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Organ Procurement and Transplantation: Administration, Oversight, and Policy Issues

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In 2022, while there were over 42,000 organ transplants being done in the U.S., there were still 103,327 people on the organ transplant wait list. The U.S. organ transplant system comprises multiple federal government, quasi-governmental, and private sector entities that either oversee or comply with a complex set of federal safety, quality, and payment requirements. The ultimate goals of the system are to increase organ donation and transplants and to expeditiously and ethically connect persons who need an organ with a donated organ.

The National Organ Transplant Act of 1984 (NOTA; P.L. 98-507, as amended) created the first U.S. national organ transplant system. NOTA brought together existing but disparate entities that had been involved in organ transplantation, created new entities, and defined their roles relative to each other. NOTA created the Organ Procurement and Transplantation Network (OPTN)—a national computerized organ donation-to-recipient matching system. OPTN was also tasked with setting policies in collaboration with the Secretary of Health and Human Services (HHS) that other entities in the organ transplant system follow. All organ procurement organizations (OPOs), transplant hospitals, and histocompatibility laboratories are required to be members of the OPTN in order to participate in the system. NOTA also required the HHS Secretary to create the Scientific Registry of Transplant Recipients (SRTR) and provide financial assistance to living donors, among other activities.

In recent years, concerns have been raised about how organs are allocated to patients, how performance is monitored for the primary entities charged with procuring organs, and the performance of the contractor administering the organ system. In response to these concerns, Congress has enacted laws and the Administration has issued new regulations aimed at increasing organ donation and transplantation, laws and regulations which are to be implemented over the next few years. These statutory and regulatory changes address modernizing technology, data transparency and analytics; governance; operations; and quality improvement and innovation of the OPTN. They also address the contracting structure for carrying out OPTN functions, moving from a single awardee for all OPTN functions to multiple awardees, with each awardee selected for a particular function. Finally, they emphasize two key performance measures for OPOs—the organ donation rate and the organ transplantation rate.

In fulfilling its oversight and legislative role, Congress may consider the following issues, particularly in light of the ongoing implementation of recent statutory and regulatory changes.

- Are appropriations for the Health Resources and Services Administration (HRSA), the federal agency in charge of overseeing and implementing the OPTN, aligned with Congress' expectations for implementation of OPTN modernization and administrative oversight by HRSA?
- How are HHS agencies monitoring patient safety and quality amid numerous recent statutory and regulatory changes to the organ transplant system?
- Are the new OPO performance measures having the intended effect of increasing organ donation and transplantation?

SUMMARY

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Introduction

The core issue in the United States guiding policy decisions in the allocation of organs to patients is the limited supply of organs. Organ demand exceeds the supply of organs. Also, organ transplantation is a complex medical procedure, often requiring coordination among multiple entities, medical teams, and medical facilities. It is also unique in that it requires the use of an organ procured from one individual, which is then implanted into another individual. The procedure also involves a complex set of policies, processes, and payments that have implications for fairness in the allocation of organs, as well as quality and patient safety.

The federal government supports organ procurement and transplantation in a variety of ways. It has established a system for allocating organs, established payment methods for organ acquisition and transplantation, and, in some cases, directly provides organ transplantation services, among other activities. This report deals with the Organ Procurement and Transplantation Network (OPTN) and the federal agencies responsible for administration of the OPTN. For information on federal payers and providers of organ transplantation, see CRS Report R48257, *Federal Support for Organ Transplantation: Frequently Asked Questions*.

In recent years, concerns have been raised about how organs are allocated to patients, how performance is monitored for the primary entities charged with procuring organs, and the performance of the contractor that administers the organ system. Many of these concerns were detailed by the Senate Finance Committee in a memorandum accompanying an August 2022 hearing on the system titled, *A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network*.[1] In response, the 118th Congress enacted The Securing the U.S. Organ Procurement and Transplantation Network Act (P.L. 118-14), which established that functions of the OPTN can be carried out by multiple entities under additional mechanisms (i.e. grants, cooperative agreements, or contracts). In addition, the Centers for Medicare & Medicaid Services (CMS) promulgated new rules for managing performance of the entities charged with procuring organs.

This report first provides background on organ transplantation focusing on the factors that led to increased federal support in the 20th century. The report next describes the OPTN and the federal agencies responsible for administration of the OPTN. The report then describes related legislation considered in the 118th Congress. Finally, the report describes policy considerations for Congress on key topics related to organ transplantation.

Background

Organ transplantation outcomes were bleak in the first half of the 20th century. The majority of patients for some organ transplants did not survive one month after the transplantation procedure and the procedures were largely considered experimental.[2] Although major breakthroughs were made in transplantation science, medicine, and practice in the first half of the 20th century,

[1] U.S. Congress, Senate Finance Committee, *A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network*, 117th Cong., 2nd sess., August 3, 2022, S.Hrg. 117-878. For the refenced memorandum, see https://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20(FOR%20RELEASE)%20on%20website.pdf.

[2] Clyde F. Barker and James F. Markmann, "Historical Overview of Transplantation," *Cold Spring Harbor Perspectives in Medicine*, vol. 3, no. 4 (April 2013), p. a014977.

transplant rejection remained a primary concern.[3] The most successful transplantations were those where a first-degree relative's organ was used—an identical twin, a fraternal twin, or other siblings, for instance. Those organs were more likely to match (i.e., be compatible with) the recipient and less likely to be rejected. Further development of organ matching increased transplantation success.[4] Some immunosuppressive agents (e.g., azathioprine) were used to prevent rejection by suppressing the immune system. However, these drugs were only marginally effective.

Organ transplantation advanced rapidly in the 1970s with the development of cyclosporine, a more effective immunosuppressive drug.[5] Cyclosporine drastically improved outcomes for transplantation patients and made previously impossible transplantation procedures possible (e.g., heart transplantation).[6]

This advancement created a relative crisis as demand for organ transplantations suddenly increased. The transplant community had been focused on scientific advancement, but a new need arose to provide the service to patients in a fair and equitable manner.[7] At the time, some organizations existed that intended to serve transplant patients both by procuring organs and performing transplantations.[8] However, no national system existed and there was concern among the public regarding the uniformity and fairness of organ allocation.

These concerns led to the enactment of the National Organ Transplant Act of 1984 (NOTA; P.L. 98-507, as amended). NOTA amended the Public Health Service Act, adding provisions:

- Requiring the Secretary of HHS to create a Task Force on Organ Transplantation to study how to best implement NOTA;
- Requiring the Secretary to establish, by contract, a national computerized system for matching patients with organs, referred to as the Organ Procurement and Transplantation Network (OPTN), [9]
- Authorizing a grant program to provide assistance to organ procurement organizations (OPOs);[10]
- Requiring the HHS Secretary to establish, by grant or contract, a scientific registry (now known as the Scientific Registry of Transplant Recipients); and[11]

[3] Transplant rejection is a process in which a transplant recipient's immune system attacks the transplanted organ or tissue.

[4] For more information on organ matching, see https://unos.org/transplant/how-we-match-organs/.

[5] Cyclosporine was first discovered in 1969 and developed for use in transplantation through the 1970s. The first successful results in kidney transplantation were reported in 1978-79. D. Colombo and E. Ammirati, "Cyclosporine in transplantation - a history of converging timelines," *Journal of Biological Regulators and Homeostatic Agents*, vol. 25, no. 4 (2011), p. 493.

[6] John C. McDonald, "The National Organ Procurement and Transplantation Network," *JAMA*, vol. 259, no. 5 (February 5, 1988), pp. 725-726.

[7] Felix T Rapaport, "A Rational Approach to a Common Goal: The Equitable Distribution of Organs for Transplantation," *JAMA*, vol. 257, no. 22 (June 12, 1987), pp. 3118-3119.

[8] The precursor to the United Network for Organ Sharing, the South-Eastern Organ Procurement Foundation, developed a computer-based organ sharing system as early as 1977, which coordinated organ procurement across multiple transplant centers. This is discussed further in **Appendix D**.

[9] 42 U.S.C. §274.

[10] 42 U.S.C. §273.

[11] 42 U.S.C. §274a. The Scientific Registry of Transplant Recipients is currently administered by the Chronic Disease Research Group of the Hennepin Healthcare Research Institute under contract from the Health Resources and Services Administration (HRSA). For more information see, https://www.srtr.org/.

- Prohibiting the purchase of organs for use in human transplantation.[12]

The first contract to operate the OPTN was awarded to the United Network for Organ Sharing (UNOS) in 1986.[13] UNOS is a not-for-profit organization incorporated in Virginia.[14] UNOS has held the OPTN contract since the OPTN's inception.

OPOs are nonprofit organizations responsible for the procurement of organs for transplantation. Today each OPO functions within a specific geographic area known as a donor service area (DSA). At the time NOTA was enacted, OPOs had already existed and received payment for activities under Medicare. They arose organically, first as organ banks to preserve organs within a hospital's transplant center. These organ banks eventually coordinated organ sharing among multiple transplant centers, especially when an organ would have otherwise gone unused at the hospital that the organ bank was affiliated with. As the organ banks' functions grew, they became independent entities and developed into the OPOs as they function today.[15]

The grants provided to OPOs under NOTA led to the creation of a more uniform system of organ procurement by establishing requirements for OPOs and expanding OPOs to geographic areas where there may not have been coverage previously. NOTA created a framework for OPO regulation, which was further developed by future legislation and rulemaking.

Today all OPOs, transplant programs, and histocompatibility laboratories (that perform testing used to match organs with transplant candidates) are members of the OPTN. They operate a complex system by which potential donors are evaluated for medical suitability for donation, and then organs are recovered and matched with patients. Simultaneously patients are assessed for candidacy for a transplant, listed on the national computer registry (i.e., wait list), and potentially matched with a donor.

Brief Legislative History of Organ Transplantation

Before the 1970s there was minimal federal involvement in organ transplantation. If an individual was in need of an organ, the hospital that performed the transplant would be responsible for procuring the organ. Patients were generally required to pay for the procedure and components of organ procurement out-of-pocket. In addition, there were concerns about the legality of donating organs and there was no clear definition of brain death that allowed for the procurement of deceased donor organs.

The legality of organ donation and brain death were addressed at the state level with the adoption of the Uniform Anatomical Gift Act (1968) and the Uniform Determination of Death Act (1981), respectively. These acts were uniform bills created by the Uniform Law Commission intended for adoption throughout the states.[16] These two acts created a legal basis at the state level by which both living and deceased individuals could donate organs.

Section 299I of the Social Security Amendments Act of 1972 (P.L. 92-603) created the End Stage Renal Disease Program (ESRD), which extended Medicare coverage to individuals under 65

[12] 42 U.S.C. §274e.

[13] U.S. Government Accountability Office, *United Network for Organ Sharing*, B-416248, July 18, 2018, p. 2. https://www.gao.gov/products/b-416248.

[14] See OPTN Charter, https://optn.transplant.hrsa.gov/media/1505/optn_charter_article_i-organization-june_2004.pdf.

[15] Richard. J. Howard, Danielle L. Cornell, and Larry Cochran, "History of deceased organ donation, transplantation, and organ procurement organizations," *Progress in Transplantation*, vol. 22, no. 1 (March 2012).

[16] The Uniform Law Commission provides states with non-partisan legislation to address issues that affect all states. For more information, see https://www.uniformlaws.org/home.

years of age if they have permanent kidney failure and authorized Medicare to pay for both dialysis and kidney transplantation when medically necessary.[17] This was the first instance where Medicare eligibility was extended to individuals under 65 years of age for a specific disease. The Medicare coverage for ESRD allowed transplant centers and OPOs to receive payment for covered kidney transplant services. At its peak, ESRD paid for the majority of transplant procedures.[18]

Together with state level legislation, a framework was established for donation and transplantation. However, there were still concerns over uniformity and equity in this growing field of medicine. Media reports were highlighting the plight of individuals in need of organs and Congress acted to consider the establishment of a nationwide system.[19]

Multiple bills were considered in the 98th Congress to establish a national computerized system for organ matching. An earlier bill, the National Task Force on Organ Procurement and Reimbursement Act (S. 1728) would have established a task force similar to the one that was eventually established by NOTA. The idea was quickly absorbed into larger bills in the House and Senate.

Two bills emerged—a House bill (H.R. 4080) and a Senate bill (S. 2048)—both named the National Organ Transplant Act. The House bill contained two provisions related to payment under Medicare and Medicaid, which garnered strong opposition. The House bill would have required Medicare and Medicaid to pay for immunosuppressive drugs and it would have allowed Medicare to limit payments for transplants to only certain medical centers.

The Senate bill did not include an analogous provision. Instead, the Senate bill required the task force to submit a report on the appropriateness of insurance coverage for long-term immunosuppressive drug therapies. On the provision, Senator Orrin Hatch said:

> The task force established by this legislation is essential to look at complex and challenging questions, such as who should pay for these expensive operations, and consider ethical, social, and cultural issues. There is great concern among the public and private sector that developing technologies in organ transplantation will become increasingly more costly and impose large financial burdens on already strained national health resources. However, I am certain that with careful analysis, recommendations can be made to develop policies insuring fair access to transplant surgery for individuals who without such surgery would be at risk of losing their lives; and a means of public and private insurance to pay for such procedures.[20]

After unsuccessful attempts to include provisions funding immunosuppressive drugs, the House adopted the Senate language and NOTA was signed into law on October 19, 1984.[21] In response

[17] End-stage renal disease (ESRD) is a stage of kidney impairment that appears to be irreversible and permanent, requiring a regular course of dialysis treatments or a kidney transplantation to maintain life. For more information, see CRS Report R45290, *Medicare Coverage of End-Stage Renal Disease (ESRD)*.

[18] U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Health and Environment, *Written Testimony of the Congressional Budget Office*, Hearing on H.R. 4080, 98th Cong., 1st sess., 1983, Serial No. 98-70, p. 80.

[19] U.S. Congress, Senate Health, Education, Labor, and Pensions Committee, *Organ Transplant and Procurement Act of 1984*, committee print, 98th Cong., 2nd sess., April 6, 1984, S. Rept 98-382, p. 13.

[20] Sen. Orrin Hatch, "Organ Procurement and Transplantation Network," Senate agreed to Conference Report, *Congressional Record*, vol. 130 (October 4, 1984), p. 29980.

[21] Rep. Albert Gore Jr., the sponsor of the House bill, introduced a new bill, H.R. 4474, which contained language that would have authorized federal funding for immunosuppressive drugs but without reference to Medicare or Medicaid. The new bill authorized the Secretary of HHS to administer the funding instead. This changed the committees that had (continued...)

to a task force recommendation that federal funds be used to provide immunosuppressive drugs, section 9335 of the Omnibus Budget Reconciliation Act of 1986 (P.L. 99-509) authorized Medicare to furnish immunosuppressive drugs to organ transplant recipients for one year. [22]

Every version of NOTA considered in Congress authorized the OPTN as a private nonprofit entity. The private nature of the OPTN was discussed throughout the debate over NOTA. Stakeholders, lawmakers, and Reagan Administration officials invoked UNOS throughout the OPTN discussion, in most cases, to point out that UNOS was already conducting the functions of the proposed OPTN. In one example, Carolyn Davis, then-Administrator of the Health Care Financing Administration (precursor to the Centers for Medicare & Medicaid Services [CMS]) strongly opposed federal funding for the OPTN, saying: "UNOS is an existing national network within the private sector which already fulfills the needs of national coordination.... We prefer this private sector activity to a federally regulated approach, particularly since Medicare reimbursement provides the core support for these activities."[23]

Title IV of the Omnibus Budget Reconciliation Act of 1986 (P.L. 99-509) amended the Social Security Act to authorize the Secretary of HHS to set conditions for transplant hospitals and OPOs to participate in Medicare.[24] This set the stage for CMS to provide oversight for OPTN members. For more information on this topic, see the "Conditions of Medicare and Medicaid Participation/Coverage for OPTN Members" section of this report.

Table 1. Selected Foundational Legislation

Legislation	Year of Enactment	Description
Uniform Anatomical Gift Act[a]	1968[b]	Created the legal basis for donating organs.
Uniform Determination of Death Act[a]	1981[b]	Created the legal basis for declaring brain death.
National Organ Transplant Act (P.L. 98-507)	1984	Created the OPTN.
Omnibus Budget Reconciliation Act of 1986 ((P.L. 99-509)	1986	Established that Medicare can set conditions for OPTN members.

Source: Compiled by CRS.

a. State law written by the Uniform Law Commission and adopted by all states in some form.

b. The state laws were approved by the Uniform Law Commission in the specified year and later adopted by each state individually.

Congressional action since the enactment of NOTA has focused primarily on further defining the duties of the OPTN and creating oversight mechanisms for OPOs and transplant centers. The Organ Transplant Amendments of 1988 (Title IV of P.L. 100-607) reauthorized the OPO grant program under NOTA and added additional oversight provisions. It also expanded the duties of

jurisdiction over the bill to those thought to be more favorable to the funding provision. "Compromise Organ Transplant Bill Passed," *CQ Almanac 1984*, (1985), pp. 476-478, 40th, http://library.cqpress.com/cqalmanac/cqal84-1151827.

[22] U.S. Congress, House Committee on the Budget, *Omnibus Budget Reconciliation Act of 1986*, committee print, 99th Cong., 2nd sess., July 31, 1986, H. Rpt. 99-727, p. 77.

[23] U.S. Congress, House Committee on Ways and Means, Subcommittee on Health, *National Organ Transplant Act*, Hearing on H.R. 4080, 98th Cong., 2nd sess., February 9, 1984, Serial 98-64, p. 67.

[24] 42 U.S.C. §1320b–8.

the OPTN to include establishing membership criteria, criteria for organ allocation, and requiring a process for HHS review of OPTN policies. Title II of the Transplant Amendments Act of 1990 (P.L. 101-616) further defined the responsibilities of OPTN and OPOs. For instance, it required the OPTN board of directors to include representatives from OPOs and transplant centers. In addition, it required the Secretary to publish rules for determining whether OPOs meet requirements for grants under NOTA. Title XXI of the Children's Health Act of 2000 (P.L. 106-310) required OPTN to recognize the differences in organ transplantation between children and adults. The Organ Donation and Recovery Improvement Act (P.L. 108-216) authorized the Secretary to carry out a program to reimburse living donors. The 110th Congress clarified language related to the prohibition on organ purchases (P.L. 110-144) and create a medal to honor organ donors (P.L. 110-413). There was no substantive legislation enacted between the 110th Congress and the 118th Congress.

The 118th Congress enacted the Securing the U.S. Organ Procurement and Transplantation Network Act (P.L. 118-14), which provides for which functions of the OPTN can be carried out by multiple entities under additional mechanisms (i.e., grants, cooperative agreements, or contracts). This legislation has not yet been fully implemented. (See the "OPTN Modernization Initiative" section of this report for more information.) For a list of additional bills considered in the 118th Congress, see **Appendix B**.

Brief Regulatory History of Organ Transplantation

Although NOTA was enacted in 1984, creating the OPTN, among other policies, HHS did not promulgate regulations to establish the structure and operations of the OPTN until 1998.[25] These regulations are known as the OPTN "final rule."[26] The final rule was originally intended to become effective July 1, 1998. However, the rule was delayed multiple times due to concerns over its effect on organ allocation and language adding HHS oversight of the OPTN. Ultimately, the rule became effective March 16, 2000.[27] The OPTN is required to serve many functions, but it fundamentally serves two primary functions: (1) it is a membership organization[28] and (2) an organ matching system.[29]

There was no regulatory framework in the period between enactment of NOTA and the final rule—the OPTN was governed solely by NOTA statutory requirements and the terms of the OPTN contract. At the time, the OPTN administered a national registry and placement system. A national list of transplant patients was kept, but organs were generally allocated locally or regionally. An organ may have gone to someone inside a region with less urgent need than someone outside of a region.[30] The organ allocation system was a "local first" system where organs only left the local area if no local patients could use the organ.[31]

[25] Department of Health and Human Services, "Organ Procurement and Transplantation Network," 63 *Federal Register* 16296, April 2, 1998, https://www.federalregister.gov/documents/1998/04/02/98-8191/organ-procurement-and-transplantation-network.

[26] 42 C.F.R. Part 121.

[27] Department of Health and Human Services, "Organ Procurement and Transplantation Network; Response to Comment Period" 65 *Federal Register* 15252, March 22, 2000.

[28] 42 U.S.C. §274(b)(1).

[29] 42 U.S.C. §274(b)(2).

[30] Lara Duda, "National Organ Allocation Policy: The Final Rule," *Virtual Mentor*, vol. 7, no. 9 (2005), pp. 604-607.

[31] Department of Health and Human Services, "Organ Procurement and Transplantation Network," 63 *Federal Register* 16303, April 2, 1998, https://www.federalregister.gov/documents/1998/04/02/98-8191/organ-procurement-and-transplantation-network.

The proposed rule would have required OPTN to establish an organ allocation policy that prioritized medical necessity and allowed for no consideration of locality. This was influenced by several evaluations of organ allocation, which recommended a national system. For instance, the Task Force on Organ Transplantation, established by NOTA, called organs a "national resource":

> The principle that donated cadaveric organs are a national resource implies that, in principle, and to the extent technically and practically achievable, any citizen or resident of the United States in need of a transplant should be considered as a potential recipient of each retrieved organ on a basis equal to that of a patient who lives in the area where the organs or tissues are retrieved. Organs and tissues ought to be distributed on the basis of objective priority criteria, and not on the basis of accidents of geography.[32]

The proposed rule would have also established an OPTN policy making process that provided for robust review by the Secretary of HHS.[33]

UNOS and the transplant community opposed aspects of the final rule. The President of UNOS claimed that the final rule would create a new organ allocation system, resulting in more deaths and longer wait times.[34] He also claimed that the rule would force small and medium sized transplant centers to close and increase overall cost for the health care system.[35] In addition, UNOS was concerned about additional oversight provisions, which would enable the Secretary of HHS to review all OPTN policies.[36]

In response to the concerns, Section 213 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (P.L. 105-277) delayed the final rule effective date to October 1999 while requiring a review of certain aspects of the rule. Implementation of the rule was further delayed by Section 413 of the Ticket to Work and Work Incentives Improvement Act of 1999 (P.L. 106-170), which delayed the effective date to March 2000. This section also required the Secretary of HHS to open a new public comment period for the rule.

Following additional review and the public comment period required by Congress, HHS published an amended final rule, which altered language related to the primary concerns of UNOS and the transplant community. The amended rule clarified that HHS does not require national lists:

> *"National" lists*: The final rule does not require single national lists for allocation of organs, beyond the national registry lists already utilized by the OPTN.... it is the Department's goal to achieve sharing of organs broad enough to achieve medically effective results for patients, especially by providing organs for patients with greatest medical urgency who are appropriate candidates for transplantation.[37]

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[32] United States. Task Force on Organ Transplantation, *Organ Transplantation: Issues and Recommendations: Report of the Task Force on Organ Transplantation* (1986), p. 91.

[33] Department of Health and Human Services, "Organ Procurement and Transplantation Network," 63 *Federal Register* 16334, April 2, 1998, https://www.federalregister.gov/documents/1998/04/02/98-8191/organ-procurement-and-transplantation-network.

[34] U.S. Congress, Joint Hearing Before the House Committee on Commerce and the Senate Committee on Labor and Human Recourses, *Putting Patients First: Resolving Allocation of Transplant Organs*, 105th Cong., 2nd sess., June 18, 1998, Committee on Commerce Serial No. 105-107, p. 136.

[35] Ibid.

[36] Ibid.

[37] Department of Health and Human Services, "Organ Procurement and Transplantation Network," 64 *Federal Register* 56651, October 20, 1999, https://www.federalregister.gov/documents/1999/10/20/99-27456/organ-procurement-and-transplantation-network.

In addition, the amended rule clarified the role of the Secretary in reviewing OPTN established policies.[38] The amended rule shifted the role of the Secretary from a primary part of the policy-making process to a reviewer after the adoption of policies. The Secretary still has the authority under the amended rule to take any action appropriate after the adoption of a policy.[39]

Administration and Oversight of Organ Procurement and Transplantation

Several federal government and nongovernment entities administer and oversee organ procurement, acquisition, transplantation process, and patient safety. The main entity charged with administering this system is the Organ Procurement and Transplantation Network (OPTN).[40] In addition to being the system that matches organs with patients, the OPTN is a private not-for-profit entity that must follow certain requirements set in both regulation and the OPTN contract.[41] Subject to oversight, OPTN takes the lead in establishing operational policies for organ procurement and allocation of organs for transplantation.

The OPTN operates under contract with the Health Resources and Services Administration (HRSA) and is subject to oversight by both HRSA and CMS within the Department of Health and Human Services (HHS). It also interacts with other federal agencies and programs. This section first describes the OPTN and its primary functions. Then it provides an overview of HRSA and CMS's roles in administration and oversight. Lastly, it includes some other considerations related to federal administration and oversight, namely, research and data privacy and the role of the Food and Drug Administration (FDA).

Organ Procurement and Transplantation Network (OPTN)

The OPTN is required to serve many functions, but it fundamentally serves two primary functions: (1) it is a membership organization[42] and (2) it is an organ matching system.[43]

The OPTN is required to establish a board of directors, which follows a structure established in law.[44] In addition, the board is authorized to establish any such committees as are necessary to perform the duties of the OPTN.[45] In addition to regulatory requirements, the OPTN has created bylaws that further establish the structure of the OPTN, such as procedures for voting, roles of board members, and standing committees. The bylaws also outline membership requirements.[46] They also sets policies that govern the operation of transplant centers, OPOs, and histocompatibility laboratories (labs).[47]

[38] Ibid.

[39] 42 C.F.R. §121.4(d).

[40] 42 U.S.C. §274.

[41] 42 C.F.R. §121.3.

[42] 42 U.S.C. §274(b)(1).

[43] 42 U.S.C. §274(b)(2).

[44] 42 C.F.R. §121.3(a).

[45] 42 C.F.R. §121.3(a)(4). For information on all of the current committees established by the OPTN, see https://optn.transplant.hrsa.gov/about/committees/.

[46] For the OPTN bylaws, see https://optn.transplant.hrsa.gov/media/lgbbmahi/optn_bylaws.pdf.

[47] For the OPTN policies, see https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.

OPTN as a Membership Organization

One of the primary functions of the OPTN is as a membership organization that includes the entire organ procurement and transplantation community.[48] **Table 2** lists the type of OPTN members and the number of each type. Each of the three primary membership types—transplant centers, OPOs, and histocompatibility labs—is intended to fulfill an essential role in the organ transplantation process. Transplant centers assess patients for medical need for transplants, register patients on the national wait list, and perform the transplants, among other things. OPOs procure organs for transplantation. Histocompatibility labs perform testing used to match organs with transplant candidates.

Table 2. OPTN Membership by Member Type

Type of OPTN Member	Number
Transplant Centers	250
Organ Procurement Organizations	55
Histocompatibility Laboratories	138
Other[a]	57
Total[b]	**405**

Source: Organ Procurement and Transplantation Network, https://optn.transplant.hrsa.gov/about/about-optn-membership/. Accessed December 18, 2024.

Notes:

a. Other includes public organizations, medical scientific organizations, individual and business members.

b. The total number of members is less than the sum of individual members, because some members operate both transplant centers and OPOs and some members operate both transplant centers and histocompatibility laboratories.

Transplant Hospitals

Transplant hospitals are hospitals that perform organ transplants and provide other medical and surgical specialty services required for the care of transplant patients.[49] Transplant hospitals must have current approval as a designated transplant program for at least one organ. The transplant hospital can either be approved for reimbursement under Medicare *or* be approved as a transplant program by the Department of Veterans Affairs (VA) or another federal agency.[50] Such a hospital can operate multiple transplant programs—one for each organ. These hospitals are legally required to establish selection criteria for transplant candidates, among other specific tasks. There are currently 250 transplant hospitals as members of the OPTN.

Organ Procurement Organizations

OPOs are nonprofit organizations that perform or coordinate the procurement, preservation, and transport of organs and maintain a system for locating prospective beneficiaries for available organs. They are legally permitted to recover organs from deceased donors. OPOs also provide support to donor families, clinical management of organ donors, and professional and public

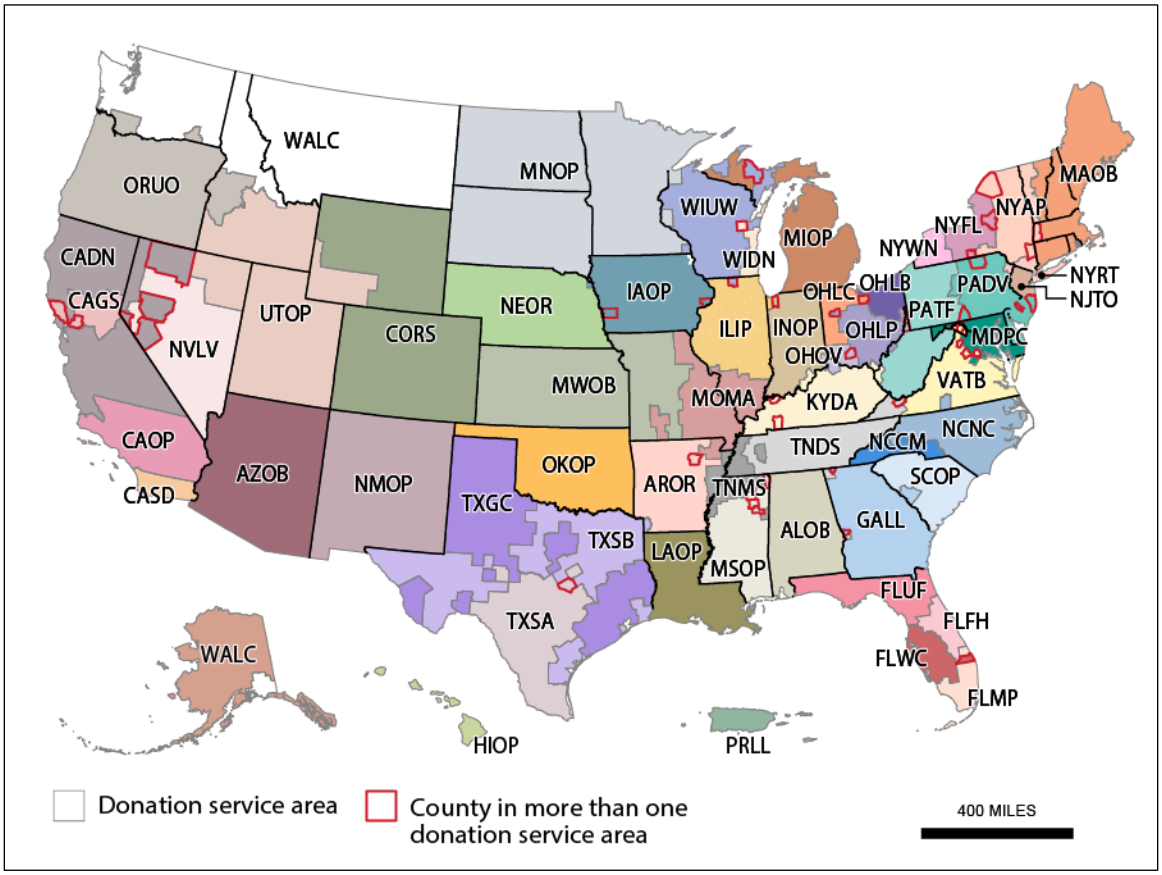
[48] 42 U.S.C. §274(b)(1)(A).

[49] 42 C.F.R. §§482.70 and 486.302; OPTN Bylaws, Article 1.2, p.5, https://optn.transplant.hrsa.gov/media/lgbbmahi/optn_bylaws.pdf.

[50] OPTN Bylaws, Appendix D.3, p.5. https://optn.transplant.hrsa.gov/media/lgbbmahi/optn_bylaws.pdf.

education about organ donation. Other specific tasks include identifying potential organ donors, requesting consent from the families of donors, procuring organs and working with other agencies to identify potential transplant recipients, and ensuring that organs are transferred to transplant hospitals. There are 55 OPOs, each assigned to a donation service area (DSA), as of February 14, 2025.

Figure 1. Donation Service Areas (DSAs)



Source: CRS analysis of data from the Scientific Registry of Transplant Recipients (SRTR), Organ Procurement Organization Statistics, OPO-specific reports (OSRs), Table G-1. Excel file accessed January 7, 2025, https://www.srtr.org/reports/opo-specific-reports/interactive-report/.

Note: For the full name associated with the OPO abbreviations contained in this figure, see **Table A-1**. OPTN and SRTR data on OPOs and DSAs do not always align due to a lag in reporting between the two organizations. For instance, LifeCenter Organ Donor Network and Kentucky Donor Affiliates merged into one OPO/DSA called Network for Hope effective October 1, 2024. This merger is not reflected in the SRTR data used to prepare this map. SRTR notes that this merger will be reflected in the OPO-specific reports (OSRs) of Spring 2025 (expected July 2025).

Histocompatibility Laboratories

Histocompatibility laboratories are clinical laboratories that perform histocompatibility testing, such as tissue typing, antibody screening, compatibility testing, or crossmatching.[51] These laboratories perform the testing required for matching organs from donors with potential

[51] OPTN Bylaws, Article 1.4, p.8, https://optn.transplant.hrsa.gov/media/lgbbmahi/optn_bylaws.pdf.

transplant candidates. There are currently 138 histocompatibility laboratories, each serving at least one transplant hospital or OPO.

Other Members

The OPTN also allows medical scientific organizations, public organizations, businesses, and individuals to become members. These membership types require specific criteria to receive membership status and such members have varying privileges.[52] Membership allows interested entities to provide input on organ procurement and transplantation policy. This could be through voting on OPTN policy or serving on a policy-making committee within the OPTN. Examples of medical scientific members include the American Society of Transplantation—a membership organization for transplant professionals, the Association of Organ Procurement Organizations—a national organization representing OPOs, and the American Society for Histocompatibility and Immunogenetics—a national organization representing histocompatibility labs. The National Kidney Foundation is an example of a public member—a nonprofit organization engaged in organ donation activities. Business members are organizations that engage in commercial activities with two or more members of the OPTN.

OPTN Policy Development Process

The OPTN final rule requires the OPTN board to develop policies within its mission. OPTN policies are generally not enforceable unless the Secretary of HHS publishes the policy in the *Federal Register*, indicating which are enforceable under the final rule.[53] In addition, CMS has included conditions for both OPOs and transplant centers requiring membership in the OPTN and adherence to criteria that are identical to some OPTN policies. (See the "Conditions of Medicare and Medicaid Participation/Coverage for OPTN Members" section of this report.)

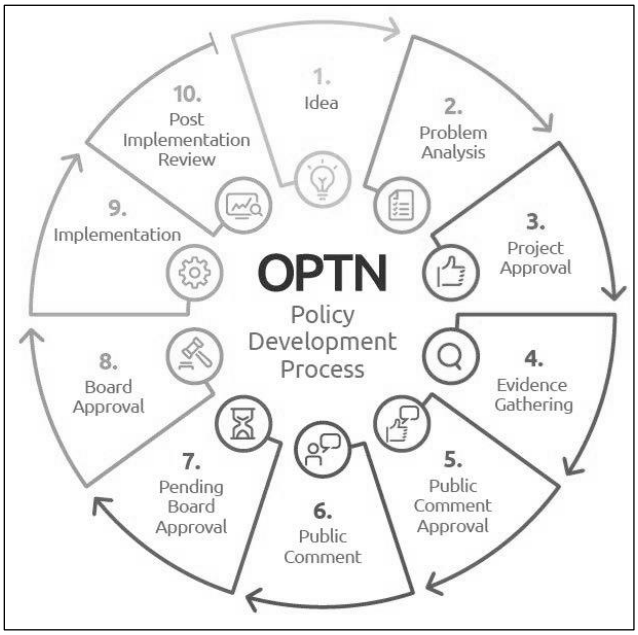
OPTN policy development includes policies to equitably allocate organs; prevent the spread of infectious disease; reduce inequities from socioeconomic status; training requirements for transplant professionals; and for nomination of members to the board, among other policies.[54] OPTN has developed a 10-step policy development process, as shown in **Figure 2**.

[52] For more information, see Article I of the OPTN Bylaws, https://optn.transplant.hrsa.gov/media/lgbbmahi/optn_bylaws.pdf.

[53] 42 C.F.R. §121.4(c).

[54] 42 C.F.R. §121.4.

Figure 2. OPTN Policy Development Process



Source: OPTN, https://optn.transplant.hrsa.gov/media/3115/optn-policy-development-process-explanatory-document.pdf.

The policy development process has both internal and external components. For steps one through four, the idea for a new policy is considered internally, before the appropriate OPTN committee makes a case for the policy and gathers evidence. Then, the policy is subject to public comment. This process differs from the public comment process for proposed rules under the federal rulemaking process. This process is a public comment process hosted by the OPTN. Following the public comment period, the OPTN board can approve the rule.

The OPTN does have some established enforcement mechanisms if members do not follow policies. For instance, the OPTN Membership and Professional Standards Committee can review a member for compliance with policies and ultimately revoke membership or take other corrective action.

Secretarial Review of OPTN Policies

The Secretary of HHS has the authority to review OPTN policies and determine which policies are enforceable. Specifically, in order for a policy to become enforceable, the OPTN must submit the policy for approval to the Secretary at least 60 days prior to the proposed implementation date.[55] OPTN policies are not enforceable until approved by the Secretary and published in the *Federal Register*. All current OPTN policies have not been approved by the Secretary. Therefore, they do not rise to the level of regulation and are voluntary from the perspective of HRSA.[56]

The Secretary may refer the policy under review to the Advisory Committee on Organ Transplantation to seek public comment in the *Federal Register*.[57] The Secretary will determine if the proposed policy is consistent with NOTA. If not, the Secretary can recommend revising the

[55] 42 C.F.R. §121.4(b)(2).

[56] See https://www.organdonor.gov/about-us/legislation-policy/optn.

[57] 42 C.F.R. §121.12. The Advisory Committee On Transplantation is described in more detail in the section "Health Resources and Services Administration's Role" of this report.

policy. The Secretary can also take such other action as necessary if the policy is still inconsistent with NOTA after revisions.

The OPTN final rule authorizes a similar process for review of any OPTN duties or policies if an interested individual or entity informs the Secretary through critical comments.[58] At the conclusion of this process, the Secretary may either reject the comments, direct the OPTN to revise the policy, or take any other appropriate action

OPTN Membership Review

The OPTN final rule authorized the OPTN to review and evaluate OPOs and transplant centers for compliance with the final rule and OPTN policies.[59] In addition, by accepting membership in the OPTN, members agree to comply with all OPTN obligations (i.e., NOTA, the OPTN final rule, OPTN charter, OPTN bylaws, and OPTN policies).[60]

The OPTN is designed to conduct deliberations and actions related to members according to medical peer review laws.[61] This is intended to function as an entirely confidential process in which the OPTN keeps all materials, information, and correspondence to and from members and directly related to the OPTN peer review process private. The intent of this process is to encourage full disclosure by members and to promote quality improvement.[62]

The OPTN Membership and Professional Standards Committee is responsible for reviewing and evaluating whether OPTN members meet and remain in compliance with OPTN obligations.[63] It generally acts through a peer review process to evaluate events identified as presenting a risk; to provide feedback on recommendations to improve member performance, compliance, and quality systems; and to review applications for membership.[64]

Organ Matching System

The ultimate goal of the OPTN is to match organs procured from donors with potential transplant patients who need them. The OPTN coordinates activities of its members to match organs with consideration of both the limited number of organs and their short shelf-life, among other considerations. The OPTN maintains a series of policies for organ allocation.[65] These policies explain the role of each member (i.e., transplant hospitals, OPOs, and histocompatibility laboratories) in matching organs. OPTN also issues white papers that highlight a variety of topics for OPTN members.[66] This section describes how the organ matching system works at a basic

[58] 42 C.F.R. §121.4(d).

[59] 42 C.F.R. §121.10. The final rule specifies review and evaluation of OPOs and transplant centers, but not laboratories or other members.

[60] The OPTN, *OPTN Bylaws*, Article I: Membership, p. 4, https://optn.transplant.hrsa.gov/media/lgbbmahi/optn_bylaws.pdf.

[61] It is unclear what medical peer review laws the OPTN refers to in its bylaws. States have adopted legislation that established medical peer review. No such laws have been adopted at the federal level. The OPTN final rule authorizes the OPTN to develop a peer review process. 42 C.F.R. §121.10.

[62] *OPTN Bylaws*, p. 195.

[63] The OPTN, *OPTN Bylaws*, Appendix L: Reviews and Actions, p. 219, https://optn.transplant.hrsa.gov/media/lgbbmahi/optn_bylaws.pdf.

[64] See https://optn.transplant.hrsa.gov/about/committees/membership-and-professional-standards-committee/.

[65] The OPTN, *OPTN Policies*, https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf. (Hereinafter: OPTN Policies)

[66] See https://optn.transplant.hrsa.gov/professionals/.

level for deceased organ donors and typical transplant patients. There are also paths for living organ donation for certain organs, which are not discussed here.[67]

First, transplant hospitals determine whether a patient is a good candidate for an organ transplantation. Transplant hospitals have wide discretion in this determination process. The OPTN does not issue policies requiring transplant centers to use specific criteria when determining whether patients would be suitable candidates for transplantation. Nor does the OPTN require transplant centers to have a specific selection process. The OPTN encourages transplant centers to develop their own guidelines for transplant consideration, noting that each potential transplant candidate should be examined individually and all guidelines should be applied without bias.[68] The OPTN has noted that "listing decisions are complex and that transplant clinicians try to work with patients to identify and mitigate risk factors for negative outcomes and foster positive ones."[69] If a patient is determined to be a good candidate for a transplant, the transplant hospital will register the candidate on the OPTN computer system wait list.[70]

Registration of a transplant candidate is accompanied by submission of clinical data and other criteria that is used later to determine if the candidate is the best match for a particular procured organ. Allocation decisions are based on many factors, such as histocompatibility, organ size, severity of illness, time on the wait list, and distance from the organ. The OPTN facilitates the process of matching organs to patients through its computer system.

Health Resources and Services Administration's Role

The Health Resources and Services Administration (HRSA) within HHS is the primary agency tasked with overseeing the OPTN. The Division of Transplantation within the Health Systems Bureau of HRSA is the primary entity responsible for oversight. The Advisory Committee on Organ Transplantation (ACOT) is supported by HRSA.[71] ACOT was established to assist the Secretary in providing advice and recommendations on OPTN proposed policies.

As noted previously, HRSA administers OPTN contracts, which include deliverables such as performance standards that OPTN contractors must meet.[72] In addition to administering OPTN contracts, HRSA also administers contracts for two other programs that support the organ system: (1) the Scientific Registry of Transplant Recipients (SRTR) and (2) the National Living Donor Assistance Center (NLDAC), described in the following sections.

[67] For more information on living organ donation, see CRS Report R48257, *Federal Support for Organ Transplantation: Frequently Asked Questions*.

[68] OPTN Ethics Committee, *General Considerations in Assessment for Transplant Candidacy*, 2021, https://optn.transplant.hrsa.gov/professionals/by-topic/ethical-considerations/general-considerations-in-assessment-for-transplant-candidacy/.

[69] Ibid.

[70] The suite of applications that encompass the OPTN computer system is referred to as UNet. For more information, see https://unos.org/technology/.

[71] The Advisory Committee on Organ Transplantation is authorized by 42 U.S.C. §217a and established in the OPTN final rule. For more information, see https://www.hrsa.gov/advisory-committees/organ-transplantation.

[72] For information on specific contract deliverables, see the most recent Request for Proposals (RFP) at https://sam.gov/opp/4f4ae2b519d7bd1d06883b6c789c063f/view.

OPTN Contract

The National Organ Transplant Act had required that the OPTN be operated by contract by a private, nonprofit entity since it was first enacted. One organization has held the contract to perform all functions of the OPTN since its inception—the United Network for Organ Sharing. Recent legislation has changed the requirement for one entity to operate OPTN (see textbox).

OPTN Modernization

The Securing the U.S. Organ Procurement and Transplantation Network Act (P.L. 118-14) established that functions of the OPTN can be carried out by multiple entities under additional mechanisms (i.e., grants, cooperative agreements, or contracts). This legislation has not yet been fully implemented. (See the "OPTN Modernization Initiative" section of this report for more information.)

United Network for Organ Sharing

The first contract to operate the OPTN was awarded to the United Network for Organ Sharing (UNOS) in 1986.[73] UNOS is a not-for-profit organization incorporated in Virginia.[74] UNOS has held the OPTN contract since the OPTN's inception. The first contract included 10 tasks to be completed by October 1, 1987.[75]

1. Develop a work order.
2. Establish the National Organ Procurement and Transplant Network.
3. Develop and implement an information system plan.
4. Develop and maintain recipient registration system.
5. Match donors and recipients.
6. Develop a telephone system.
7. Develop transport assistance.
8. Develop procurement standards.
9. Develop high panel reactive antibody protocols.[76]
10. Develop professional education.

UNOS continues to perform all of the functions of the OPTN. Until recently, the two organizations shared the same boards of directors.

The primary vehicle by which the UNOS has historically received payment is registration fees paid by transplant centers to add patients to the organ wait list.

For a brief history of UNOS, see **Appendix D**.

[73] U.S. Government Accountability Office, *United Network for Organ Sharing*, B-416248, July 18, 2018, p. 2, https://www.gao.gov/products/b-416248.

[74] See OPTN Charter, https://optn.transplant.hrsa.gov/media/1505/optn_charter_article_i-organization-june_2004.pdf.

[75] John C. Mcdonald, "The National Organ Procurement and Transplantation Network," *JAMA*, vol. 259, no. 5 (February 5, 1988), pp. 725-726.

[76] These are protocols developed to match donated organs to recipients. For more information, see https://optn.transplant.hrsa.gov/data/allocation-calculators/about-cpra/.

Scientific Registry of Transplant Recipients Contract

NOTA also required that the Secretary of HHS establish a scientific registry of transplant recipients (SRTR).[77] The SRTR is currently operated by the Chronic Disease Research Group of the Hennepin Healthcare Research Institute under contract with HRSA.

Members of the OPTN are required to submit certain data to the OPTN which then submits data to the SRTR.[78] This includes data on wait list candidates, transplant recipients, organ donors, program costs, and performance. This data is then used to create three types of reports: (1) transplant program-specific reports, (2) OPO-specific reports, and (3) OPTN/SRTR annual data reports.

The SRTR collects data and reports on both pre- and post- transplant outcomes. The data is used to determine what measurements have the largest effects on patient survival.[79] Data compiled by the SRTR is also used to enforce membership performance requirements through the OPTN.[80] SRTR data is also used by CMS to assess OPO and transplant hospital performance.[81]

The OPTN/SRTR annual data reports provide an overview of nationwide trends in wait list and transplant activity.

National Living Donor Assistance Center

The Secretary is authorized to award grants to manage a program for reimbursing living organ donors for qualifying expenses incurred during the donation process.[82] Qualifying expenses include travel, subsistence, and incidental nonmedical expenses.[83] The program is also required to give preference to individuals otherwise unable to meet such expenses.

The initial grant award to establish and operate the National Living Donor Assistance Center (NLDAC) was made in September 2006 to the University of Michigan. The program was transferred to the University of Arizona in May 2016. However, since the program was operated under a subcontract with the American Society of Transplant Surgeons, which was maintained with the transfer, all program operations remained the same.

The NLDAC funding is subject to the annual appropriations process, therefore the amount available for donors is limited. The program prioritizes reimbursing individuals who meet certain income thresholds. Specifically, a recipient's yearly household income should not be more than 350% of the current HHS poverty guidelines. If a recipient has a higher household income, but would experience difficulty paying for donor expenses, then the recipient can submit a financial hardship waiver to qualify for assistance subject to the availability of funds. The program facilitated 1,230 living organ transplants of the over 42,000 total transplants in calendar year 2022.[84]

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[77] 42 U.S.C. §274a.

[78] 42 C.F.R. §121.11

[79] See https://www.srtr.org/about-the-data/guide-to-using-the-srtr-website/txguidearticles/metrics-marked-as-most-important/.

[80] OPTN Bylaws, Appendix D.12, pp. 78-79.

[81] For information on CMS oversight of OPTN members, see the "Centers for Medicare & Medicaid Services' Role" section of this report.

[82] 42 U.S.C. §274f.

[83] 42 U.S.C. §274f(c)(2).

[84] HHS, HRSA, Justification of Estimates for Appropriations Committees FY2025, p. 308, https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2025.pdf.

NLDAC works directly with transplant hospitals. Individuals who would like to become living donors are assessed for eligibility by the transplant hospital. The donor and recipient then have to fill out an application with NLDAC.[85] If the donor is not found to be eligible, the transplant recipient can cover the donor's travel expenses, lost wages, and dependent care. However, the donor cannot receive payment for donating an organ.[86]

Table 3. NLDAC Income Thresholds for Priority by Household Size

Contiguous States and the District of Columbia, 2024

Household Size	HHS Poverty Guideline	NLDAC Eligibility (350% of HHS Poverty Guideline)
1	$14,580	$52,710
2	19,720	71,540
3	24,860	90,370
4	30,000	109,200
5	35,140	128,030
6	40,280	146,860
7	45,420	165,690
8	50,560	184,520

Source: National Living Donor Assistance Center; Department of Health and Human Services, "Annual Update of the HHS Poverty Guidelines," 89 *Federal Register* 2961, January 17, 2024, https://www.govinfo.gov/content/pkg/FR-2024-01-17/pdf/2024-00796.pdf.

Notes: HHS poverty guidelines, and thereby NLDAC eligibility, differ for Alaska and Hawaii. For that information, see https://www.livingdonorassistance.org/How-to-Apply/Eligibility-Guidelines.

Centers for Medicare & Medicaid Services' Role

Conditions of Medicare and Medicaid Participation/Coverage for OPTN Members

The Centers for Medicare & Medicaid Services (CMS) set patient health and safety requirements for transplant hospitals and organ procurement organizations (OPOs).[87] This includes requiring transplant hospitals and OPOs to be OPTN members and follow the requirements established by the OPTN.[88] OPOs *must* comply with OPTN requirements that have been reviewed and approved by the HHS Secretary;[89] OPOs *may* comply, voluntarily, with OPTN requirements that have not been approved by the HHS Secretary (as noted in "Health Resources and Services Administration's Role").

[85] See https://www.livingdonorassistance.org/portals/0/NLDAC/Documents/NLDAC_How_to_Apply.pdf.

[86] 42 U.S.C. §274e.

[87] 42 C.F.R. §§482.90-104 for transplant hospitals, and 42 C.F.R. §§486.301-360 for OPOs.

[88] 42 C.F.R. §482.72 for transplant hospitals; Social Security Act (SSA) §1138(b)(1)(D), and 42 C.F.R. §§486.320 for OPOs.

[89] SSA §1138(b)(1)(D).

Organ Procurement Organizations

CMS promulgates and enforces health and safety regulations for organ procurement organizations (OPOs), referred to as the OPO *Conditions for Coverage* (*CfCs*). OPOs must comply with the CfCs in order to receive Medicare and Medicaid reimbursement for covered organ procurement services. CMS evaluates compliance with the CfCs through onsite observations, interviews and document/record reviews of each OPO at least every four years, and through ongoing data collection and analysis that are the basis for annual performance feedback to OPOs.

Beginning in 2026, CMS will determine whether an entity will continue to be approved (i.e., re-certified) as an OPO based on its performance on outcome measures described in regulations.[90] Each OPO will be evaluated on two outcome measures—organ *donation rate* and *transplantation rate*—in their DSA. These are intended to be more objective and transparent than previous outcome measures.[91]

Based on performance benchmarks for each outcome measure established by CMS, OPOs will be ranked and assigned to one of three performance tiers based on their rank. The top tier, Tier 1, are OPOs that rank at or above the 25th percentile of OPO performance threshold on *both outcome measures*. The second tier, Tier 2, are OPOs that rank at or above the median (i.e., 50th percentile) for both outcome measures but below the Tier 1 threshold on at least *one outcome measure*. And Tier 3 are OPOs that rank below the median performance threshold on at least *one outcome measure*.

Tier 1 OPOs will be automatically recertified for an additional four-year period. Tier 2 OPOs would have to compete to be recertified. Tier 1 OPOs may compete for the DSA of a Tier 2 OPO. Tier 3 OPOs will be de-certified, pending any appeal by an OPO, and will not be able to compete for any DSA. Additional information about OPO DSAs and OPO performance is contained at "Organ Procurement Organizations" and "OPO Performance Evaluation and Competition."

Transplant Programs/Hospitals

CMS promulgates and enforces health and safety regulations for organ transplant programs.[92] Hospitals with transplant programs, like other hospitals, must meet health and safety regulations promulgated by the HHS Secretary in order to receive Medicare and Medicaid reimbursement (e.g., inpatient and outpatient services such as surgical procedures). These are referred to as the Medicare hospital *conditions of participation* (*CoPs*). Hospitals with transplant programs have additional and distinct CoPs from non-transplant hospitals and from OPOs.[93] These additional requirements are specific to the services and care associated with organ transplantation.

Laboratories

CMS generally evaluates a clinical laboratory's compliance with the Clinical Laboratory Improvements Amendments of 1988 (CLIA), among other requirements, in order for a laboratory

[90] 42 C.F.R. §486.318.

[91] CMS, "Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations," 85 *Federal Register* 77898, December 2, 2020, https://www.federalregister.gov/documents/2020/12/02/2020-26329/medicare-and-medicaid-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to.

[92] Not all hospitals have transplant programs, but all transplant programs are located within a hospital. In this report we use transplant program(s) and transplant hospital(s) and transplant center(s) interchangeably unless otherwise noted.

[93] Organ transplant hospitals must comply with hospital CoPs at 42 C.F.R. §§482.1 through 482.57, except for §482.15; plus, organ transplant program-specific CoPs at §§482.72 through 482.104.

to receive Medicare and Medicaid reimbursement.[94] For purposes of organ transplantation, the clinical laboratory CoPs contain requirements related to the testing of histocompatibility—testing the compatibility of tissues of different individuals. CMS evaluates laboratory compliance with the CoPs every two years through onsite surveys involving observation of lab facilities and processes, staff and leadership interviews, and record review.[95]

Demonstration Projects

CMS undertakes time-limited demonstration projects that test models of service delivery, coordination, and Medicare and Medicaid payment and their effect on expenditures and quality.[96] Demonstration projects permit CMS to waive certain Medicare (and Medicaid as applicable) requirements. For example, CMS may waive Medicare and/or Medicaid payment requirements or apply safe harbor protection of demonstration participants (e.g., hospitals, physicians) from fraud and abuse laws such as anti-kickback and gainsharing.[97] Thus, permitting flexibility to test alternative delivery and payment models that otherwise could not be tested under existing Medicare and Medicaid requirements. CMS may implement such models on a permanent basis and on a national scale if a formal program evaluation shows that particular demonstration achieved cost-savings while preserving or improving quality.[98] Below are selected organ-related demonstrations undertaken by CMS.

[94] Section 353 of the PHSA, among other requirements, adopted by CMS as the Medicare/Medicaid clinical laboratory CoPs at 42 C.F.R. §§493.1 through 493.2001.

[95] Washington and New York survey their own clinical labs. For further information on accreditation see https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/accreditation-exemptions.

[96] SSA §1115A.

[97] For an overview of key federal health care fraud, waste, and abuse laws, see CRS Report RS22743, *Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview*; and HHS OIG, Special Advisory Bulletin, "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries," July 1999, https://oig.hhs.gov/documents/special-advisory-bulletins/895/gainsh.htm.html.

[98] SSA §1115A(1).

Selected Organ-Related Demonstrations

Comprehensive ESRD Care (CEC) Model

This model was designed to identify, test, and evaluate new ways to improve care for Medicare beneficiaries with End-Stage Renal Disease (ESRD), also known as kidney failure. The model involved payment flexibility and incentives to encourage care coordination and partnership/ownership of care delivery by providers across the care continuum. This demonstration's duration was from October 2015 through March 2021. This model was not extended or implemented permanently.[99]

Kidney Care Choices (KCC) Model

This model is both independent of and a complement to the CEC model above. It focuses on financial incentives for health care providers to manage the care for Medicare beneficiaries with chronic kidney disease (CKD) stages 4 and 5 and ESRD with the aim of delaying the onset of dialysis and to incentivize kidney transplantation. This model began in October 2020 and is active as of February 14, 2025.[100]

ESRD Treatment Choices (ETC) Model

This model provides financial incentives to health care providers to educate about the full range of treatment options and support patients in their choice of such options. It is designed to increase patient independence by encouraging greater use of home dialysis and kidney transplants for Medicare beneficiaries with ESRD—treatment modalities that CMS states provide patients with a greater quality of life versus dialysis in a dialysis facility/center. This model began in January 2021 and is active as of February 14, 2025.[101]

Increasing Organ Transplant Access (IOTA) Model

This model will provide financial incentives to transplant hospitals to promote the goals, among others, of maximizing the use of deceased donor kidneys, identifying more living donors, and assisting living donors through the donation process. This is a six-year model that begins on July 1, 2025.[102]

Research and Data Privacy

Organ transplantation relies on the appropriate, authorized and timely exchange of and access to health and other information about organ transplant recipients, individuals waiting for a transplant, and donors (or potential donors). This information is collected and used by OPOs, healthcare providers, and transplant centers to facilitate care, and is used by researchers and other entities, such as the Scientific Registry of Transplant Recipients, to evaluate and examine trends in organ transplantation and transplant outcomes. Donors, donor families, and recipients have a privacy interest in individually identifiable health and other information, and privacy law and regulation will apply based generally on who is holding the information (e.g., healthcare provider, OPO), to whom it is being disclosed, and for what purpose. Relevant law includes the Privacy Act of 1974, the HIPAA Privacy Rule, and the Common Rule, as well as state law in some cases.

OPOs and the OPTN are not subject explicitly to confidentiality or privacy standards in their authorizing statute,[103] although the OPTN and its records are covered by the Privacy Act of 1974.[104] The Scientific Registry of Transplant Recipients, a part of the OPTN, is also subject to

[99] See https://www.cms.gov/priorities/innovation/innovation-models/comprehensive-esrd-care.

[100] See https://www.cms.gov/priorities/innovation/innovation-models/kidney-care-choices-kcc-model.

[101] See https://www.cms.gov/priorities/innovation/innovation-models/esrd-treatment-choices-model.

[102] See https://www.cms.gov/priorities/innovation/innovation-models/iota.

[103] Organ procurement and transplantation network, PHSA §372, 42 U.S.C. §274; Organ Procurement Organizations, PHSA §371, 42 U.S.C. §273. Implementing regulations are at 42 C.F.R. Part 121.

[104] HRSA, "System of Records Notice 09-15-0055," https://www.hrsa.gov/about/privacy-act/09-15-0055. The Privacy Act "prescribes how federal agency records with individually identifying information are to be stored, who may access such information, and when the government may use or disclose it." For more information, see CRS Report R47863, *The Privacy Act of 1974: Overview and Issues for Congress*.

the Privacy Act, as a system of government records.[105] OPOs, which are not government entities, are not subject to the Privacy Act, and they handle a large amount of individually identifiable patient data, including being allowed to "access any patient medical record, contact any family member, request information from any provider, and even perform examinations at the bedside of the patient to collect data and information for the purposes of possible organ donation."[106] OPOs may be subject to state privacy laws on a state by state basis.

The HIPAA Privacy Rule[107] (the Privacy Rule) applies only to covered entities, as defined in the Privacy Rule, including healthcare providers, payers and healthcare clearinghouses, and to their business associates—entities that carry out work using protected health information (PHI) on behalf of covered entities. The OPTN is not a covered entity under the Privacy Rule, and being an OPO doesn't make an entity a covered entity or a business associate, although they might qualify in certain limited cases for independent reasons. Transplant centers, hospitals and other healthcare providers are covered entities, and are covered by the Privacy Rule.

The Privacy Rule generally restricts the use and disclosure of PHI by covered entities except with an individual's authorization or as permitted or required by the Privacy Rule. There are a number of lawful disclosures of PHI allowed for broad non-health purposes, without authorization and to non-covered entities, as there is a recognized value and need for health care information in many situations outside of health care (e.g., for research, law enforcement, public health, or other purposes). In these cases, once PHI is disclosed to a non-covered entity,[108] the requirements of the Privacy Rule generally no longer apply.

Specifically with respect to organ transplantation, the Privacy Rule allows covered entities, without individual authorization, to "use or disclose protected health information to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of *cadaveric* organs, eyes, or tissue for the purpose of facilitating organ, eye or tissue donation and transplantation."[109] The exception does not apply to living donors, who are presumed to be able to provide consent and authorization. The purpose generally of this exception is to allow healthcare providers to have conversations with OPOs about suitability for possible donation, prior to involving family members.

The Common Rule[110] applies generally to all federally funded research involving human research subjects, requiring, with some exceptions, research to be reviewed by an Institutional Review Board for approval. The Common Rule includes requirements for adequate informed consent, equitable subject selection, and has special requirements for research with certain vulnerable subpopulations (e.g., children). Human research subjects are living individuals about whom a researcher "obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens" or "obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."[111]

[105] Individuals' records are provided to both the OPTN and SRTR contractors from organ procurement organizations, histocompatibility laboratories, organ transplant centers, and health care providers which obtain the information directly from individuals or their representatives. Records can include information from other sources of data, such as from CMS. 87 *Federal Register* 46967, August 1, 2022.

[106] Eric D. Perakslis et al., "Opinion: Doing it right: Caring for and protecting patient information for US organ donors and transplant recipients," Patterns (2023), https://doi.org/10.1016/j.patter.2023.100734.

[107] 45 C.F.R. Part 164, Subparts A and E.

[108] Here, the term covered entity includes business associates.

[109] 45 C.F.R. §164.512(h). Cadaveric means relating to, pertaining to, or from a dead body.

[110] 45 C.F.R. Part 46.

[111] 45 C.F.R. §46.102(e).

With respect to organ transplantation, the Common Rule may apply where research occurs during or as part of the process, specifically involving a living donor and/or the transplant recipient of a "research" organ, depending on the parameters of the research protocol. Specifically, a recipient who receives an organ that has "been subjected to research interventions, and in whom transplanted organs are now being studied for their function, efficacy, and safety, should be treated as research subjects."[112]

Food and Drug Administration's Role

While the Food and Drug Administration (FDA) does *not* regulate the transplantation of vascularized human organs (e.g., lung, heart, etc.), it is involved in regulating some of the products used in the organ transplantation process. These include immunosuppressive products to increase the chance of a successful transplantation, medical devices used for organ transportation, products used in anesthesia, blood used for transfusion during transplant surgery, and others.[113] FDA does, however, regulate human cells or tissues intended for implantation, transplantation, infusion, or transfer into a human recipient. These products are referred to as human cells, tissues, and cellular and tissue-based products (HCT/Ps). Examples include bone, ligament, skin, heart valves, and others.[114] This is in contrast to organs intended for transplantation, the procurement and allocation of which are regulated by HRSA and CMS as detailed in preceding sections of this report.

FDA also plays a role in regulating emerging technologies that may lead to replacing human organs in certain procedures. Two illustrative examples of experimental technologies include xenotransplantation and three-dimensional tissue bioprinting. Recent advances in science and technology have led to development in the field of xenotransplantation. Xenotransplantation is a procedure that involves the transplantation, implantation, or infusion of live organs, tissues, or cells from a nonhuman animal source.[115] Potential uses for xenotransplantation products can be pig skin for burn patients and a pig kidney for a kidney failure patient. Three-dimensional printing is a process to make a physical object from a three-dimensional digital model, typically by laying down layers of materials in succession. Three dimensional bioprinting for organs (3D-printed organs) involves using biological materials, such as a patient's cells, to grow an organ in the laboratory that could then be transplanted into a patient.[116] Although emerging technologies hold promise to help meet demand for human organs, they are experimental. Concerns like potential cross-species infections (xenotransplantation), ethical and regulatory clarification (3D

[112] HHS, OHRP, "Attachment B - Deceased Donor Intervention Research 45 CFR part 46," https://www.hhs.gov/ohrp/sachrp-committee/recommendations/august-12-2020-attachment-b-deceased-donor-intervention/index.html.

[113] For information on immunosuppressive products, see Michael D. Duncan and David S. Wilkes, "Transplant-related Immunosuppression," *American Thoracic Society*, vol. 2, no. 5 (December 2005), pp. 449-455. An example of an FDA-regulated medical device used in organ transplantation is the OCS Lung System; see FDA, *Devices@FDA: Organ Care System (OCS™) Lung System*, last accessed March 20, 2024, at https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pma&id=381677. Examples of anesthetics include products such as *Azathioprine*, *Tacrolimus* and many others. See Dhruti Diwan and Paramvir Singh, "Anesthesia for Transplant Surgery," *StatPearls*, January 2022, at https://www.ncbi.nlm.nih.gov/books/NBK572086/. [Updated August 2022]. For information on FDA regulation of blood, see FDA, *Regulation of the Blood Supply*, July 12, 2021, at https://www.fda.gov/vaccines-blood-biologics/blood-blood-products/regulation-blood-supply.

[114] 21 C.F.R. Part 1271.

[115] See FDA, *Xenotransplantation*, March 03, 2021, at https://www.fda.gov/vaccines-blood-biologics/xenotransplantation.

[116] Nabanita Panja et al. "3D Bioprinting of Human Hollow Organs," AAPS PharmSciTech 23, no. 5, May 10, 2022, https://doi.org/10.1208/s12249-022-02279-9.

bioprinting) may need to be addressed.[117] FDA would regulate most of these products as biological products under its existing authority in the Public Health Service Act (PHSA) and the Federal Food, Drug, and Cosmetic Act (FFDCA).[118] FDA has provided limited guidance for industry stakeholders concerning product development or conducting clinical studies on these emerging technologies.[119]

Considerations for Congress

In recent years, concerns have been raised regarding the contractor that historically administered the OPTN as well as concern over uneven OPO performance. First, observers suggest the contractor, UNOS, failed to provide adequate oversight over OPTN members as well as lack of technical expertise in information technology.[120] Failures in both areas may have resulted in potential harm to transplant patients and fewer organs available for transplant.[121]

Regarding OPO performance, organ recovery rates have varied across OPO DSAs. There have been concerns for years that OPO outcome measures did not incentivize organ recovery and that there was little incentive to increase performance.[122] There were also concerns that there were no negative consequences for underperforming OPOs. HHS has never decertified an OPO despite having the authority to do so.

These concerns led both the executive branch and Congress to take significant action to reform the system. In 2019, President Trump issued an executive order on advancing American kidney health, which, among other actions, directed CMS to propose new regulations on OPO performance.[123] A final rule was published on December 2, 2020, to revise outcome measures for OPOs.[124] In 2023, Congress enacted the Securing the U.S. Organ Procurement and Transplantation Network Act (P.L. 118-14), which made fundamental changes to the administration of the OPTN. The next section discusses considerations related to these executive and legislative actions. As such, the considerations for Congress that we detail below largely deal with implementation oversight. Two topics are discussed in this section: (1) modernization of the OPTN and (2) OPO performance and competition.

[117] Elizabeth Kelley, "FDA Regulation of 3D-Printed Organs and Associated Ethical Challenges." University of Pennsylvania Law Review 166, 2018, https://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=9610&context=penn_law_review.

[118] For information on authority in PHSA, see PHSA §351; 42 U.S.C. §262. For information on authority in FFDCA see 21 U.S.C. §§321 *et seq*.

[119] See FDA, Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans, Updated December 2016, at https://www.fda.gov/media/102126/download.

[120] U.S. Congress, Senate Finance Committee, *A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network*, 117th Cong., 2nd sess., August 3, 2022, S.Hrg. 117-878, https://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Memo.pdf.

[121] Ibid. pp. 12-116.

[122] The Bridgespan Group, *Reforming Organ Donation*, January 2019, pp. 7-8, https://www.bridgespan.org/getmedia/415a0075-8b2f-4441-ab43-275c2a111fa1/reforming-organ-donation-in-america-12-2018.pdf.

[123] Executive Order 13879, "Advancing American Kidney Health," 84 *Federal Register* 33817, July 10, 2019, https://www.govinfo.gov/content/pkg/FR-2019-07-15/pdf/2019-15159.pdf.

[124] CMS, "Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations," 85 *Federal Register* 77898, December 2, 2020, https://www.federalregister.gov/documents/2020/12/02/2020-26329/medicare-and-medicaid-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to.

OPTN Modernization Initiative

Congress may consider monitoring implementation of the OPTN modernization initiative and consider whether HRSA has the appropriate resources to modernize the system. There has been interest in recent years in modernizing the OPTN, specifically by making statutory changes to NOTA and altering future vendor solicitations to allow for more oversight, flexibility, transparency, among other improvements. Both HRSA and Congress have acted to accomplish this goal.

Congress enacted the Securing the U.S. Organ Procurement and Transplantation Network Act (P.L. 118-14, signed Sept. 22, 2023) and HRSA has issued a pre-solicitation notice for transitional OPTN contracts. This section describes the actions taken thus far and potential considerations as the modernization initiative continues to be implemented.

HRSA Modernization Initiative

In March 2023, in anticipation of congressional action, HRSA launched the OPTN Modernization Initiative.[125] The aims of this initiative are multi-faceted, including the following aspects:

- Technology;
- Data transparency and analytics;
- Governance;
- Operations; and
- Quality improvement and innovation.

At the time of the launch, HRSA made available certain organ donation and transplantation data as an initial dataset with the intention to refine and update data regularly.[126]

HRSA, as part of the modernization initiative, sought legislative proposals to modify NOTA to improve HHS oversight. Specifically, HRSA sought legislative changes to enhance oversight and transparency, increase competition around OPTN procurement, and improve efficiency in the system.[127] HRSA also requested an increase in appropriations to $67 million for FY2024 ($36 million over the FY2023 enacted appropriation of $31 million).[128]

The main goal of the OPTN modernization initiative is to change the way that HRSA administers the OPTN. Specifically, HRSA proposed utilizing multiple vendors to carry out mandated functions of the OPTN rather than relying on one vender to carry out all the functions of the OPTN. To accomplish this, HRSA published a legislative proposal seeking a statutory change to strengthen OPTN functions and improve outcomes for patients and families by enhancing oversight and transparency, increasing competition around OPTN procurements, and improving efficiency in the organ transplantation system.[129]

[125] HRSA, "HRSA Announces Organ Procurement and Transplantation Network Modernization Initiative," press release, March 22, 2023, https://www.hrsa.gov/optn-modernization/march-2023.

[126] To view the publicly available datasets, see https://data.hrsa.gov/topics/health-systems/organ-donation.

[127] HRSA, *FY2024 Justification of Estimates for Appropriations Committees*, p. 438, https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2024.pdf.

[128] Ibid., p. 311.

[129] Ibid., p. 438.

Congressional Action to Modernize the OPTN

The Securing the U.S. Organ Procurement and Transplantation Network Act (P.L. 118-14) was enacted on September 22, 2023. This act amended the National Organ Transplant Act to provide the Secretary of HHS with flexibility in how awards are made to operate the OPTN. Rather than one contract to operate all functions of the OPTN, the amended statute authorizes multiple awards to carry out different functions of the OPTN. It also authorizes grants and cooperative agreements in addition to contracts. It also requires that the organization tasked with operating the board of directors be distinct from entities operating the OPTN. Finally, it removes a statutory requirement that the OPTN be operated by a nonprofit entity.[130]

Implementation Considerations

HRSA is in the midst of implementing changes to the OPTN contract authorized by the Securing the U.S. Organ Procurement and Transplantation Network Act. In 2024, HRSA established an independent OPTN board of directors and awarded a contract to support the newly incorporated board. HRSA also awarded a multi-vendor operations transition contract for critical OPTN functions. These critical functions include increasing patient safety, supporting IT modernization, improving OPTN policy development, communication, and financial management. Finally, HRSA has awarded additional contracts related to transplantation logistics and transportation, evaluating organ allocation policy, IT modernization strategy implementation, and program management. [131]

As this initiative is implemented, there are some considerations for Congress regarding resource needs and congressional oversight.

Resource Needs for the New System

HRSA requested additional funding and FTEs in the FY2024 budget request to implement the modernization initiative. While Congress passed the Securing the U.S. Organ Procurement and Transplantation Network Act in September 2023, and the act provided the authority to issue multi-vendor contracts, HRSA did not receive funds for its modernization initiative until FY2024 appropriations were enacted in March 2024—six months after the enactment.[132] HHS noted that implementation was contingent on final FY2024 appropriations: "The scope and scale of HRSA's awards under these new solicitations is contingent on final Fiscal Year 2024 appropriations. HRSA's Fiscal Year 2024 Budget proposes a $36 million increase over Fiscal Year 2023 to support these modernization efforts."[133]

HRSA again requested the additional funding and FTEs in the FY2025 budget request.[134]

It is unclear whether the delay in receiving resources needed to implement the initiative may have an impact on HRSA's implementation timeline. In addition, HRSA received less than requested

[130] For recent updates on HRSA's OPTN modernization initiative, see https://www.hrsa.gov/optn-modernization.

[131] Ibid.

[132] Labor, Health and Human Services, Education, and Related Agencies Appropriations Act, 2024 (Division D – Consolidated Appropriations Act, FY2024; P.L. 118-42).

[133] HHS Press Office, "Health Resources and Services Administration Takes Historic New Steps to Transform the Organ Transplant System to Better Serve Patients," press release, February 6, 2024, https://www.hhs.gov/about/news/2024/02/06/health-resources-and-services-administration-takes-historic-new-steps-transform-organ-transplant-system-better-serve-patients.html.

[134] HRSA, FY2025 Budget Justification, March 2024, p. 305, https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2025.pdf.

for the initiative. On March 29, 2024, HRSA extended the contract for UNOS to operate the OPTN for nine months (i.e., until December 29, 2024) with the option for two six-month extensions (i.e., until December 29, 2025).[135]

In the long-term, the modernization initiative may necessitate a new funding scheme for the OPTN. Under the previous one-contractor model, UNOS was paid a registration fee by transplant hospitals for each patient listed.[136] This fee, the OPTN fee, was the primary funding mechanism for administration of the OPTN. Under the new multi-vendor model there are considerations for how such a fee structure would be allocated to the various vendors or whether a different funding model would function better. As one policy option, a bill introduced in the 118th Congress, S. 5437, would have authorized the Secretary of HHS to collect registration fees from OPTN members.

Congressional Oversight of Implementation

The OPTN modernization initiative has the potential to transform the US organ transplantation system more than any change since enactment of the National Organ Transplant Act in 1984. The changes being made affect all aspects of the system—changes to organ allocation, the technology used to allocate organs, new administrators of the OPTN, among other changes. As this initiative is implemented, Congress's role in providing oversight becomes highlighted. There have been some concerns raised by professional organizations related to the timing of OPTN policy changes related to modernization.[137] As implementation proceeds and HRSA transitions functions of the OPTN to new vendors there is potential for disruption in the system that could impact quality and patient safety. Transfer of functions from UNOS to new vendors along with technology changes have the potential to disrupt the 24-hour functionality of the OPTN, which could result in lost organs or patient safety concerns.

OPO Performance Evaluation and Competition

The OPTN's role as a coordinating and operational standard-setting entity for OPOs will be key to ensure that a transfer of a DSA from one OPO to another OPO does not affect patient safety. (See **Appendix A** for a list of current OPOs and a map of OPO DSAs.)

Table 4. Tier 3 Organ Procurement Organizations (OPOs) Based on 2018 Donor and Transplant Rates

OPO Name	OPO Code	Tier 3 Donor Rate	Tier 3 Transplant Rate
Legacy of Hope—Alabama	ALOB		29.04
Mississippi Organ Recovery Agency	MSOP		28.21
Donor Alliance	CORS		29.26
Texas Organ Sharing Alliance	TXSA		28.57

[135] For more information, see https://unos.org/media-resources/releases/unos-and-hrsa-agree-on-new-short-term-optn-contract/.

[136] 42 C.F.R. §121.5.

[137] The OPTN proposed an amendment to the OPTN Bylaws to separate the OPTN board from the contractor's board—a requirement of the Securing the U.S. Organ Procurement and Transplantation Network Act (P.L. 118-14). The timing of the OPTN Bylaws change in consideration of the contracting timeline raised concerns among stakeholders. For more information, see American Society of Transplant Surgeons letter to HRSA, https://www.asts.org/docs/default-source/public-comments/asts-letter-to-hrsa-regarding-optn-and-unos-board-separation—february-26-2024.pdf?sfvrsn=88194ed3_3.

OPO Name	OPO Code	Tier 3 Donor Rate	Tier 3 Transplant Rate
Life Connection of Ohio	OHLC		27.26
Sharing Hope SC	SCOP		28.05
LiveOnNY	NYRT	8.5	
OneLegacy	CAOP	8.31	
Iowa Donor Network	IAOP	7.98	
LifeNet Health	VATB	7.97	27.65
Finger Lakes Donor Recovery Network	NYFL	7.8	26.16
Indian Donor Network	INOP	7.79	25.06
LifeCenter Organ Donor Network	OHOV		26.44
Arkansas Regional Organ Recovery Agency	AROR	7.06	25.8
Carolina Donor Services	NCNC	7.58	26.82
LifeQuest Organ Recovery Services	FLUF		26.55
Legacy of Life	HIOP		22.91
New Mexico Donor Services	NMOP		23.53
Kentucky Organ Donor Affiliates	KYDA	7.15	24.17
Life Alliance Organ Recovery Agency	FLMP	6.87	23.81
Mid-South Transplant Foundation	TNMS	6.66	18.94

Source: CRS analysis of CMS, Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations, Final Rule. 85 *Federal Register* 77898, December 2, 2020.

Note: Since this analysis was conducted and the rule was published, some OPOs have merged. Thus, the table reflects OPOs as of the publication of the final rule by CMS, December 2, 2020.

Payment and Delivery Reforms

Given the number of demonstration projects CMS is undertaking related to organ transplants and ESRD, *Congress may consider monitoring their progress and results to determine whether to adopt any payment and delivery reforms that appear effective through legislation.* (see "Demonstration Projects" for more detail about organ transplant-related demonstrations.) Congress may also consider creating new demonstration projects or modifying existing demonstrations through legislation.

Organs and Organ Cells Used for Research

Congress may consider monitoring implementation of regulations related to measuring OPO performance, specifically related to organs and organ cells used for research rather than for transplantation. Regulations allow OPOs to count pancreatic islet cells used for transplantation *or research* (emphasis) toward achieving Medicare performance thresholds.[138] (See "OPO Performance Evaluation and Competition" for an overview of Medicare's OPO performance

[138] 84 *Federal Register* 70631.

measures and implications for OPOs that do not meet performance thresholds.) Analysis shows differences in the volume of pancreatic islet cells collected pre- and post- the CMS final rule published in 2020 that allowed research-only pancreatic islet cells to count toward Medicare performance.[139] In a follow-up analysis, researchers found that tier-2 and tier-3 OPOs were over-represented in the group of OPOs that showed the greatest increase in pancreata procured for research.[140] CMS also noted these changes in its own analysis of procurement data and issued guidance to OPOs clarifying the definition of "donor," specifically as the definition relates to "the use of pancreata for islet cell research."[141] Given the new performance-based environment for OPOs, this raises questions about potentially creating unintended incentives for OPOs to increase research-only pancreatic islet cell donations, donations that do not ultimately get transplanted to patients. Thus, potentially unintentionally undermining the transplantation goals of the new regulations.

[139] David Goldberg, Darius Chyou, Rachael Wulf, Matthew Wadsworth, "Temporal Changes in Procurement of Pancreata for Research," *American Journal of Transplantation*, Volume 23, Issue 9, September 2023, Pages 1465-1467.

[140] David S. Goldberg, Darren D. Lahrman, Matthew Wadsworth, "Procurement of Pancreatic Tissue for Research From Deceased Donors Before vs After the CMS Final Rule in 2020," *JAMA Network Open*, 2023, 6(9):e2332395. doi:10.1001/jamanetworkopen.2023.32395.

[141] CMS, Organ Procurement Organization (OPO) Conditions for Coverage – Definition Clarification, Memorandum QSO-24-04-[OPO], January 18, 2024.

Appendix A. Organ Procurement Organizations and Donation Service Areas

Table A-1. States Served by Organ Procurement Organizations (OPOs)

OPO Code	OPO Name	States Served
ALOB	Legacy of Hope	Alabama, Georgia
AROR	Arkansas Regional Organ Recovery Agency	Arkansas
AZOB	Donor Network of Arizona	Arizona
CADN	Donor Network West	California, Nevada
CAGS	Sierra Donor Services	California
CAOP	OneLegacy	California
CASD	Lifesharing - A Donate Life Organization	California
CORS	Donor Alliance	Colorado, Wyoming
FLFH	OurLegacy	Florida
FLMP	Life Alliance Organ Recovery Agency	Florida
FLUF	LifeQuest Organ Recovery Services	Florida
FLWC	LifeLink of Florida	Florida
GALL	LifeLink of Georgia	Georgia, South Carolina
HIOP	Legacy of Life Hawaii	Hawaii
IAOP	Iowa Donor Network	Iowa
ILIP	Gift of Hope Organ & Tissue Donor Network	Illinois, Indiana, Iowa
INOP	Indiana Donor Network	Indiana, Kentucky
KYDA	Kentucky Organ Donor Affiliates	Indiana, Kentucky, Ohio, West Virginia
LAOP	Louisiana Organ Procurement Agency	Louisiana
MAOP	New England Organ Bank	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
MDPC	Infinite Legacy	District of Columbia, Maryland, Virginia
MIOP	Gift of Life Michigan	Michigan
MNOP	LifeSource Upper Midwest Organ Procurement Organization	Minnesota, North Dakota, South Dakota, Wisconsin
MOMA	Mid-America Transplant Services	Arkansas, Illinois, Missouri
MSOP	Mississippi Organ Recovery Agency	Mississippi
MWOB	Midwest Transplant Network	Kansas, Missouri
NCCM	LifeShare Carolinas	North Carolina, Tennessee
NCNC	HonorBridge	North Carolina, Virginia
NEOR	Live On Nebraska	Iowa, Nebraska
NJTO	New Jersey Organ and Tissue Sharing Network OPO	New Jersey

OPO Code	OPO Name	States Served
NMOP	New Mexico Donor Services	New Mexico
NVLV	Nevada Donor Network	Arizona, Nevada
NYAP	Center for Donation and Transplant	Massachusetts, New York, Vermont
NYFL	Finger Lakes Donor Recovery Netwok	New York
NYRT	LiveOnNY	New York, Pennsylvania
NYWN	Upstate New York Transplant Services Inc	New York
OHLB	Lifebanc	Ohio
OHLC	Life Connection of Ohio	Ohio
OHLP	Lifeline of Ohio	Ohio, West Virginia
OHOV	LifeCenter Organ Donor Network	Indiana, Kentucky, Ohio
OKOP	LifeShare Transplant Donor Services of Oklahoma	Oklahoma
ORUO	Cascade Life Alliance	Idaho, Oregon, Washington
PADV	Gift of Life Donor Program	Delaware, New Jersey, Pennsylvania
PATF	Center for Organ Recovery and Education	New York, Pennsylvania, Ohio, West Virginia
PRLL	LifeLink of Puerto Rico	Puerto Rico
SCOP	We Are Sharing Hope SC	South Carolina
TNDS	Tennessee Donor Services	Georgia, Kentucky, Tennessee, Virginia
TNMS	Mid-South Transplant Foundation	Arkansas, Mississippi, Tennessee
TXGC	LifeGift Organ Donation Center	Texas
TXSA	Texas Organ Sharing Alliance	Texas
TXSB	Southwest Transplant Alliance	Arkansas, Texas
UTOP	DonorConnect	Idaho, Nevada, Utah, Wyoming
VATB	LifeNet Health	Maryland, North Carolina, Virginia
WALC	LifeCenter Northwest	Alaska, Washington
WIDN	Versiti Wisconsin, Inc	Wisconsin
WIUW	UW Health Organ and Tissue Donation	Michigan, Wisconsin

Source: Scientific Registry of Transplant Recipients (SRTR) Organ Procurement Organization Statistics, OPO-specific reports (OSRs), https://www.srtr.org/reports/opo-specific-reports/interactive-report/.

Note: OPTN and SRTR data on OPOs and donation service areas (DSAs) do not always align due to a lag in reporting between the two organizations. For instance, LifeCenter Organ Donor Network and Kentucky Donor Affiliates merged into one OPO/DSA called Network for Hope effective October 1, 2024. This merger is not reflected in the SRTR data used to prepare this table. SRTR notes that this merger will be reflected in the OSRs of spring 2025 (expected July 2025).

Appendix B. Bills from the 118th Congress

Congress continues to consider bills pertaining to organ procurement and/or transplantation. Other bills considered by the 118th Congress include

- The Living Donor Protection Act (H.R. 2923; S. 1384), which would have prohibited insurance carriers from denying, cancelling, or imposing conditions on life, disability, or long-term care insurance policies based on status as a living organ donor;
- The Charlotte Woodward Organ Transplantation Discrimination Prevention Act (H.R. 2706; S. 1183), which would have prohibited entities involved in organ matching from denying or restricting a patient from receiving organs on the basis of a disability, unless an individual evaluation by a physician demonstrates that the disability would be medically significant to provision of the transplanted organ;
- Lost Opportunities to Supply Transplantable Organs Act of 2023, which would have required the OPTN to take specified actions related to tracking and publicly reporting the status of organs in the transplant supply chain;
- The Organ Donation Clarification Act of 2023 (H.R. 4343), which would have amended NOTA to "clarify the definition of valuable consideration, to clarify that pilot programs that honor and promote organ donation do not violate that Act, and for other purposes"[142]
- The Increase Support for Life-saving Endocrine Transplantation Act (ISLET Act; H.R. 4304; S. 2205), which would have regulated human cadaveric islets for transplantation as organs rather than as biological products.
- The Saving Organs One Flight at a Time Act (H.R. 4362), which would have required the Transportation Security Administration (TSA) and Federal Aviation Administration (FAA) to issue regulations to enable human organs to be transported in the cabin of an aircraft, and for TSA and FAA to consult with OPTN to identify metrics for the handling of organs by air carriers.
- The Living Organ Donor Tax Credit Act of 2023 (H.R. 6171) which would have amended the Internal Revenue Code (IRC) to establish a refundable tax credit to reimburse costs such as travel, lodging, and medical expenses for living organ or bone marrow donors.
- The End Kidney Deaths Act (H.R. 9275), which would have amended IRC and NOTA to establish a refundable tax credit for non-directed living kidney donations.
- The Honor Our Living Donors Act (H.R. 6020), which would have amended PHSA to "eliminate consideration of the income of organ recipients in providing reimbursement of expenses to donating individuals, and for other purposes."
- The Kidney Donation Anti-Discrimination Act (H.R. 9840), which would have prohibited life insurance providers from discriminating based on a person's status as a living kidney donor in the absence of evidence of increased actuarial risks.

[142] Valuable consideration refers to payment for an organ donation. It does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ. 42 U.S.C. §274e.

- The Organ Donation Referral Improvement Act (H.R. 9939), which would have directed the HHS Secretary to conduct a study on "existing efforts of hospitals with respect to electronic automated referrals for purposes of organ donation."

Appendix C. GAO and OIG Reports

This section contains two tables. **Table C-1** lists available Government Accountability Office (GAO) reports related to the Organ Procurement and Transplantation Network (OPTN) since its inception. **Table C-2** lists available U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) reports related to the OPTN since its inception.

Table C-1. GAO Reports Related to the OPTN and OPOs

Report	Report Number	Publication Date	Hyperlink
Federal Agency Major Rule Report: Department of Health and Human Services, Centers for Medicare and Medicaid Services: Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations	B-332771	January 14, 2021	https://www.gao.gov/products/b-332771
Organ Transplants: Changes in Allocation Policies for Donated Livers and Lungs	GAO-21-70	October 16, 2020	https://www.gao.gov/products/gao-21-70
Federal Agency Major Rule Report: Department of Health and Human Services, Centers for Medicare & Medicaid Services: Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs	B-331594	December 20, 2019	https://www.gao.gov/products/b-331594
VA Health Care: Additional Training Could Improve Organ Transplant Referral and Evaluation Processes	GAO-20-4	October 2, 2019	https://www.gao.gov/products/gao-20-4
Federal Agency Major Rule Report: Department of Health and Human Services, Centers for Medicare & Medicaid Services: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs	GAO-17-245R	December 15, 2016	https://www.gao.gov/products/gao-17-245r

Report	Report Number	Publication Date	Hyperlink
Federal Agency Major Rule Report: Department of Health and Human Services, Centers for Medicare & Medicaid Services: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals	GAO-14-253R	December 20, 2013	https://www.gao.gov/products/gao-14-253r
Organ Transplant Programs: Federal Agencies Have Acted to Improve Oversight, but Implementation Issues Remain	GAO-08-412	Apr 29, 2008	https://www.gao.gov/products/gao-08-412
Federal Agency Major Rule Report: Department of Health and Human Services, Centers for Medicare and Medicaid Services: Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs)	GAO-06-841R	Jun 14, 2006	https://www.gao.gov/products/gao-06-841r
Organ Transplants: Allocation Policies Include Special Protections for Children	GAO-01-498	September 28, 2001	https://www.gao.gov/products/gao-01-498
Organ Procurement and Transplantation Network: Legal Liability and Data Confidentiality	OGC-99-47R	May 3, 1999	https://www.gao.gov/products/ogc-99-47r
HCFA: Medicare and Medicaid Programs; Hospital Conditions of Participation; Identification of Potential Organ, Tissue, and Eye Donors and Transplant Hospitals' Provision of Transplant-Related Data	OGC-98-58	July 7, 1998	https://www.gao.gov/products/ogc-98-58

Report	Report Number	Publication Date	Hyperlink
Appropriations Decision: Department of Health and Human Services, Health Care Financing Administration: Medicare and Medicaid Programs; Hospital Conditions of Participation; Identification of Potential Organ, Tissue, and Eye Donors and Transplant Hospitals\' Provision of Transplant-Related Data, B-280432, July 7, 1998	B-280432	July 7, 1998	https://www.gao.gov/products/b-280432
Appropriations Decision: Department of Health and Human Services, Health Resources and Services Administration: Organ Procurement and Transplantation Network, B-279684, April 17, 1998	B-279684	Apr 17, 1998	https://www.gao.gov/products/b-279684
Health Resources and Services Administration: Organ Procurement and Transplantation Network	OGC-98-41	April 17, 1998	https://www.gao.gov/products/ogc-98-41
Organ Donation: Assessing Performance of Organ Procurement Organizations	T-HEHS-98-131	April 8, 1998	https://www.gao.gov/products/t-hehs-98-131
Correspondence: Impact of Organ Allocation Variances	HEHS-98-26	November 26, 1997	https://www.gao.gov/products/hehs-98-26
Correspondence: Immunosuppressant Drugs	HEHS-95-203R	July 31, 1995	https://www.gao.gov/products/hehs-95-203r
Organ Transplants: Increased Effort Needed to Boost Supply and Ensure Equitable Distribution of Organs	T-HRD-93-17	April 22, 1993	https://www.gao.gov/products/t-hrd-93-17
Organ Transplants: Increased Effort Needed to Boost Supply and Ensure Equitable Distribution of Organs	HRD-93-56	April 22, 1993	https://www.gao.gov/products/hrd-93-56
Heart Transplants: Concerns About Cost, Access, and Availability of Donor Organs	HRD-89-61	April 22, 1993	https://www.gao.gov/products/hrd-89-61

Source: Prepared by CRS based on search results of GAO resources.

Table C-2. HHS OIG Reports Related to the OPTN and OPOs

Report	Report Number	Publication Date	Hyperlink
The Health Resources and Services Administration Should Improve Its Oversight of the Cybersecurity of the Organ Procurement and Transplantation Network	A-18-21-11400	August 2022	https://oig.hhs.gov/documents/audit/6076/A-18-21-11400-Complete%20Report.pdf
Medicare Could Have Saved Millions if Organ Procurement Organizations Had Correctly Reported Procurement of Double Lungs as Two Organs	A-09-12-02085	December 2013	https://oig.hhs.gov/oas/reports/region9/91202085.asp
Medicare-Approved Heart Transplant Centers	OEI-01-02-00520	March 2004	https://oig.hhs.gov/oei/reports/oei-01-02-00520.pdf
Variation in Organ Donation Among Transplant Centers	OEI-01-02-00210	May 2003	https://oig.hhs.gov/oei/reports/oei-01-02-00210.pdf
Organ Donor Registries: A Useful, but Limited, Tool	OEI-01-01-00350	February 2002	https://oig.hhs.gov/oei/reports/oei-01-01-00350.pdf
Problems Pervade the Renal Beneficiary and Utilization System	OEI-07-01-00250	February 2002	https://oig.hhs.gov/oei/reports/oei-07-01-00250.pdf
Informed Consent in Tissue Donation: Expectations and Realities	OEI-01-00-00440	January 2001	https://oig.hhs.gov/oei/reports/oei-01-00-00440.pdf
Medicare Conditions of Participation for Organ Donation: An Early Assessment of the New Donation Rule	OEI-01-99-00020	August 2000	https://oig.hhs.gov/oei/reports/oei-01-99-00020.pdf
Fostering Equity in Patient Access to Transplantation: Local Access to Liver Transplantation	OEI-01-99-00470	August 1999	https://oig.hhs.gov/oei/reports/oei-01-99-00470.pdf
Fostering Equity in Patient Access to Transplantation: Differences in Waiting Times for Livers	OEI 01-99-00211	May 1999	https://oig.hhs.gov/oei/reports/oei-01-99-00210.pdf
Fostering Equity in Patient Access to Transplantation: Differences in Waiting Times for Kidneys	OEI 01-99-00211	May 1999	https://oig.hhs.gov/oei/reports/oei-01-99-00211.pdf
Racial and Geographic Disparity in the Distribution of Organs for Transplantation	OEI-01-98-00360	June 1998	https://oig.hhs.gov/oei/reports/oei-01-98-00360.pdf
Organ Procurement Organizations and Tissue Recovery	OEI-01-91-00250	May 1994	https://oig.hhs.gov/oei/reports/oei-01-91-00250.pdf
Addressing Increased Organ Acquisition Costs	OEI-01-88-01331	October 1991	https://oig.hhs.gov/oei/reports/oei-01-88-01331.pdf

Report	Report Number	Publication Date	Hyperlink
The Distribution of Organs for Transplantation: Expectations and Practices	OEI-01-89-00550	March 1991	https://oig.hhs.gov/oei/reports/oei-01-89-00550.pdf
Organ Acquisition Costs	OAI-01-86-00108	September 1987	https://oig.hhs.gov/oei/reports/oai-01-86-00108.pdf
The Access of Dialysis Patients to Kidney Transplantation	OAI-01-86-00107	March 1987	https://oig.hhs.gov/oei/reports/oai-01-86-00107.pdf
The Access of Foreign Nationals to U.S. Cadaver Organs	OAI-01-86-00074	August 1986	https://oig.hhs.gov/oei/reports/oai-01-86-00074.pdf

Source: Prepared by CRS based on search of HHS OIG resources.

Appendix D. Brief History of UNOS

The precursor to UNOS was established as the South-Eastern Regional Organ Procurement Program (SEROPP) at the Medical College of Virginia in 1969.[143] The organization functioned in a similar manner to the future OPOs—facilitating kidney sharing among multiple transplant centers. This was at a time when there was no national network to facilitate these activities. In 1969, SEROPP was awarded a federal contract for $153,000 to develop an organ procurement and sharing network.[144]

By 1974, SEROPP had grown to an extent that it could no longer be administered at the Medical College of Virginia. In 1975, it was transformed to the South-Eastern Organ Procurement Foundation (SEOPF), which was incorporated as an independent not-for-profit organization. SEOPF began with 18 transplant centers. In the same year, SEOPF purchased a computer and developed a computerized system for matching and sharing organs.[145]

By 1977, non-affiliated transplant centers requested to use the computer system to register potential transplant recipients and share organs. The system became available to any transplant center who wished to share organs.[146] The system included transplant candidates from at least 28 states representing 145 million people. SEOPF renamed the computer system the "United Network for Organ Sharing." By 1982, the UNOS computer system grew to be a nearly national candidate registry. UNOS was linked with 144 of the 159 kidney transplant centers in existence at the time.[147]

In 1982, SEOPF launched a call center to provide assistance with organ placement. The call center was called the "Kidney Center" at the time and operated a 24-hour service to match kidneys that could not be matched locally. This call center, now called the "Organ Center" has continuously operated since.

On March 21, 1984, seven months before the enactment of NOTA, UNOS branched off from SEOPF. UNOS incorporated as a private nonprofit organization with its primary components being the computerized national recipient registry and placement coordination through the Organ Center.

[143] Richard. J. Howard, Danielle L. Cornell, and Larry Cochran, "History of deceased organ donation, transplantation, and organ procurement organizations," *Progress in Transplantation*, vol. 22, no. 1 (March 2012).

[144] Ibid.

[145] Ibid.

[146] U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Health and Environment, *Statement of the Executive Committee of the SEOPF*, Hearing on H.R. 4080, 98th Cong., 1st sess., 1983, Serial No. 98-70, p. 212.

[147] U.S. Congress, House Committee on Ways and Means, Subcommittee on Health, *National Organ Transplant Act*, Hearing on H.R. 4080, 98th Cong., 2nd sess., February 9, 1984, Serial 98-64, p. 67.

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