and evolving IT security threats?*
> 5. *How would you/a vendor ensure adherence to the latest industry best practices for IT security infrastructure, practices, and standards? See our previous response.*

Answer to A.3, A.4, and A.5:

The answers to these questions relate to each other. Data collection requirements must be systematically established including processes to amend them and soliciting them from stakeholders including OPOs and transplant centers. Standardized processes to minimize data entry errors must be established, including automatic data validation, data profiling, and reduction in data redundancy.

Securing modern information processing systems is a complex endeavor that requires a holistic approach. Absolute security for such systems does not exist; rather, the basis for systems that are secure and resilient throughout is a balance of security concerns (Confidentiality, Integrity, and Availability) against constraints such as cost, agility, and functionality. Development of robust software platforms designed to achieve this balance necessitates an understanding of security in context, employing Secure Development Lifecycle (SDLC) frameworks and recognized best practices that include threat-informed requirements, architectural analysis, development of measurable security parameters, and security testing at the system and sub-system levels (risk-based security testing, red-teaming of artifacts, and penetration testing). Augmented with control-based measures, a coordinated,

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OBJECTIVE ANALYSIS. EFFECTIVE SOLUTIONS.

security-first lifecycle approach has been shown to provide the most efficient security outcomes against an evolving security landscape.

B. Data Collection Activities

The NASEM report recommends the creation of a dashboard of metrics to track performance and evaluate results, and modernize the data collection for deceased donor organ procurement, allocation, distribution, and transplantation. Enhancing OPTN data collection and dissemination could improve performance assessment, reduce practice variation, and support quality improvement and innovation. HRSA is seeking feedback on the following questions:

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.*

Answer to B.1:

To develop performance metrics, HRSA should avoid "reinventing the wheel" and instead look to existing, proven processes for health care measure development. The NASEM report notes the possibility of collaboration with an existing organization like the National Quality Forum (NQF) to develop these metrics. We agree that HRSA should rely on existing processes like the NQF's Consensus Development Process (CDP) for developing quality measures. In an NQF-like CDP, HRSA would convene several standing committees of key stakeholders who would be responsible for reviewing candidate measures for different measure domains (e.g., organ donation, procurement, allocation, transplantation), and then put out calls for measures from interested researchers, clinicians, and quality improvement organizations. These parties would then work with experts, patients, and donors to develop candidate measures for endorsement, including measure specifications and rationale for the measure, conduct reliability and validity testing of candidate measures, and write up these candidates for submission to the relevant standing committee. Each standing committee would then select its domain's top measures for presentation to the public for comment and then to a final advisory committee responsible for selecting a final set of measures across all domains.

RAND has extensive experience assisting quality improvement organizations and other stakeholders develop performance metrics for other health care domains, including anticoagulation care, stroke care, and care for people with serious mental illnesses. This includes convening subject matter experts, developing and testing measure specifications, and making the business case for quality improvement on these metrics.

Patients (transplant candidates, recipients, donors) and their families can be engaged throughout this process. Patient representatives should have membership on the standing committees. Patient engagement should be required as part of the measure development process for all candidate measure developers, and patients should be encouraged to comment on measures and be included on the final advisory committee.

HRSA should note that metrics developed in this kind of process may not necessarily work well in practice. For example, it is conceivable that many of the clinical activities that will likely be included in the numerators and denominators of quality measures may not be directly related to patient care. Moreover, HRSA should take care to adopt metrics that will not inadvertently create perverse incentives: ratio-based metrics for example, can potentially provide two margins of action for the subject if they control both the numerator and denominator. In general, metrics should have one margin of action that clearly connects to a desired outcome and meaningful incentives. HRSA should oversee analysis of CDP-suggested metrics before providing final endorsement and allowing their deployment.

2. *Describe how you would/how vendors could structure data collection and reporting mechanisms for the system:*
   a. *To report OPTN performance metrics including process, outcome, and patient engagement measures.*
   b. *To establish OPTN member performance benchmarks.*
   c. *To capture patient and donor demographics, including race, ethnicity, language, and socioeconomic factors.*
   d. *To create public OPTN national, regional and local performance dashboards.*
   e. *To track long-term patient outcomes and health and non-health-related factors that contribute to outcomes.*

Answer to B.2.a. – B.2.e.:

To best structure data collection, HRSA should explore the development of a common data model (CDM) for the OPTN that includes the relevant data for OPTN performance tracking and long-term patient outcomes. HRSA could model this effort off of existing CDM projects, like the PCORnet project, in which regional clinical data networks have harmonized data standards to create a large national distributed database that can be used for health outcomes research. In a PCORnet-like model, each OPTN region would serve as a regional network, and be responsible for collecting and harmonizing data from OPOs and transplant centers within its borders. Then the regions could come together to submit data as part of a national network. This network would build off of existing data submission requirements, such as the requirements of the Scientific Registry of Transplant Recipients, so institutions would not be starting from nothing. This data could feed into OPTN performance measure benchmarks and performance dashboards in near-real time.

RAND Health Care completed an evaluation of Phase I of the PCORnet model and identified both strengths and limitations of these types of models, as well as the time and resources required to establish a CDM.[1] The PCORnet model has expanded and continues to be used to conduct research and inform policy today. Lessons learned from evaluating this effort would be important for any entity looking to build a model like this in the future.

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[1] Timbie, Justin W. et al. National Patient-Centered Clinical Research Network (PCORnet) Phase I: Final Evaluation Report. 2015. https://www.rand.org/pubs/research_reports/RR1191.html

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C. OPTN Finances

Currently, the OPTN contractor charges additional fees (outside of OPTN registration fees) to provide services to the donation and transplantation community. Although no OPTN member is required to pay such fees in order to participate in the OPTN, in practice, many OPTN members may view them as necessary to receive the services they need from the OPTN contractor. HRSA seeks to increase accountability and transparency in OPTN financial structures. HRSA is seeking feedback on the following questions:

1. 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.

Answer to C.1.a.:

RAND Health Care has extensive experience working with Medicare payment data and determining the risk of duplication of payments from Medicare or medical insurance reimbursement for materials, equipment, and labor. Through other units at RAND, we provide support to federal grant programs to identify and measure these risks at the project and applicant levels. In the course of our work, we have catalogued and analyzed the full spectrum of provider-level data systems that can be used to inform the connection of various resources or activities to insurance or Medicare reimbursement based on a granular, "bottom-up" analysis. At the same time, we use health system financial data over time to provide a "top-down" cross-check to identify potential duplication of payments risk. While we cannot provide a precise answer on how to ensure OPTN fees do not result in duplicate or unnecessary payments, we encourage HRSA to similarly deploy multiple methods that use distinct data streams to identify and estimate such payments.

Answer to C.1.d.:

Financial incentives drive behavior, even within non-profit entities. If some members of the donation and transplantation community pay fees to the OPTN contractor while others do not, economic logic would hypothesize that the OPTN contractor will work on some margin to increase receipts of those fees. HRSA can mitigate impacts and the perception of impacts in at least two ways: by distributing costs levelly across the community or by maintaining something like the current system and monitoring for impacts on a select set of metrics. The first approach has the advantage of making each member of the community financially equal from the OPTN contractor's point of view; on the other hand, members who use the OPTN contractor's services less than the average would in effect be financing more than their share.

The second approach allows for variation in payments from members but expects some impact. Completely mitigating that impact along every conceivable avenue may prove challenging, but HRSA could require that OPTN auditors periodically examine the relationship between these kinds of fees and select, critical metrics connected to organ allocation. As with any metrics meant to matter, HRSA should ensure that the OPTN contractor knows *ex ante* what constitutes acceptable and unacceptable findings on these metrics, what actions unacceptable findings will precipitate, and that the findings will be published.

>   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?*

Answer to C.2:

In prior years, UNOS treasurer reports were published, and these included calculations supporting OPTN registration fee changes.[2] In a cursory search of the UNOS website, we did not find current treasurer reports or similar documents. At a minimum, HRSA should require that the OPTN treasurer's reports to the board are publicly available, that they relay all relevant information in a non-redacted form, and that they are subject to public comment and HRSA approval before new fees go into effect.

With respect to determining the appropriateness of specific fees, HRSA and other observers of the OPTN face a problem similar to that faced by transfer pricing. Transfer pricing denotes the accounting practice of setting the price a firm pays for a service it produces internally. When a service has an analog with an external market, the transfer price is typically set to the market price, reflecting the value of the service in an "arms-length" transaction. Given the non-profit nature and lifesaving mission of the OPTN, this same "arms-length" quality should be required of any fees. The inherent monopoly that the OPTN has on procurement services makes determining a fair fee difficult.

Through research for the Department of Defense, US Air Force, and US Army, RAND has published extensively on efficient transfer pricing.[3] A critical conclusion of this body of work is that transfer prices should reflect marginal costs rather than average costs. To improve efficiency and reduce distortions, OPTN registration fees and other contractor fees should only cover what it takes to provide the next unit of the service in question. To the

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[2] E.g., "Treasurer's Report." OPTN/UNOS Board of Directors Meeting, June 6-7, 2016. Available May 2022: https://unos.org/wp-content/uploads/OPTN_Budget-and-Finance-Report.pdf.

[3] See *inter alia:* Frank Camm and H. L. Shulman, *When Internal Transfer Prices and Costs Differ: How Stock Funding of Depot-Level Reparables Affects Decisionmaking in the Air Force*, Santa Monica, CA: RAND, MR-307-AF, 1993.Laura H. Baldwin and Glenn A. Gotz, *Transfer Pricing for Air Force Depot-Level Reparables*, Santa Monica, CA: RAND, MR-808-AF, 1998. Marygail K. Brauner, Ellen M. Pint, John R. Bondanella, Daniel A. Relles, and Paul Steinberg, *Dollars and Sense: A Process Improvement Approach to Logistics Financial Management*, Santa Monica, CA: RAND, MR-1131-A, 2000.

greatest practicable extent, fixed costs that the OPTN contractor incurs regardless of the quantity of service provided should not be included in its various per unit fees.

Finally, we note that to comply with federal regulations for contract awards exceeding $300,000, the OPTN contractor is required to obtain an annual A-133 Compliance Report and, if recommended, a full audit. To ensure compliance, executives responsible for overseeing OPTN contractor operations should have contractual penalties explicitly tied to adverse findings of these reports, and the OPTN contract itself should similarly contain express language conditioning potential for contract renewal on good financial stewardship in line with the fiduciary trust given to the contractor.

D. OPTN Governance

HRSA seeks additional robust accountability and oversight measures regarding the OPTN. Today, the same individuals concurrently serve as members of the OPTN Board of Directors and the OPTN contractor's corporate board, which may hinder implementation of such accountability and oversight measures. HRSA is seeking feedback on the following questions:

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.*

Answer to D.1:

The present OPTN governance structure raises concerns of perceived or actual "regulatory capture," which is the domination of a rule-making body by the industry it governs. Captured regulators can shape rules to their industry's advantage, resulting in inefficiencies borne by the public and accruing to the industry's benefit.[4] In theory, the power of a captured regulator increases with informational asymmetry: when the public understands relatively little about an industry or process, they cannot readily discern the implications of regulatory choices.[5] Arguably, the complexities of organ transplant heighten the potential for capture to lead to inefficient outcomes in the OPTN.

Although regulatory capture has been well-explored as a theory, empirical findings and clear policy prescriptions remain elusive. The main tools available to reduce capture are strong management of present conflicts of interest (COI) and anti- "revolving door" policies, which either slow or prohibit regulators from joining or rejoining an industry after their term. While such rules do reduce connections between industry and regulators, they can impact current or future compensation for would-be regulators and thereby narrow the pool of individuals with the specialized knowledge necessary to craft effective rules. Information

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[4] For a discussion of different theories of regulatory behavior, see *inter alia* Levine, Michael E., and Jennifer L. Forrence. "Regulatory Capture, Public Interest, and the Public Agenda: Toward a Synthesis." *Journal of Law, Economics, & Organization* 6 (1990): 167–98. http://www.jstor.org/stable/764987.

[5] Laffont, Jean-Jacques and Jean Tirole, The Politics of Government Decision-Making: A Theory of Regulatory Capture, *The Quarterly Journal of Economics*, Volume 106, Issue 4, November 1991, Pages 1089–1127, https://doi.org/10.2307/2937958.

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asymmetry again exacerbates the issue: more complex industries or processes have relatively few people who understand precisely how they work. Narrowing an already narrow pool of competent individuals may leave very few candidates eligible and willing to regulate the industry in question.

To improve OPTN governance, HRSA should consider the following steps. First and at minimum, the boards governing the OPTN and the OPTN contractor's corporate board should not be the self-same individuals. On its face, this structure invites the perception of capture—even if the boards are operating completely in accord with the public interest. Information asymmetry arising from the complexity of transplant implies that the public at large has difficulty understanding whether OPTN policies are indeed in the public interest. Having an independent, expert body serving as the regulator that is distinct from the OPTN contractor's corporate board provides at least one degree of institutional separation from the appearance of capture.

Second, HRSA can improve board member COI management and put some degree of anti-revolving door policies in place. While overly strict COI management and anti-revolving door policies can hamper effective regulation, these tools are not binary and can be exercised to degrees. We discuss COI management strategies in the answer to D.2 below. Anti-revolving door policies can range from short prohibitions (e.g., one year) against working with a regulated entity after leaving the regulatory body to a full, life-time ban. We note that longer bans appear more onerous to individuals facing them and are also more difficult to enforce. In theory, a short revolving door prohibition would have the effect of providing a check against the most egregious actors engaged in the support of regulatory capture while not eliminating the narrow pool of expertise available to serve in a regulatory capacity.

HRSA can complement anti-revolving door policies by recruiting board members from the senior ranks of transplant who are closer to retirement. Anti-revolving door policies are less likely to have a negative impact on lifetime earning potential for these individuals. As such, highly qualified individuals planning to retire shortly are less likely to be dissuaded from serving as a regulator by these rules.

Finally, we note that the present board has several general public representatives as well as a minority transplant representative. We commend this feature of the board, but the bylaws of UNOS states that board members are elected by a national vote of the entire membership.[6] As an alternative, HRSA may consider segmenting the voting base for specific representatives on the OPTN board. For example, the minority transplant representative would arguably be best chosen by OPTN members who work principally with minority populations rather than by the broader membership. Under such a structure, specific board members could be more tied to the types of members they represent.

2. *Describe the conflict of interest policies you would/vendors could implement to ensure independence of the OPTN board of directors.*
3. *Describe the reporting mechanisms you would/vendors could utilize to hold operational contractors' accountable for system performance and outcomes.*

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[6] https://optn.transplant.hrsa.gov/media/3esbin4v/optn_bylaws.pdf

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

Answer to D.2 – D.4:

Conflicts of interest and COI management are common features of modern medicine. In a 2011 study of the prevalence of financial conflicts of interest among members of panels producing clinical practice guidelines for hyperlipidemia or diabetes, for example, Neuman *et al.* note that, "[their] results are similar to those of a study done more than a decade ago, which found that 59% of authors of guidelines admitted to having received funding from manufacturers whose products were included or considered in the guideline."[7] The authors conclude that requirements for disclosure do not necessarily translate into decreased COI, although evidence from membership of government-sponsored expert panels suggests that it is nonetheless possible to convene panels with relatively few COIs.

The conflict of interest (COI) policies of the current OPTN contractor, UNOS, state:

> When a Board or Committee member has a personal or institutional interest in the outcome of a matter before the Board or Committee for decision, the member can satisfy his/her legal obligation to the UNOS by:
> 1. Disclosing at the beginning of the discussion of the matter the nature of his/her interest in the outcome: and
> 2. Abstaining from voting on the matter.
>
> In addition, avoidance of the appearance of impropriety and encouragement of a full and open discussion of the matter would be best served by the Board or Committee member by:
> 1. Offering at the beginning of the discussion, and after disclosing his/her interest, to furnish such information as the Board should request;
> 2. Leaving the meeting for the balance of the discussion of the matter (but remaining available in the event of additional inquires by the Board or Committee): and
> 3. Taking no part in the discussion or the debate on the matter.[8]

Furthermore, board or committee members are empowered to raise questions as to other members' potential COIs, and the board or committee can agree (by majority) to remove another member from a discussion or vote if a COI is perceived by the group but not acknowledged by that member. The corporate rules also state that any abstentions from voting or absences from a meeting related to COI must be clearly noted in minutes of the meeting. These rules are largely consistent with, and arguably go further than, COI policies of the National Academies.[9]

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[7] Neuman, Jennifer, Deborah Korenstein, Joseph S Ross, Salomeh Keyhani, *BMJ* 2011;343:d5621.

[8] https://unos.org/wp-content/uploads/unos/UNOS_CorporatePolicies.pdf

[9] See policies posted at https://www.nationalacademies.org/about/institutional-policies-and-procedures/conflict-of-interest-policies-and-procedures.

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Nonetheless, these COI policies could be further strengthened. Neuman *et al.* point to the policies of the US Preventive Services Task Force (USPSTF) and the UK National Institute for Health Care Excellence (NICE) as exemplars.[10,11] We do not enumerate or analyze the features of these policies here, but we note that each of these sets of guidelines provides more precise descriptions or ratings of the level of COI and connects these with potential actions. COIs are assessed at time of appointment as well as an ongoing (periodic and *ad hoc*) basis, and information on members COIs are published and readily accessible.[12] We suggest that HRSA consider requiring such features in the OPTN board and OPTN contractor's COI policies, and that HRSA otherwise review the policies of USPSTF and NICE for best practices.

E. Increasing Organ Donation and Improving Procurement

The NASEM report identifies concerns with organ donation rates, including geographic and demographic variations. HHS is actively taking steps to enhance the accountability of Organ Procurement Organizations (OPOs). HRSA is seeking feedback on the following questions regarding increasing the donation of organs and improving the procurement of organs.
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.*

Answer to E.1:

The OPTN and participating OPOs exist within a complex system. Caution is required as modifications to OPTN policy requirements to reduce variations in practices and procedures risk unintended consequences or discourage innovation by OPOs. For example, statewide variances in kidney procurement policy in 1992[13] allowed OPOs in some regions of the country to better manage geographic variation in procurement outcomes such as cold ischemia time.

RAND envisions supporting the OPTN by emphasizing a system engineering and systems analysis approach for organ procurement, which has been successfully applied in

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[10] For a full discussion of USPSTF COI policies, see Quyen Ngo-Metzger, Virginia Moyer, David Grossman, Mark Ebell, Meghan Woo, Therese Miller, Tana Brummer, Joya Chowdhury, Elisabeth Kato, Albert Siu, William Phillips, Karina Davidson, Maureen Phipps, Kirsten Bibbins-Domingo, Conflicts of Interest in Clinical Guidelines: Update of U.S. Preventive Services Task Force Policies and Procedures, American Journal of Preventive Medicine, Volume 54, Issue 1, Supplement 1, 2018, Pages S70-S80,

[11] https://www.nice.org.uk/Media/Default/About/Who-we-are/Policies-and-procedures/declaration-of-interests-policy.pdf

[12] E.g., https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/conflict-interest-disclosures.

[13] Davis, Ashley E., et al. "The effect of the Statewide Sharing variance on geographic disparity in kidney transplantation in the United States." *Clinical Journal of the American Society of Nephrology* 9.8 (2014): 1449-1460.

recent years to improve deceased donor organ allocation.[14] Systems analysis and engineering are exactly the interdisciplinary fields best suited to analyzing the processes causing the variations in OPO performance and to identifying methods to increase organ donation.

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

Answer to E.2:
   The OPTN must manage inherent tradeoffs between demanding accountability and innovation from OPOs. Information and tool sharing among OPOs and transplant centers will be necessary for benchmarking procurement operations as there currently is lack of standardized tools to help OPOs prioritize potential donors for procurement.[15]
   HRSA has promulgated various regulations and final rules in the past decade to accomplish this goal. The research literature, including work performed by RAND researchers,[16,17] is replete with examples of geographic, demographic, and clinical disparities in access to transplants. In addition to the foregoing discussion on OPOs, there is observed variation in registration, organ acceptance, and risk assessment practices of transplant centers that contribute to this inequitable access.
   RAND argues that policy changes will always carry unintended consequences and that to mitigate the risks thereof, systems engineering, and systems analysis frameworks must be a part of the policy development process. For example, triangulation of allocation policy simulations and trials by transplant centers or OPOs to improve access should be systematically coordinated and corroborated before implementing a wider, more permanent policy.

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

Answer to E.3:
   The literature on OPO performance improvement has made several advancements in recent years and data-driven initiatives and tools are now showing promise for improving procurement.[18] Benchmarking, program evaluation studies, and process mapping/analyses of

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[14] Mehrotra, Sanjay, et al. "Modeling the allocation system: principles for robust design before restructuring." *Transplantation* 99.2 (2015): 278-281.; National Academies of Sciences, Engineering, and Medicine. "Opportunities for organ donor intervention research: Saving lives by improving the quality and quantity of organs for transplantation." (2018).

[15] Ersoy, Ozge Ceren, Diwakar Gupta, and Timothy Pruett. "A critical look at the US deceased-donor organ procurement and utilization system." *Naval Research Logistics (NRL)* 68.1 (2021): 3-29.

[16] Predmore, Zachary, et al. "Barriers experienced by organ procurement organizations in implementing the HOPE Act and HIV-positive organ donation." *AIDS care* (2021): 1-7.

[17] Davis, Ashley E., et al. "Changes in geographic disparity in kidney transplantation since the final rule." *Transplantation* 98.9 (2014): 931-936.

18 Doby, Brianna L., et al. "Results of a data-driven performance improvement initiative in organ donation." American Journal of Transplantation 21.7 (2021): 2555-2562.

the procurement processes are not generalizable because no single authoritative study has compared a large number of OPOs nationally and yielded definitive conclusions on best practices and benchmarks. Such an undertaking would help establish a baseline for the entire nation.

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

Answer to E.4:

HRSA has promulgated various regulations and final rules in the past decade to accomplish the goal to increase access to transplant. The research literature, including work performed by RAND researchers, is replete with examples of lingering geographic, demographic, and clinical disparities in access to transplants. [19,20] In addition to the foregoing discussion on OPOs, there is observed variation in registration, organ acceptance, and risk assessment practices of transplant centers that contribute to this inequitable access.

Policies, governance structures, and incentives must continue to be experiment with and modified. However, policy changes will always carry unintended consequences and that to mitigate the risks thereof, systems engineering, and systems analysis frameworks must be a part of the policy development process. Moreover, the use of mixed methods to corroborate the impact of policy changes, for example, triangulation of allocation policy simulations and trials by transplant centers or OPOs to improve access should be coordinated before implementing a wider, more permanent policy.

F. Organ Usage
The NASEM report identifies concerns with the current high level of organ non-usage (discards), estimated at an unacceptable 25%. Over the past several years, the OPTN Collaborative Improvement and Innovation Network (COIIN) projects and the current CMS/HRSA End Stage Renal Disease Treatment Choices Learning Collaborative (ETCLC) have worked to build and share best practices models to aid the community in addressing variables that adversely impact organ usage. HRSA is seeking feedback related to the following questions on increasing organ usage and simultaneously decreasing organ non-usage (discards).
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. Organ under-utilization is an ongoing area of research. For example, about one in five of deceased donor kidneys, or approximately 4,000 kidneys, recovered from a pool of approximately 11,000 deceased donors were not transplanted in the same 2019. Additionally, about 1,000 more kidneys were not even recovered annually from*

19 Predmore, Zachary, et al. "Barriers experienced by organ procurement organizations in implementing the HOPE act and HIV-positive organ donation." AIDS care (2021): 1-7.
20 Davis, Ashley E., et al. "Changes in geographic disparity in kidney transplantation since the final rule." Transplantation 98.9 (2014): 931-936.

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donors who had otherwise donated another type of solid organ – a related phenomenon known as "non-procurement".

Answer to F.1:

The research literature, including work performed by RAND and its partners, has identified explanations for the significant number of discards including transplant center selectivity and risk aversion; more stringent regulatory environments; and decentralized decision-making in which transplant centers with high-priority candidates may be incentivized by allocation policy to reject certain offers.

RAND would support additional research that would address mechanisms to help OPOs manage selectivity and risk aversion of transplant centers, navigate more stringent regulatory environments, or provide research on possible new incentives to promote uptake.

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

Answer to F.2:

As discussed previously, organ matching must be modified to manage the selectivity and risk aversion of transplant centers and incentives to reject organs (particularly marginal organs) by high-priority candidates. Policy studies with a system engineering focus can test various mechanisms to accomplish these ends while informing potential unintended consequences for other metrics such as accessibility, outcomes, etc.

G. OPTN Operations and Policy Development Improvements

The NASEM report recommends making that the improvements to the OPTN policymaking process including increasing racial, ethnic, professional, and gender diversity on the board and committees responsible for developing OPTN policies. NASEM also recommended seeking engagement with external organizations, such as the National Quality Forum (NQF) or the National Academy of Public Administration, with expertise in guiding federal programs through unique challenges in leadership and stakeholder collaboration. HRSA is seeking feedback on the following questions:

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.*
2. *Describe how you would/vendors could engage with experts in quality improvement and stakeholder collaboration in executing OPTN deliverables.*
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.*
4. *What other improvements to OPTN operations and policy development processes can and/or should be incorporated into the OPTN contact?*

H. Stakeholder Engagement

The NASEM report outlines how transplant centers should be required to improve their stakeholder engagement efforts and activities, specifically by making transplant candidates, transplant recipients, other affected patients, organ donors and family members aware of all organs they have been offered and by monitoring their changing health and attitudes impacting organ acceptance decisions. HRSA is soliciting feedback related to the following questions:

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.*

Answer to H.1:

To incorporate NASEM's recommendation to improve stakeholder engagement, the OPTN needs better data collection at the point of organ acceptance or decline. Vendors could support the development of a real-time or near-real-time data collection tool to be administered to a patient or their caregiver soon after an organ acceptance decision to assess both the patient's current health status as well as their attitude towards the organ they were just offered. This tool could be longitudinal and contain information about previous organ acceptance decisions. Automated data collection and linking to EHRs would enhance the validity of such decision tools.

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.*

Answer to H.2:

The OPTN could conduct periodic evaluations of stakeholder engagement among OPTN members (or a random sample of members) and produce reports highlighting both high and low performing members. These evaluations would likely be qualitative reviews consisting of interviews with or surveys of stakeholders at each OPTN member to assess the degree of stakeholder engagement, drawing from existing frameworks for stakeholder engagement in health care research.[21] These frameworks could include the approach outlined in discussions of "broadly engaged team science," which identifies different potential roles for stakeholders in research and translation efforts.[22] Key to these stakeholder engagement efforts are including different types of stakeholders, sustaining active partnerships with these stakeholders, allowing patients and other stakeholders to lead the relationships with the

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[21] Concannon, Thomas W., et al. Practical Guidance for Involving Stakeholders in Health Research. Journal of General Internal Medicine. 34, (2019):458-463

[22] Selker, Harry P., and Consuelo H. Wilkins. "From community engagement, to community-engaged research, to broadly engaged team science." *Journal of Clinical and Translational Science* 1.1 (2017):5-6.

researchers, choosing the appropriate level of involvement for the patients (communication, consulting, collaboration, coproducing),[23] and considering the lifecycle of patient involvement through research and care.

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

Answer to H.3:

The FDA is pioneering the use of patient preference information (PPI) in regulatory decision-making for medical devices.[24] PPI, as distinguished from patient reported outcomes, captures the importance patients place on aspects of treatment decisions. PPI may not be just limited to patients, but include other stakeholders such as clinicians, caregivers, families, etc.

HRSA could encourage this paradigm of decision-making in transplant. Transplant involves multiple stakeholders: patients, clinicians, and donor families being the most prominent. Collection of PPI can inform tradeoffs patients and providers make regarding care (e.g., the tradeoffs of accepting an organ now vs. waiting more) and even evaluate the willingness of donor families and the general public to utilize donor organs in a specific way. Moreover, as mentioned in previous responses, there is also a need for more accurate and standardized decision tools regarding organ acceptance. Such tools could also utilize PPI to be even more effective.

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[23] Concannon, Thomas W., et al. "Stakeholder engagement in the design and conduct of pragmatic randomized trials." *Pragmatic Randomized Clinical Trials*. Academic Press, (2021):33-45.

[24] https://www.fda.gov/about-fda/cdrh-patient-science-and-engagement-program/patient-preference-information-ppi-medical-device-decision-making

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Organ Procurement and Transplantation Network (OPTN)

Prepared for Health Resources and Services Administration
Request for Information Response
May 23, 2022

Contact:

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Table of Contents

A.   COVER PAGE

May 23, 2022

Naomi Inazawa
Health and Human Services (HHS) Health Resources and Services Administration (HRSA)
5600 Fishers Lane
Rockville, MD

Re: Response to Request for Information Organ Procurement and Transplantation Network (OPTN)

Dear Ms. Inazawa,

Thank you for this opportunity to provide Health and Human Services (HHS) Health Resources and Services Administration (HRSA) with a response to a Request for Information (RFI) for Organ Procurement and Transplantation Network (OPTN) services. Ready Computing Government Solutions (Ready) is a team of health IT experts with a long history of developing and implementing the standards that are advancing the interoperability of electronic health data. We serve public and private sector clientele, including the U.S. Department of Veterans Affairs (VA), statewide agencies, and nationwide healthcare systems.

Below is information requested for the RFI Cover Page:

	RFI Request	RFI Response
1.	Notice number, title, and date of issuance	Notice Number: Not available Title: Organ Procurement and Transplantation Network (OPTN) Date of Issuance: • Original: April 8, 2022 • Amendment 1: May 5, 2022
2	Company Name	Ready Computing Government Solutions LLC.
3	Address	150 Beekman St. Floor 3; New York, NY 10038
4	Point of Contact (if applicable), Phone and Email address	Raymond Kahre, (212) 877-3307, Raymond.kahre@readycomputing.com

We appreciate this opportunity and will do everything we can to make this project a tremendous success for HRSA. If you have any questions about our proposal or require additional information, please contact me.

Sincerely,

Raymond Kahre
Manager Federal Sales and Marketing

B. RESPONSES TO QUESTIONS

Healthy Communities, Healthy People through Health Information Technology (IT)

The Health and Human Services (HHS) Health Resources and Services Administration (HRSA) mission is " *To improve health outcomes and achieve health equity through access to quality services, a skilled health workforce, and innovative, high-value programs*." One of HRSA's many vital services is the Organ Procurement and Transplantation Network (OPTN), which manages the effective and safe care and allocation of organ transplants. One area that HRSA would like to enhance is in the area of the Information Technology (IT) infrastructure that supports the needs of the OPTN transplantation process.

Ready Computing Government Solutions (Ready) shares HRSA's mission as a full-services health IT consulting firm that has been delivering innovative technology solutions to improve patient health and well-being for more than a decade. Our clientele includes public and private sector healthcare organizations, including the U.S. Department of Veteran Affairs, statewide agencies, nationwide healthcare systems and health information networks, and international organizations.

Ready agrees with many of the recommendations in the "Realizing the Promise of Equity in the Organ Transplantation System" report, and the area that we can provide the greatest value is in the enhancement of "OPTN Technology – IT System" and " Data Collection Activities". HRSA can take advantage of the latest technologies to build a data-driven foundational system to effectively manage the identification, allocation, and reporting of the OPTN process with an implementation approach that minimizes risk for HRSA and patient lives.

Table 1 OPTN IT System Factors for Success

Success Factor	Importance to HRSA and OPTN
High-Quality Integrated Data	Proven delivery of integrated healthcare data from multiple, disparate sources for unified care records, analytics, and other uses for large, complex implementations, including statewide and nationwide health information exchanges (HIEs), state and federal agencies, national healthcare systems, and private and public payers.
Streamlined Workflow and Reporting	Enhance the usability and performance of the OPTN IT system and related tools by automating the management of organ transplant distribution through a robust data-driven workflow, augmented by real-time statistics and reporting to effectively and efficiently manage the transplant process.
Sustain Operations with Minimal Risk	Sustain operations during migration to new OPTN IT systems as well as providing foundational platform for sustainable models of care that adapt to changing healthcare needs, technology, and policy over the long-term reduce risk and increases confidence in taxpayer investment.
Secure, Safe, Equitable	Maintaining patient privacy, safety, and equity is vital to ensuring equitable organ allocation and access to transplantation.
Agility, Speed, Quality	Identifying, responding to, and measuring the timely, efficient, and effective distribution of transplants.

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. (A.1.a)

Ready understands that HRSA requires a foundational architecture that will enable OPTN to provide a comprehensive, foundational, and scalable solution that enhances the management, tracking, and operation of HRSA's organ identification, donation, procurement, allocation, and distribution process. Ready will deliver these capabilities with an integrated solution of software, hosting, and services that will enhance OPTN's current operations with minimal risk and disruption to HRSA's current process.

Figure 1 Enhanced Fully-Integrated OPTN IT System Delivered by Ready Computing
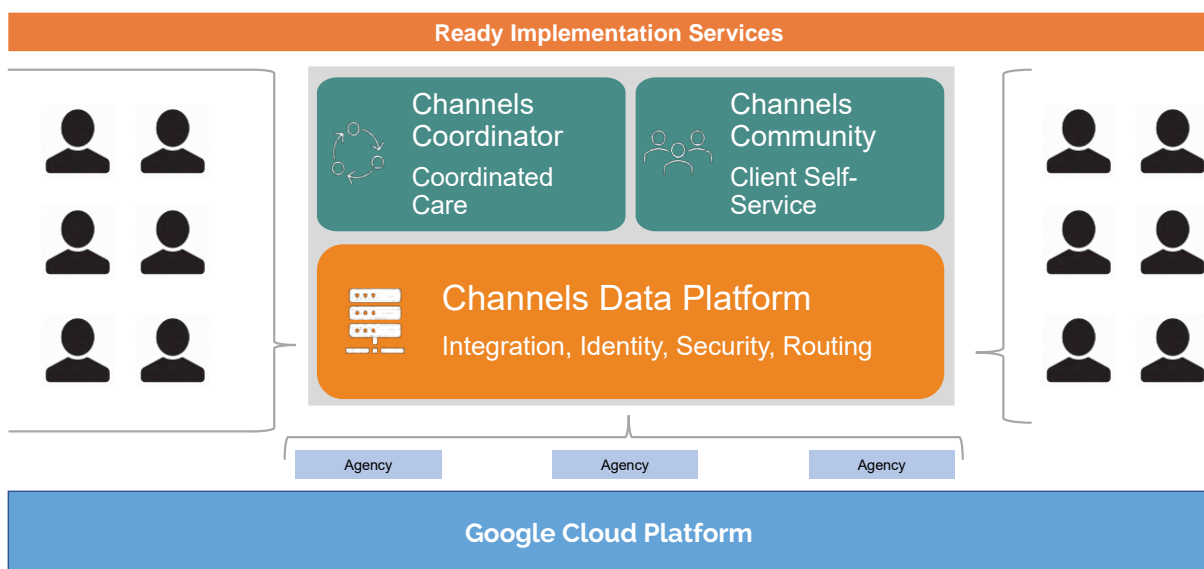
OPTN will benefit from the following key capabilities from our proposed solution:

- **Data management**: OPTN patient data arrives from a number of electronic health record systems worldwide. Ready's expertise is integrating and managing this data so that it can be actionable. Utilizing Channels, OPTN IT will be able to gather, organize, and synthesize the data from a variety of OPTN-defined sources.
- **Workflow.** OPTN must have a robust workflow process to coordinate, manage, and measure organ transplant process in a timely and efficient manner. Ready's Channels solution provides a robust data-driven workflow solution to automate and enhance HRSA's current process.
- **Hosting**. Ready delivers on-prem and cloud-hosted solutions. Cloud-hosted solutions provide the greatest security and scalability for nationwide management of organ transplant data. Ready works with a variety of hosting vendors, including Google, AWS, and Azure, and can provide OPTN with a flexible and scalable solution that best meets requirements.

- **Systems monitoring and management**. Healthcare is a 24-hour 365-day operation and requires high availability. Ready's primary focus has been delivering solutions with these requirements using application and system monitoring tools to achieve consistently high service level agreements (SLAs).

Channels

Channels is the cornerstone of our proposed solution to enable HRSA to digitally connect, implement, and scale out your system of care vision. This framework will enable you to consolidate and share necessary data across the spectrum of care to support residents and their families. The framework is capable of connecting health plans and human service providers to your model of care—including housing, wellness programs, self-care management, transportation, bereavement, and educational programs.

These components were developed under a set of core tenets that serves as the foundation upon which we develop and implement any solution:

- Capture a digital system of care using intuitive, easy-to-use, drag-and-drop controls.
- Demonstrate a comprehensive, 360-degree view of care incorporating all aspects of clinical and social care.
- Focus on connected care while hiding the technical complexities of keeping systems integrated.
- Perform and scale to meet your ever-growing needs of care.
- Promote innovation through dynamic workflows that may be adapted as needed to engage technical staff.
- Protect the client through comprehensive privacy and security policies.
- Provide a single source of truth through a unified and curated care record.
- Recognize that human services need to stay human-centered, and technology should focus on bringing the right people together at the right time.

Cloud Hosting

Ready maintains relationships with several leading hosting providers, including Google Cloud Platform (GCP), Amazon Web Services, and Microsoft Azure. Each provider has nationally distributed data centers. They are all certified under HIPAA, HITECH, and HITRUST and meet all of HRSA's compliance requirements. Based on the requirements presented to us by HRSA, we have selected GCP to host the proposed solution. We are a premier GCP partner, and their service offering provides the availability, security, and scalability required to support HRSA's requirements. Ready will install, configure, and manage a dedicated instance of the InterSystems IRIS data integration engine with GCP cloud hosting to achieve your systems integration objectives. If we determine that HRSA is better served through another hosting solution, then we can also provide and configure that solution for HRSA as well.

Wellbase System Monitoring and Management

A unique capability of our Wellbase offering is its single pane of glass to monitor and proactively respond to application and system issues. We developed this suite from years of experience

managing diverse client implementations across industries. Wellbase is built on Ready's commitment to manage risk and maintain high availability, security, and integrity for our clients' systems. Our Wellbase monitoring and management platform is used in every managed services implementation to help our Operations Team maximize the efficiency of tracking and resolving issues and avoid potential problems. Our key service differentiators include:

- A multitier support model for application and system management
- Flexible solutions with 24/7 support or just during business hours
- Multichannel client communications portal
- Staff with more than 90 years of combined IT Industry certifications, experience, and expertise
- Additional services through strategic partnerships with best-in-class industry providers

Ready's Proven Implementation Methodology

Replacing legacy solutions with newer cloud-based software solutions can be costly and risky endeavors if not implemented and managed correctly with a proven approach. Successful technology implementations—in particular those that require data integration—call for seasoned consultants with expertise maximizing software to achieve your objectives. Ready has delivered more than 50 integrated healthcare data and workflow solutions to public and private sector clientele. We do this through our experienced staff members who have partnered with our clients to design, implement, and maintain solutions that are improving delivery of care and patient health across the nation.

Ready also has a mature, proven implementation methodology based on the Project Management Institute (PMI) Project Management Book of Knowledge (PMBOK) and honed through the extensive experience of our team members. The value of our methodology is in the regimented and gated series of project stages below, bolstered by strong governance, quality focus, proactive risk mitigation, and continual communications with key project stakeholders. Each gate has its own set of deliverables, work products, and quality assurance procedures tailored to the specific requirements of the project and involves collaboration with the client to provide input, review, and approval. Our methodology is also characterized by robust project management, with seasoned Project Managers, including those who are certified Project Management Professionals (PMP) with expertise in health care and other application integration projects.

Our implementation methodology is comprised of five key stages:

Our process maps well to both agile and Waterfall principles. Under agile principles, each sprint, which is typically defined as a period lasting between two and four weeks, is delivered according to this five-stage process. Under Waterfall principles, the entire project follows our five-stage process in a linear, sequential manner. Often, hybrid approaches are taken where different project phases follow either agile or waterfall principles, as dictated by project requirements.

The five stages of our process are as follows:

- Discover: The team defines use cases, technical architecture, and requirements with <<Client>> to align with the business objectives of the solution.
- Design: The requirements defined in the Discover stage are transformed into a solution design and documented in a Solution Design Document.
- Build: The technical team installs and configures the solution based on the solution design document and conducts unit testing throughout the process.
- Validate: The work performed during the Build stage undergoes comprehensive testing, including quality, integrated, and user acceptance testing (UAT).
- Deploy: At the conclusion of UAT, the solution is published to the production environment and brought to a live state.

This five-stage process ensures all members of the implementation team—both Ready and HRSA resources—are fully coordinated under a process that includes the checks and balances essential to a successful delivery.

HRSA gains the maximum value for an OPTN IT system by partnering with an experienced health IT solution provider that has delivered integrated healthcare data and workflow solutions for the nation's largest public and private sector clientele.

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. (A.1.b)*

The proposed solution contains a highly functional and proven integration data platform to collect, manage, and share clinical, administrative, social, behavioral, and other data pertinent to a patient's well-being. The power of InterSystems IRIS for Health data management platform is its capacity to collect, assemble, and provide timely access to that data.

The platform's data collection and assembly features support all common health IT standards (e.g., HL7, C-CDA, FHIR, DICOM) and other custom protocols that may be identified during the design phase of the project. The platform will ingest and integrate content from HRSA's data sources through standard or custom protocols such as:

- APIs
- Data governance tools through which business maintenance owners (data stewards) perform data quality functions
- System interfaces that collect and transmit data

HRSA data managed in the Channels Data Platform can be securely accessed by authorized consumer applications. Access for privileged applications is provided via APIs published on the Service Bus, which may be standards-based APIs such as IHE (e.g., PDQv3, PIXv3, XDS.b) and FHIR, or custom APIs if needed for integration with a particular consumer application.

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.c)

Channels

Channels is our commercial off-the-shelf framework we recommend as the solution to enable HRSA to digitally manage organ donation, procurement, allocation, transportation, and transplants. This framework will enable you to consolidate and share necessary data across the spectrum of organ management services which are needed to support HRSA patients and transplant centers in support of organ acceptance decisions. The framework is capable of connecting all needed stakeholders including, if needed, health plans, hospitals, and community-based organizations to offer coordinated service delivery. Using the tools inherent in the system, HRSA can manage and coordinate connections between patients, transplant centers, organs, and all supporting services allowing fast and efficient organ acceptance decisions and managing the coordination of organ delivery services into a single source of truth.

Channels was designed as a workflow, task, and event management system. As such, it can be tailored to address a wide variety of solution and decision needs. Using Channels as a foundation, HRSA will be able to establish and then and expand your existing programs. Whether users are managing donors and recipients, designing new workflows, or analyzing outcomes, team members will quickly be up and running with Channels due to its intuitive, user-friendly interface.

Our Channels solution is made up of three main components:
- Channels Data Platform for integrating and sharing data from and between HRSA participants including patients, OPTN members, and other supporting assets
- Channels Coordinator for connecting transplant centers, patients, care teams, transportation resources, and other relevant organizations
- Channels Community for engaging HRSA clients

Each of these components was developed under certain core tenets that hold true for all solutions we develop and implement:
- Capture a digital system of care using intuitive, easy-to-use, drag-and-drop controls
- Focus on connected care while hiding the technical complexities of systems integration
- Perform and scale to meet the potential of ever-growing needs of event and care coordination
- Promote innovation through dynamic workflows that may be adapted without needing to engage technical staff
- Protect our users through comprehensive privacy and security policies
- Provide a single source of truth through a unified and curated care record
- Recognize that human services need to stay human-centered, and technology should focus on bringing the right people and resources together at the right time.

Figure 2 Channels Solution Components
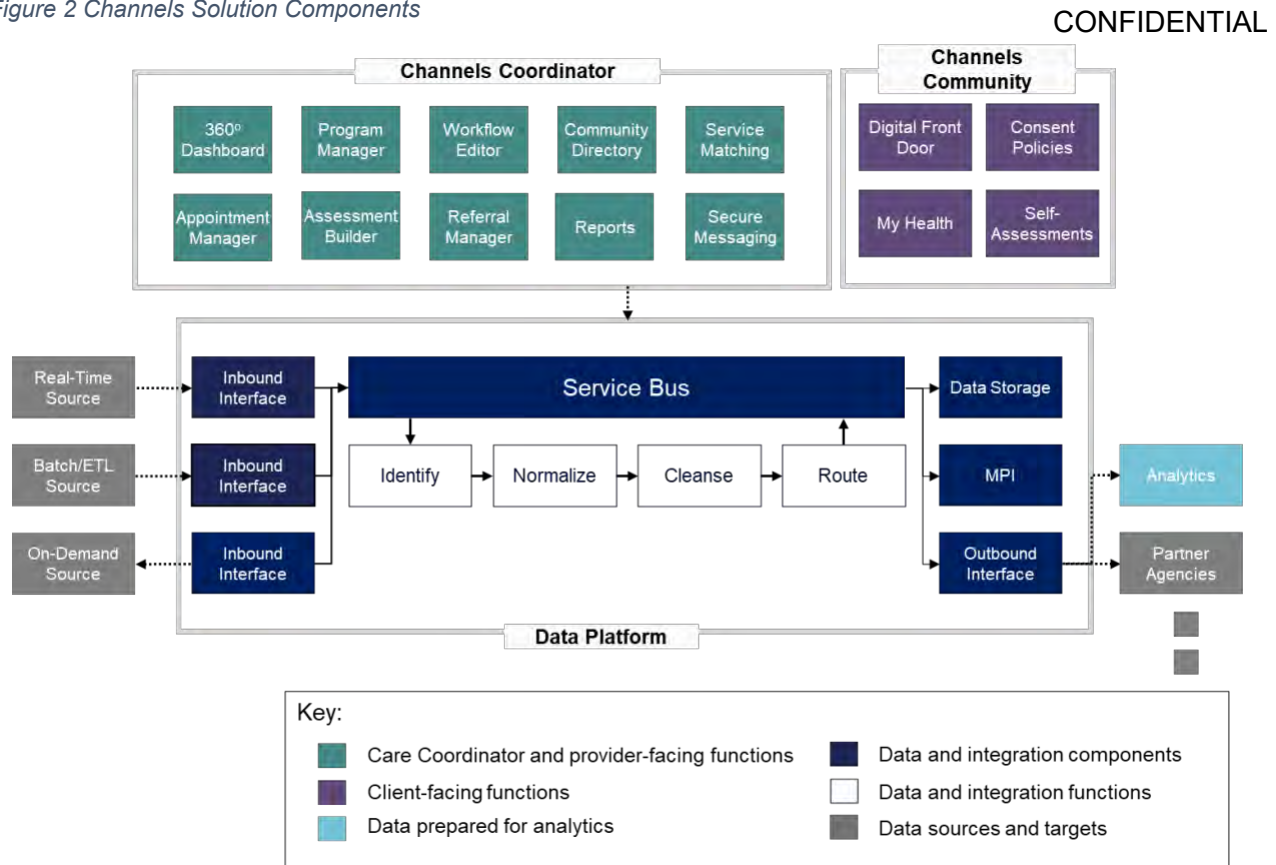
At a high level, the turnkey, integrated solution contains components within the Channels Coordinator and Channels Community applications that securely connect to the downstream Channels Data Platform (the strategy for integrating and managing data).

Channels Coordinator

Channels Coordinator is a program management web application that streamlines the creation, implementation, and management of a variety of patient and event coordination and collaboration activities. The application is designed to support the entire life cycle of your model of care (organ management)—from referral through screening, risk and needs assessment, service delivery, transplant center coordination, resource identification, and after care. This portal is intended for case workers and providers.

Care Modeling

Channels Coordinator offers program leaders intuitive tools to capture their service models so they can effectively model and digitally capture patients, tasks, events, and resources which reduces the fragmentation that occurs with paper-based methods. Our unique approach to this challenge is to model program workflows into a graphical, drag-and-drop interface that allows a program leader to quickly create, validate, and deploy their service models.

Each modeled workflow guides and coordinates team members responding to a trigger event using a standardized protocol. These workflows are digitized, HRSA-specific assets intended to be carried

out by team members for a common goal. Each workflow contains actions that are performed either interactively by a team member as a task (labeled in orange below) or automatically by the system (labeled in blue above). All actions taken against a task are recorded and traceable throughout the solution. For example, if a doctor refers a client to a specialist or schedules an appointment, that action will be recorded and shown in the case timeline.

Any outbound integration configured in the Channels Data Platform can be invoked via an action in the Channels workflow. For example, after the "check in about food programs" task, you could drag a "push to medical carrier" action. When the case gets to that part of the workflow, the contents of the case would be pushed into the medical carrier's care management system. Or if a user wants to push the client's care record to a health information exchange (HIE), they drag in the appropriate "push to HIE" stencil and connect it to the workflow; when a case gets to this point in the workflow, a care record gets securely sent to the local HIE, sharing the new housing social determinant of health (SDOH) attributes entered by HRSA. Channels handles coding these attributes to standards-based vocabularies the HIE understands and wants in its client record.

Figure 3 Channels provides an easy-to-use user interface to setup and modify a workflow process
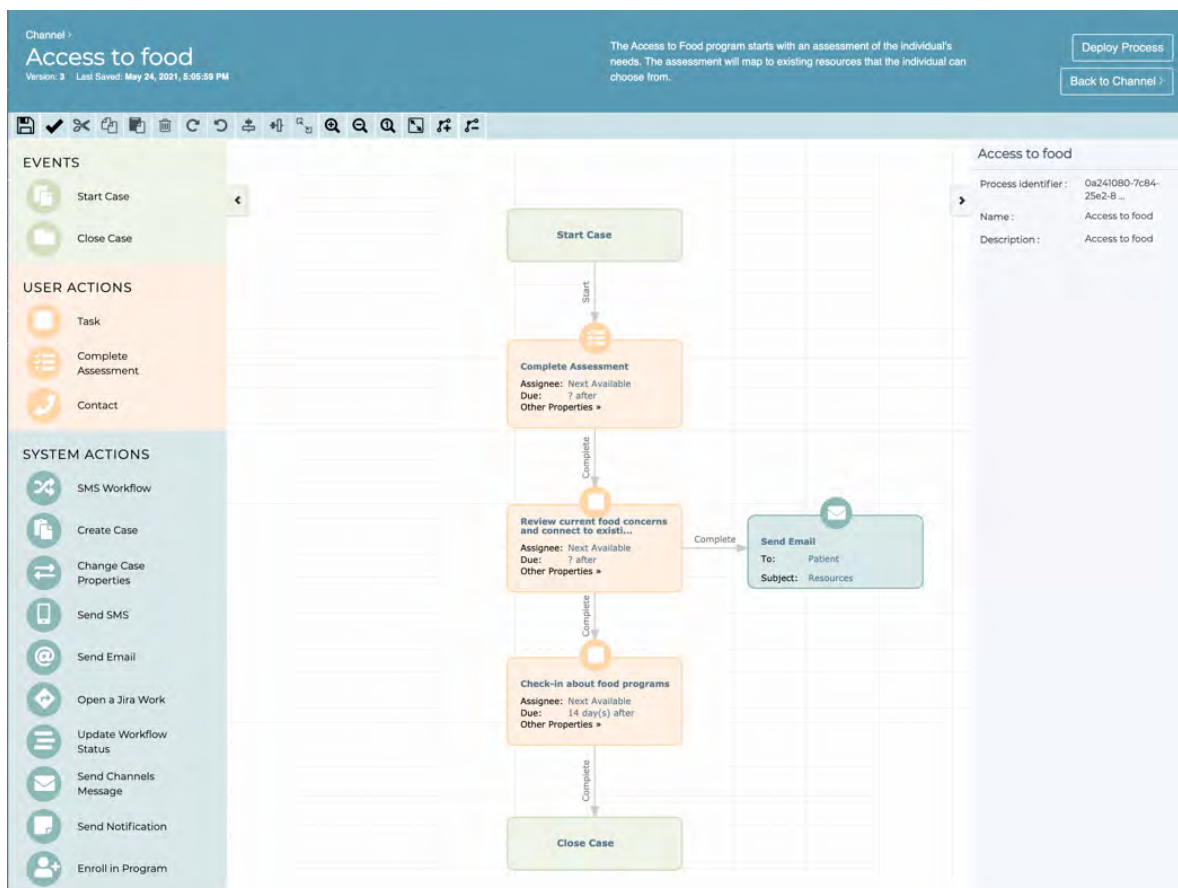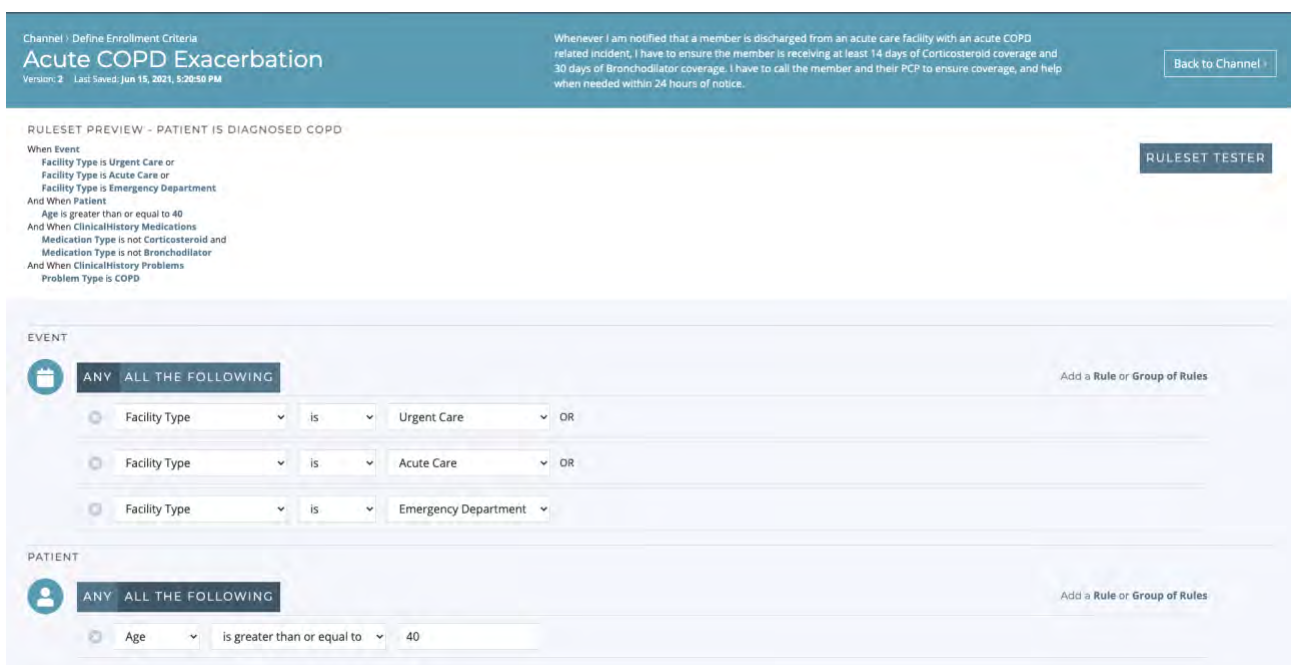
Allowing HRSA program leaders to use this simple drag-and-drop modeler reduces the burden on busy IT departments while enabling HRSA to act on opportunities in near-real time. This "click not

code" functionality will support HRSA by digitally transforming your enterprise by standardizing and automating actions and interventions to achieve the best outcomes for HRSA clients.

Workflow Triggers From Incoming Data

Automation opportunities aren't limited to our Channels Workflow Editor. A user can automatically trigger a workflow based on new data flowing into the platform. Channels Coordinator's event recognition parses incoming real-time events from the Channels Data Platform such as referrals, notices of admission, discharges, transfers, and other electronic transactions. Elements in these transactions can trigger automatic enrollment in programs and workflows to engage the care team with full tracking capabilities to ensure task completion and closed-loop referrals. These are set up using simple rules at the beginning of program creation.

Figure 4 Channels can automatically trigger an event, such as re-routing a transplant based on the status of an organ recipient or donor

Setting up this ruleset allows for automated enrollment of a client based on an HIE clinical alert but could support an alert from any data source such as population health systems, analytics engines, and even spreadsheets.

Channels Community

Channels Community starts with the Digital Front Door, a visually engaging, responsive web page that can be accessed from a computer, tablet, or smartphone. Content includes anonymous self-assessments, a browsable and searchable resource directory, videos, and other content that leads the user to step through the door and engage with resources further.

This approach allows potential users to engage quickly and with no up-front sharing of their personal information. HRSA can use the Digital Front Door to grab their attention and will unobtrusively

prompt them with entry questions that will lead them to take an assessment to reveal all resources with which they could or should engage.

Figure 5 HRSA can use the Channels Digital Front Door to increase organ donor awareness and donations
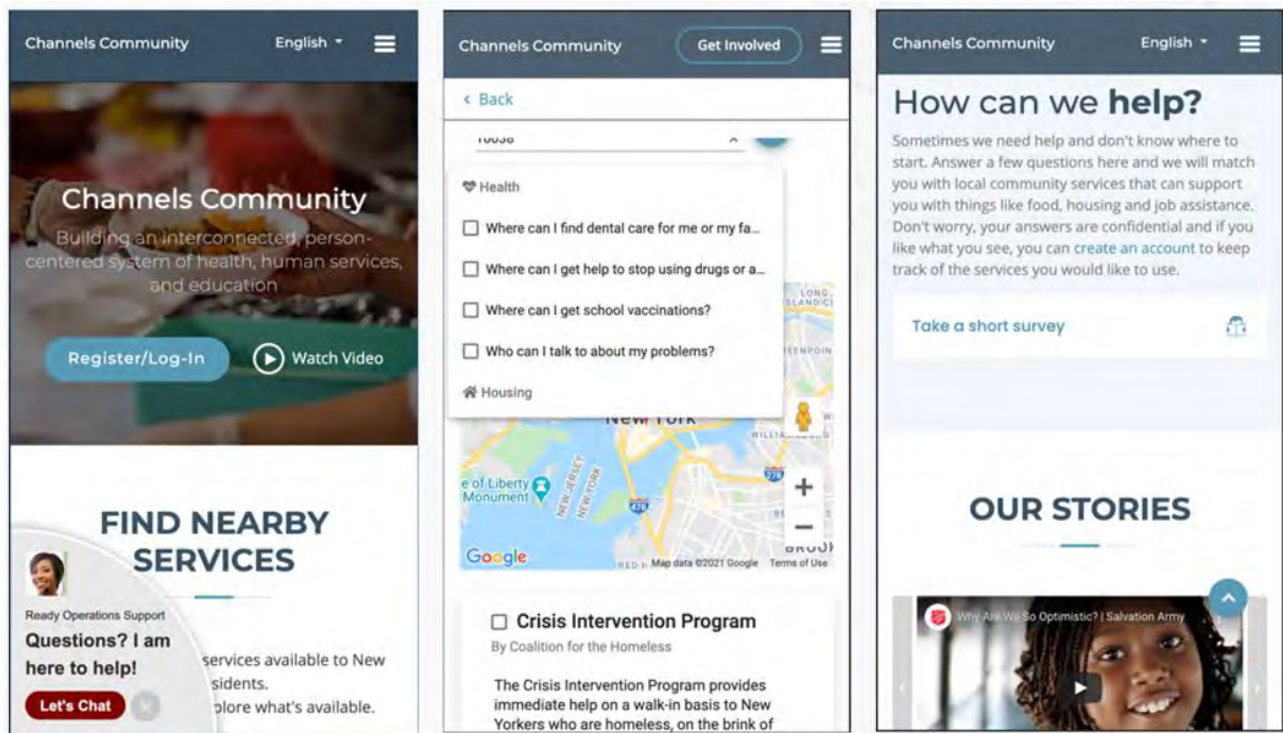
The Digital Front Door can be expanded to include general educational material, blog content, community events such as support groups, and educational sessions.

Clients have the option to register from the Digital Front Door to a secure portal where they can work in private with their care team, with one-stop shopping for community resources. A registered community user can see risks, manage to-do lists, review and update assessments, search for resources and save them, manage consent, and communicate with the care team via secure messaging. All elements and field sections are configurable.

Figure 6 Channels Digital Front Door is easily configurable
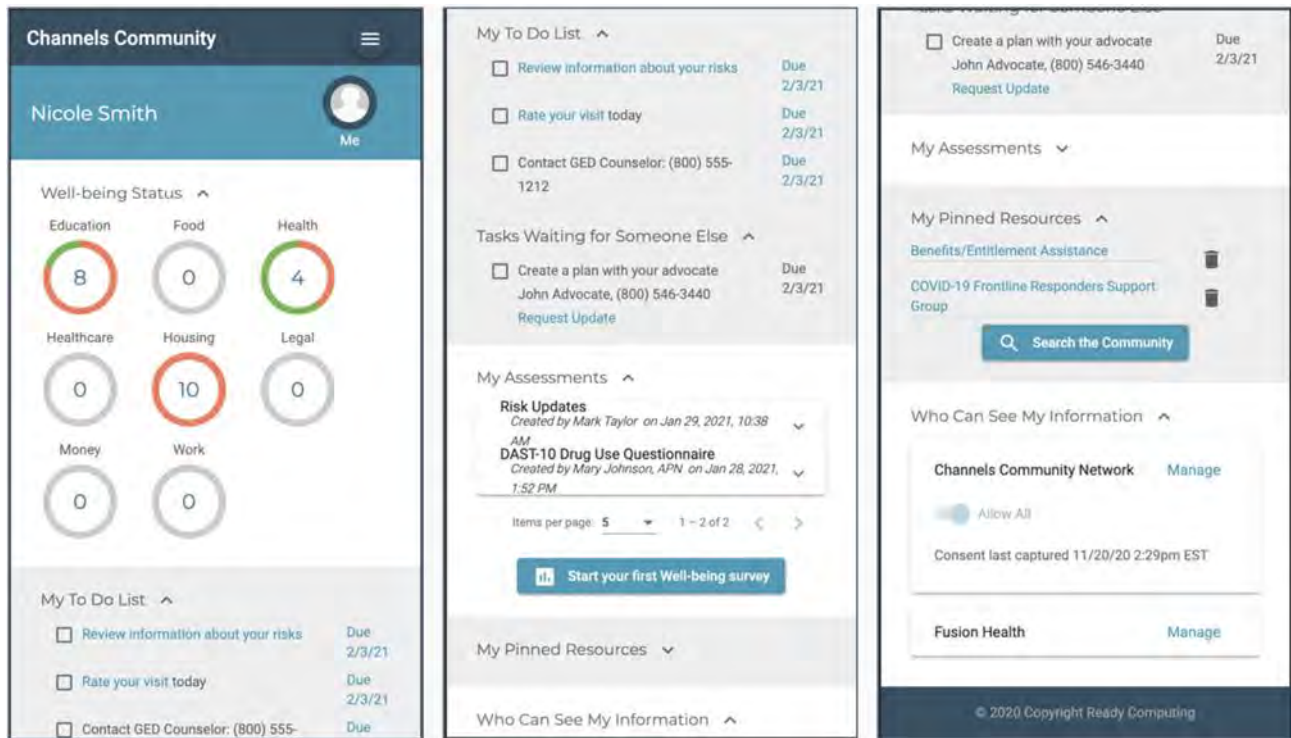
d. ***Produce public performance dashboards and actionable data to identify opportunities for program improvement, reduce inequities, and benchmark OPTN member performance. (A.1.d)***

Increased Efficiency

Once the Channels workflow is deployed, the care team can begin working with clients. The program leader can follow along case by case for each channel and get a high-level understanding of how services are being delivered. A summary of program activity tells the story of the team's performance and is available on screen or as a downloadable PDF. Additional reports can be designed and created upon request.

Figure 7 Channels provides a rich set of configurable dashboards with real-time metrics
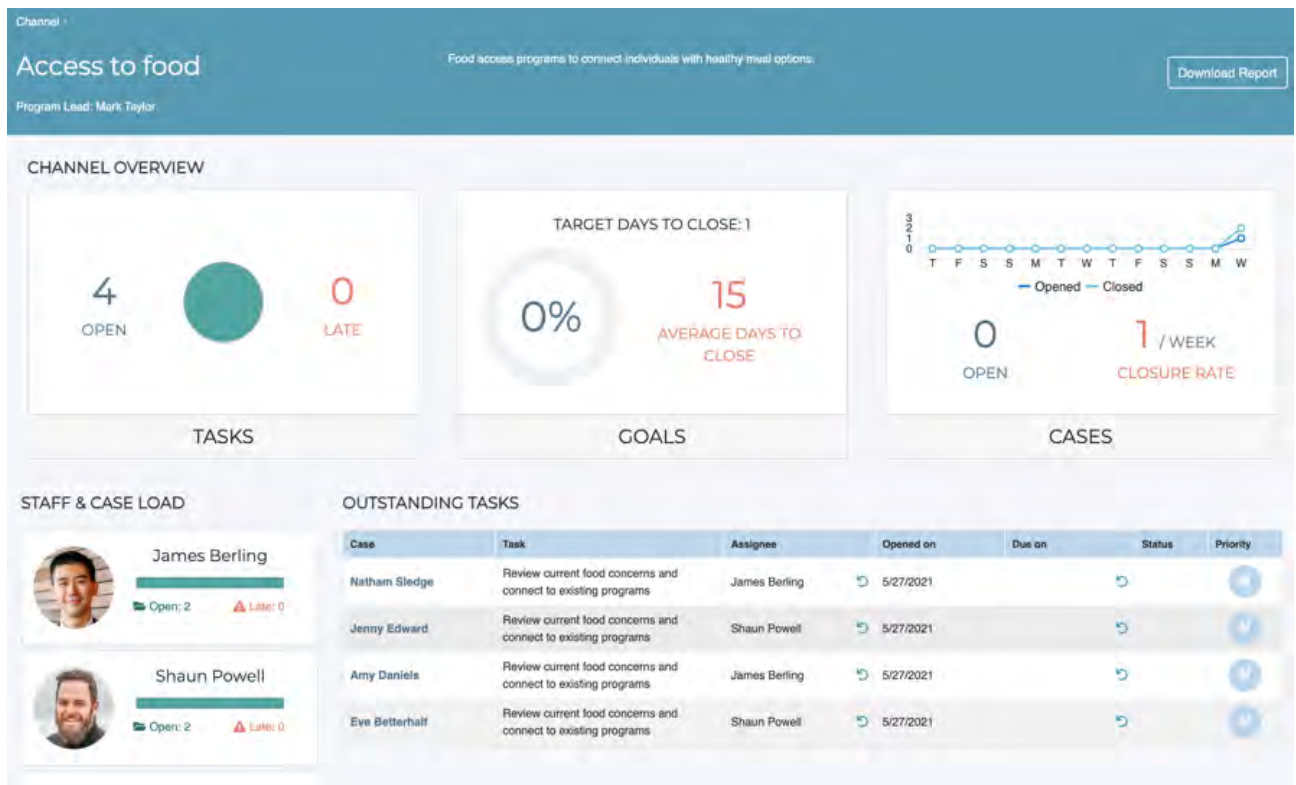
These metrics are based on the operational targets set up during program creation and are actively tracked with each case that comes through the system. The program leader can adjust their team's workload directly from this dashboard to better distribute load and priorities.

Channels Coordinator natively provides metrics that support the measurement of case closure rates. This "time to close" metric is fully configurable and allows program leaders to track workflow efficiency and adjust up or down as needed.

Figure 8 Channels can be configured to display pending deadlines or other targets

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

As stated above, targets can be established and tracked within Channels. Additional custom targets can be designed and added to Channels depending on HRSA's unique workflows.
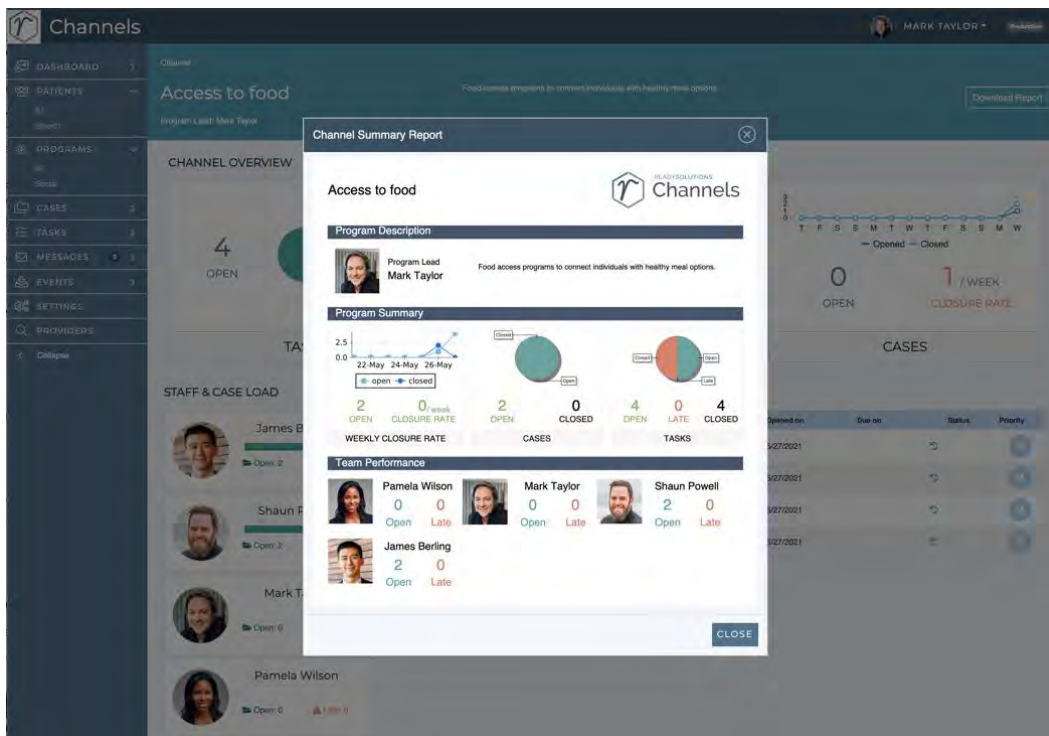
At a portfolio level, the program leader can see dashboards of all of their program's execution. Goals are tracked on both the coordinator and program leader's dashboards, providing full transparency into program performance so course corrections can be made along the way.
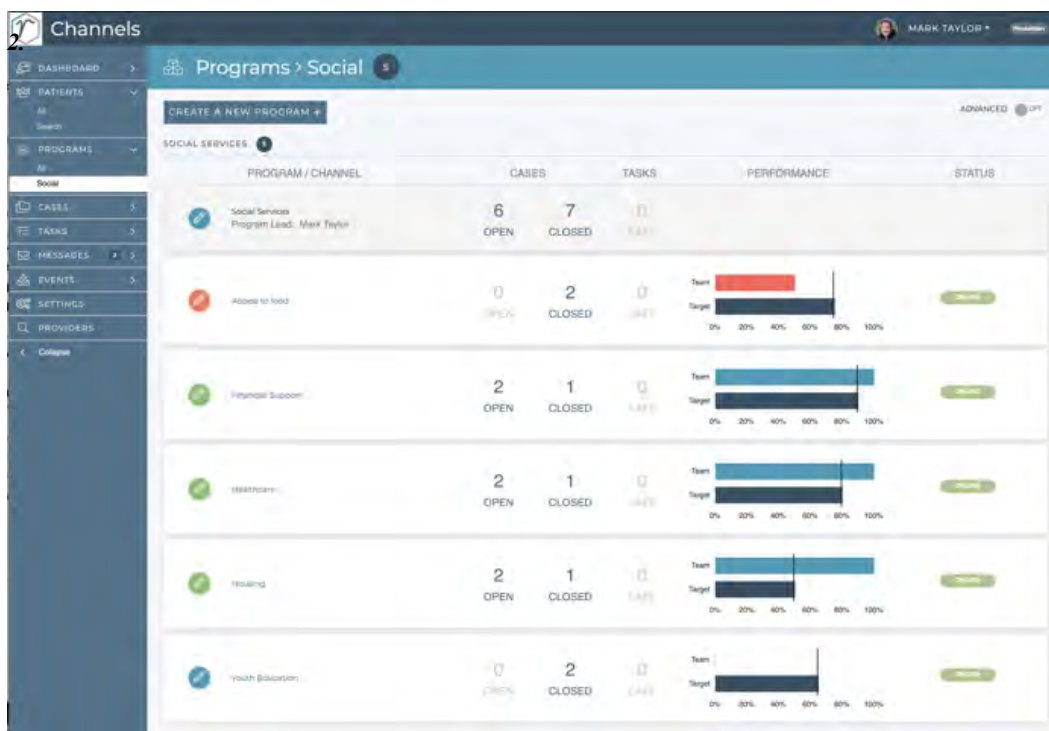
Besides what comes out of the box with Channels Coordinator, we offer customizations that allow a HRSA-specific SQL view of the data to perform your analyses and reporting using your preferred tools. Referral partner source reporting can be accommodated through program design by creating a unique set of programs and workflows specific to each partner.

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4. ***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.2)***

Hosting and Support

All Channels technologies are secure, cloud-based software-as-a-service (SaaS) offerings, and Ready will provide a one-stop shop with hosting, implementation, operations, and support services. Licensing includes all hosting, system, and application support necessary to run your solution. Ready has been implementing and supporting integrated data solutions for more than a decade, and our staff have extensive experience in the industry. Exceptional and reliable support services drive our clients' long-term return on investment for technology solutions. As clients have come to rely on our solutions for business operations, we are committed to organizations that work to improve the health and well-being of individuals and families. We also recognize that these organizations want to concentrate their time and resources on improving care rather than managing IT platforms and systems.

A key part of our proposed solution is Wellbase, our fully managed, cloud-based managed services offering designed for mission-critical applications and systems. Based on our years of experience hosting and managing IT platforms, Wellbase was developed to allow clients to focus on their core duties instead of their IT infrastructure and associated operations. Ready will lead the engagement, working closely with HRSA to identify and document project requirements and finalize the solution design. We will configure and deploy the Ready platform to meet HRSA's specific needs.

Our solution licenses support services based on the following three-tiered support model:

Figure 9 Ready's 3-tiered support to provide achieve high SLAs
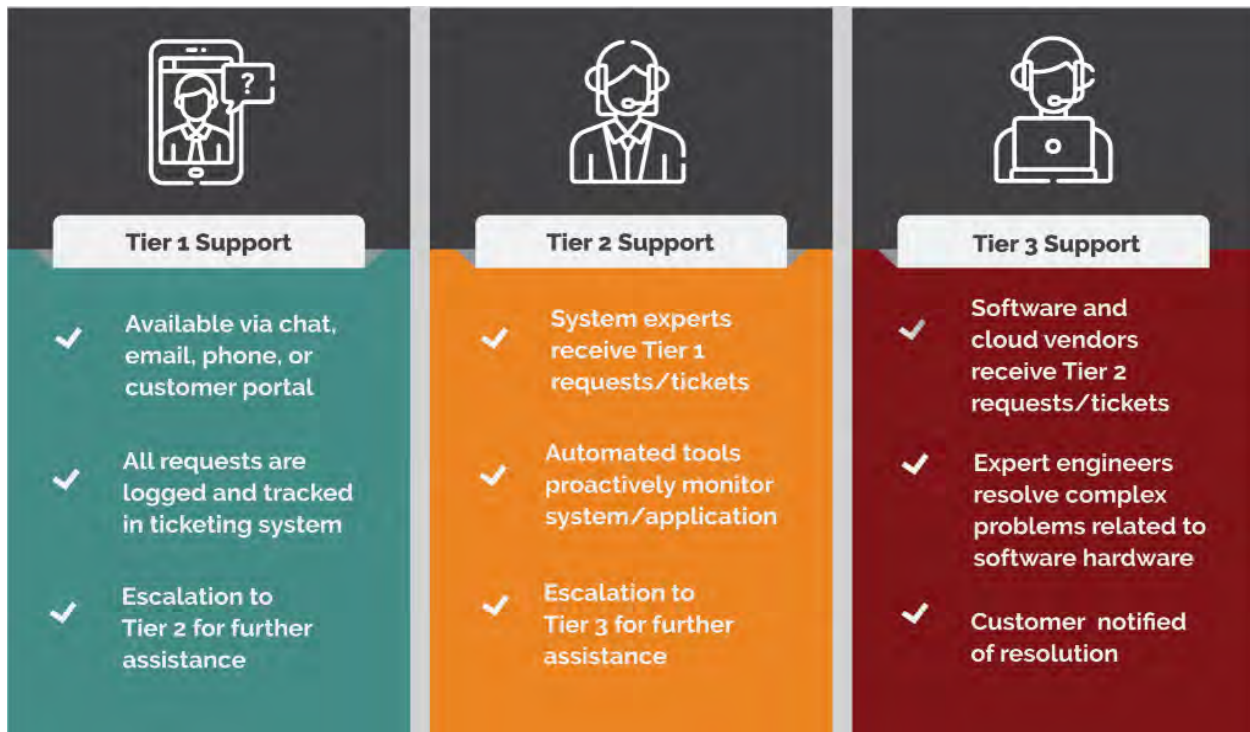
Ready understands the importance of high availability to serve our healthcare delivery clientele and their patients and developed our Wellbase offering to ensure this level of service. Our standard hosting service level agreement (SLA) is 99.9% uptime, and our proposed platform has an expected SLA of 99.5% within a month. Should an unexpected outage occur, the affected SLA should not drop below 1% of the expected SLA. We can work with HRSA to configure the optimal solution to achieve HRSA's availability requirements.

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

Channels Data Platform with InterSystems IRIS for Health

The proposed solution leverages InterSystems IRIS for Health, a highly functional, proven integration data platform that collects, manages, and shares clinical, administrative, social, behavioral, and other data pertinent to a client's well-being.

The power of the Channels Data Platform is its capacity to collect and assemble data into a 360-degree view of an individual and provide timely access to that data.

Connecting diverse technologies means you need an extensible interoperability layer that can connect systems of various technical maturity.

Data can be imported into the Solution by any number of technologies including flat file, XML doc, JSON file, SQL Exports, etc. InterSystems IRIS for Health utilizes its extensive library of adapters

to establish connections to data source providers using healthcare standards-based adapters (such as HL7, FHIR, IHE/CCD/CDA, X12, DICOM, etc.), vertical-agnostic adapters (such as SOAP/REST, XML/JSON, FTP/SFTP/FTPS, SQL, etc.), and tools for working with proprietary formats (such as fixed-width or delimited files). We support virtually any data capture methodology including real-time, bulk-loads, pub/sub, request/response, ETL, ELT, batch, etc. For any data that can be tied back to a patient such as clinical data, CRM data, Social Determinant data, medical documents, images, etc. the InterSystems Solution provides a robust, patient-centric data model known as Summary Document Architecture (SDA).

During the Design phase, we work with you to identify data sources and the relevant data components that need to be ingested and utilized for optimum system performance. Using tools inherent in InterSystems IRIS for Health, we will configure interfaces and data adapters to ingest, transform, normalize, and validate incoming data. We then test these implementations at three levels: Unit Testing, Regression Testing, and User Acceptance Testing. The testing is conducted in a Staging environment with broad samples of candidate data.

Inbound and Outbound Interfaces

Outside data sources are brought into Channels through inbound interfaces, which may be either **listeners** for input submitted by a source or **consumers** that retrieve data from a batch or on-demand source. Key features of each of these inbound interface types are described below:

Interface Type	Integration Pattern	Description
Listener	Real-time	This interface accepts input from EMRs, CPOEs, scheduling systems, and other data sources that share data in real time or near-real time. Data is accepted using common standards such as HL7, IHE, FHIR, C-CDA, and X12 or nonstandard protocols and content formats, then transformed and loaded according to implemented data processes.
Consumer	Batch/ETL	This interface runs on a scheduled interval and obtains data from databases (e.g., Oracle, SQL Server, Postgres), transaction files (e.g., claims file), and other batch data sources. Data is extracted using SQL or a custom file parser, then transformed and loaded according to implemented data processes.
	On-demand	This interface also runs on a scheduled interval and obtains data from regional HIEs, national HIEs, and other on-demand sources. Data is obtained using IHE, FHIR, or other APIs, then transformed and loaded according to implemented data processes.

6. *How would you/a vendor ensure ongoing security enhancements to protect against emerging and evolving IT security threats? (A.3)*

Privacy, Security, and Choice

At all levels, we safeguard protected health information (PHI) through four key privacy and security functions of authentication, authorization, encryption, and auditing. These core functions are elements of trust/security, role-based access management, and content management.

- **Trust/security:** The proposed solution enables comprehensive privacy and security policies and procedures. Both users and nodes are authenticated. Users are authenticated using single- or two-factor authentication, and nodes are mutually authenticated using SSL certificates. Data encryption is supported for data at rest (i.e., data stored on disk, which is encrypted using the Advanced Encryption Standard (AES) algorithm with 256-bit encryption keys) and data in motion (i.e., data being transferred to or from the solution over a network connection, which is encrypted using SSL, virtual private network (VPN), or a combination of the two). Audit logging is supported at many levels and may be customized by HRSA to include more or fewer audit events. We record key events in an internal, tamper-proof audit repository. The audit function includes protocols for managing breach notifications in which authorized parties are alerted that a potential or actual breach occurred.
- **Role-based access management:** Authorization is enforced using role-based access control. Each user account has one or more security roles associated with it, and based on the privileges assigned to those roles, the user can access only certain areas of the solution and only certain protected areas of the client's record. For example, only members of the Administration role can access back-end system configuration settings, and only members of the Coordinator role can act on defined workflow tasks.
- **Consent management:** Our system enables individuals to configure consent policies that dictate which services the individual is willing to receive. Consent policies are evaluated and applied in real time. In the consent function, we take special consideration in complying with state policy and law on which services may be performed on minors and emancipated minors.

Our approach to privacy and security ensures an individual's and family's right to privacy isn't compromised by any decisions we make as we build and refine our products. A key part of implementation will be to define and configure privacy and security services that are comprehensive and fully address your needs.

The Ready Computing organization takes all matters involving privacy, data, and security very seriously. Various information security laws, regulations, and industry standards apply to Ready and the data we handle. Ready is committed to complying with all applicable laws, regulations, and standards. In Ready's most recent Risk Analysis and Management Audit, our Overall Risk Status was considered to be "exceptional".

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

The proposed system incorporates a comprehensive multi-faceted security solution providing protections through software, infrastructure, and data management. Security and privacy are tantamount to the Ready Team, and the company fully complies with HIPAA, HITECH, HITRUST, and other security, privacy, and regulatory compliances. These facets include User Accounts; Access privileges; User, Role, and Consent privileges, tokenized URLs, or other mutually agreed upon mechanism; Data at Rest encryption; Logs (Emergency Access, User Activity, and Audit); and encrypting all data in movement.

All data and databases within the solution are encrypted. The system encryption is based on FIPS 140-2, which is the current federal cryptographic standard, (For more information, please see: The National Institute of Standards and Technology, Computer Security Resource Center's publication on FIPS 140-2: *Security Requirement for Cryptographic Modules*.)

Data at rest is encrypted in the following ways:
- Application database encryption – The application encrypts the database
- Data-element encryption – The application encrypts data elements in the database
- Encryption key management – The application encrypts with a unique data encryption key which it then manages
- Hardware encryption – The Google Cloud encapsulates the Platform with hardware encryption

The Google Cloud encryption layer uses AES 256 symmetric key encryption. Google uses Tink, a cross-platform cryptographic library, Tink incorporates BoringCrypto, a FIPS 140-2 validated module, to implement encryption consistently across Google Cloud products.

The system encrypts all data in motion and manages SSL certificates for all interactions directly exposed to the Internet using HTTPS/TLS connections. Data is transmitted through an IPSec tunnel for additional security. The purpose of the IPSec protocol is to secure IP packets through encrypting, authentication, protecting against replay, and ensuring data confidentiality.
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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.1)***

Star Administrators can set performance goals in Channels as described above. These metrics are based on the operational targets set up during program creation and are actively tracked with each case that comes through the system. The program leader can adjust their team's workload directly from this dashboard to better distribute load and priorities. Channels Coordinator natively provides metrics that support the measurement of case closure rates. This "time to close" metric is fully configurable and allows program leaders to track workflow efficiency and adjust up or down as needed. Additional metrics can be gleaned from any data collected in the system as all data is accessible for reporting purposes.

2. ***Describe how you would/how vendors could structure data collection and reporting mechanisms for the system: (B.1)***

a. ***To report OPTN performance metrics including process, outcome, and patient engagement measures. (B.1.a)***

Channels' flexibility can be utilized to configure data collection for performance and metric reporting. Data collected and generated in the system is available for reports.

Channels will allow HRSA to generate vital reports, including:

- Collection of statistical data: Channels can provide any type of outcome measure as long as the numerator and denominator are well-defined, and the underlying data is available. Our performance and quality measure modules can be customized to handle these requirements.
- Compliance with future claims submissions: Billing and claim submissions can be custom-developed to support your specific needs.
- Consumer reporting form data submissions: The proposed solution will adhere to HRSA's specifications.
- Detail-level invoicing: Generation of invoices for nonclinical services will be custom-developed to support your specific needs.
- Identification of barriers to outcome or performance measures: Once the scope of quality, outcomes, and performance measures are technically defined, we can tune our standard data quality analysis to scan the database to find data gaps and expose barriers.
- Provider-derived performance measures: Our performance and quality measure modules can be customized to handle these requirements.
- Reporting and outcome measures: Outcome measures can be calculated and reported based on available data using standard or custom measurement rules.
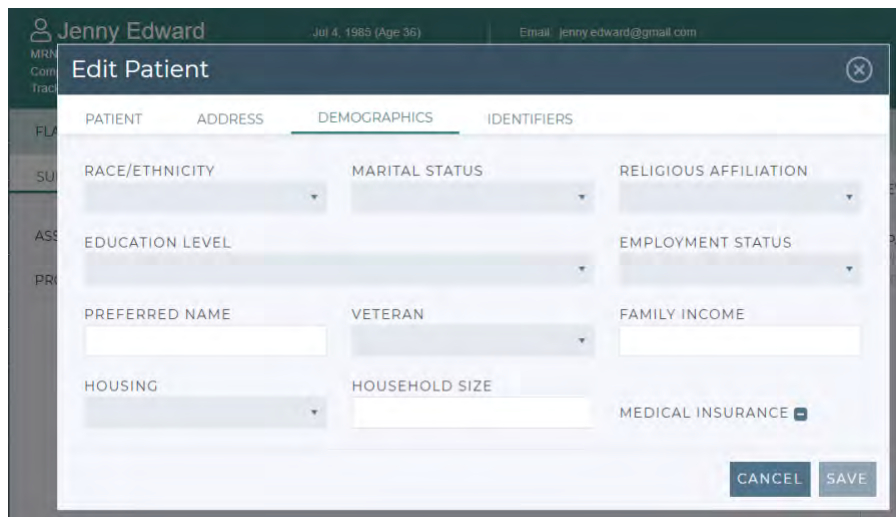
b. To establish OPTN member performance benchmarks. (B.1.b)

The same approach described above can be taken to establish OPTN member performance benchmarks. This can be done within Channels or via data collected that is associated with a given member.

c. To capture patient and donor demographics, including race, ethnicity, language, and socioeconomic factors. (B.1.c)

Patient demographic information is captured and stored in Channels as data is ingested from approved data sources. Additions and corrections to the stored demographic information can be done by authorized Channel users.
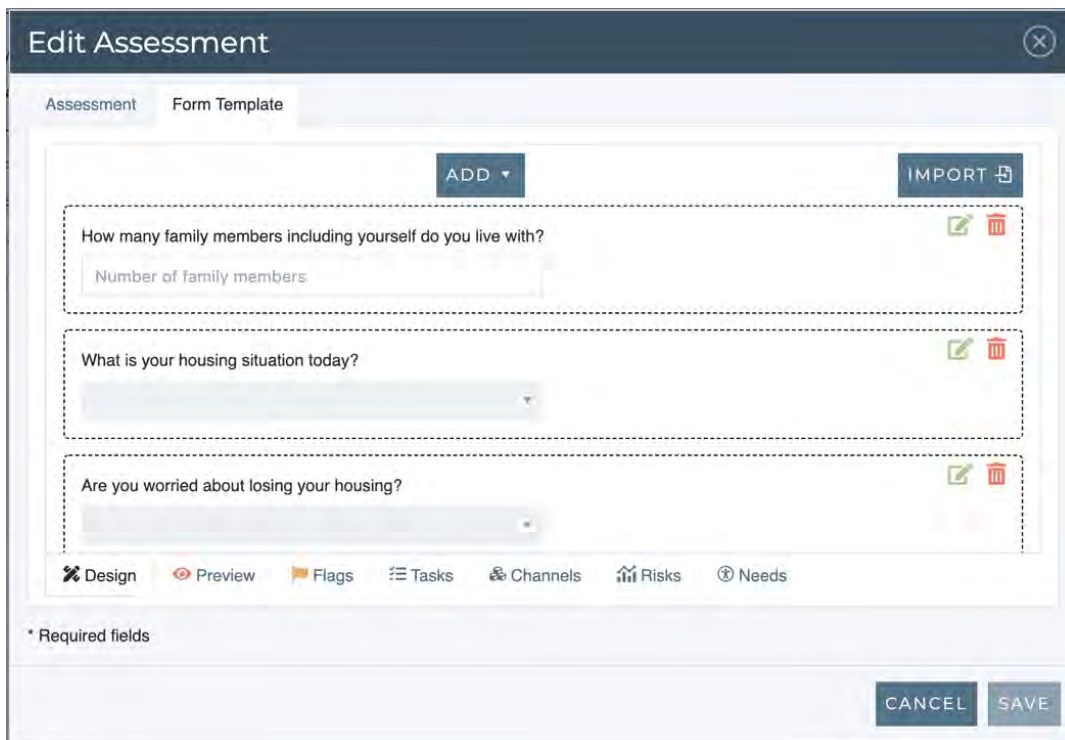
Figure 10 Capturing patient data can be done through Channels, or populated directly through an EHR

Customized demographic information, such as socioeconomic factors, can also be collected via a customizable assessment feature built into Channels. Channels Coordinator supports a wide range of assessments (e.g., PHQ-9, PRAPARE surveys) that can be captured in the individual's 360-degree record. Assessments are instrumental in a variety of specialized information gathering, so Channels Community includes a feature-rich assessment builder to create custom assessments targeted to any topic. Assessments are an effective vehicle to collecting social determinants of health (SDOH) and responses can be used to initiate other activities in the system.

Figure 11 Channels Assessments are one method HRSA can use gather information about a potential donor

Using simple, intuitive web tools, and without requiring custom development, a program leader can create these assessments, which can be used as part of a Channels workflow or can be administered ad hoc. In the assessment builder, your program leader can:
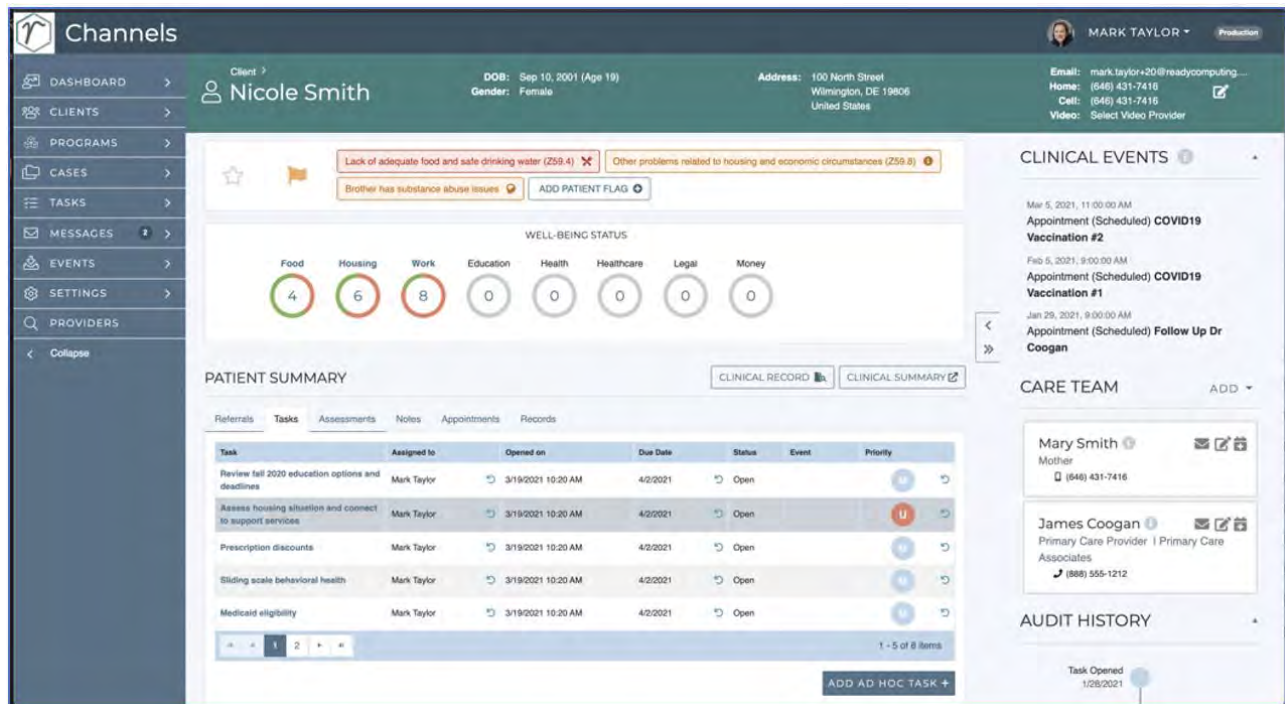
- Build simple question-and-response pairs
- Set client flags based on survey responses
- Initiate tasks based on survey responses
- Set "well-being scores" to identify and track an individual's risk
- Map responses to community services categories
- Enroll in a Channels workflow

d. To create public OPTN national, regional and local performance dashboards. (B.1.d)

Data at Your Fingertips

Channels Coordinator is securely hosted in a cloud infrastructure, enabling your staff to access critical data from anywhere with an internet connection through any current browser. The solution is highly available, and client data is kept securely up to date through our Channels Data Platform. With the help of this platform and HRSA's partnered sources, Channels Coordinator allows you to follow up on the latest client events in an easy-to-understand, consolidated view known as our 360-Degree Dashboard.

Figure 12 Channels 360-Degree Dashboard provides comprehensive view of all activities related to a patient

Details about the individual, including risks, well-being scores, assessment results, referrals, events, and care team members are easily accessible via the 360-Degree Dashboard. This dashboard allows you to know your clients better by tracking each person's services from start to finish, identifying future needs, and closing service gaps every step of the way.

e. To track long-term patient outcomes and health and non-health-related factors that contribute to outcomes. (B.1.e)

Channels offers the capability to continuous add information to a patient record. Coupled with the capability to collect Social Determinant of Health (SDoH) which can store and track non-health-related factors, the system can track long-term patient outcomes.

C.   STATEMENT OF INTENT

Ready welcomes the opportunity to respond to a solicitation to enhance HRSA's OPTN IT systems. We can deliver a comprehensive solution for OPTN to achieve success, maximize taxpayer investment, and enhance operations with minimal risk.

Table 2 OPTN IT System Factors for Success

Success Factor	Ready Benefits to HRSA
High-Quality Integrated Data	Ready has the proven experience and expertise to guide HRSA through the process of reviewing, designing, implementing, and maintaining an integrated data solution to manage the nationwide identification, receipt, and distribution of organ transplants.
Streamlined Workflow and Reporting	Ready's Channels enables HRSA to enhance the transplant processes, reporting, and metrics through real-time, actionable data and reports, and automated processes that can streamline the management and distribution of organ transplants.
Sustain Operations with Minimal Risk	Ready's proven Implementation Methodology and Wellbase application and system monitoring capabilities, ensure HRSA that we can implement and sustain a robust, scalable OPTN IT system with minimal risk and as a long-term investment for OPTN patients.
Secure, Safe, Equitable	Ready complies with all privacy and security laws, regulations, policies, and standards to protect health IT data to ensure that our solutions maintain patient privacy, safety, and equity.
Agility, Speed, Quality	Ready's solutions provide the real-time for OPTN to efficiently and effectively respond to and measure the effective and equitable distribution of transplants.

Ready respectfully requests that the following factors be considered for an OPTN IT solicitation:

Table 3 OPTN IT System Factors for Success

Recommendation	Benefit to HRSA
We highly recommend that an OPTN IT Modernization solicitation be released as a standalone contract that includes software, hosting and services to deliver, at a minimum, data integration and interoperability, workflow, reporting, cloud-hosting, and post implementation sustainment.	HRSA would receive a comprehensive solution to meet OPTN IT requirements.
We highly recommend that the OPTN IT Modernization solution includes strategies for master data management, integration standards, interoperability, and accessibility.	HRSA would benefit from high quality integrated data from multiple disparate data sources to drive workflow, reporting, and metrics.
We highly recommend that HRSA consider the qualifications of the prime contractor. Our suggestion is to indicate that the prime contractor must have proven experience deploying integrated healthcare data and workflow solutions for private and public sector clientele.	HRSA would reduce risks during implementation and increase confidence in the investment of taxpayer dollars.

ABOUT READY COMPUTING

Ready Computing Government Solutions (Ready) is a full-service health IT consulting firm that specializes in developing, implementing, and sustaining integrated health care data solutions to improve patient health and well-being. We've deployed more than 50 large-scale, complex integrated data solutions for public and private-sector clients, including the U.S. Department of Veterans Affairs (VA), nationwide health care systems, statewide agencies, and international organizations. Our solutions protect public health by managing data from multiple disparate sources, including electronic health record, claims, financials, and social determinants of health data.

Ready provides many distinct services to help clients fulfill their health IT goals, including:

- Assessments of IT strategy and adoption for organizations of any size
- Enhancing the information and workflow between care organizations to improve patient health
- Data management and analytics to gain business intelligence about health care data
- Development of programs to further engage patients in their personal and family care
- Expert modeling of transactional and analytical databases
- Guidance and education on state and national programs
- Terminology management and consultation
- Turnkey IT solutions including server hosting and related managed services
- Unmatched capabilities in integration technologies and platforms
- World-class design and implementation of data-centric health IT solutions

The foundation of our experience and expertise is our recognized leadership in data interoperability and standards. From the earliest days of the Nationwide Health Information Network Trial Implementations, Ready has been at the forefront of standards definition and validation. We are a Benefactor Member of HL7 and have held influential positions with organizations focused on interoperability.

We are also driving nationwide health care data interoperability as the lead architect and implementer of the national eHealth Exchange Hub (eHX) and connecting eHX to other networks, including Carequality, eClinicalWorks, CommonWell, and the VA.

Our work with the VA is enabling the delivery of comprehensive health care services for more than nine million veterans in communities across the country. Our dedication to the development of health IT standards underpins our implementations and enables us to future-proof the solutions we deliver and sustain.

Since the company's inception, Ready has grown to more than 190 employees in four countries and continues to grow at a healthy rate. We have had long careers in the health care and technology industries, and as a result, our collective health IT expertise enables us to successfully deploy future-proof solutions—to deliver a state-of-the-art value for years to come.

From:	Christopher G. Yanakos <chris@relipartner.com>
Sent:	Monday, May 23, 2022 10:23 AM
To:	Inazawa, Naomi (HRSA)
Subject:	[EXTERNAL] UNOS RFI RESPONSE

To whom it may concern:

I am providing comments specifically requested by HRSA through RFI related to UNOS/OPTN. I am struck by the submissions of all former HHS CTOs and the submission provided by former Clinton-Bush-Obama-Trump staffers.

I have provided additional comment below. **Beyond this technical content I will add the it is not only risky to retain UNOS/OPTN as a contractor it is dangerous. People die every day because of their incompetence and have for the last 35 years. Make no mistake, that people will continue to die unnecessarily if they are retain. In particular, no part of the UNOS/OPTN technology system should be retained. The boards UNOS/OPTN must be separated as directed by HRSA itself 4 years ago. Lastly, increased availability to information will cause the retention of failed UNOS/OPTN technology, leadership, culture, policy, and procedure to be scrutinized leaving HRSA with the untenable position of defending their decision to retain UNOS as people die.**

Thank you for your attention,
Chris

Christopher G. Yanakos
President

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Summary: In the almost 40 years the OPTN has existed, HRSA has never run a competitive cycle for the OPTN contract, which has led to regulatory capture, and deadly outcomes for patients due to massive system inefficiencies and opacity.

The Senate Finance Committee is two years into a bipartisan investigation into UNOS failures which has escalated to a subpoena, following problems hiding in plain sight for decades:

- Forbes (1999): *"[UNOS is a] cartel" and "the federal monopoly that's chilling the supply of transplantable organs and letting Americans who need them die needlessly."*
- LA Times (2006): *"The little-known organization that oversees the nation's organ transplant system often fails to detect or decisively fix problems at derelict hospitals -- even when patients are dying at excessive rates... When it does act, [UNOS] routinely keeps findings of its investigations secret, leaving patients and their families unaware of the potential risks."*
- Washington Post (2018) stories on HRSA OPTN contracting restrictions here and here.
- New York Times ed board (2019): *"an astounding lack of accountability and oversight in the nation's creaking, monopolistic organ transplant system is allowing hundreds of thousands of potential organ donations to fall through the cracks"; "Revisit the UNOS monopoly".*

UNOS is the only organization ever even to bid for the OPTN contract, leading to calls for a first-ever competitive contract in the upcoming cycle, as called for by the House Appropriations Committee.

To have a competitive cycle that serves patients, and then a high-functioning organ donation/transplant system serviced by a patient-centered OPTN requires the following reforms:

- **Governance**: OPTN and contractor(s) should have separate boards as called for by HRSA in 2018, and reaffirmed by GAO.
- **Technology**: technology should be a separate contract, given different core capacities, and the field should be opened to innovators from all sectors, including as recently called for by NASEM.
- **OPO oversight**: given the failures of OPTN oversight of OPOs (see the Senate Finance investigation below), OPO oversight should be handled by HHS (which already has the responsibility to certify/decertify), instead of being fractured to the OPTN where, as Senators Grassley and Young wrote to the Inspector General in 2019 is like "the fox guard[ing] the hen house."
- **Office of Organ Policy:** given that much of the lack of oversight over federal organ donation contractors has resulted from a fracturing of jurisdictional responsibilities at HHS, we strongly support the creation of an Office of Organ Policy in the Office of the Secretary, as called for by major patient groups, Congressional leaders, past NAACP President Ben Jealous, Nobel Laureate Al Roth, and alumni of the U.S. Digital Service.:
    - Letter from Jerry Mande, former Congressional Aide to Al Gore central to the drafting of NOTA, to HHS in 2019: *"HHS, CMS, and HRSA have not provided the expected oversight. The result has been ineffective organ donation oversight, with jurisdiction splintered across various bodies. Far from enabling more oversight, this dynamic has allowed federal oversight to slip through the cracks, as no one agency has truly felt both responsible for and empowered to clean up the clear abuses and chronic underperformance of the OPO industry. When we passed NOTA, we had hoped that organ donation responsibilities would be consolidated within the Office of the Secretary. We were disappointed by the decision to place the Division of Transplantation within HRSA which, given its many and varied mandates, has seemed unable to make transplantation a priority. It is perhaps unsurprising then that OPO underperformance has persisted unaddressed."*
- **Data transparency**: OPTN contractors should make data readily available so that the government and other stakeholders can have immediate evidence of equitable and effective treatment of donors and patients; something notably lacking from UNOS now.
- **NOTA amendments**: NOTA should be amended to empower HHS to act in patients' interests through contractors and financing as HHS sees fit, rather than empowering a single contractor and locking in financing that does not serve patients over time. (See report from alumni of the United States Digital Service, including how NOTA has "erod[ed] the government's leverage" in managing the OPTN contract.)

Support for reforms: the House Appropriations Committee, ACLU, the New York Times editorial board, leaders from the American Society of Nephrology (ASN) and the Global Liver Institute (GLI), the ACLU, and other leaders including DJ Patil, the former U.S. Chief Data Scientist and alumni of the Clinton-Bush- Obama-Trump administrations.

Background on failures of the incumbent contractor (UNOS)

The OPTN contractor (UNOS) performs three key functions: policymaking, technology delivery, and OPTN member compliance (including OPO failures). Its functions in all three have drawn criticism

from Congressional oversight, the media, and external stakeholders, leading to calls to subdivide the contract and open it to innovative bidders. (which could be 2022 or 2023).

Per report from alumni of the U.S. Digital Service (USDS) endorsed by all 5 past HHS Chief Technology Officers: *"The OPTN contractor has devolved into a hostage-taking situation, where it has convinced the government that no one else can do what it does, but it doesn't perform its functions particularly well."* Examples:

- Policymaking has been divisive and secretive, drawing criticism across administrations. An example is allocation policies which (irrespective of final outcome) have been decided in ways that erode public trust. Examples:
  - In 1998, HHS Secretary Shalala cited UNOS misinformation seven times: *"I have received numerous letters from Members of Congress, transplant professionals, patients, and the public that reflect inaccuracies published by UNOS. I am especially distressed that UNOS is needlessly frightening transplant patients."*
  - In 2021, a federal judge unsealed emails with incendiary statements further eroding trust, and prompting Congressional criticism of HHS. Example from a UNOS board member to the UNOS CEO, emphasis added: "*The fact that some states do better than others in preventing preventable deaths and providing health care insurance coverage and access means you're a **dumb fuck** for living there."*
  - Note: The above is not meant to relitigate any individual policy, but speaks to a lack of care as well as conflicts in how UNOS functions as the OPTN.
- Technology: per USDS alumni "technology poverty": *"Our research indicates the vendor [UNOS] maintains an antiquated technology and limited technical acumen."* e.g.,
  - UNOS tech is so dated that 17% of kidney offers go to dead people.
  - Kaiser Health News: *"a startling number of lifesaving organs are lost or delayed after being shipped on commercial flights… [because UNOS] typically tracks [them] with a primitive system of phone calls and paper manifests."*
  - The American Society of Nephrology highlighted UNOS is 15X more likely to lose an organ in transit than an airline is luggage.
- OPTN member compliance: per SFC, "*We have serious concerns related to UNOS' role in overseeing our nation's OPOs.*" In almost 40 years, UNOS has only ever listed two OPOs as "members not in good standing", and even then that did not result in meaningful consequence, despite reported failings such as deadly patient safety issues, wasted taxpayer dollars, criminality, or for the failure to recover organs.
-

Fact check: UNOS claims 11 years of record-breaking transplants, but former U.S. Chief Data Scientist DJ Patil showed after controlling for increases in procurement rates outside of OPO influence (e.g. opioid epidemic), rates have gotten worse. UNOS' "best in the world" claim ignores the U.S. has more organ-donation eligible deaths per capita: 20-30X opioid deaths; 25X gun deaths; the highest suicides rates; and 2X as many fatal car accidents. See MedPage tying these stats/context on the need to make OPTN contract competitive.

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April 28, 2022

RE: Organ Procurement and Transplantation Network (OPTN) Request for Information

The Southeastern Kidney Transplant (SEKTx) Coalition of Georgia, North Carolina, and South Carolina appreciates the opportunity to respond to the Organ Procurement and Transplantation Network (OPTN) Request for Information issued by the Health Resources and Services Administration (HRSA). In 2010, the Southeastern United States, including Georgia, North Carolina, and South Carolina, was identified as having the lowest rates of kidney transplant in the nation. End-Stage Renal Disease Network 6 collaborated with stakeholders in the kidney disease community to form the SEKTx Coalition to improve transplant outcomes in our Network. For over ten years, the Coalition's grassroots efforts have focused on collaborative research and quality improvement efforts to identify and reduce barriers to kidney transplantation for ESKD patients in the Southeast U.S. and reducing disparities in access to transplant. The Coalition's goal to improve access to and equity in kidney transplantation is well-aligned with the HRSA goal of improving the OPTN contract. Thus, we are making several recommendations to improve the OPTN contract to strengthen equity, access, and transparency in the kidney donation, allocation, procurement, and transplantation process.

One overarching recommendation to HRSA is the need for national data on the critical and necessary steps required for patients to get on the national waiting list for a transplant (e.g., referral for transplantation and start and completion of the transplant evaluation process) nationally to improve transparency in access and equity in transplantation. While access to transplant and placement on a waiting list for transplant have been well-studied, there are a limited number of research studies that have explored variation in access to transplant at earlier steps in the process prior to waitlisting. Evidence has shown that barriers and facilitators at each step in the kidney transplant process vary, and exploration of barriers to referral and evaluation for transplant are limited by the lack of national surveillance data collection at these steps[1]. We have established an Early Transplant Access data registry on early kidney transplant steps among all nine kidney transplant centers across GA, NC, and SC, which has collected data on referral and evaluation for transplantation since 2012 and was recently expanded to include the collection of data among transplant centers in New York, New England, and the Ohio River Valley. With data from 31 transplant centers, we have demonstrated feasibility of data collection from transplant centers as well as the importance of these data. For example, in our study of ~35,000 ESKD patients starting dialysis in 2012-2016 in Georgia, North Carolina, and South Carolina, the median within-dialysis facility proportion of ESKD patients referred within 1 year was 33.7%, ranging from 0% to 100%[1]. Fewer than half of referred patients started the evaluation within 6 months of referral, representing only 16.1% of all incident dialysis patients. Evidence also suggests that the factors associated with referral for transplant differ from factors associated with start of the transplant evaluation. Collection of these data on a national scale would allow us to better understand factors that influence access to transplant nationwide and allow us to study how barriers to accessing the early steps to transplant may differ geographically and then target interventions to the appropriate transplant step to have the highest impact on improving access and equity in transplantation. The process of collecting these data from transplant centers demonstrated feasibility. We strongly recommend that this be included within the purview of OPTN to require these data collection from transplant centers, specifically Part 121 of the contract that states in section 121.8.c.3: "For each organ-specific allocation policy, the OPTN shall provide to the Secretary data to assist the Secretary in assessing organ procurement and allocation, access to transplantation, the effect of allocation policies on programs performing different volumes of transplants, and the performance of OPOs and the OPTN contractor...Such data shall be required on performance by

organ and status category, [and] patients who were inappropriately kept off a waiting list or retained on a waiting list." Specific recommendations for the rationale and for how these data collection could occur are outlined in a recent publication, most notably that OPTN should require data collection from transplant centers[2]. Additionally, it is of note and of interest that there is currently a working group (led by UNOS Data Advisory Committee, the Minority Affairs Committee, the Patient Affairs Committee, and the Ethics Committee) that has attempted to form to develop a plan and recommended path to collect these data at UNOS. HRSA has agreed that the OPTN does have the authority to collect pre-waitlist data, but that the authority would not be given only after the UNOS Board of Directors approves it and is under OMB review. Thus, the main reason why we do not have a clear path forward for collecting these critical data that were called out a number of times in the NASEM report is due to a regulatory/process hurdle despite significant support from the transplant community to move forward with data collection. The new OPTN contract should explicitly call out the requirement to collect data that affects access to the waiting list, including all referrals to the transplant center, as well as data on when patients start the transplant evaluation process and when they complete the evaluation process (typically defined as when they are presented to a listing conference and a decision is made for waitlisting). This action would increase transparency in the transplant process for patients and their family members.

Additionally, these data could inform quality improvement for transplant programs and could lead to improved quality metrics that are better aligned with referring provider metrics. Kidney transplant program performance in the U.S. is commonly measured by transplant rates and short-term post-transplant outcomes, and there are few quality metrics used to evaluate patient access to kidney transplant. **Therefore, the SEKTx Coalition has several recommendations for improving quality measures in transplantation, including reporting of longer-term post-transplant metrics beyond 1 year, the inclusion of pre-transplant measures, and alignment of quality measures across health systems.** Improvement of these metrics could provide a more comprehensive assessment of transplant program performance, and thereby provide necessary information for patient decision-making.

Specifically, one suggestion for improving quality metrics for assessing transplant program performance (e.g., Scientific Registry of Transplant Recipients Program Specific Reports) would be the creation of a waitlisting rate among referred patients to a transplant program. Using our Early Transplant Access Registry data, we previously proposed a new metric for transplant programs, the waitlisting rate, which is defined as the ratio of patients who are waitlisted in a center relative to the person-years referred for evaluation to a program. This metric has a distinct advantage to prior metrics by using the number of patients referred to a transplant center in the denominator, which importantly, is outside of the control of transplant centers. In comparing this metric to the currently used transplant rate metric, we found centers that have high transplant rates do not necessarily have high waitlisting rates, and vice versa[3]. This pattern suggests that the transplant rate metric currently utilized by SRTR may not be representative of patient access for all patients seeking to pick a transplant center based on current transplant rate metrics. Utilizing a waitlisting rate metric in addition to a transplant rate metric may be appropriate for evaluating access to transplantation for patients, patients' family members, and their referring nephrologist or providers. The transplant community has recognized the need for measuring transplant access and improving metrics. For example, recommendations of the American Society of Transplantation and the American Society of Transplant Surgeons Metrics Task force work[4,5], as well as the new HRSA initiative for SRTR (Task 5) to convene a steering committee of stakeholders to discuss community quality metrics for transplant programs. A quality metric for transplant centers that focused on improved access to the waiting list would be more well aligned with the current quality metrics in dialysis facilities (the proportion of prevalent patients waitlisted), whereas now from a transplant program's perspective, current metrics such as the waitlisting mortality rate decrease the incentive for transplant programs to get patients on the waiting list. To utilize a new quality metric for transplant centers of the waitlisting rate (among referred patients), national data collection is needed to document when a patient is referred for kidney transplantation. In the interim while these referral data are not yet available, we recommend the use of appropriate denominators of end-stage organ failure, where patient attribution could be based on prior market referrals such as hospital referral regions. We have developed and demonstrated the application of these in research[6].

The SEKTx Coalition also recognizes the need for alignment of transplant quality measures across dialysis organizations, transplant programs, and OPOs. Historically, the metrics used to evaluate and compare transplant programs and those

used to assess dialysis organizations' efforts to get dialysis patients transplants have been at odds. Since 2018, the Centers for Medicare and Medicaid have mandated the End-Stage Renal Disease Networks and the dialysis facilities they oversee to conduct quality improvement activities focused on increasing the proportion of patients on a transplant waiting list. **Though the dialysis facility quality metric of the proportion of patients waitlisted is important, it misses all of the important steps prior to waitlisting, such as referral and evaluation for transplant.** While dialysis facilities are mandated to improve waitlisting for transplant, transplant center national trends show waitlisting has been declining since the implementation of the National Kidney Allocation System in December 2014 that changed how waiting time is calculated[7]. Additionally, the recent implementation of the waitlist mortality metric by UNOS may encourage transplant programs to be more conservative with placing transplant candidates on their waiting lists, resulting in decreased transplant waitlisting rates. Thus, the dialysis facility proportion of patients waitlisted quality metric is less relevant and helpful to evaluate dialysis facilities on their transplant access performance, given that there are many transplant program and patient factors that influence waitlisting that dialysis facilities have little control over. Monitoring and evaluating patient access to transplant at earlier steps in the transplant process may be more relevant to target for a dialysis facility-based quality measure. Using our Early Transplant Access Registry data, we also developed a new quality measure for dialysis facilities called the Standardized Transplantation Referral Ratio[8]. In summary, our Coalition recommends that in order to improve the quality metrics used to assess transplant programs and dialysis facilities, metrics need to be aligned across health systems with an increased focus on equitable access to transplant, rather than focusing exclusively on post-transplant outcomes.

Increasing the number of organs available for transplant is crucial in reducing disparities. It is critical that the Health Resources and Services Administration partner with other organizations like CMS to implement systems-level improvements to increase rates of organ procurement and reducing variability across programs and regions. To reduce disparities, we also recommend implementing requirements for OPOs to engage with the communities they serve in order to build trust and improve rates of organ donation. Given the nature of OPO territories, or donor service areas, it is critical that OPOs engage with their local communities to provide education, develop trust in organ donation, and effectively communicate with people of all races, ethnicities, and socioeconomic backgrounds.

Another way OPOs and transplant programs can actively work to reduce disparities in transplant would be to require that **staff within these organizations demographically reflect the communities they serve**. In complicated decisions such as organ donation and transplant, trust between the provider, staff and patient are of the utmost importance. Evidence has suggested that provider-patient race and language concordance improve communication and patient satisfaction. CMS should require OPO and transplant center staff to report on provider diversity and the degree to which it reflects their current and future target donor and patient population. Further, we also suggest that staff be required to complete regular and continuous training on cultural sensitivity to reduce implicit racial biases. Any individuals involved in clinical donor management and speaking with next of kin for donation authorization should complete training on donor family communication best practices, implicit bias, racial-equity, and trauma-informed care.

While it is the shared responsibility of CKD providers, ESRD dialysis facilities, transplant programs, and OPOs to educate kidney disease patients on transplant, it is **essential that basic transplant education be standardized and provided to all patients in an equitable and culturally-sensitive manner**. Unfortunately, research suggests that one of the key barriers to kidney transplantation reported by patients, dialysis staff, and transplant staff is lack of education about transplant as a treatment option and the complicated transplant process[9,10]. Dialysis units play a critical role in helping patients receive kidney transplants; CMS requires that dialysis facilities inform patients about transplantation and are mandated by ESRD Networks to implement quality improvement measures to increase transplant waitlisting among their patients. However, while dialysis facilities are required to educate patients about transplant, there is no standardized basic transplant education given to all patients and there is limited required data collection on the type or quality of education provided.

Another way that HRSA can ensure that underserved communities receive adequate information and education about transplant is by **improving communication between dialysis facilities, transplant centers, and OPOs, which are often**

siloed healthcare systems. Communication between these organizations is often time- and resource-intensive for staff, and there is little transparency in the process from when a patient is referred for transplant to when a patient is placed on a waiting list or not[10]. HRSA should invest in opportunities for patient engagement and improved transparency in the transplant process, for example implementing platforms such as T-REX (Transplant Referral Exchange). Developed by SEKTx Coalition collaborators, T-REX is a HIPAA-compliant software that allows transmittal of electronic referrals to help facilitate communication between healthcare systems and with patients from referral through evaluation and waitlisting. Ensuring that education about the transplant process is standardized, and that both dialysis facilities (or referring providers) and transplant centers are aware of what education the patient has or has not received in real time, is critical to ensuring equitability in access to transplantation. We recommend that HRSA implements policies and measures mandating transplant centers and referring providers to improve communication with each other and with the patient to ensure access to information about transplant.

We know that racial minorities, and patients of low socioeconomic status, have lower rates of initiating and completing the transplant evaluation process and of being placed on the transplant waiting list. HRSA should support the use of transplant navigators to overcome barriers these patients face in completing the complex steps required by the transplant evaluation process. The use of navigators can help offset the lack of social support required to reach the transplant waiting list. Navigators may also be helpful in helping living donor candidates complete the multiple steps required to become living donors to abrogate the extreme disparity in living donation rates from African Americans.

Thank you for raising these critical issues for our country's organ donors, kidney disease patients, and transplant recipients. We greatly appreciate the opportunity to contribute to this CMS Request for Information and we thank you for your consideration of our Southeastern Kidney Transplant Coalition's response.

Sincerely,

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HSB115C1031, Organ Procurement and Transplantation Network (OPTN) RFI, May 05, 2022

Request for Information on Ways to Strengthen and Improve the Organ Procurement and
Transplantation Network[1] [2]
Submitted by
Persharon M. Dixon, MD
Board Certified Pediatrician
901 Centennial Avenue, Deltona, FL. 32732

I am the mother of a 26-year-old son who has a complex congenital heart defect. This heart
defect is expected to ultimately require a heart transplant for long-term survival. Because of
advances in heart deformity surgical procedures, we have avoided this need that only a few years
ago would have been needed by age 10. Our family has been aware and active in our
participation in the organ procurement space. We are listed donors ourselves and share our
message with others whenever we can. Additional to my son's journey, our family has
experienced the joy of extended life through organ donation for my youngest brother. Anthony
Mathis was a retired veteran of the Air Force when he contracted a virus that attacked his heart.
This viral infection led to a cardiomyopathy that progressively worsened. My brother received
the gift of a heart transplant and was recovering well. Unexpectedly, he succumbed about 3
weeks post-transplant but, during those three weeks he experienced increased strength and ability
to walk longer distances and had begun plans for a cruise and other activities. He was the
happiest I had seen him in a few years. We were thankful for even this short time of joy and
strength.

I have had a much greater opportunity to learn and be a part of messaging and programming
around organ procurement through my professional services organization, The Links,
Incorporated. I serve as the Health and Human Services Chair for the Southern Area of The
Links, Incorporated which is made up of 84 chapters cover 7 states and the Bahamas.   The
Links, Incorporated is an international, not-for-profit corporation, established in 1946. The
membership consists of more than 16,000 professional women of African descent in 299
chapters located in 41 states, the District of Columbia, the Commonwealth of the Bahamas, and
the United Kingdom.[3] It is one of the nation's oldest and largest volunteer service organizations
of extraordinary women who are committed to enriching, sustaining, and ensuring the culture
and economic survival of African Americans and other persons of African ancestry.

The Links, Incorporated focuses five facets for our service and programming, including health.
Specifically, the Health and Human Services[4] facet was established in response to the chronic
health disparities that persist in black communities and result in the decreased life expectancy of
African Americans and other people of African ancestry. Through education, advocacy, and
outreach, The Links, Incorporated initiates and supports programs that support the maintenance
of good health and the elimination of chronic health disparities in communities of color. The

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[1] https://www.hrsa.gov/about/news/press-releases/hrsa-releases-organ-procurement-transplantation-network-rfi, Accessed on
May 8, 2022
[2] https://sam.gov/opp/005656500e5741538ce72d57b9b3d558/view, Accessed on May 9, 2022
[3] https://linksinc.org/the-links-incorporated/, Accessed on May 19,2022
[4] https://linksinc.org/health-and-human-services/, Accessed on May 9, 2022

Organ, Tissue and Bone Marrow Donation Awareness Signature Program, "Linkages to Life" was established in response to the health disparities in organ, eye, and tissue (including bone marrow) transplantation. The goal of Linkages to Life is to decrease disparities in donor registration and transplantation in the African American community. Our members work to increase the number of registered donors through community-based events and multi-media awareness campaigns. In partnership with the national organization Donate Life America, we strive to register hundreds of donors each year through a Links, Incorporated and Donate Life America co-branded national donor registration page.

In response to E.4.[5] Increasing Organ Donation and Improving Procurement: How can HRSA best incorporate the NASEM report's recommendations on increasing equitable access to transplants?

Leveraging trusted networks to emphasize organ donation and transplant opportunities.
As a physician, I believe a focus at the level of educating existing physicians and training medical students to include the organ donation and procurement conversation in their work with go a long way towards educating minority communities. Additionally, community-based organizations with a long-standing foothold in communities like The Links, Incorporated, can also be excellent resources for trusted messages and education through collaborative strategies. The HBCU Medical Schools Collaborative and the Links, Incorporated are each positioned to underscore the need for improved equity in the field of organ donation and transplantation.

Some suggested ways to increase outreach include:
- Career exposure to STEM, medicine, health professions, and specifically inclusion of transplantation.
- Cultural and linguistically tailored materials geared to educate minority individuals about transplantation for those receiving dialysis.
- Augmented programming with HBCUs, medical schools, and schools of nursing, public health, healthcare administration, and allied health professions.
- Presence at health fairs and organ donor drives, distributing said materials focused on living and deceased organ donation; and
- Continued collaboration with service organizations, faith-based congregations, and community influencers around organ donations.

Members of the Links, Incorporated through local and national Linkages to Life programming have been engaging in several of these activities. There are numerous opportunities to expand this programming by integrating with the Services to Youth Facet[6] that includes the Links – STEMReady Signature Program and the National HBCU Initiative to encourage youth to pursue careers in the STEM fields. Additionally, I have served with members of the Links, Incorporated who either work as clinical or healthcare professionals, are employed by an HBCU or both.

Recognizing the multiplying impact of poverty on social determinants of health on treatment access. Patients who are poor and African American are often rejected for surgery because transplanting them will decrease transplant outcomes. This, in turn may result in the

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[5] https://sam.gov/opp/005656500e5741538ce72d57b9b3d558/view, Accessed on May 19, 2022
[6] https://linksinc.org/services-to-youth/, Accessed on May 19

transplant centers becoming decertified. A system must be put in place that does not penalize a transplant center for transplanting such high-risk patients. This phenomenon is important but never discussed. This practice is a form of institutionalized racism and bias that keeps socio-economically deprived patients from accessing organ and tissue transplants at rates proportionate to the prevalence of end-stage organ disease or other related injury. National and regional paired donations are performed but they rarely benefit people of color, in the way that local paired donations do. Encouraging local paired donations is more beneficial to people of color; and is an option that should be incentivized and encourage.

G.1. OPTN Operations and Policy Development Improvements: 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.

Staffing for cultural sensitivity and to minimize biases is an area of opportunity. Representation of culturally sensitive individuals and organizations at every level of OPTN operations and policy development is necessary to transform the current system for attaining health equity. Specifically, priority in notification should be given to organizations of color including Historically Black Colleges and Universities, Black Greek letter sororities and fraternities, and other Black services organizations and programs. Priority in funding should be given to such organizations as well as programs led by people of color. Additionally, specific minimum allocations of funding proportional to the need for transplantation (or the incidence of end-stage disease and organ failure) should be allocated in each area related to organ transplantation. Input from these individuals and organizations must also be integrated in the writing of RFPs and the review of RFP submissions.

Incentivizing equitable outcomes through oversight. Individuals from diverse backgrounds must have a seat at the table to participate in the authority, finance and control of OPTN operations and policy development, to change the paradigm from health disparity to true health equity. This means there must be more oversight of the OPOs to require the presence of diverse representation at the highest administrative levels. When negotiating collaborations between the Links, Incorporated and potential partner health organizations, we strive to leverage greater representation on their decision-making boards. This strategy has been met with varying results. OPO compliance in this regard must be monitored. In addition, there must be mentoring, opportunities and funding for education, training and fellowships to allow for the advancement of persons of color to these positions.

G. 4. OPTN Operations and Policy Development Improvements: What other improvements to OPTN operations and policy development processes can and/or should be incorporated into the OPTN contact?

Increasing the ethnic diversity of OPO executive leadership is an opportunity. There are 57 OPOs very few of these OPOs have persons of color at the highest administrative level (CEO or Chairperson of the Board of Directors)[7]. It is important therefore to increase the number of

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[7] https://aopo.org/find-your-opo/, Accessed May 19, 2022

CEOs and Board Chairs who are people of color (African American, Hispanic or Latino, Asian, Pacific Islander or Native American). Nearly 60% of people waiting for transplant are people of color. Systems should be put in place to eradicate explicit and implicit exclusionary hiring practices and monitor OPO compliance. Increasing the proportion of individuals from diverse backgrounds in leadership positions to better reflect the ethnic diversity of the community of patients being served by the OPO is paramount. Currently, oversight to combat against the current level of executive disparity is completely lacking and desperately needed as indicated by the statistics previously cited.

Living donation policy is an area of opportunity for African Americans. We know the living donations among African Americans are significantly below that of whites, underscoring the need for augmented education of living donation opportunities. In 2020, 16.4 percent of blacks were living donors as compared to 33.4 percent of white living donors[8]. Instances of African Americans who receive a "second chance at life" through organ donation are celebrated in our community in churches, at family gatherings, in the workplace, and in our social and service organizations. It is important to peel back the crucial steps to allow these donations and transplants to happen, which begins with increasing the education outreach to minority communities about the benefits of living donation and simultaneously speaking to the fears, myths, and hesitancy associated with being a living donor. Overcoming this obstacle is best addressed with recipients and trusted community-based organizations delivering the information, not the transplant centers and organ procurement organizations. The education should be multi-generational and culturally tailored, addressing the most pressing concerns and highlighting the successes in minority communities. The Linkages to Life National Program Committee has increased its awareness and advocacy specifically around living donation in the 2021-2022 program year with several recorded webinars on the topic. These efforts by The Links, Incorporated or other historically Black service and civic organizations may often be superior to those of the transplant centers and OPOs to address this need. The Links, Incorporated was able to produce culturally sensitive content to meet patients in their communities. The data also shows that non-whites have lower rates of pre-emptive kidney transplantation, especially for living donation. It is important to highlight these disparities and use fund opportunities to educate our communities of color. While serving as National Chair for Linkages to Life, I've learned that people cannot properly advocate for themselves if they lack awareness of all treatment options available. Our campaigns work to increase this awareness.

H.2-3 Stakeholder Engagement: 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. How can and/or should the contract incorporate new or better approaches for including stakeholders in a shared decision model for organ acceptance?

Bringing diverse voices to the table early and through the organ procurement process is a tremendous opportunity for system improvement. Stakeholders including transplant recipients, prior living donors and families members of deceased donors should be engaged early, often and meaningfully. Stakeholders from ethnically diverse backgrounds should be included in the oversight bodies referenced earlier in these comments. Executive search

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[8] https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=27, Accessed May 19, 2022

committees or contracted executive search firms should either include stakeholders from ethnically diverse backgrounds or specialize in diversity, equity and inclusion. Finally, through past experiences serving on stakeholder advisory boards for research funded by Patient Centered Outcomes Research Institute (PCORI), I consider them to have a portfolio of best practices[9] in engagement strategies. There is significant value in OPTN members together with a more diverse cross-section of stakeholders examine these engagement techniques and employ them at numerous levels of planning, policymaking and operations, including the development of a shared decision-making model for organ acceptance. If serving patients in need of organ and tissue transplantation is the goal, OPTN members will transform stakeholder engagement practices and where appropriate will hone engagement relations ships to meaningful collaboration and shared leadership to attain more inclusive health outcomes.

Each of these areas of increased emphasis must be met with thoughtful planning and financial resources. Critical to the proper planning is the involvement of organizations and individuals such as ours.

Thank you for considering this feedback.

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[9] https://www.pcori.org/engagement/value-engagement, Accessed May 19, 2022

HSB115C1031, Organ Procurement and Transplantation Network (OPTN) RFI, May 05, 2022

Request for Information on Ways to Strengthen and Improve the Organ Procurement and Transplantation Network[1] [2]
Submitted by
LeCresha A. Peters, MD
Western Area
Health and Human Services Facet Chair
The Links, Incorporated

9403 Sundown Drive
Pearland, Texas 77584

My husband, Dr. Ronald J. Peters, Jr., was diagnosed with Autosomal Dominant Polycystic Kidney Disease shortly before our marriage in 1999. His father died of End Stage Renal Disease at the age of forty-five as a result of the same hereditary condition. Beginning in 2012, my husband's renal function rapidly declined and he was diagnosed with End Stage Renal Disease just as his father had been decades before. Sadly, the treatment options for patients with End Stage Renal Disease remained unchanged although decades had passed. As a physician, I was aware of the increased success rate and prolonged function of kidney donations received when transplantation is performed preemptively prior to the start of hemodialysis. Being an only child with both parents preceding him in death, I knew the likelihood of finding a compatible living donor was extremely low. With this in mind, I asked to be evaluated as a potential living donor. On June 26, 2014, my wish to become a living donor was granted with the successful transplantation of my donated kidney to my husband. I am grateful to share that my husband's transplanted kidney continues to function well as we near our eighth "Life-aversary". However, not every person in need of organ transplantation is as fortunate as my husband so I would like to amplify the message of The National Minority Organ Tissue Transplant Education Program (MOTTEP)[3]. I am currently serving as the Western Area Health and Human Services Committee Chair of The Links, Incorporated. The Health and Human Services Facet of the Links, Incorporated was created to address and combat health inequity and reduce health disparities among African Americans. The Links, Incorporated is an international, not-for-profit corporation, established in 1946. The membership consists of more than 16,000 professional women of African descent in 299 chapters located in 41 states, the District of Columbia, the Commonwealth of the Bahamas, and the United Kingdom.[4] It is one of the nation's oldest and largest volunteer service organizations of extraordinary women who are committed to enriching, sustaining and ensuring the culture and economic survival of African Americans and other persons of African ancestry.

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[1] https://www.hrsa.gov/about/news/press-releases/hrsa-releases-organ-procurement-transplantation-network-rfi, Accessed on May 8, 2022

[2] https://sam.gov/opp/005656500e5741538ce72d57b9b3d558/view, Accessed on May 9, 2022

[3] https://www.natlmottep.org/, Accessed on May 19, 2022

[4] https://linksinc.org/the-links-incorporated/, Accessed on May 19,2022

The Links, Incorporated focuses on five facets for our service and programming, including health. Specifically, the Health and Human Services[5] Facet was established in response to the chronic health disparities that persist in black communities and result in the decreased life expectancy of African Americans and other people of African ancestry. Through education, advocacy, and outreach, The Links, Incorporated initiates and supports programs that support the maintenance of good health and the elimination of chronic health disparities in communities of color. The Organ, Tissue and Bone Marrow Donation Awareness Signature Program, "Linkages to Life" was established in response to the health disparities in organ, eye, and tissue (including bone marrow) transplantation. The goal of Linkages to Life is to decrease disparities in donor registration and transplantation in the African American community. Our members work to increase the number of registered donors through community-based events and multi-media awareness campaigns. In partnership with the national organization Donate Life America, we strive to register hundreds of donors each year through a Links, Incorporated and Donate Life America co-branded national donor registration page.

I have collaborated with Linkages to Life National Program committee members in my role as the Western Area Health and Human Services Facet Chair and my concern about increasing inequalities in organ and tissue procurement in African American communities continues to grow. It is for this reason that I offer the following comments in response to the Request for Information and hope it will be valuable in determining the final policy.

In response to E.4.[6] Increasing Organ Donation and Improving Procurement: How can HRSA best incorporate the NASEM report's recommendations on increasing equitable access to transplants?

Leveraging trusted networks to emphasize organ donation and transplant opportunities.
There are many ways to connect members of the African American community to sources of information and knowledge related to organ and tissue transplantation. African American physicians are an excellent source for connecting with members of the African American community on this topic. Regardless of the physician's specialty, African American physicians as well as those serving African American patients should emphasize the benefits of organ and tissue transplantation. As discussed by MOTTEP Founder, Dr. Clive Callender at NASEM[7], the historically Black medical schools are a tremendous resource for instilling this message into minority and minority-serving physicians. The HBCU Medical Schools Collaborative and the Links, Incorporated are each positioned to underscore the need for improved equity in the field of organ donation and transplantation.

Some suggested ways to increase outreach include:
- Career exposure to STEM, medicine, health professions, and specifically inclusion of transplantation.
- Cultural and linguistically tailored materials geared to educate minority individuals about transplantation for those receiving dialysis.

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[5] https://linksinc.org/health-and-human-services/, Accessed on May 9, 2022

[6] https://sam.gov/opp/005656500e5741538ce72d57b9b3d558/view, Accessed on May 19, 2022

[7] https://www.nationalacademies.org/event/07-15-2021/a-fairer-and-more-equitable-cost-effective-and-transparent-system-of-donor-organ-procurement-allocation-and-distribution-virtual-public-listening-session, Accessed on May 19, 2022

- Augmented programming with HBCUs, medical schools, and schools of nursing, public health, healthcare administration, and allied health professions.
- Presence at health fairs and organ donor drives, distributing said materials focused on living and deceased organ donation; and
- Continued collaboration with service organizations, faith-based congregations, and community influencers around organ donations.

Members of the Links, Incorporated through local and national Linkages to Life programming have been engaging in several of these activities. There are numerous opportunities to expand this programming by integrating with the Services to Youth Facet[8] that includes the Links – STEMReady Signature Program and the National HBCU Initiative to encourage youth to pursue careers in the STEM fields. Additionally, I have served with members of the Links, Incorporated who either work as clinical or healthcare professionals, are employed by an HBCU or both.

Recognizing the multiplying impact of poverty on social determinants of health on treatment access. Patients who are poor and African American are often rejected for surgery because transplanting them will decrease transplant outcomes. This, in turn may result in the transplant centers becoming decertified. A system must be put in place that does not penalize a transplant center for transplanting such high-risk patients. This phenomenon is important but never discussed. This practice is a form of institutionalized racism and bias that keeps socio-economically deprived patients from accessing organ and tissue transplants at rates proportionate to the prevalence of end-stage organ disease or other related injury. National and regional paired donations are performed but they rarely benefit people of color, in the way that local paired donations do. Encouraging local paired donations is more beneficial to people of color; and is an option that should be incentivized and encourage.

F.3. Organ Usage: 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.1. OPTN Operations and Policy Development Improvements: 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.

Staffing for cultural sensitivity and to minimize biases is an area of opportunity.
Representation of culturally sensitive individuals and organizations at every level of OPTN operations and policy development is necessary to transform the current system for attaining health equity. Specifically, priority in notification should be given to organizations of color including Historically Black Colleges and Universities, Black Greek letter sororities and fraternities, and other Black services organizations and programs. Priority in funding should be given to such organizations as well as programs led by people of color. Additionally, specific minimum allocations of funding proportional to the need for transplantation (or the incidence of end-stage disease and organ failure) should be allocated in each area related to organ

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[8] https://linksinc.org/services-to-youth/, Accessed on May 19

transplantation. Input from these individuals and organizations must also be integrated in the writing of RFPs and the review of RFP submissions.

Incentivizing equitable outcomes through oversight. Individuals from diverse backgrounds must have a seat at the table to participate in the authority, finance and control of OPTN operations and policy development, to change the paradigm from health disparity to true health equity. This means there must be more oversight of the OPOs to require the presence of diverse representation at the highest administrative levels. When negotiating collaborations between the Links, Incorporated and potential partner health organizations, we strive to leverage greater representation on their decision-making boards. This strategy has been met with varying results. OPO compliance in this regard must be monitored. In addition, there must be mentoring, opportunities and funding for education, training and fellowships to allow for the advancement of persons of color to these positions.

G. 4. OPTN Operations and Policy Development Improvements: What other improvements to OPTN operations and policy development processes can and/or should be incorporated into the OPTN contact?

Increasing the ethnic diversity of OPO executive leadership is an opportunity. There are 57 OPOs very few of these OPOs have persons of color at the highest administrative level (CEO or Chairperson of the Board of Directors)[9]. It is important therefore to increase the number of CEOs and Board Chairs who are people of color (African American, Hispanic or Latino, Asian, Pacific Islander or Native American). Nearly 60% of people waiting for transplant are people of color. Systems should be put in place to eradicate explicit and implicit exclusionary hiring practices and monitor OPO compliance. Increasing the proportion of individuals from diverse backgrounds in leadership positions to better reflect the ethnic diversity of the community of patients being served by the OPO is paramount. Currently, oversight to combat against the current level of executive disparity is completely lacking and desperately needed as indicated by the statistics previously cited.

Living donation policy is an area of opportunity for African Americans. We know the living donations among African Americans are significantly below that of whites, underscoring the need for augmented education of living donation opportunities. In 2020, 16.4 percent of blacks were living donors as compared to 33.4 percent of white living donors[10]. Instances of African Americans who receive a "second chance at life" through organ donation are celebrated in our community in churches, at family gatherings, in the workplace, and in our social and service organizations. It is important to peel back the crucial steps to allow these donations and transplants to happen, which begins with increasing the education outreach to minority communities about the benefits of living donation and simultaneously speaking to the fears, myths, and hesitancy associated with being a living donor. Overcoming this obstacle is best addressed with recipients and trusted community-based organizations delivering the information, not the transplant centers and organ procurement organizations. The education should be multi-generational and culturally tailored, addressing the most pressing concerns and highlighting the

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[9] https://aopo.org/find-your-opo/, Accessed May 19, 2022

[10] https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=27, Accessed May 19, 2022

successes in minority communities. The Linkages to Life National Program Committee has increased its awareness and advocacy specifically around living donation in the 2021-2022 program year with several recorded webinars on the topic. These efforts by The Links, Incorporated or other historically Black service and civic organizations may often be superior to those of the transplant centers and OPOs to address this need. The Links, Incorporated was able to produce culturally sensitive content to meet patients in their communities. The data also shows that non-whites have lower rates of pre-emptive kidney transplantation, especially for living donation. It is important to highlight these disparities and use fund opportunities to educate our communities of color. While serving as National Chair for Linkages to Life, I've learned that people cannot properly advocate for themselves if they lack awareness of all treatment options available. Our campaigns work to increase this awareness.

H.1. 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.

H.2-3 Stakeholder Engagement: 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. How can and/or should the contract incorporate new or better approaches for including stakeholders in a shared decision model for organ acceptance?

Bringing diverse voices to the table early and through the organ procurement process is a tremendous opportunity for system improvement. Stakeholders including transplant recipients, prior living donors and families members of deceased donors should be engaged early, often and meaningfully. Stakeholders from ethnically diverse backgrounds should be included in the oversight bodies referenced earlier in these comments. Executive search committees or contracted executive search firms should either include stakeholders from ethnically diverse backgrounds or specialize in diversity, equity and inclusion. Finally, through past experiences serving on stakeholder advisory boards for research funded by Patient Centered Outcomes Research Institute (PCORI), I consider them to have a portfolio of best practices[11] in engagement strategies. There is significant value in OPTN members together with a more diverse cross-section of stakeholders examine these engagement techniques and employ them at numerous levels of planning, policymaking and operations, including the development of a shared decision-making model for organ acceptance. If serving patients in need of organ and tissue transplantation is the goal, OPTN members will transform stakeholder engagement practices and where appropriate will hone engagement relations ships to meaningful collaboration and shared leadership to attain more inclusive health outcomes.

Each of these areas of increased emphasis must be met with thoughtful planning and financial resources. Critical to the proper planning is the involvement of organizations and individuals such as ours.

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[11] https://www.pcori.org/engagement/value-engagement, Accessed May 19, 2022

Thank you for considering this feedback.

May 23, 2022

Naomi Inazawa
Contract Specialist
Office of Acquisition Management & Policy
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857-5600

Via email – ninazawa@hrsa.gov

RE: Notice number: HSB115C1031
        Title: Organ Procurement and Transplantation Network (OPTN)
        Date of issuance: April 8, 2022

Dear Ms. Inazawa:

Thank you for the opportunity to respond to HRSA's OPTN Request for Information. This response is submitted by the United Network for Organ Sharing (UNOS), 700 North Fourth Street, Richmond, VA 23219.

The point of contact for UNOS' response is Maureen McBride, (804) 782-4649, Maureen.McBride@unos.org.

Sincerely,

Matthew Cooper, MD, FACS
UNOS Board of Directors President

Brian Shepard, MBA
UNOS Chief Executive Officer

Cc: Maureen McBride, PhD

<u>**UNOS' Response to the 2022 OPTN RFI**</u>

UNOS is pleased to take this opportunity to respond to HRSA's OPTN RFI. United Network for Organ Sharing is the mission-driven, values-based nonprofit solely focused on continually uniting and strengthening the donation and transplant community to save more lives. Having had the honor of being awarded the OPTN contract each contract cycle since 1986, UNOS brings a depth of experience, insight and knowledge that ensures the continuity of services that have resulted in the highest performing donation and transplant system in the world.

We continuously seek ways to enhance the effectiveness and transparency of the system to save even more lives. Our collaborative approach leverages the expertise of our workforce, OPTN members, and experts in other fields to drive continuous improvement, expand equity, improve access, and increase patient engagement.

Our modern technology platform builds upon an IT infrastructure designed to make complex allocation policies possible. This infrastructure is integrated within the OPTN policy development framework and our experts in technology and data science collaborate closely with our operations and clinical teams to ensure we are efficiently developing, implementing, and monitoring these policies, constantly adapting our secure, reliable, and efficient infrastructure to meet the evolving needs of the community.

UNOS is deeply invested in this lifesaving work, and we are honored to be at the center of a community with a shared mission to save and improve lives through organ donation and transplant.

While HRSA is already familiar with the technologies and processes UNOS employs to fulfill the current OPTN contract, UNOS does wish to comment on certain aspects of this RFI. Below, please find responses to selected RFI questions.

A. <u>**OPTN Technology – IT system**</u>

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

While serving as the OPTN, UNOS developed and has continually enhanced UNet^{SM}, a state-of-the-art, intricately designed technology platform and IT infrastructure uniquely built to make the nation's complex allocation policies possible and save more lives. This platform is designed to take a one-of-a-kind approach that weds robust technology capabilities with in-depth policy knowledge.

Additionally, we would respectfully offer a correction: the RFI states that organ procurement organizations and transplant programs do not submit data to the OPTN IT system in real time. We would like to clarify that **both OPOs and transplant programs currently do submit data to the OPTN IT system in real time.**

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 extremely important that we have an agile, safe and secure system. That is why the OPTN IT infrastructure should and currently does consist of multi-cloud (private and public) components to ensure continuity of OPTN technology operations and that it can scale securely while reducing costs. Relying solely on public cloud brings risk of cloud provider outages, which though rare, would be impactful and could cost lives.

The success of the entire donation and transplantation system depends on the consistent and accurate implementation of OPTN policies in the OPTN IT system. It is essential that OPTN policy development be supported by an integrated team of technology and data science professionals and subject matter experts to ensure efficient and accurate implementation of allocation algorithms. A requirement for an organ allocation policy assurance program with continuous automated validation and testing of all historical, current, and future organ allocation policies is also a key contributor to the successful operation of the OPTN system.

We agree that the IT development approach must be agile and include the leveraging of open source frameworks for continued modernization of the system. The agile approach has to be balanced with the required, fixed OMB approval cycles to maintain timely responsiveness to the needs of the transplant community.

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 agree that APIs are essential data sharing and integration tools, which is why, through UNet, we have made it possible for transplant hospitals, OPOs, and histocompatibility laboratories to easily exchange data through application programming interfaces. These APIs were developed with direct input from, and in collaboration with, the transplant community and EHR vendors to eliminate providers' need to enter data manually, allowing them to focus instead on patient care. UNet APIs are tailored to the most frequently exercised transplant processes where automation and improvement in data quality are paramount.

With regard to APIs, there are a few important considerations. First, not all OPTN data are appropriate for submission via an API – some need the interaction of a human (e.g., ABO verification); and some OPTN data (e.g., candidate donor acceptance criteria) do not exist in hospital EHRs.

Furthermore, numerous EHRs have automated generation of OPTN required forms within their systems. This automation, a result of collaboration between EHRs and UNOS, has been in place for many years, saving valuable time for both transplant professionals, and, most importantly, for patients.

We recommend that HRSA work with other federal agencies to incentivize the complete implementation of hospital-side enhancements so that hospitals can take fuller advantage of the existing APIs and file transfer functionality available to them in UNet, creating critical efficiencies that can save lives.

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?**

System availability of is critical importance, and we are pleased to have the opportunity to discuss this topic.

Recently, the OPTN Network Operations Oversight Committee (NOOC), which is a committee of the OPTN Board of Directors and includes users of the OPTN IT system, studied whether increasing system uptime to 99.999% was reasonable and weighed a variety of impacts, including on patients, practitioners and cost to the system. The NOOC concluded that, while 99.999% was achievable, the preferred standard for system availability should instead be 99.9%. While enhancing system efficiency to 99.9% would benefit thousands of patients waiting for an organ, the NOOC found that raising the standard any higher would not translate to clinical benefit to patients and would needlessly consume resources that could be spent on more impactful technology improvements.

Organ donation and transplantation is a process that happens over a period of two to four days, as clinical data is gathered, organ offers made and accepted, transportation for multiple hospital teams arranged and performed, and operating rooms reserved for recovery, so second-to-second interactions may not be required as they are in other healthcare and first responder environments. The NOOC determined that the data systems that support organ donation need to be reliable and available, but 99.999% availability would not translate to better patient outcomes or improve practitioner experience. Notably, the major hospital EHRs do not guarantee 99.999% availability. Further, because OPO and hospital employees use the OPTN system in multiple environments, the variability of their own systems and access would mean that the actual user experience of availability would be less than 99.999% regardless of the availability of the OPTN system.

Gartner, a leading industry research organization, has observed that when supporting a healthcare application like the organ matching system on a nationwide scale, it is virtually impossible to achieve 99.999% availability due to the quantity and variety of client environments and national network grid dependencies.

UNOS suggests that HRSA adopt the recommendation of the NOOC, which represents the users of the system, and require a standard of 99.9%.

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

UNOS is committed to constantly evolving our state-of-the-art, safe and effective IT infrastructure to make the OPTN even stronger. The system is regularly audited and meets and often exceeds the requirements of third-party and HHS auditors. Additionally, the OPTN has consistently met the terms of the OPTN contract and has never experienced a security breach.

Because the security of the patient information held in trust by the OPTN is critical, UNOS believes HRSA should require a combination of "Defense-in-Depth" and "Zero-Trust" approaches to ensure there are multiple ways to protect the OPTN IT system and data.

This includes requiring the system to meet NIST 800-171 standards. This is an externally established, updated benchmark to ensure a high level of performance in non-federal IT systems.

HRSA should also require cyber security certifications for IT security staff required to perform at the highest levels, continuous 24x7 security monitoring and response, and participation in federally sponsored cyber-security programs like Health-ISAC, CISA, and others as appropriate for federal contractors.

Membership and monitoring of industry and federal cybersecurity programs should be required to ensure all known cyber threats are identified with associated Indicators of Compromise (IOCs) to be included in the security tools and processes.

HRSA should clarify the role of the OPTN in improving the IT security of transplant hospitals, OPOs, and histocompatibility labs, taking into account best practices for securing critical patient data, and the roles of federal agencies, particularly CMS, in setting standards for IT security within health care organizations.

C. OPTN Finances

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?

In UNOS' capacity as the OPTN, we prioritize being responsible stewards of all budgetary funds as we continue to efficiently and effectively pursue our lifesaving mission. Federal contracting processes provide significant oversight into contract finances by the agency contracting office as well. UNOS recommends that HRSA not create special contractor-specific requirements for each contract they oversee, nor should HRSA require a contractor to forsake all other customers and revenue in order to serve as the OPTN contractor. To require that the OPTN contractor have no other customers or revenue may restrict the pool of potential bidders.

HRSA should continue to require key financial review and transparency steps:

- Approval of the OPTN fee by HRSA (on the Secretary's behalf)

- HRSA participation in the OPTN Finance Committee and OPTN Board of Directors discussion and approval of the OPTN budget
- HRSA participation in quarterly discussions with contractor finance staff
- HRSA review and approval of detailed monthly vouchers
- HRSA review of annual independent external audit

D. OPTN Governance

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.

UNOS recognizes that this has been a longstanding goal of HRSA's and proposes a potential solution below. The solution is complicated, because NOTA requires that the OPTN be a private, nonprofit <u>entity</u> with a Board of Directors. The OPTN Board of Directors is not simply a policy board, but the *governing body* for an organization with legal authorities, responsibilities, and finances, including the statutory authority to collect an OPTN registration fee.

These are not simple issues, but we believe that they are resolvable. These are structural issues that will exist regardless of the identity of the OPTN contractor. We believe that creating a functional, legally viable, independent OPTN could be achieved through a series of the following steps:

- Incorporate and enroll members into a new independent OPTN. Under the current model, the OPTN takes its corporate existence from the contractor. This is important, because the OPTN needs to establish itself as a corporation to meet the NOTA and Final Rule requirements of being a "private nonprofit entity." Members of the current OPTN, which is UNOS serving as the OPTN, should affirmatively indicate their desire to be members of the new OPTN, a legally distinct organization, in order to avoid any questions about the authority of the OPTN.

- Create a Memorandum of Understanding between HRSA and the new independent OPTN in order to bind the OPTN to these requirements. The current model gives HRSA a direct legal agreement with the OPTN, through the contractor. This provides specific requirements that the OPTN, through the contractor, agrees to follow in fulfilling the responsibilities of the OPTN. While the authority may exist for the Secretary to direct the OPTN on policy issues, the contract is a much more comprehensive and detailed set of expectations than has ever been delivered by Secretarial direction before.

- Create OPTN contract language specificity to clarify the financing mechanism of the cost-sharing contract to clarify that the contractor's portion of the cost sharing is funded by the assignment of the OPTN registration fees from an independent OPTN to the contractor. Additionally, there should be a contract task to collect the OPTN fee on behalf of the OPTN and manage the funds as necessary to complete the tasks of the OPTN contract.

At a minimum, UNOS suggests that HRSA show that any new arrangement still guarantees that the OPTN fees used to pay contract expenses are actually committed to the OPTN contractor and cannot be diverted or held up by a third party outside the HRSA-contractor contract.

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

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

Working collaboratively with the donation and transplant community and HRSA, UNOS, in its role as the OPTN, is focused on improving the equity, effectiveness, and transparency of the national system, building trust among all communities the system serves, and saving more lives. In this capacity, we view the NASEM report as an important blueprint forward in a variety of areas, including increasing equitable access to transplant, engaging diverse stakeholders, and involving patients in shared decision making. In fact, many of NASEM's recommendations mirror efforts that UNOS is currently undertaking in collaboration with the community at-large, and we are also undertaking additional efforts to address some of NASEM's specific recommendations.

NASEM commended the continuous distribution framework as a tool for increasing equity and engaging public participation. We have been working with the nation's organ donation and transplant community to develop and implement this complex framework for years, and we believe HRSA should expect the OPTN contractor to continue toward full implementation. The OPTN contractor should also be equipped to bring to life complex allocation policies for all organs within the framework and operationalize them seamlessly into OPTN technology.

Further, the NASEM report called upon HHS to achieve equity in the U.S. organ donation and transplant system in the next five years. The NASEM report identifies differences in access to health care prior to being placed on the transplant waitlist as the driver of inequity in access to transplant.

To assist in providing more equitable access to pre-transplant and transplant health care, the report suggests expanding oversight and data collection to better understand the widely-acknowledged inequities in accessing the national waitlist, from diagnosis of end stage organ failure to one year post transplant. We suggest that the RFP thoroughly contemplate this recommendation, explicitly describing any new data collection and work desired, as well as enhanced expectations of the contractor for additional analysis to support this expansion in scope. Critically, the role that HRSA determines that the OPTN should play must work in concert with other federal strategies for improving access to health care in order to effectively address inequity. While strong HRSA oversight practices are already in place for the waitlisted population per the OPTN contract, patients would ultimately benefit from more holistic oversight of the journey to and through transplant.

NASEM also encouraged HHS to consider ways to speed the policymaking process while still providing opportunities for public input and consensus building. HRSA should require potential bidders to outline their public policy development process and how they plan to fully engage

patients and the public throughout. The RFP should also clarify the minimum requirements for public comment preparation and release so that bidders can meet the donation and transplant communities' and the government's needs.

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

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

Since 1986, it has been our honor to convene and collaborate with a diverse and growing community, united by our commitment to saving and improving lives through donation and transplant. Serving as the OPTN contractor, UNOS has prioritized increasing diverse representation within the OPTN governance structure. We engage patients, donors, donor families, and advocates from across the country, with different experiences, backgrounds, and areas of expertise. These ongoing, community-wide efforts have yielded a faster, more responsive policy development process that reflects the diverse views of a wide variety of stakeholders, and remains an ongoing focus for us.

In addition to external collaboration, UNOS has found that there are major efficiencies in keeping all OPTN policy development, implementation, education, communication, analysis, IT infrastructure and subject matter experts all under one roof. Seamless and coordinated collaboration between all parties yields the best, most comprehensive results, as each functional area is intimately involved in each project from inception to implementation to post-implementation. Anything less may introduce inefficiencies and slow down the policy development and implementation process. This integration also allows the contractor to provide HRSA additional insight, analysis and reports on all OPTN topics.

As HRSA considers improvements to the systems and operations of the OPTN and the donation and transplant community, UNOS feels it is vitally important to also consider that transplant hospitals and OPOs have designed their own operations and IT systems to interact with the existing OPTN IT system (which vary widely in security, functionality and complexity), UNOS believes that HRSA's contract requirements should ensure that the systems used to deliver the next OPTN contract provide the range of functionality and security that the donation and transplant community currently depends on.

Thank you for the opportunity to comment on HRSA's OPTN RFI. It is UNOS' intention to respond to the OPTN RFP at the appropriate time.

May 23, 2022

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration
Office of Acquisition Management & Policy
5600 Fishers Lane
Rockville, MD 20857-5600

NInazawa@hrsa.gov

Attached please find the response from UW Organ & Tissue Donation to the following Request for Information (RFI):

Notice Number: HSB115C1031
Notice Title: Organ Procurement and Transplantation Network (OPTN)
Original Date of Issuance: Friday, April 8, 2022
Updated: Saturday, May 7, 2022
Deadline: May 23, 2022 at 1 PM ET

Name: UW Organ & Tissue Donation, 448 Science Dr., #250, Madison, WI, 53711

Point of Contact: Kristen Audet
                            Regulatory & Quality Manager
                            kaudet@uwhealth.org
                            608.333.6074

UW Organ & Tissue Donation does NOT intend to supply a proposal on any future solicitation related to this requirement.

A. OPTN Technology - IT System:

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

The UNet system would benefit from a much-needed update with increased system ability across all platforms but most specifically, DonorNet. For example, the DonorNet platform was just only recently updated to include time zone stamps on times entered; a system that is designed to serve professionals in organ procurement and transplantation should be far more advanced and sophisticated. Allocation rules, especially concerning multi-organ offers and acceptances, should be built into the system to allow for easier compliance with complicated important regulations. Another example is out of sequence allocation reports should be able to be directly entered into the system, not emailed to an individual staff member at UNOS. Finally, the system must be updated to easily accommodate and connect with platforms providing e-referral services and electronic health record systems. Overall, UNet should be significantly updated to reflect the technology available in 2022.

B: Data Collection Activities

B.1: Describe the ideal process for developing superior performance metrics and benchmarks, including consulting with experts, subcontractors, transplant candidates, recipients, organ donors, and their families.

New data tools, such as the OUT Tool, should be available to all members free of cost. Resources that can improve our overall donation and transplantation system should be accessible to all members.

The O/E Calculator should continue to be available and also updated regulatory to take into account evolving medical standards and requirements, such as including DDR biopsy results which is a common reason organs are not transplanted, but performance metrics do not reflect this.

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

Including a more sophisticated and holistic process for assessment of organ utilization metrics including all partners—not just OPOs—can identify ways the system as a whole can improve to increase the number of lifesaving organs transplanted.

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.

Policies need to be developed that prevent "gameification," but are not overly restrictive to the point of organ wastage due to difficulty placing organs.

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

See response to A.3 detailing updated capacity of the UNet system.

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 could be better achieved with increased public outreach and education from the OPTN Contractor. The general public often only knows about organ donation from what they see in the news or entertainment media. More nuanced public education is often left to individual OPOs and states or Donate Life organizations. What can OPTN do to dispel myths about organ donation and increase awareness in a way that reaches diverse communities?

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.

Allowing all members access to OPTN Committee meetings and the ability to provide comments would increase engagement of a broader community. A larger amount of individuals and agencies able to become familiar with and participate in policy development will hopefully lead not only to feedback from a more diverse membership but an increase in the number of people applying for committee appointments.

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NOTICE

Notice ID: HSB115C1031
Organ Procurement and Transplantation Network (OPTN) RFI
Issuance Date: April 8, 2022

SUBMISSION

Valeos Transplant Society
601 Massachusetts Avenue NW
Washington, D.C. 20001
policy@valeos.org

Valeos

Valeos Transplant Society
601 Massachusetts Avenue NW
Washington, DC 20001

May 20, 2022

Health Resources & Services Administration
5600 Fishers Lane
Rockville, MD 20857

RE Notice ID HSB115C1031

Dear Health Resources & Services Administration (HRSA):

Thank you for your attention to the United States' organ allocation, procurement, and transplantation ecosystem. Your commitment to its improvement is profoundly needed given its unacceptable and insufficient current state.

Valeos is a newly-formed nonprofit society focused on adult heart transplants. Patient-driven and patient-centric, we're composed of and work in collaboration with current and former executives, engineers, and researchers of the world's most impressive organizations and health systems who have come together to save and improve lives.

We respectfully and urgently call for HRSA, under the direction of the U.S. Department of Health & Human Services (HHS) and in conjunction with the Office of Acquisition Management and Policy (OAMP), to address the organ transplant ecosystem's failings including an "urgent health equity issue" as bipartisanly cited by U.S. Congressional leaders.

To prevent tens of thousands of unnecessary deaths and to redress persistent and long-overlooked transplant inequities, immediate systemic and cultural changes are necessary, including:

- Modernize technology for organ referrals and matches, track and trace recovered organs, and outcomes monitoring, using cloud infrastructure, GPS, redundancy systems to minimize downtime to the highest SLA, and version control for iterative development
- Create well-supported, well-documented API framework including tools and repository to be adopted by the ecosystem for real-time, high-quality, standardized data
- Leverage homomorphic data encryption to simultaneously provide real-time, no-cost access to public parties with de-identified and anonymized data and to HRSA-approved researchers with encryption key access with complete, patient-identified datasets
- Eliminate real or perceived conflicts of interest

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- Reabsorb oversight of Organ Procurement Organizations (OPOs) from the Organ Procurement and Transplantation Network (OPTN), and separate governance of the OPTN from any OPTN Contractor(s)
- Increase competition and incentives for critical components of the OPTN — including subdividing the contract as recommended by the NASEM report, so that technology may be provided by an innovative and highly-competent contractor — as well as for OPOs
- Realign incentives for the OPTN, the OPTN Contractor(s), OPOs, and transplant centers
- Require transparency, oversight, and accountability for all stakeholders including the OPTN, the OPTN Contractor(s), OPOs, and transplant centers

The functional and cultural failures of the organ transplant ecosystem across policymaking, technology, compliance, awareness, governance, integrity, transparency, and accountability do a gross and incalculable injustice to donors and patients — including listed candidates *and* recipients, as well as patients who failed to be listed because of the artificially constrained organ supply — as well as their families, friends, and caretakers.

In the United States of America, the world's most developed country, today's statistics are appalling and unimaginable:

- 33 Americans die every day from the lack of an organ transplant, *as cited by the U.S. House Committee on Oversight and Reform and the U.S. Senate Finance Committee*
- The public-private partnership responsible for the U.S. ecosystem is 15x more likely to lose or damage a donated organ than an airline is a suitcase, *according to the American Society of Nephrology and Kaiser Health News' reporting*
- As few as 1 in 5 potential donors have a donated organ recovered, *according to a study funded by the United States Department of Health and Human Services (HHS)*
- Black Americans face a 10x variability in having their organs recovered based on where they live, *according to the Centers for Medicare & Medicaid Services (CMS)*
- 66% of the nation's organ donation recovery nonprofits are failing or underperforming, *according to HHS based on key metrics set by CMS*

These facts represent systemic, repeated failures with daily consequences for American lives, and raise questions about the operations of the OPTN.

In 1984, the newly-approved National Organ Transplant Act afforded for the creation of the OPTN and its capacity to procure a nonprofit contractor to administer the U.S. organ transplant ecosystem. The contractor was and is meant to perform three primary functions:

- Policymaking
- Technology implementation and delivery

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- Enforcing compliance

The OPTN's current contractor, UNOS (notably, the only bidder of every OPTN RFP since the network's first RFP more than three decades ago), has received criticism, including:

- "[UNOS is a] cartel" and "the federal monopoly that's chilling the supply of transplantable organs and letting Americans who need them die..." *(Forbes, 1999)*
- "The little-known organization that oversees the nation's organ transplant system often fails to detect or decisively fix problems at derelict hospitals — even when patients are dying at excessive rates." *(Los Angeles Times, 2006)*
- "An astounding lack of accountability and oversight in the nation's creaking, monopolistic organ transplant system is allowing hundreds of thousands of potential organ donations to fall through the cracks" *(The New York Times, 2019)*
- "A startling number of lifesaving organs are lost or delayed… [because] they are typically tracked with a primitive system of phone calls and paper manifests, with no GPS or other electronic tracking required." *(Kaiser Health News, 2020)*
- "[UNOS] maintains an antiquated technology and limited technical acumen…[and] has devolved into a hostage-taking situation, where it has convinced the government that no one else can do what it does, but it doesn't perform its functions particularly well." *(Report from alumni of the U.S. Digital Service and endorsed by all 5 former HHS CTOs, 2020)*

Today, there are parallel bipartisan U.S. Congressional investigations by the U.S Senate Finance Committee and the U.S. House Committee on Oversight and Reform, focused en masse on problems amongst government organ contractors, including conflicts in oversight, "shocking mismanagement," and technology failings.

In October 2020, U.S. Congressional leaders sent a letter to HHS stating, "Our concerns regarding the Department's role in overseeing our nation's organ procurement organizations (OPOs) stem from Inspector General audits/reports, whistleblower accounts, investigative reporting, and research. Additionally, our internal analysis has shed light on the gaps in the federal government's oversight, resulting in fraud, waste, and abuse of our nation's Medicare program and American taxpayer dollars." In February 2021, U.S. Congressional leaders issued UNOS a subpoena, noting, "We have serious concerns related to UNOS' role in overseeing our nation's OPOs, which have been severely underperforming for decades. Our review has shed light on the improper use of Medicare funds, conflicts of interest and gaps in oversight."

HRSA, on behalf of its governing department HHS, should reaffirm its administration's responsibility to donors and patients by delivering critical reforms necessary to these investigations, as well as satisfying the Equity Executive Order, the Equitable COVID Response Executive Order, and the Competition Executive Order.

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Additionally, HRSA should communicate its commitment within communities of healthcare, technology, government, and logistics through incentives for innovative OPTN RFP bids as the U.S. House Appropriations Committee last year called on HHS to "make all efforts to promote competition for the OPTN contract." Given the ecosystem's state, the OPTN contract should be recompeted in 2023, and subdivided as applicable, to ensure potential bidders may have adequate time to create qualified alternate bids than maintain or minimally improve the ecosystem's status quo.

Without such reforms to the organ transplant ecosystem and its requirements that result in modern technology, data quality and accessibility, reabsorption of oversight capacity, independent governance, competition, and policies to avoid conflicts of interest, the organ transplant ecosystem will continue to jeopardize the generosity of donors and lives of patients who rely on its altruistic function and depend on efficient, communicative, virtuous, and transparent processes.

We must acknowledge our collective failings and recognize our willingness to do better so that we may fulfill the promise of each available organ with a high-quality transplant that saves lives and improves life expectancy and sustained quality of life.

On behalf of donors, patients, and Valeos' society members, philanthropic supporters, team, board of directors, and advisory committees, we look forward to working with you in this effort.

With gratitude,

Tristan & Jordan Mace
Founders & Co-Chairs of the Board of Directors, Valeos Transplant Society

Enclosed   **RFI Answers**
                     Statement on Proposal Intent

CC   **U.S. Department of Health & Human Services**
                     200 Independence Avenue, S.W.
                     Washington, D.C. 20201

                     Office of Acquisition Management and Policy
                     9000 Rockville Pike
                     Bethesda, Maryland 20892

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RFI ANSWERS

A.1.a. Describe how you would/a vendor 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.

Modern technology implemented and deployed by the OPTN Contractor, and subsequently adopted by the organ transplant ecosystem's stakeholders, should include but not be limited to:

- Cloud-native infrastructure, such as Amazon Web Services (AWS), Google Cloud Platform (GCP), or Oracle Cloud Infrastructure (OCI)
- Containerization for automating software deployment, scaling, and management, which will in tandem with cloud infrastructure, can increase uptime SLA to 99.999%
- API framework with tools and repository for ecosystem collaborative development
- Blockchain for immutable ledgers
- Data governance protocols for privacy, security, and architecture
- Homomorphic encryption for data standardization
- Versioning control system, such as Github, Gitlab, Bitbucket, etc.
- Iterative, agile development sprints to account for user research, user story creation, UX, UI, development, front-end design, testing, QA, DevOps, release, and feedback collection
- Continuous code development through appropriate testing, staging, and production instances with automated testing suite integration into continuous workflow
- Application health monitoring and public access for accountability

A.1.b. Describe how you would/a vendor would 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.

According to the USDS alumni report, the ecosystem's current technology is composed of "disparate systems that each handle their own data." Instead, by leveraging the utility of Application Programming Interfaces (APIs), or software intermediaries that allow two applications to communicate together that are ubiquitous in the modern technology stack, the ecosystem can reduce the risk for data latency and errors while making data more accessible while simultaneously maintaining privacy and security.

An API framework should include:

- API tools to accelerate design, testing, and discovery
- API repository to store, iterate, and collaborate
- API documentation to ensure API framework can be used across teams and stakeholders

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- API operations for alerts, security warnings, reporting, etc.

Adopting an API framework, the ecosystem can support integrations to EMRs/EHRs for bidirectional data sharing of relevant data variables and attract third-party innovators to contribute solutions. The open ecosystem, likewise, should have a no-cost mandate applied to all nonprofit researchers.

A.1.c. Describe how you would/a vendor would 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.

OPTN technology should have an intuitive, simple user interface predicated on functionality and clear visual design, interactive design, and information architecture. The interface, a continued iterative work, should be as a result of cyclic collaborative collection, research, validation, and evaluation of user requirements. The interface should also provide intuitive feedback to users with interaction or status alerts.

For time-sensitive delivery information of waitlist candidates, donors, and match runs, among others, the user interface should be facilitated via native applications to support location services and deliver push notifications; for data accessible by the public such as dashboards and status updates, the interface should be delivered via a mobile-first, responsive design website.

A.1.d. Describe how you would/a vendor would produce public performance dashboards and actionable data to identify opportunities for program improvement, reduce inequities, and benchmark OPTN member performance.

"The black box...," according to the USDS alumni report, "provides no opportunity for collaboration or outside competition to drive innovation."

The OPTN Contractor should use a cloud data warehouse to manage, in real-time, its massive datasets. As a "single source of truth," this could facilitate visibility by the public and third parties into the real-time performance of the organ transplant ecosystem, the OPTN Contractor, OPOs on an individual- or collective-basis, and transplant centers on an individual- or collective-basis, all benchmarked across variables including different time periods, locations, organs, etc.

Additionally, by using homomorphic encryption with data governance protocols to enable limited data availability when necessary, the data allows researchers to make hypotheses and model expected outcomes based on real historical data.

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A.1.e. Describe how you would/a vendor would maximize these and other tools to save critical time in the organ allocation process, minimize errors, and improve patient outcomes.

The technology stack should use leading tools to maximize uptime, reduce latency, reduce necessary node dependencies, execute provenance, facilitate track and trace, and create and maintain APIs for industry transparency, accessibility, and accountability.

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?

Yes, 99.999% is a reasonable uptime SLA given the system's responsibility for managing minute-by-minute life-dependent operations, which holds similar importance to other critical societal functions such as homeland security and intelligence operations.

Furthermore, the SLA's for Amazon Web Services and Google Cloud Platform are "at least 99.99%" and ">=99.99% across multiple instances," respectively.

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

The OPTN should require the use of APIs — not latent flat files or "cron jobs" — for instantaneous, real-time data collection of standardized data. By leveraging APIs, this could minimize any disparate and duplicative inputs and use technology for input and unit checks to improve data accuracy and cleanliness.

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

The OPTN Contractor should work with the U.S. Department of Homeland Security's Cybersecurity & Infrastructure Security Agency to monitor new and ongoing security threats, as well as the U.S. Digital Service and leading Chief Information Security Officers and their affiliated associations. Furthermore, by incorporating and adhering to one or more information security management systems (ISMS), regular compliance requires ongoing security enhancements.

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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Selection and adherence to a leading, internationally-recognized ISMS, such as ISO 27001 and/or SOC2 + HIPAA, would provide a framework to include and maintain the latest security practices as agreed upon by the broader international community. Additionally, the OPTN should require an annual audit, if not performed biannually, to ensure perpetual compliance to protect the security and privacy of donors and patients.

B1. 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.

The OPTN Contractor should be required to make data accessible with appropriate data permissions for interaction and visualization by various ecosystem stakeholders such as transplant centers, health systems, societies and nonprofits supporting cohorts of patients, and for-profit corporations seeking to innovate within the ecosystem.

This longitudinal dataset should include but not be limited to pre-transplant evaluations, transplant, post-transplant biopsies, blood work, medicine changes, rejection episodes, and other notable updates. Other parties such as patient cohort registries and research studies should augment their dataset with voluntary surveys, wearables, and other quantifiable technologies. Collectively, this data should lead to increased oversight, directly translating into more organs recovered and transplanted and higher rates of transplant outcomes and sustained quality of life.

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.

Data collection, predicated on adopted APIs by stakeholders as a core requirement of OPTN membership, should drive data collection for unified and consistent processes without necessitating open text input forms. There should be no flat file export dependency as API integrations into EMRs/EHRs and the OPTN Contractor's technology should enable consistent data transfer. Conversely, these APIs can deliver data for reporting mechanisms that provide visibility and accountability into the ecosystem.

B.2.b. Describe how you would/how vendors could structure data collection and reporting mechanisms for the system to establish OPTN member performance benchmarks.

Exhaustive standardized data should enable performance benchmarking against like transplant centers and like OPOs, on the basis of geography type, region size, populations of cities, population

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density, aggregate ICU beds, size of transplant center(s), ratio of deaths to listed candidates, outcomes, among other cohort variables.

B.2.c. 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.

The OPTN Contractor should capture donor and patient demographics upon collection, and then apply cascading preference in deferential respect to the applicability of each situation.

Donors:
1. If a living donor, provided by donor
2. If deceased donor:
    a. Donor's hospital records if previously provided by donor
    b. Donor's hospital medical records, as verified by next of kin
    c. Donor's hospital medical records

Patients:
1. Provided by patient
2. Patient's hospital medical records, as verified by next of kin
3. Patient's hospital medical records

The collected data should be facilitated by API, if integrated, and stored in a data warehouse.

B.2.d. 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.

Data reporting mechanisms should be as real-time as possible to create transparency and accountability within the ecosystem as compared to the current latent reports ranging from three months to two years. The dashboards should be accessible to the general public, specifically to anticipatory candidates, waitlisted candidates, and recipients, to provide detailed information as means to make an informed selection of transplant center including the underlying quality of the associated OPO to successfully recover and transport organs. Furthermore, other nonprofit and research organizations that work with data in the industry should be able to make their data accessible for even more specific patient cohorts.

B.2.e. 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-

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related factors that contribute to outcomes.

Pre- and post-transplant protocol variance exists intra-center and inter-center, whether across the street or across the country. Non-standardized care is clearly evident to patients participating in other nonprofit registries or shared via Facebook patient support groups.

The OPTN Contractor should provide for bidirectional data transfer with intrinsic data governance and privacy permissioning that allows for longitudinal data to provide holistic insights pre, intra-, and post-transplant outcomes. By further integrating with EMR/EHR providers, AI/ML models can uncover relationships that, by sharing outputs with centers, OPOs, and other parties, may further improve transplant outcomes and sustained quality of life by demonstrating a virtuous feedback loop.

C.1.a. Describe how you would/vendors could ensure that any fees, beyond OPTN registration fees, charged to transplant centers or others do not duplicate Medicare payment or result in unnecessary additional Medicare reimbursement.

The general public's trust and conviction in the ecosystem's altruistic principles is paramount. The current fee is misaligned given its structure is oriented on waitlist candidate registrations as compared to successfully transplanted organs, which, as highlighted by The New York Times, creates a perverse incentive for the OPTN contractor to grow the waiting list rather than to increase the success of the system for patients.

The OPTN Contractor should also only be allowed to charge transplant centers a single fee on a standardized fee schedule with no optional fee to prevent real or perceived conflicts of interest by needlessly creating "classes" of transplant centers. Additionally, the current "UNOS Fee," which CMS ultimately reimburses, falls outside of the controls of the current OPTN contract, allowing UNOS (or any future contractor(s)) to spend taxpayer dollars for organizational-benefit rather than taxpayer-benefit. The current OPTN Contractor, for example, has recently misappropriated such dollars to lobby against accountability and further amplify misinformation.

C.1.b. Describe how you would/vendors could ensure that any fees, beyond OPTN registration fees, charged to transplant centers or others do not charge for functions that are OPTN contract-supported functions.

Please see above.

The OPTN Contractor should not be permitted to charge optional fees as this creates misalignment between transplant centers that feel obligated to pay the optional fee as a requirement versus centers that do not pay the optional fee. If a core-function service needs to be provided by the

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OPTN Contractor, its associated cost(s) should be included in the per unit fee schedule applied to all transplant centers.

As data transparency and accessibility and the resulting accountability are the underpinnings of the ecosystem's credibility, data comprehensiveness and granularity can prevent cost duplication. The OPTN Contractor-related fee schedule should be subject to approval by the OPTN, and adhere to both the letter and spirit of the OPTN contract awarded by HRSA.

C.1.c. Describe how you would/vendors could ensure that any fees, beyond OPTN registration fees, charged to transplant centers or others are not perceived as mandatory for participation in the OPTN or for receiving core OPTN services.

Please see above.

C.1.d. Describe how you would/vendors could ensure that any fees, beyond OPTN registration fees, charged to transplant centers or others do not impact, or create a perception of impact, status in or allocations through the OPTN.

Please see above.

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?

An independent board of directors for the OPTN should be responsible for approval of any fee(s) charged by the OPTN Contractor. The OPTN Contractor should be able to request, within reason, fee-basis reviews by the OPTN, so the independence of determination is not made or influenced by transplant centers, OPOs, or other ecosystem parties.

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.

In 1998, then HHS Secretary Shalala cited, "I have received numerous letters from Members of Congress, transplant professionals, patients, and the public that reflect inaccuracies published by UNOS." Nearly two decades later, a federal judge unsealed UNOS' emails revealing private communications between a UNOS board member and its CEO that stated: "The fact that some states do better than others in preventing preventable deaths and providing health care insurance coverage and access means you're a dumb fuck for living there." The UNOS CEO further stated that "[UNOS] doesn't have a real board." These statements clearly represent insufficient oversight,

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especially given that objective data and reporting reveal such oversight gaps directly contribute to the perpetuation of a broken system with fatal consequences for patients.

Today's governance conflict of interest is profoundly egregious and disconcerting given the above examples. The OPTN is responsible for providing oversight and accountability of the OPTN Contractor, while the OPTN Contractor is responsible for administering the U.S. organ ecosystem. However, as the same individuals currently serve as board members of both the OPTN and the OPTN Contractor simultaneously, there's a gross and inappropriate governance structure that inadequately reflects the ecosystem's needs.

The OPTN board, without actual or perceived conflict(s) of interest, should be more akin to:

- 11 board members represented in aggregate by government healthcare members, OPOs, and Transplant Centers
    - 6/5 Government Healthcare Members, such as current and former government healthcare leaders, such as commissioners, administrators, CTOs, and CIOs
    - 5/6 Regional Members, such as CMS-passing OPO members and CMS-certified transplant centers, which invert every 2 years and rotate
    - The 5/6 - 6/5 dynamic should invert every 4 years
- 3-5 independent board members, served by ecosystem nonprofits, patients, donors, etc.
- 2 ex-officio, non-voting board members from the OPTN Contractor

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

The OPTN Contractor should be denied representation on the OPTN board of directors beyond two ex-officio, non-voting board members. All OPTN board members should be subject to strengthened — and publicly disclosed — conflict of interest disclosures, including prevention of receiving any compensation, whether cash, shares, or otherwise, from consulting or advising any party with a vested interest in the ecosystem. Additionally, there should be term limits placed upon all board members.

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

Visibility and transparency creates accountability. The OPTN Contractor should define key performance indicators, communicate them to OPOs and contractors, and then publicly publish performance metrics on dashboards with timely releases of data to the ecosystem's stakeholders.

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These key performance indicators can serve as leverage to incentivize contract extensions, or, whenever necessary if subpar performance, as probation to accelerate contract periods.

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.

Please see above.

Effective operations require a competitive OPTN contract inclusive of appropriate incentives and conflict of interest policies.

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.

With 66% of the nation's OPOs classified as failing or underperforming according to HHS based on key performance metrics set by CMS, the U.S. Senate Finance Committee stated, "We have serious concerns related to UNOS' role in overseeing our nation's OPOs."

The OPTN Contractor must establish and uphold certification requirements and oversight of each OPO relative to its individual performance and results to effectively and permanently end the local monopoly each currently holds. Although failing OPOs are set to be replaced by higher performers until 2026, this timeline should be urgently accelerated to avoid unnecessary deaths and wasted taxpayer dollars. Increased transparency and oversight, as evident in the case of Indiana's OPO which improved 44% in one transplant year, demonstrates that OPO turnarounds can be systematized during probation and decertification if necessary.

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

According to peer-reviewed research from the University of Pennsylvania, 28,000 organs go untransplanted every year. Additionally, the 2015 HRSA-funded "OPTN Deceased Donor Potential Study" discovered even greater missed lifesaving potential, concluding that: "Organs for transplantation are recovered from about 8,000 deceased donors per year, potentially only one-fifth of the true potential." The OPTN Contractor should be principally responsible for organizing research standards in procurement, recovery, and transport, and then coordinate with the collective OPO body to incorporate innovative practices based on the data and research.

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Additionally, given the unfortunate recent increases in opioid deaths, car accidents, and gun deaths have added to such potential which UNOS and OPOs have misleadingly promoted such increases as evidence of improved system performance, the ecosystem should require more transparency regarding the donor potential year. In fact, after controlling for such increases outside of OPO control, donations have not even kept pace with population growth over the last 10 years according to the former U.S. Chief Data Scientist as published in JAMA.

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

Disappointingly, among all mature international transplant systems, the United States provides the most opaque system for OPOs. Data collection and accessibility across the OPTN nodes for a longitudinal dataset can result in the identification of successful organ procurement practices, including related to engaging hospitals making timely referrals, interactions with donor families, clinically managing donor cases, recovering and transporting organs, and successfully placing organs with transplant centers. In other words, the greater and more exhaustive the dataset size, the higher likelihood independent researchers can engage in modeling and drive learnings to incorporate in practice.

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

With 43% of listed candidates awaiting a new heart from communities of color according to OPTN, heart transplants have inequitably benefitted wealthy, white patients since the first performed heart transplant in 1967.

Equitable access to transplants is critical as communities of color are especially disadvantaged by failures of the OPTN, the OPTN Contractor, and OPOs. Access should not be limited or discriminated by race, ethnicity, gender, sexual orientation, finances, travel, geography, and other disproportionate factors.

The OPTN Contractor should engage, among other tactics, HRSA's Office of Planning, Analysis, and Evaluation to work with data initiative partners to drive life-saving changes. HRSA can also publish more detailed analysis of the data, such as where organs are missed to prompt and require evidence of equitable performance to hold all stakeholders accountable.

HHS should publish OPO process data, mirroring other well-established international standards for mature transplant systems. Such process data will allow for the government and public to ensure that OPOs provide more equitable service, in line with not only the recent Executive Order on Equity but also basic legal expectations for healthcare providers, given peer-reviewed research has

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found that OPOs are less likely to approach the family of a Black versus a white donor, spend less time with their families, answer fewer questions, and exhibit less compassion.

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.

Discarded organs are the unacceptable result of prolonged ischemic times and inefficient "marketplace dynamics," in which unsatisfactory and insufficient matches reduce the viability of an organ's utility so dramatically that the organ must be discarded instead of transplanted successfully for a patient to sustain life.

As the current OPTN Contractor matches 17% of kidney offerings to deceased patients, these unacceptable marketplace dynamics can be dramatically improved by implementing modern technology. Additionally, data visibility can illustrate the chronology of organ availability to turn down(s) to final acceptance/discard.

Lastly, CMS believes that "performance results [related to minimizing organ discards] such as those achieved in France could be achievable in the U.S. with greater accountability for OPO performance." Thus, HHS should increase accountability for OPOs, as has been supported by patient groups, bipartisan and bicameral Congressional leaders, and equity advocates.

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

The OPTN Contractor should use data and its underlying statistics to drive accountability and change. By creating an expiring time window for transplant centers to review offers and formalizing a ratio of offer to turn-down, the OPTN can ensure transplant centers are not unreasonably or needlessly reviewing offers.

Also, the OPTN Contractor should work with the Federation of American Scientists and leading academic health systems to uncover fixable causes of organ loss, such as differences in response rates by race/ethnicity or rural/urban status.

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.

The public stakeholders of the ecosystem, such as anticipatory candidates, candidates, recipients, donors and their family members, should have access and opportunity to ongoing education and

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awareness resources for the organ donation process and the matching process for waitlisted candidates. Transplant candidates and recipients should have access to their accepted offer number (and associated number of turn downs), ischemic times, etc.

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.

HHS should identify and communicate the primary outcome(s) the department seeks (e.g. to eliminate accessibility discrepancies across racial groups), and then incentivize the OPTN Contractor to meet the provided goals or face potential retribution including loss of the contract.

Subsequently, as patients of color are more likely to need an organ transplant but less likely to receive them, the boards and committees should look like the people representing and advocating for them. Lastly, it is critical that the OPTN Contractor and OPOs should be prevented from engaging in anti-patient lobbying as means to obstruct reform in the rightful interest of donors and patients.

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

Experts in quality improvement and stakeholder collaboration can promote strategies and provide direction to establish appropriate representation beyond the transplant community and healthcare.

However, this requires a culture of innovation and radical transparency through aggressive publication of objective, transparent data, as well as re-tilting leverage back to HHS through structural reforms to ensure OPTN contract competitiveness.

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.

While adopting or amending a code of business ethics and conduct is schmaltzy and an act of showmanship, the difficulty is in strict adherence and deference to the code, which serves as the primary reason HRSA and the OPTN should engage in strict oversight.

To maintain the altruistic nature of the ecosystem, the OPTN Contractor's code should include:

- Unending focus on the donor, the patient, and the responsibility to the donated organ

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- The collective good of public interest
- Donor and patient confidentiality
- Ethical leadership without conflict of interest
- Radical data transparency and accessibility
- Commitment to accountability and improvement

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

The ecosystem should stipulate requirements and expectations for incentivizing competition, adopting modern technology, and providing public accessibility to performance metrics.

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.

Waitlisted candidates and their next of kin should have real-time visibility in their current position on the waitlist to demonstrate the ecosystem's spirit of transparency and culture. They should also be informed if and when their transplant team has turned down previous organ offer(s).

Lastly, the OPTN and OPTN Contractor should closely track HRSA's ongoing survey, "National Survey of Organ Donation Attitudes and Practices," to understand the broader population's attitudes, sentiments, and decisions towards organ donation, including developing insight into how the current OPTN Contractor has failed to successfully translate the 90% public support for organ donation into recovering, per the "OPTN Deceased Donor Potential Study," as few as 20% of potential donors.

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.

Advancement of equity, accessibility, and transparency singularly results from accountability based on the key prerequisite: access to the data of the OPTN Contractor and OPOs. Despite the intrinsic goodwill nature that should exist for the OPTN Contractor and OPOs, the OPTN must realign incentives and requirements to access all data.

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?

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The OPTN contract should require transparency into waitlist dynamics and further demystify the waitlist process by providing public dashboards, using de-identified and anonymized data, so everyday Americans can see the list in real-time and its demonstrated culture of transparency. This transparent ethos should extend to include information and data regarding how transplant centers make such decisions to refer patients for transplant, which inherently involves some discretion.

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STATEMENT OF PROPOSAL INTENT

Valeos will not supply a proposal to any OPTN RFP issued in 2022.

Several Valeos affiliates, however, have indicated that they would consider a joint or independent proposal submission, *provided* the OPTN RFP was recompeted in 2023 and HRSA provided competition assurances so that appropriate and qualified bids may occur.

With gratitude,

Tristan & Jordan Mace
Founders & Co-Chairs of the Board of Directors, Valeos Transplant Society

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Request for Information on Ways to Strengthen and Improve the Organ Procurement and
Transplantation Network[1] [2]
Submitted by
Lisa Haynes-Scott
Founder and Visionary GriefZone, LLC
1039 Maple Avenue Fresno, CA 93625

My daughter, Essence Camille Scott , transitioned from this side to her heavenly reward on June
17, 2017. Essence was only 28 years old and had accomplished her dreams including
graduating from Whitter College. She went on and obtained her MSW and was working as a
Social Worker with the State of California Prison System. Essence registered to be an organ
donor when she became a licensed driver with the State of California. Due to Essence illness,
she was not able to donate organs but was a blessing for so many with the gift of tissue including
her eyes. I have been volunteering for over 20 years with our local Black Nurses Association
with our local Donor West in Fresno, California. Essence loved to volunteer with me during her
teen years and learned the importance of organ donation. She was proud to share with all her
friends the importance of organ donation.

I continue to volunteer and advocate with for organ donation with the following organizations,
Jack and Jill of America Fresno Chapter and local chapter of Alpha Kappa Alpha Sorority ,
Incorporated. I am honored to be a national committee member of Linkages to Life, a Signature
Program of The Links, Incorporated. The Links, Incorporated is an international, not-for-profit
corporation, established in 1946. The membership consists of more than 16,000 professional
women of African descent in 299 chapters located in 41 states, the District of Columbia, the
Commonwealth of the Bahamas, and the United Kingdom.[3] It is one of the nation's oldest and
largest volunteer service organizations of extraordinary women who are committed to enriching,
sustaining and ensuring the culture and economic survival of African Americans and other
persons of African ancestry.

The Links, Incorporated focuses five facets for our service and programming, including health.
Specifically, the Health and Human Services[4] facet was established in response to the chronic
health disparities that persist in Black communities and result in the decreased life expectancy of
African Americans and other people of African ancestry. Through education, advocacy, and
outreach, The Links, Incorporated initiates and supports programs that support the maintenance
of good health and the elimination of chronic health disparities in communities of color. The
Organ, Tissue, and Bone Marrow Donation Awareness Signature Program, "Linkages to Life"
was established in response to the health disparities in organ, eye, and tissue (including bone
marrow) transplantation. The goal of Linkages to Life is to decrease disparities in donor
registration and transplantation in the African American community. Our members work to

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[1] https://www.hrsa.gov/about/news/press-releases/hrsa-releases-organ-procurement-transplantation-network-rfi, Accessed on
May 8, 2022
[2] https://sam.gov/opp/005656500e5741538ce72d57b9b3d558/view, Accessed on May 9, 2022
[3] https://linksinc.org/the-links-incorporated/, Accessed on May 19,2022
[4] https://linksinc.org/health-and-human-services/, Accessed on May 9, 2022

increase the number of registered donors through community-based events and multi-media awareness campaigns. In partnership with the national organization Donate Life America, we strive to register hundreds of donors each year through a Links, Incorporated and Donate Life America co-branded national donor registration page.

I offer the following comments in response to the Request for Information and hope it will be valuable in determining the final policy.

In response to E.4.[5] Increasing Organ Donation and Improving Procurement: How can HRSA best incorporate the NASEM report's recommendations on increasing equitable access to transplants?

Leveraging trusted networks to emphasize organ donation and transplant opportunities. There are numerous ways to connect members of the African American community to sources of information and knowledge related to organ and tissue transplantation. African American physicians are an excellent source for connecting with members of the African American community on this topic. Regardless of the physician's specialty, African American physicians as well as those serving African American patients should emphasize the benefits of organ and tissue transplantation. As discussed by MOTTEP Founder, Dr. Clive Callender at NASEM[6], the historically Black medical schools are a tremendous resource for instilling this message into minority and minority-serving physicians. The HBCU Medical Schools Collaborative and the Links, Incorporated are each positioned to underscore the need for improved equity in the field of organ donation and transplantation.

Suggested ways to increase outreach include:
- Career exposure to STEM, medicine, health professions, and specifically inclusion of transplantation.
- Cultural and linguistically tailored materials geared to educate minority individuals about transplantation for those receiving dialysis.
- Augmented programming with HBCUs, medical schools, and schools of nursing, public health, healthcare administration, and allied health professions.
- Presence at health fairs and organ donor drives, distributing said materials focused on living and deceased organ donation; and
- Continued collaboration with service organizations, faith-based congregations, and community influencers around organ donations.

Members of the Links, Incorporated through local and national Linkages to Life programming have been engaging in multiple activities. Along with numerous opportunities to expand this programming by integrating with the Services to Youth Facet[7] that includes the Links – STEMReady Signature Program and the National HBCU Initiative to encourage youth to pursue careers in the STEM fields. Additionally, I have served with members of the Links, Incorporated who either work as clinical or healthcare professionals, are employed by an HBCU or both.

[5] https://sam.gov/opp/005656500e5741538ce72d57b9b3d558/view, Accessed on May 19, 2022
[6] https://www.nationalacademies.org/event/07-15-2021/a-fairer-and-more-equitable-cost-effective-and-transparent-system-of-donor-organ-procurement-allocation-and-distribution-virtual-public-listening-session, Accessed on May 19, 2022
[7] https://linksinc.org/services-to-youth/, Accessed on May 19

Recognizing the multiplying impact of poverty on social determinants of health on treatment access. Patients who are poor and African American are often rejected for surgery because transplanting them will decrease transplant outcomes. This, in turn may result in the transplant centers becoming decertified. A system must be put in place that does not penalize a transplant center for transplanting such high-risk patients. This phenomenon is important but never discussed. This practice is a form of institutionalized racism and bias that keeps socio-economically deprived patients from accessing organ and tissue transplants at rates proportionate to the prevalence of end-stage organ disease or other related injury. National and regional paired donations are performed but they rarely benefit people of color, in the way that local paired donations do. Encouraging local paired donations is more beneficial to people of color; and is an option that should be incentivized and encourage.

G.1. OPTN Operations and Policy Development Improvements: 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.

Staffing for cultural sensitivity and to minimize biases is an area of opportunity. Representation of culturally sensitive individuals and organizations at every level of OPTN operations and policy development is necessary to transform the current system for attaining health equity. Specifically, priority in notification should be given to organizations of color including Historically Black Colleges and Universities, Black Greek letter sororities and fraternities, and other Black services organizations and programs. Priority in funding should be given to such organizations as well as programs led by people of color. Additionally, specific minimum allocations of funding proportional to the need for transplantation (or the incidence of end-stage disease and organ failure) should be allocated in each area related to organ transplantation. Input from these individuals and organizations must also be integrated in the writing of RFPs and the review of RFP submissions.

Incentivizing equitable outcomes through oversight. Individuals from diverse backgrounds must have a seat at the table to participate in the authority, finance, and control of OPTN operations and policy development, to change the paradigm from health disparity to true health equity. This means there must be more oversight of the OPOs to require the presence of diverse representation at the highest administrative levels. When negotiating collaborations between the Links, Incorporated and potential partner health organizations, we strive to leverage greater representation on their decision-making boards. This strategy has been met with varying results. OPO compliance in this regard must be monitored. In addition, there must be mentoring, opportunities and funding for education, training, and fellowships to allow for the advancement of persons of color to these positions.

G. 4. OPTN Operations and Policy Development Improvements: What other improvements to OPTN operations and policy development processes can and/or should be incorporated into the OPTN contact?

Increasing the ethnic diversity of OPO executive leadership is an opportunity. There are 57 OPOs very few of these OPOs have persons of color at the highest administrative level (CEO or Chairperson of the Board of Directors)[8]. It is important therefore to increase the number of CEOs and Board Chairs who are people of color (African American, Hispanic, or Latino, Asian, Pacific Islander or Native American). Nearly 60% of people waiting for transplant are people of color. Systems should be put in place to eradicate explicit and implicit exclusionary hiring practices and monitor OPO compliance. Increasing the proportion of individuals from diverse backgrounds in leadership positions to better reflect the ethnic diversity of the community of patients being served by the OPO is paramount. Currently, oversight to combat against the current level of executive disparity is completely lacking and desperately needed as indicated by the statistics previously cited.

Living donation policy is an area of opportunity for African Americans, We know the living donations among African Americans are significantly below that of whites, underscoring the need for augmented education of living donation opportunities. In 2020, 16.4 percent of Black people were living donors as compared to 33.4 percent of white living donors[9]. Instances of African Americans who receive a "second chance at life" through organ donation are celebrated in our community in churches, at family gatherings, in the workplace, and in our social and service organizations. It is important to peel back the crucial steps to allow these donations and transplants to happen, which begins with increasing the education outreach to minority communities about the benefits of living donation and simultaneously speaking to the fears, myths, and hesitancy associated with being a living donor. Overcoming this obstacle is best addressed with recipients and trusted community-based organizations delivering the information, not the transplant centers and organ procurement organizations. The education should be multi-generational and culturally tailored, addressing the most pressing concerns and highlighting the successes in minority communities. The Linkages to Life National Program Committee has increased its awareness and advocacy specifically around living donation in the 2021-2022 program year with multiple recorded webinars on the topic. These efforts by The Links, Incorporated or other historically Black service and civic organizations may often be superior to those of the transplant centers and OPOs to address this need. The Links, Incorporated was able to produce culturally sensitive content to meet patients in their communities. The data also shows that non-whites have lower rates of pre-emptive kidney transplantation, especially for living donation. It is important to highlight these disparities and use fund opportunities to educate our communities of color. While serving as National committee member for Linkages to Life, I have learned that people cannot properly advocate for themselves if they lack awareness of all treatment options available. Our campaigns work to increase this awareness.

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[8] https://aopo.org/find-your-opo/, Accessed May 19, 2022
[9] https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=27, Accessed May 19, 2022

H.2-3 Stakeholder Engagement: 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. How can and/or should the contract incorporate new or better approaches for including stakeholders in a shared decision model for organ acceptance?

Bringing diverse voices to the table early and through the organ procurement process is a tremendous opportunity for system improvement. Stakeholders including transplant recipients, prior living donors and families' members of deceased donors should be engaged early, often, and meaningfully. Stakeholders from ethnically diverse backgrounds should be included in the oversight bodies referenced earlier in these comments. Executive search committees or contracted executive search firms should either include stakeholders from ethnically diverse backgrounds or specialize in diversity, equity, and inclusion. There is significant value in OPTN members together with a more diverse cross-section of stakeholders examine these engagement techniques and employ them at various levels of planning, policymaking, and operations, including the development of a shared decision-making model for organ acceptance. If serving patients in need of organ and tissue transplantation is the goal, OPTN members will transform stakeholder engagement practices and where appropriate will hone engagement relations ships to meaningful collaboration and shared leadership to attain more inclusive health outcomes.

Each of these areas of increased emphasis must be met with thoughtful planning and financial resources. Critical to the proper planning is the involvement of organizations and individuals such as ours.

Thank you for considering this feedback.