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Initiative to Modernize National Organ Transplant System

Authors: Alisa L. Chestler, Darwin A. Hindman, III, Tenia L. Clayton, Melodie Hengerer
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On March 22, 2023, the Health Resources and Services Administration (HRSA), an agency of the U.S. Department of Health and Human Services, launched the Organ Procurement and Transplantation Network Modernization Initiative (the Initiative). The Initiative is intended to strengthen accountability and equity, and generally improve the performance of the organ donation and transplantation system, by focusing on these following key areas:

1. Technology
2. Data transparency
3. Governance
4. Operations
5. Quality improvements and innovation

The Organ Procurement and Transplantation Network (OPTN) is tasked with overseeing the nation's organ procurement organizations, transplant centers, and histocompatibility labs. The OPTN's role also includes operating the national transplant waiting list, establishing policies and procedures regarding organ allocation, assisting in organ distribution, and adopting quality standards for collecting and transporting donated organs.

Since 1986, the OPTN has been operated by a single federal contractor, United Network for Organ Sharing (UNOS). Under the Initiative, HRSA will apportion the contract into multiple parts and ask that Congress expand the pool of eligible contract entities to enhance performance and innovation through increased performance, particularly with regard to information technology.

In recent years, after widespread critiques of the OPTN and its management of the organ donation and transplantation system, HRSA has implemented certain accountability measures, including:

- Required enhanced OPTN security and performance
- Sought expert and community input on ways to improve transparency, accountability, and performance in OPTN operations
- Convened a conference with patients and families to strengthen performance measures
- Formally engaged technology partners to improve OPTN IT systems
- Undertaken ongoing collaboration with CMS and other HHS agencies

In furtherance of the objectives that triggered these accountability measures, the initial phase of the Initiative includes:

- **Making Data Available for Informed Decisions:** To support patients, clinicians, researchers, and other stakeholders, HRSA is launching an initial data set of organ donation and transplantation data that will aim to improve decision-making in the organ donation process.
- **Securing Support for Modernization:** The [President's FY 2024 Budget](#) allocates approximately \$67 million to support the Initiative; additional increases are expected.

- **Building HRSA Capacity for Modernization:** HRSA is using program management support services to further its overall approach of focusing on engaging more stakeholders in the process of modernization design and implementation.
- **Ongoing Consultation with USDS:** HRSA will continue to consult with the U.S. Digital Service (USDS) as it actively works to create a strategy for advancing OPTN IT modernization.
- **Engaging Stakeholders:** HRSA will prioritize the critical needs affecting patients and clinicians by engaging with a diverse group of various stakeholders.
- **Collaborating with Industry:** In late spring 2023, HRSA will host collaborative forums that promote participation from vendors and the IT community.
- **Soliciting Proposals for Modernization:** HRSA intends to issue requests for proposals (RFPs) for multiple contract awards to further support and improve the OPTN. HRSA will also increase the OPTN Board of Directors' autonomy through this expanded contracting process.

The push for robust competition is a key priority of the Biden-Harris Administration that has historically been absent in the oversight of this industry. Increased eligibility for contracts will help further the Initiative's goals of promoting innovation and the best quality of service for patients. Information about additional steps and updates will be forthcoming on [HRSA's website](#) and are likely to result in sweeping changes for the OPTN's 400 member organizations.

HRSA's Initiative raises a number of issues for organ procurement organizations, providers, and potential contractors regarding compliance, data privacy, and government contracting. If you have questions related to the Initiative, contact [Alisa L. Chestler](#), [Darwin A. Hindman III](#), [Melodie Hengerer](#), [Tenia L. Clayton](#), or any member of the Baker Donelson [Health Law Team](#).