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Outwit Complexity

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STATEMENT FOR THE RECORD
Submitted by Guidehouse, Inc.

"A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network."

U.S. Senate Committee on Finance
August 3, 2022

Guidehouse appreciates the opportunity to submit a statement for the record to the Senate Finance Committee (the "Committee") on this critical public health issue. Guidehouse is a leading global provider of healthcare consulting services to the public sector, including the U.S. federal government, 40 U.S. state governments, and commercial markets providing broad capabilities in management, technology, and risk consulting. As a result of the services we provide across the entire health ecosystem, we are in a unique position to provide perspective across the various policies, governance, stakeholders, and technology influencing the OPTN. Our statement for the record includes two sections. The first section details our view on challenges and recommendations facing the OPTN with a focus on *"Rebuilding Trust Through Policy & Governance Reform, Stakeholder Engagement, and Communications to Improve Quality"* and *"IT Modernization: Digital Twin Study & Impact with Performance Metrics."* In the second section we detail our background, experience, and previous related engagements to establish our qualifications in the tasks necessary to modernize the OPTN. We applaud the bipartisan support and ongoing examination by this Committee in its efforts to reform the OPTN to provide equity, transparency, and quality of care to save lives in an efficient and timely manner.

OPTN Challenges & Recommendations:
Health Resources and Services Administration's (HRSA) released two Requests for Information, issued April 8, 2020, and April 8, 2022, but later modified and re-released on May 5, 2022, identifying required services to modernize and maintain the OPTN. Recommendations from the NASEM 2022 Report "*Realizing the Promise of Equity in the Organ Donation Process*," provided additional detail and prescriptive feedback for the OPTN. Based on this awareness of OPTN programming, Guidehouse provides the following lessons learned from implementing programs similar in scale and complexity for OPTN reform and modernization:

OPTN Operational Transformation: Rebuilding Trust Through Policy & Governance Reform, Stakeholder Engagement, & Communications to Improve Quality

Modernizing the OPTN requires rebuilding stakeholder trust through outcome focused policy and governance reform. We recommend HRSA and the OPTN to access a similar network of multi-discipline thinking and established partnerships for the OPTN to support national reform. We, along with additional partners, manage coalitions of the nation's existing medical research institutions and professional networks, including representation from Historically Black Colleges and Universities and other Minority Serving Institutions, can guide OPTN's health equity policy agendas and priorities. Part of this effort may include restructuring the OPTN Board, reassessing organ distribution criteria, and integrating quality control and evidence-based best practices with oversight management policies. The OPTN and government programs can leverage this expertise across health and medicine, gain access to unique and existing data resources, and realize valuable opportunities to collaborate with communities, including those underserved by current organ donation and transplant systems. Patient and provider engagement strategies must consider early on how cultural nuances influence communications outcomes, participation, implementation, and evaluation methods. Our Guidehouse and partnership programs engage racially and ethnically diverse stakeholders and keep them involved throughout the process. This is critical for the future of the OPTN network and helps to quickly identify and eliminate cultural biases. It is also an approach that helps minimize or avoid conflict of interest and rebuild trust with underserved communities.

Challenges: 20% discarded or unused; limited availability especially with underserved and minority communities, rural areas and Midwest states; status on the waiting list is a mystery
Solutions: Increase targeted education with cultural appropriateness and community champions; create transparency with data and access to waiting list status; onboard patient advocates with hospital care transplant teams; maintain a Patient Advocacy Coalition and network of donors, recipients, and families; create additional opportunities to register as a donor besides the DMV (driver's license) including options with paired donations/living donors for kidneys through primary care providers.

In our experience assisting executive leadership teams launch system-wide, patient focused modernization initiatives in large health systems we have collected several lessons learned that are relevant to the OPTN. Accountability and transparency regarding tough decisions is necessary for optimizing change, building skills and redesigning processes that sustain success while focusing on measurable results and outcomes to address issues in real time. For the OPTN, we can apply these lessons learned from commercial industry best practices to align a redesign process with performance incentive models that drive accountability with the organ procurement organizations (OPOs). We also recommend partnerships, as recommended by the NASEM report, with the National Quality Forum and the National

Academy of Public Administration to integrate oversight and monitoring standards with certified and contracted OPOs.

Increasing culturally appropriate and audience-segmented communication and education about organ donation and transplants is critical. The transplant process is less familiar and can be stressful to even the most informed patients. Having a better understanding through all phases of the process, especially from the patient journey perspective or the living donor perspective may encourage more donor registrations and accessibility to organs. Communication strategies need to be patient-centric and relevant to cultures and communities, especially with underserved communities and subpopulations. Using a "human-centered design" approach will engage patients who have already been through the process of donating or receiving an organ to inform new patients and families what they need to know prior to their journey. This approach can also highlight where challenges or bottlenecks in the process typically occur and where additional support may be needed.

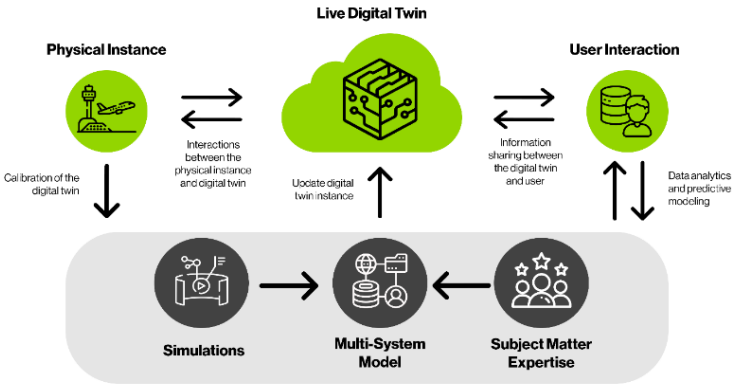
Stakeholder engagement is also imperative when reforming the nation's OPTN. It is particularly important to maximize this engagement by diversifying partnerships and enlisting nontraditional organizations that can inspire community organizations among underserved populations to help recruit new organ donors. We have experienced success enlisting organizations to support clinical trial recruitment while building future workforces. Our vision for OPTN is to fully immerse the stakeholder voice into the OPTN Board through the formation and management of a virtual "roundtable" with ongoing feedback for the transplantation community through patient feedback and monitoring to provide quality improvement, influence and increase organ procurement, and represent diversity and inclusion across all OPOs.

IT Modernization: ***Digital Twin Study & Impact with Performance Metrics***

Modernization of complex data collection systems in the 21st century requires the ability to model, represent, and evaluate inputs and outcomes of interdependent systems while interacting with the system's variables, dependencies, and connections. Led by Guidehouse's Chief Innovation Officer, Dr. Rod Fontecilla, Guidehouse understands that a real-time understanding of a complex network of people, places, policies, processes, and data is the first and most critical step towards achieving true data transparency and insight into the performance and quality metrics of that network and its individual components.

A unique concept Guidehouse proposes for HRSA and the OPTN is the "digital twin" virtual representation of physical entities such as devices, people, processes, or systems that use computer simulation, machine learning, reasoning, and real-time data to help organizations make model-driven decisions related to detection, prevention, prediction, and optimization.

Digital twins are more easily adaptable than their physical counterparts, as organizations can modify digital assets and assess the results without incurring the time or monetary costs needed to adjust physical assets. Digital twin architectures use data from the assets being



modeled and from related systems, to provide a method of storing and providing access to that data, and track and organize that data so that it stays in sync with real-world data about the asset and other digital twins. Industries use digital twins to track assets, such as products, throughout their lifecycles. For example, a hospital might use a digital twin based on its emergency room attributes to simulate and evaluate their readiness (e.g., resources, infrastructure, processes) under different scenarios (e.g., infectious disease pandemic response, emergency due to civil unrest, or natural disasters etc.), to explore changes and predict outcome (i.e., improved readiness) prior to making changes.

The digital twin concept was first introduced in 2002 for use in large manufacturing applications such as defense and aerospace engineering. Today's digital twins are accessible to any enterprise due to the scalable, cost-effective computing capabilities of the cloud. The level of maturity has driven commercial toolkits with cloud providers now offered at a price point that allows a broader set of use cases to use digital twins for enterprise applications. A digital twin's performance is driven by the effective use of cloud-based technologies for compute and storage, as well as the ability to ensure that the data is representative of live data in the field, so that data scientists and SMEs can more rapidly derive algorithms that ensure the simulations are operationally relevant.

Challenges: Conflict of Interest with the current OPTN Board and UNOS participation; lack of Quality Improvement monitoring.

Solutions: OPTN Board to be comprised of elected and credentialed members with backgrounds in medical research, bioinformatics, epidemiology, patient safety, transplant expertise; no engagement from the awarded contractor; equal representation from minority serving institutions and geographic diverse OPOs; use of evidence-based research and OPO performance metrics for decision-making; transparency of all OPTN Board communications and decisions.

Guidehouse proposes creating a digital twin of the OPTN to unite elements of the operational network environment (e.g., organ donor-specific, organ recipient-specific, processes related to procurement/logistics etc.) to inform HRSA performance metrics and impact of potential policy or process changes without changing the physical configuration of OPTN itself. Digital twins can incorporate relevant data, such as logistics, supply chain, physical and human resources, donor registration policy, recipient registration/waitlist practices, data collection and sharing, and social determinants of health. We propose a phased approach to simulate the behavior and future performance, as well as deliver real-time synchronization for data access, visualization, and dynamic decision making.

Background on Guidehouse

Guidehouse is comprised of public and commercial health executives, strategists, actuaries, PhDs, regulators, physicians, nurses, technologists, programmers, and consultants with direct experience modernizing IT systems and managing business operations for large scale health systems, including several of the U.S.'s largest transplant centers and the largest health system, Veteran's Affairs. We also provide expertise with finance and payer/insurance models, business process improvement, clinical transformation, and strategy for health equity and governance infrastructure that integrates transparency and performance metrics reporting. Examples of our related work to the OPTN include:

- *Subject Matter Expertise*: Edward Abraham, MD, is a partner and executive physician leading and transforming academic medical centers, including healthcare delivery, finances, research, and educational programs. Most recently, he served as Executive Vice President for Health Affairs of the University of Miami and CEO of the University of Miami Health System, an academic medical center with more than $2.5 billion/year in revenues, 1,300 physicians, and 10,000 employees. He led the oversight of the Miami Transplant Institute, which has performed more organ transplants than any other center in the country. He served as Dean of two medical schools (University of Miami and Wake Forest School of Medicine), leading strategic planning initiatives including those around organ transplantation.
- *Public Sector Transplantation & Veterans*: Guidehouse manages the VA's national program that integrates healthcare services from the private sector for veterans for acute and chronic diseases where transplantation may be an option. Guidehouse supports VA in assisting with implementing the new Live Donor benefit and the Chimeric Antigen Receptor (CAR) T-cell therapy, coordinating with VA Medical Centers, VA Transplant Centers, community specialists, and the **OPTN**.
- *Commercial Sector Transplantation & Business Process Improvement*: St. Louis University Hospital engaged Guidehouse to evaluate and prepare responses to transplant contracts associated with payers. We developed a price transparency tool based on the provider files to create a comparative database of reimbursement by payer, plan, facility, geography, and service code. By integrating social determinants of health indicators, market share information, and hospital statistics, we detected trends in reimbursement for transplants.
- *Medicare Claims with End-Stage Renal Disease (ESRD):* We support contract work with the Centers for Medicare and Medicaid Innovation Center Business Services Group to identify, test, and evaluate new ways to improve care for Medicare beneficiaries with the Comprehensive ESRD Care model. This includes managing participant compliance and assessment of data collection and analysis of payment and service delivery.
- *IT Infrastructure Modernization & Support:* Guidehouse provides a full suite of enterprise IT services for a large, national defense contract including project management; application administration; application operations and maintenance support; cloud services planning and implementation; infrastructure management; ITSM implementation; and security operations, with 99.99+% availability. With 150+

full-time employees, including engineering, operations, and support personnel, the team securely designs, develops, and deploys all technical services for over 60 applications used by 150,000+ international users via 5,000+ hardware devices and serviced by 2000+ servers. Key modernization efforts have included server technology refresh, network upgrades, security compliant private cloud implementation, and converting the existing operating environment from traditional server-based infrastructure to a virtualized server environment with real-time back-ups and redundancy. These efforts, and other supported program initiatives, have led to multi-million-dollar savings on an annual basis.

- *Modernizing IT for a Federal Health Research Agency:* This agency required collations, analysis, and storage of large-scale datasets while using a wide range of digital tools for complex research processes. Guidehouse assessed the existing operating model and collaborated with the federal IT staff to develop a strategic roadmap to support the adoption of cloud technology, proactively mitigated risks, and defined critical processes to optimize IT operations and provide higher quality IT services for the agency. Our team also provided a change management strategy and training to support the maintenance of the new solutions.

Conclusion

We believe HRSA can reform and modernize the OPTN through a combined clinical and operational program transformation. This effort should focus on two major areas. First, rebuilding trust in the OPTN system by implementing a human centered approach to modernizing policy, governance, stakeholder engagement, and communications; and, second, accelerating technology implementations by using digital twins and performance metrics. Modernizing OPTN is essential for enhancing quality, optimizing distribution channels, and ensuring access for all patients involved with the OPTN. Thank you again for this opportunity to submit a statement for the record to the Committee on this critical public health issue.

For any further discussion or to answer any questions, please contact Steve Reynolds, Partner, Guidehouse Health, at (703) 258-2083 or sreynolds@guidehouse.com.