

POLICY CHART

Policy Type	Name	Description	Affects	Alerts ⚠️
Law	Social Security Act	Covers conditions of participation and payment	CMS, ESRD network, OPOs, transplant centers, donor hospitals	
Law	Public Health Service Act: Amended by National Organ Transplant Act (NOTA)	Created OPTN; prohibits "transfer of valuable consideration" in exchange organs for transplant	HHS (CMS/HRSA), OPTN, transplant centers, OPOs	<p>Established a requirement that the OPTN operates under contract, rather than mandate that HHS Secretary ensures that certain things happen.</p> <p>Unnecessarily limits competition for the OPTN contract.</p> <p>Does not restrict profiteering (e.g., from tissue) by government contractors or business partners</p>
Law	Public Health Service Act: Amended by Organ Procurement Organization Certification Act	Called for the creation of OPO outcome and process measures	CMS, OPOs	Has been interpreted as closing the field to new entrants.
Law	Uniform Anatomical Gift Act	Model state law which sets framework	OPOs, donor hospitals, donors and donor families	

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Regulation	Final Rule	Lays out functioning of OPTN and SRTR	OPOs, transplant centers and OPTN (written by HHS, currently delegated to HRSA)	<p>Creates perverse incentives as OPTN fees derived from adding patients to the waitlist, rather than facilitating transplants for them. (See Money Map.)</p> <p>Allows stakeholders to self-regulate and has splintered oversight between CMS and OPTN. Despite documented underperformance, lapses in patient safety, and financial improprieties, no OPO has lost its CMS contract or OPTN membership. (See Governance Map.)</p>
Regulation	Organ Procurement Organization (OPO) Outcome Measures	Creates criteria on which OPOs are evaluated for outcomes	OPOs (CMS enforces via CCSQ)	Self-reported, self-audited data means regulation currently unenforceable; no OPO has ever been decertified.
Bylaws	Organ Procurement and Transplantation Network (OPTN) Bylaws	Outlines requirements for OPTN membership	OPTN member institutions (i.e. OPOs and transplant centers), HHS must sign off	<p>Mandates a large board (34-42 people), which can be operationally burdensome. Of note: board for OPTN and UNOS (OPTN contractor) are the same (see Governance Map), and UNOS has been criticized as "mired in bureaucracy and... resistant to change."</p> <p>Self-regulated; OPTN bylaws are enforced by the UNOS Membership and Professional Standard Committee (MPSC), which is composed of OPTN members.</p> <p>Defines conflicts of interest so narrowly as to be functionally immaterial.</p>