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

### OPTN (Organ Procurement & Transplantation Network)

**Role**
The OPTN 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 committees initiate projects.

The OPTN's role is governed by the National Organ Transplant Act (NOTA) and the Final Rule.

The OPTN contract has been competitively bid 8 times since the OPTN's establishment in 1986. Effective March 30, 2024, UNOS has a new short-term contract with HRSA to oversee the OPTN for a nine-month base period with an option to extend it for two additional six-month periods.

### HRSA (Health Resources & Services Administration)

**Role**
HRSA awards the competitively bid contract to operate the OPTN, oversees the OPTN contractor, and approves the OPTN registration fee collected from transplant programs to add patients to the waitlist in accordance with the Final Rule. The registration fee comprises approximately 90% of the OPTN's funding with the rest being appropriated by Congress.

HRSA also awards the competitively bid contract to operate the Scientific Registry of Transplant Recipients (SRTR) and oversees this contractor.

In 2000, HRSA issued a Final Rule establishing the regulatory framework for the structure and operations of the OPTN. The Final Rule requires the Secretary of Health and Human Services (the Secretary) to approve proposed policies prior to implementation that the OPTN Board recommends be enforceable. It also grants the Secretary the authority to consult with the Advisory Committee on Organ Transplantation (ACOT) on proposed policies.

### CMS (Centers for Medicare & Medicaid Services)

**Role**

The CMS issued a regulation in November 2020 revising outcome measure requirements and conditions for coverage for organ procurement organizations (OPOs). CMS set forth a process to decertify OPOs, at which point Medicaid and Medicare will not reimburse the decertified OPO for services.

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

**Transplant Programs**
A condition of participation in the Medicare program for transplant programs is membership in the OPTN.

**Donor Hospitals**
CMS' conditions for participation 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, performed on humans through the Clinical Laboratory Improvement Amendments (CLIA).
The OPTN Final Rule\textsuperscript{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.

The OPTN Charter\textsuperscript{xviii} notes that the third category of Board members should include at least one member representing pediatric-specific interests. The Charter also outlines that the Contracting Officer’s Representative (COR) for the OPTN Contract and the Director of the Division of Transplantation, within the Health Resources and Services Administration, HHS, or their designees, will serve as ex-officio, non-voting members.\textsuperscript{xxi}

The OPTN and OPTN contractor have used a unitary board approach since 1986. As of March 30, 2024, the OPTN board is separate from the OPTN contractor’s board.\textsuperscript{xx}
Oversight Authority

OPOs, transplant programs, and histocompatibility laboratories must be OPTN members to participate in the organ donation and transplant system.xxii

Pursuant to the OPTN Bylaws,xxiii the OPTN can impose two forms of adverse actions on an OPTN member: probation or designate it as a member not in good standing.

Although the OPTN can put a member on probation or designate it as not in good standing, the member can continue to operate and does not lose OPTN membership privileges unless the Secretary acts.xxiv

Adverse actions are publicly announced, and if a member is designated as a member not in good standing, it will be subject to a corrective action plan and 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. 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 a OPTN recommendation.xxviii

Oversight Authority

HRSA is responsible for managing and overseeing the OPTN and SRTR contractors. HRSA and the Final Rule require the OPTN to monitor and review OPTN member performance.xxx

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.xxxi 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.xxxii

Oversight Authority

OPOs

CMS can decertify OPOs if the OPO does not meet CMS’ certification requirements.xxxiv As of the date of decertification, Medicaid or 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, or suspend its ability to receive Medicare payments, 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.xli

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. The OPTN focuses on OPO and transplant program quality improvement.

The OPTN establishes performance metrics for OPOs and transplant hospitals to conduct ongoing and periodic reviews and evaluations of each member OPO and transplant hospital for compliance with membership rules, requirements to be a designated transplant program, and OPTN policies.

CMS' OPO Final Rule 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 contractor meets at least weekly with HRSA.

In addition to regular meetings with the OPTN contractor, 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.

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.

Appendix


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.


*OPTN Charter, Organ Procurement and Transplantation Network* (Sept. 27, 2022), https://optn.transplant.hrsa.gov/about/optn-charter/


*OPTN Bylaws at p. 205-209 (July 27, 2023).*

*OPTN Bylaws at p. 211 ("Termination of membership requires Secretarial approval.") (July 27, 2023).*

*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.*

*Id.*

*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).*


*42 C.F.R. § 121.4(d).*

*42 C.F.R. § 121.4(d).*

*42 C.F.R. § 486.312(b); 42 C.F.R. § 486.303.*
The OPTN reviews both OPO and transplant hospital performance. The MPSC's goal is to work with organizations, business members, and individuals can join the OPTN. Provide an update on the member's corrective action plan and ongoing compliance with OPTN obligations.