

Re-Envisioning OPTN/UNOS: HRSA Role as a Force for Innovation in Organ Transplantation

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Presentation Overview

- **HRSA Responsibilities**
- **Statute: National Organ Transplant Act (NOTA)**
- **Regulation: Organ Procurement and Transplantation Network (OPTN) Final Rule**
- **Contract Oversight**
- **Opportunities**



Health Resources and Services Administration (HRSA)

- HRSA is the primary federal entity responsible for oversight of the solid organ and blood stem cell transplant systems in the United States and for initiatives to increase the level of organ and tissue donation in this country
- HRSA oversight is exercised according to statutory requirements, federal regulations, and federal contracts
- HRSA staff serve as ex-officio, non-voting members of the OPTN Board of Directors, the Executive Committee, and all OPTN committees



Federal Government and Organ Transplantation



- **Legislative – House and Senate makes our laws**
 - e.g., NOTA, amended
- **Executive – enforces the laws that the legislative branch makes**
 - e.g., OPTN Final Rule, OPTN policies
- **Judicial – Supreme Court interprets the laws according to the Constitution**

Organ Transplantation Statutory Authorities

- HRSA has oversight of many organ transplantation-related activities under different statutory authorities.
- **National Organ Transplant Act** (NOTA) (P.L. 98-105, October 19, 1984), as amended, enables:
 - Organ Procurement and Transplantation Network (OPTN)
 - Scientific Registry of Transplant Recipients (SRTR)
 - Congressional report on the Scientific and Clinical Status of Organ Transplantation
- **The Charlie W. Norwood Living Organ Donation Act** (Norwood) (P.L. 110-144, Dec. 21, 2007) enables:
 - Enables and clarifies that organ paired donation is not valuable consideration
 - Congressional report on the Long-Term Health Effects of Living Organ Donation



Organ Transplantation Statutory Authorities

The Organ Donation and Recovery Improvement Act (ODRIA)

(P.L 108-216, April 5, 2004) enables:

- **Public Education** – public and professional education to increase awareness of the need for organ donation and improve organ procurement practices
- **Grant Authority** – public awareness grants to states and public entities
- **Living Donor Assistance** – mechanism to provide reimbursement of travel and subsistence expenses for living organ donors
- **Congressional Report** – Organ Donation and the Recovery, Preservation, and Transportation of Organs



HRSA's Role – Organ Transplantation

U.S. Department of Health and Human Services

Establishes organ donation regulatory framework according to NOTA



HRSA

- Awards and oversees the contracts for the operation of the Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR)
- Monitors OPTN/SRTR adherence to applicable statutes and regulations
- Funds grants and supports other activities aimed at increasing supply of donated organs and increasing efficiency of transplantation system



OPTN
SRTR



Regulatory Framework

The OPTN Final Rule (42 CFR, Part 121) provides regulatory requirements for:

- OPTN structure, membership, and function;
- Waiting list/match run, donor testing, OPTN policy making (particularly allocation of organs);
- OPTN oversight activities and performance indicators;
- Data collection and dissemination;
- Establishing the Advisory Committee on Organ Transplantation;
- Organ procurement, packaging, labeling, and transport

HRSA Contract Oversight

- **Organ Procurement and Transplantation Network**
 - National system that maintains the waiting list and allocates donor organs to individuals waiting for an organ transplant
 - Develops OPTN allocation policies and data collection requirements
 - Current contractor is United Network for Organ Sharing
- **Scientific Registry of Transplant Recipients**
 - Provides analytical support to the OPTN in the formulation and evaluation of OPTN policies
 - Provides ongoing performance evaluation of solid organ transplantation in the United States
 - Current contractor is Minneapolis Medical Research Foundation
- **HRSA monitors OPTN/SRTR adherence to applicable statutes and regulations**



System Requirements

Must adhere to:

- Statutory authorities
- OPTN Final Rule
- OPTN Policy Development process

Developing Innovative Ideas

- **Think of organ donation and transplantation as a system rather than isolated component parts**
- **Set a goal and work with a deadline**
- **Work with people outside your immediate field – include multiple viewpoints**
- **Think in terms of what the ideal solution would look like – not what is the current system or what are the constraints**

Opportunities for Innovation

- **OPTN policy development process**
- **OPTN committee structure**
- **Consider how feedback is obtained from the donation and transplantation community**
 - Policy development
 - Soliciting innovative ideas
 - Use of technology to increase inclusiveness
- **Allocation policy**
 - How to include others, such as engineers, who have expertise in systems to help develop new approaches
 - How to incorporate research findings into policy development
 - How to improve developing patient-centered policy, taking the system into consideration



Opportunities for Innovation

- **Collection and use of data**

- Moving beyond OPTN-collected data
- Using EMRs more effectively
- Finding a sweet spot for risk adjustment

- **Donation and transplantation as a system**

- How do we better align this system?
- What does a cooperative system look like?

- **Donation and transplantation community-driven solutions to challenges in transplantation**

- Better solutions
- Stronger voice



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