

OPTN, HRSA, and CMS Roles in the Nation's Organ Donation and Transplant System

OPTN *Organ Procurement & Transplantation Network*

Role

The OPTN public private partnership works to maintain an equitable organ allocation system for patients on the national waitlist through: (1) data-driven organ allocation policy development and implementation; (2) quality improvement; and (3) technology, which is used to match donor organs to transplant candidates.

OPTN projects can include changes to allocation policy, bylaws, data collection, member requirements, guidance documents, white papers, and patient education materials. OPTN committeesⁱⁱ initiate projects with OPTN Board of Directors approval.

The OPTN is governed by the National Organ Transplant Act (NOTA) and the Final Rule, and is supported by contracts awarded by HRSA.ⁱⁱⁱ The OPTN contract has been competitively bid 8 times since the OPTN's establishment in 1986.^{iv} HRSA extended the current OPTN contract, a cost-share, cost-reimbursement contract which began in 2019, on March 30, 2024 for 9 months. The extension includes two additional 6-month optional extension periods, and HRSA has exercised both. The expiration date is now December 29, 2025. HRSA is currently transitioning contractor support to a multi-vendor IDIQ contractual framework. HRSA selected 13 Contractors to be eligible for OPTN Task Orders.

HRSA Health Resources & Services Administration

Role

HRSA awards the competitively bid contract to operate the OPTN, oversees the OPTN contractors, and approves the OPTN Board-determined registration fee collected from transplant programs to add patients to the waitlist in accordance with the Final Rule.^v The registration fee comprises approximately 92% of the OPTN's operating budget, with the rest being contributed by HRSA through funds appropriated by Congress.^{vi}

HRSA also awards the competitively bid contract to operate the Scientific Registry of Transplant Recipients (SRTR) and oversees this contractor.^{vii} SRTR conducts special studies and advanced statistical analyses of OPTN data in accordance with NOTA that inform the OPTN Board action.

In 2000, HRSA issued a Final Rule^{viii} establishing the regulatory framework for the structure and operations of the OPTN. The Final Rule includes composition requirements for the OPTN Board of Directors, membership requirements for the OPTN, substantive and procedural policy-making requirements, compliance monitoring requirements for the OPTN and the Secretary, and data collection and data access requirements. It also grants the Secretary the authority to consult with the Advisory Committee on Organ Transplantation (ACOT) on proposed policies.^{ix}

CENTERS FOR MEDICARE & MEDICAID SERVICES

Role

OPOs

Pursuant to the authority granted to the Secretary under 42 U.S.C. §273 to make grants for the establishment and operation of organ procurement organizations (OPOs), CMS issues Requirements for Certification and Designation and Conditions for Coverage. CMS issued a regulation^{xii} in November 2020 revising outcome measure requirements and conditions for coverage for OPOs, and setting forth a process to decertify OPOs, at which point Medicaid and Medicare will not reimburse the decertified OPO for services.^{xiii}

Transplant Programs

A condition of participation in the Medicare program for transplant programs is membership in the OPTN.^{xiv}

Donor Hospitals

CMS' conditions for participation^{xv} require hospitals to report to OPOs patient-level data of individuals whose death is imminent or who have died in the hospital.

Histocompatibility Laboratories

CMS regulates all laboratory testing, including histocompatibility testing (an integral component of organ donor and recipient matching) performed on humans through the Clinical Laboratory Improvement Amendments (CLIA).^{xvi}

Leadership

The OPTN Final Rule^{xvii} outlines the composition of the OPTN Board and requires the board to be composed as follows:

- Approximately 50 percent transplant surgeons or transplant physicians;
 - At least 25 percent transplant candidates, transplant recipients, organ donors and family members. These members should represent the diversity of the population of transplant candidates, transplant recipients, organ donors and family members served by the OPTN including, to the extent practicable, the minority and gender diversity of this population. These members shall not be employees of, or have a similar relationship with OPOs, transplant centers, voluntary health organizations, transplant coordinators, histocompatibility experts, or other non-physician transplant professionals; however, the OPTN Board may waive this requirement for not more than 50 percent of these members; and
 - Representatives of OPOs, transplant hospitals, voluntary health associations, transplant coordinators, histocompatibility experts, non-physician transplant professionals, and the general public.
- As of March 30, 2024, the OPTN board is separate from any OPTN contractor's board.^{xx} The OPTN Board has been supported by the American Institutes for Research since August 2024.

Leadership

HRSA's Division of Transplantation is responsible for managing and overseeing the OPTN and SRTR and their respective contractors.^{xxi}

Leadership

CMS's Center for Clinical Standards and Quality is responsible for the OPO regulations.

CMS' Center for Medicare is responsible for Medicare reimbursement and conditions for participation.

Oversight Authority

OPOs, transplant programs, and histocompatibility laboratories must be OPTN members to participate in the organ donation and transplant system.^{xxii} By agreeing to be members of the OPTN, members agree to adhere to all OPTN Obligations, which includes complying with the OPTN Final Rule, OPTN policies, and OPTN bylaws, as well acting to avoid risk to patient health and public safety.

Pursuant to the OPTN Management and Membership Policies^{xxiii}, the OPTN can impose two forms of adverse actions on an OPTN member if the OPTN finds the member out of compliance with OPTN Obligations: **probation** or designate it as a **member not in good standing**.

Adverse actions are publicly announced and the member will be subject to a corrective action plan, and for members not in good standing, at least one unannounced on-site review.^{xxv} Additionally, members not in good standing cannot vote in OPTN matters, and personnel associated with the member cannot serve on OPTN committees and the Board of Directors.^{xxvi}

By regulation, the OPTN cannot unilaterally terminate OPTN membership, even for those members on probation or member not in good standing. The OPTN can only recommend to the Secretary to take action.^{xxvii} The Secretary is not compelled to wait for any OPTN recommendation to take action against a member nor is the Secretary required to act on an OPTN recommendation.^{xxviii}

Oversight Authority

HRSA is responsible for managing and overseeing the OPTN and SRTR contractors and their supporting contractors. HRSA and the Final Rule require the OPTN to monitor and review OPTN member performance.^{xxix}

Any individual or entity may submit written critical comments related to the way the OPTN is carrying out its duties or Secretarial policies related to the OPTN.^{xxxii} The Secretary may reject the comments, direct the OPTN to revise policies or practices consistent with the Secretary's direction, or take other action deemed appropriate by the Secretary.^{xxxiii}

Oversight Authority

OPOs

CMS can decertify OPOs if the OPO does not meet CMS' certification requirements.^{xxxiv} As of the date of decertification, Medicaid nor Medicare will not pay for OPO services.^{xxxv} CMS can also immediately decertify OPOs if there is an urgent need (e.g., discovery of unsound medical practices).^{xxxvi} A CMS condition of certification for an OPO is that it be a member of the OPTN.^{xxxvii}

Transplant Programs

CMS can **suspend** Medicare payments to a hospital's transplant program if CMS finds the program is not in compliance with the Medicare conditions of participation for transplant programs.^{xxxviii} Of note, a condition of participation in the Medicare program for transplant programs is membership in the OPTN.^{xxxix}

Histocompatibility Laboratories

CMS can **revoke** a histocompatibility laboratory's CLIA certificate,^{xli} or **suspend** its ability to receive Medicare payments,^{xlii} if it does not comply with the specific requirements required of such laboratories that conduct testing for transplants, or any other condition of participation applicable to all laboratories.^{xliii}

As of the date of termination of Medicare approval, Medicare will not pay for a transplant program or a histocompatibility laboratory's services.



Monitoring Member Performance

The OPTN is required by regulation to conduct ongoing and periodic peer reviews and evaluations of each OPO and transplant program to monitor performance and compliance with OPTN Obligations.^{xliv}



Monitoring Member Performance

The OPTN contract requires the OPTN contractor to immediately report patient safety events that pose a significant risk to patient health, public safety, or the integrity of the transplant system to HRSA.^{xlvii}

HRSA may direct that the contractor conduct a special review of OPTN members when concerns related to compliance with OPTN obligations and/or risks to patient health or public safety exist.^{xlviii} HRSA also oversees the contractor's provision of compliance monitoring for all OPTN members.



Monitoring Member Performance

Certification of compliance with Federal requirements is accomplished through observations, interviews and document/record reviews.

CMS' OPO Final Rule^{xlix} implemented new donation rate and transplant rate measures. CMS reviews OPO performance every 12 months during the 4-year recertification cycle. CMS assigns each OPO to a tier at the end of each recertification cycle. OPOs that are ranked in the top 25 percentile will be assigned to Tier 1 and recertified for another 4 years. Tier 2 OPOs are those whose performance on both measures exceeds the median but are not in the top 25 percentile. Tier 2 OPOs will be required to compete to retain their Donation Service Areas (DSAs). Tier 3 OPOs are those that perform below the median on one or both measures. Tier 3 OPOs will be decertified and will not be able to compete for any other open DSA.

Coordination

The OPTN contractors meet multiple times per week with HRSA.

Coordination

In addition to regular meetings with OPTN contractors, HRSA serves as an ex-officio member of the OPTN Board of Directors, OPTN Executive Committee, OPTN Finance Committee, OPTN Network Operations Oversight Committee, OPTN Nomination Committee, and 22 other OPTN Committees.ⁱ

Coordination

The Organ Transplant Affinity Group (OTAG) was established by HRSA and CMS in 2021 to ensure coordination and collaboration related to organ donation and transplant.ⁱⁱ

Appendix

ⁱⁱ Current Committees, Organ Procurement & Transplantation Network – Health Resources and Servs. Admin., <https://optn.transplant.hrsa.gov/about/committees/>.

ⁱⁱⁱ 42 C.F.R. § 121.3(c)(1).

^{iv} History & NOTA, Organ Procurement and Transplantation Network, <https://optn.transplant.hrsa.gov/about/history-nota/>. To address the nation's critical organ donation shortage and improve the organ matching and placement process, the U.S. Congress passed the *National Organ Transplant Act* (NOTA; P.L. 98-507) in 1984. The act established the OPTN to maintain a national registry for organ matching. The act also called for the network to be operated by a private, non-profit organization under federal contract. Following further study and recommendations from a task force commissioned through NOTA, the U.S. Department of Health and Human Services (HHS) solicited proposals in 1986 for the operation of the OPTN. In 2000, The U.S. Department of Health and Human Services (HHS) implemented a final rule establishing a regulatory framework for the structure and operations of the OPTN. HRSA awarded an OPTN contract in 1986, 1987, 1990, 1993, 1996, 2000, 2005, and 2018.

^v 42 C.F.R. § 121.5(c).

^{vi} Congress enacted the *Securing the U.S. Organ Procurement and Transplantation Network Act* (P.L. 118-14) to lift the cap on federal funding for the OPTN. Prior to the legislation being enacted, the cap on appropriations was \$7 million each fiscal year.

^{vii} The current SRTR contract is held by Hennepin Healthcare Research Institute (HHRI), *see, Mission, Vision, and Values*, Scientific Registry of Transplant Recipients, <https://www.srtr.org/about-srtr/mission-vision-and-values/>.

^{viii} *OPTN Budget and OPTN Registration Fee Set for New Fiscal Year*, Organ Procurement & Transplantation Network (Sept. 2, 2021), <https://optn.transplant.hrsa.gov/news/optn-budget-and-optn-registration-fee-set-for-new-fiscal-year/> and 42 C.F.R. § 121; Organ Procurement and Transplantation Network, 63 Fed. Reg. 16296 (Apr. 2, 1998); Organ Procurement and Transplantation Network; Response to Comment Period 65 Fed. Reg. 15252 (Mar. 22, 2000).

^{ix} 42 C.F.R. § 121.12.

^{xii} Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations, 85 Fed. Reg. 77898 (Dec. 2, 2020).

^{xiii} 42 C.F.R. § 486.312(e); *see also* 42 U.S.C. § 1320b-8 (b)(1)(A)(ii) (“The Secretary shall provide that payment may be made under title XVIII or XIX with respect to organ procurement costs attributable to payments made to an organ procurement agency only if the agency . . . has been certified or recertified by the Secretary within the previous 2 years (4 years if the Secretary determines appropriate for an organization on the basis of its past practices) as meeting the standards to be a qualified organ procurement organization.”).

^{xiv} 42 C.F.R. § 482.72.

^{xv} 42 C.F.R. § 482.45(a)

^{xvi} 42 C.F.R. § 498.3.

^{xvii} 42 C.F.R. § 121.3(a) (see: <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-K/part-121>)

^{xviii} OPTN Charter, Organ Procurement and Transplantation Network (Sept. 27, 2022), <https://optn.transplant.hrsa.gov/about/optn-charter/>

^{xix} *Id.*

^{xx} HRSA letter to the OPTN Board of Directors Regarding our plan for continuity of operations and initial steps towards an independent OPTN Board of Directors <https://www.hrsa.gov/sites/default/files/hrsa/about/optn-board-separation-plan-letter.pdf>

^{xxi} About Us, Organdonor.gov, Health Resources and Servs. Admin., <https://www.organdonor.gov/about-us>.

^{xxii} 42 C.F.R. §§ 121.3(b); 121.5; Organ Procurement and Transplantation Network Bylaws, Organ Procurement and Transplantation Network, at *1 (Dec. 5, 2022), https://optn.transplant.hrsa.gov/media/lgbbmahi/optn_bylaws.pdf (henceforth OPTN Bylaws). This is not an inclusive list of the types of OPTN membership, as medical/scientific members, public organizations, business members, and individuals can join the OPTN.

^{xxiii} OPTN Bylaws at p. 205-209 (July 27, 2023).

^{xxiv} OPTN Bylaws at p. 211 (“Termination of membership requires Secretarial approval.”) (July 27, 2023).

^{xxv} OPTN Bylaws at p. 207 (July 27, 2023). Additionally, a member not in good standing must present at least once before the OPTN’s Membership and Professional Standards Committee (MPSC) to provide an update on the member’s corrective action plan and ongoing compliance with OPTN obligations.

^{xxvi} *Id.*

^{xxvii} 42 C.F.R. § 121.10(c); OPTN Bylaws at p. 210-11 (July 27, 2023) (explaining that even if the OPTN Board of Directors finds that a member’s violations pose a severe and urgent risk to patient health and safety, the Board can only *recommend* that the Secretary take immediate action without a required interview or hearing).

^{xxviii} 42 C.F.R. § 121.10(a).

^{xxix} *OPTN Member Monitoring Process*, Organ Procurement and Transplantation Network, at p. 12-13 (Aug. 1, 2023), https://optn.transplant.hrsa.gov/media/gqrbxjba/optn_member_monitoring_processes.pdf.

^{xxxii} 42 C.F.R. § 121.4(d).

^{xxxiii} 42 C.F.R. § 121.4(d).

^{xxxiv} 42 C.F.R. § 486.312(b); 42 C.F.R. § 486.303.

^{xxxv} 42 C.F.R. § 486.312(e); see also 42 U.S.C. § 1320b-8 (b)(1)(A)(ii) (“The Secretary shall provide that payment may be made under title XVIII or XIX with respect to organ procurement costs attributable to payments made to an organ procurement agency only if the agency . . . has been certified or recertified by the Secretary within the previous 2 years (4 years if the Secretary determines appropriate for an organization on the basis of its past practices) as meeting the standards to be a qualified organ procurement organization.”).

^{xxxvi} *Id.*

^{xxxvii} 42 C.F.R. § 486.320.

^{xxxviii} 42 C.F.R. § 488.61; 42 C.F.R. § 482.72 *et. seq.*

^{xxxix} 42 C.F.R. § 482.72.

^{xli} 42 C.F.R. § 493.1806.

^{xlii} 42 C.F.R. § 493.1807.

^{xliii} 42 C.F.R. § 493.1278(f) (specific requirements for histocompatibility laboratories performing services for transplant); 42 C.F.R. Part 493 (general requirements for laboratories).

^{xliv} 42 C.F.R. § 121.10(b)(1) (The OPTN *shall* design appropriate plans and procedures, including survey instruments, *a peer review process*, and data systems for purposes of . . . [c]onducting ongoing and periodic reviews and evaluations of each member OPO and transplant hospital for compliance with these rules and OPTN policies.”) (emphasis added).

^{xlv} *OPTN Member Monitoring Process*, Organ Procurement and Transplantation Network, at p. 15-19 (Aug. 1, 2023),

https://optn.transplant.hrsa.gov/media/gqrbxjba/optn_member_monitoring_processes.pdf (“The OPTN reviews both OPO and transplant hospital performance. The MPSC’s goal is to work with members identified through these reviews to implement performance improvement measures.”).

^{xlvi} 42 C.F.R. § 121.10(b).

^{xlvii} *OPTN Member Monitoring Process*, Organ Procurement and Transplantation Network, at p. 12-13 (Aug. 1, 2023),

https://optn.transplant.hrsa.gov/media/gqrbxjba/optn_member_monitoring_processes.pdf.

^{xlviii} *OPTN Member Monitoring Process*, Organ Procurement and Transplantation Network, at p. 19 (Aug. 1, 2023),

https://optn.transplant.hrsa.gov/media/gqrbxjba/optn_member_monitoring_processes.pdf.

^{xlix} Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations, 85 Fed. Reg. 77898 (Dec. 2, 2020).

ⁱ *Current Committees*, Organ Procurement & Transplantation Network – Health Resources and Servs. Admin., <https://optn.transplant.hrsa.gov/about/committees/>.

ⁱⁱ Organ Transplantation Affinity Group (OTAG): Strengthening Accountability, Equity and Performance, Ctrs. for Medicare & Medicaid Servs (Sept. 15, 2023),

<https://www.cms.gov/blog/organ-transplantation-affinity-group-otag-strengthening-accountability-equity-and-performance>.