OPTN: Legal and Regulatory Framework & How OPTN Policy Development Works

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Disclosures

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Learning Objectives

• To describe the legal and regulatory basis of the OPTN
• To explain the current OPTN policy development process
• To review the public comment process and how not only the transplant community but also the general public can comment regarding proposed policies
UNOS = the private, non-profit organization that is the OPTN under contract with the federal government

UNOS does work beyond the scope of the OPTN contract- center-specific services, system innovations, quality improvement, conferences, etc
In the Beginning...

- All organ recovery and allocation was hospital-based
- No designated donation service area (DSA)
- Informal, referral relationships were developed, some based on ESRD Networks
- Some programs shared the same donor hospital
- Independent OPOs began in late 1960s/early 1970s
Foundations of the OPTN

NOTA

The Final Rule

OPTN Contract

OPTN Bylaws
### National Organ Transplant Act (NOTA)

- Federal law passed in 1984
- Established the Organ Procurement and Transplantation Network (OPTN)
- Established the Scientific Registry of Transplant Recipients (SRTR)
- Established Organ Procurement Organizations (OPOs) and prohibits sale or purchase of human organs
# The OPTN and the SRTR

<table>
<thead>
<tr>
<th></th>
<th>OPTN</th>
<th>SRTR</th>
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<tbody>
<tr>
<td><strong>Mission</strong></td>
<td>Organ Allocation/Policy Development</td>
<td>Research/Policy Evaluation</td>
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<tr>
<td><strong>Data Responsibilities</strong></td>
<td>Data Collection/Descriptive Analyses</td>
<td>Inferential Analyses/Simulated Allocation Modeling (SAMs)</td>
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<tr>
<td><strong>Contractor</strong></td>
<td>United Network for Organ Sharing (UNOS)</td>
<td>Minneapolis Medical Research Foundation (MMRF)</td>
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What is HRSA?

- The Health Resources and Services Administration (HRSA) is an agency of the U.S. Department of Health and Human Services (HHS)

- The Department of Transplantation (DoT) is one branch of HRSA’s Healthcare Systems Bureau that oversees organ and blood stem cell transplant

- HRSA issues the OPTN and SRTR Contracts and oversees that contract terms are met
Federal regulation implemented by HHS in 2000

Establishes OPTN structure and operations

Directs OPTN to establish Board of Directors (specifies certain rules around composition of Board)

Directs Board of Directors to establish an Executive Committee, appoint an Executive Director, establish other committees as necessary

Establishes a process for OPTN membership, outlines appeals for members who are denied
<table>
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<tr>
<th>Directs the OPTN to develop policies for organ allocation that:</th>
<th>Shall be based on sound medical judgment</th>
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<tr>
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<td>Shall seek to achieve the best use of donated organs</td>
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<td>Shall avoid wasting of organs, avoid futile transplants, promote patient access, and promote efficient organ placement</td>
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<td>Shall not be based on a candidate’s residence or place of listing, except to the extent required to avoid wastage and reduce costs</td>
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<td>Shall set candidate priority based on objective &amp; measurable medical criteria, ordered from most to least medically urgent</td>
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<td>Shall distribute organs over as broad a geographic area as feasible</td>
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# OPTN Final Rule (45 CFR §121)

Directs the OPTN to develop policies in a way that:

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<th>Policy Requirement</th>
<th>Accomplishment Method</th>
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<td>Must provide opportunity for OPTN membership and other interested parties to provide comments on proposed policies</td>
<td>Accomplished through OPTN website public comment, regional meetings, professional society feedback</td>
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<td>Must provide members with copies of policies adopted</td>
<td>Accomplished through the semiannual policy notice, along with education and other tools</td>
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Changes to OPTN Final Rule

2014

• Vascular Composite Allografts (VCA) now included in definition of organ

2015

• Allocation of organs from HIV+ donors now permissible to HIV+ candidates (HOPE Act)
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<th>OPTN Bylaws</th>
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<td>Outlines membership requirements and process for approval, appeal of membership decisions</td>
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<tr>
<td>Establishes structure, authority, and composition of the Board of Directors and standing committees</td>
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<tr>
<td>Outlines process for changes to Bylaws/policies</td>
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OPTN Governance Structure

OPTN Board of Directors

Executive
Nominating
Finance
Network Ops. Oversight

Policy Oversight
Data Advisory
MPSC
Policy Governance Committees

Disease Transmission
International Relations
Ethics
Histocompatibility
Kidney
Liver & Intestinal
Living Donor
Minority Affairs
Operations and Safety
OPO
Pancreas
Patient Affairs
Pediatric
Thoracic
Transplant Administrators
Transplant Coordinators
Vascularized Composite Allograft

☐ = Committees of the Board
☐ = OPTN Operating Committees
OPTN Policies

- OPTN policies are rules that govern operation of all member transplant hospitals, organ procurement organizations (OPOs) and histocompatibility labs in the United States. Policies are made through a collaborative process involving committees, the board of directors and the public.

- Policies available at https://optn.transplant.hrsa.gov/governance/policies/
Policy Development Process
Policy Development Process

- Case study related to the ongoing development of a continuous distribution algorithm for lung transplantation
Geography Principles (as defined by Geography Committee)

Deceased donor organs are a national resource to be distributed as broadly as feasible. Any geographic constraints pertaining to the principles of organ distribution must be rationally determined and consistently applied to minimize the effect of geography on a candidate’s access to transplantation. Geographic distribution may be constrained in order to:

- Reduce inherent differences in the ratio of donor supply and demand across the country
- Reduce travel time expected to have a clinically significant effect on ischemic time and organ quality
- Increase organ utilization and prevent organ wastage
- Increase efficiencies of donation and transplant system resources
Geography – continuous distribution
Hypothetical Match Run – Points-Based System

Example

Medical Priority
Ischemic Time
Candidate Age Group
Blood Type Compatibility
System Efficiency
Sensitization
Waiting Time
Committee activity to date