

Legal Underpinnings of the Transplant System – Do the laws and regulations maximize performance towards the goal?

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Legal Structures

Laws and Regulations



Policies



System Performance

Laws Foundational to Donation

Law	Legal Structure	Ethical Principle	Policy Goal
Uniform Determination of Death Act (UDDA)	Definition of death	Utility	Clear standard
Uniform Anatomical Gift Act (UAGA)	Legal mechanism of gift law to donate organs	Autonomy	Facilitate donation through donor registration and surrogate permission
National Organ Transplant Act (NOTA)	Nonprofit OPOs designated by the government responsible for donation in a designated area	Utility	Nationwide high reliability network of collaborative community-based nonprofit organizations to coordinate donation for transplant
National Organ Transplant Act (NOTA)	Prohibits purchase or sale of organs	Equity/Justice	Non-market based system of organ donation for transplantation

Laws Foundational to Transplant

Law	Legal Structure	Ethical Principle	Policy Goal
National Organ Transplant Act (NOTA)	Federal regulation of organ allocation	Public Trust, Utility and Equity/Justice	National system of organ transplantation
National Organ Transplant Act (NOTA)	Creation of OPTN to develop policies	Professional and Public Trust	Self governance of the field by experts and patient stakeholders
National Organ Transplant Act (NOTA)	based on objective criteria to maximize best use	Utility and Equity/Justice	Maximize utilization and equity through sound medical judgment and not social values

Donation and Transplant Regulations: better alignment would drive better results

Performance metrics misalignments: OPO new final regs example

OPO regulations: required competition amongst OPOs

misaligned with

Statutory policy goal: network of collaborative community-based organizations

➡ Align by limiting competition for decertified OPOs

OPO regulations: Deliberate state of organizational survival

misaligned with

Statutory policy goal: nationwide high reliability organizations

➡ Create performance thresholds for recertification around a mean

Donation and Transplant Regulations: better alignment would drive better results

Performance metrics misalignments: transplant programs example

Transplant outcome-focused measurement

misaligned with

NOTA policy goal to maximize transplant

- ➡ Implement transplant program performance metric incentivizing the goal of transplanting patients (utility) such as offer acceptance rates and the goal of access to transplant (equity) such as measuring waitlist outcomes

Transplant programs are not accountable for utilizing organs from older or complex donors

misaligned with

Regulatory Policy goal for OPOs to maximize transplant

- ➡ Align transplant program utilization metrics with OPO recovery metrics

Donation and Transplant Regulations: Scope of Authority and Cross Agency Collaboration

Siloed regulatory authority as barriers to systemwide policy goals - examples

- Equitable access to transplant requires patient access to the waitlist
 - ➡ recognize OPTN authority to evaluate and address racial and social economic equity in waitlisting practices
- Cost efficiencies in donation and transplant requires alignment within CMS and with HRSA
 - ➡ cross-collaboration between HRSA and CMS

Donation and Transplant: Regulation versus Policy

Regulations authorizing OPTN allocation align ethical principles and policy goals

- ➡ balancing equity and utility with evolving medical standards
- ➡ policies provide faster path to reform in a dynamic system
- ➡ policy development provides opportunity for a fair and transparent process with broad stakeholder input but does not always result in consensus

in a dynamic system law is a blunt tool of reform

- Current laws align core legal structures, ethical principles and policy goals
- Regulations require better alignment to remove barriers and leverage better systemwide results for both utility and equity measures
- Policies are the most efficient path for faster, effective allocation reform
- Process provides fairness and transparency but doesn't guarantee a result