

## **The Organ Transplant System Improvement Act - Discussion Draft Section by Section**

In August 2022, the Senate Finance Committee held a hearing entitled “[\*A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network\*](#),” which addressed serious concerns raised by Finance Committee investigators regarding national organ transplantation. That hearing and related investigation led to the passage of [the Securing the U.S. Organ Procurement and Transplantation Act](#) on a wide bipartisan basis in 2023, legislation to modernize the Organ Procurement and Transplantation Network (OPTN). This legislation builds on that momentum in the organ transplant system by cracking down on bad actors and persistent conflicts of interest.

### **TITLE I - ENSURING SAFETY AND FAIRNESS IN THE ORGAN DONATION SYSTEM**

**Section 101. Ensuring standardization requirements.** This section creates a civil monetary penalty for Organ Procurement Organizations and hospitals that are members of the OPTN but are found not to be in compliance with established OPTN policies. This section also addresses inconsistencies in the U.S. Code between the Social Security Act (SSA) and the Public Health Services Act (PHSA). Previously, various sections of the SSA and PHSA referred to the non-profits which carry out organ procurement and transplantation in the U.S as “Organ Procurement Organizations” (OPOs) or as “Organ Procurement Agencies.” This section changes all references to these entities to “Organ Procurement Organizations.”

**Section 102. HIPAA compliance.** This section ensures protection of patient privacy during evaluation of potential organ donors and organ procurement by requiring that OPOs comply with the Health Insurance Portability and Accountability Act (HIPAA) through business associate contracts with each hospital in the OPO’s Designated Service Area (DSA).

**Section 103. Requiring clear protocol standards in organ donation recovery proceedings.** This section requires OPOs to develop, implement, and train staff on written policies regarding patient safety. This section also requires hospitals to educate their staff members that any hospital or OPO staff can pause organ procurement if there is any clinical sign of life and initiate a reevaluation of organ donor eligibility.

**Section 104. Organ Recovery Centers.** This section provides that requirements for Medicare and Medicaid OPO coverage apply whether organ recovery occurs in a donor hospital setting or an Organ Recovery Center (ORC) operated by an OPO. Currently, OPOs must meet stringent requirements under the SSA to legally perform organ procurement and be reimbursed under Medicare or Medicaid. However, OPOs across the country have developed ORCs. These on or off-site OPO-controlled facilities often perform traditional OPO functions, such as organ procurement and preparation for organ shipment to transplant centers. This provision would

mandate that the same requirements that OPOs must meet under the SSA are also applied to any ORCs run by an OPO. The provision further stipulates that when the Secretary of Health and Human Services (HHS) performs their statutory evaluation of OPOs for compliance, the Secretary also evaluates any ORCs contemporaneously for compliance.

**Section 105. Regulations regarding Organ Recovery Centers.** This section requires the Secretary to promulgate regulations for the safe operation of ORCs and clarifies the reimbursement structure for organs procured at an ORC.

**Section 106. Intra-agency coordination.** This section requires agencies within HHS, such as Centers for Medicare and Medicaid Services (CMS) and Health Resources and Services Administration (HRSA), to coordinate on improvements to the organ transplant system. The Coordinating Committee tasked with facilitating interagency coordination will be responsible for submitting a biennial action plan to authorizing Congressional Committees.

## **TITLE II - STRENGTHENING THE QUALITY OF ORGAN PROCUREMENT ORGANIZATIONS**

**Section 201. Allowing new Organ Procurement Organizations.** The section provides the Secretary with the authority to certify new organizations that meet requirements for operating an OPO to serve as an OPO and be awarded a Designated Service Area in which to provide organ procurement services.

**Section 202. Clarifying timelines for certification and recertification.** This section clarifies the timeline for recertification of OPOs. OPOs are required to be recertified every 2 years; however, this section allows the Secretary to designate certain high-performing OPOs to be moved to a 4-year cycle for certification if appropriate. This section also permits the HHS Secretary to decertify an OPO outside of the certification cycle (i.e., before the OPO is due to be recertified). The Secretary is required to formulate and publish a transition plan for the DSA that the decertified OPO was covering. This plan would address how coverage for care in that area would be handled while the decertified OPO is winding down and the newly designated OPO for that DSA begins operation.

**Section 203. Clarification regarding research.** This section addresses a loophole within CMS regulations that OPOs have been abusing in recent years. Previously, the vague nature of the CMS regulation allowed OPOs to count pancreata procured for research as a procured organ for the purpose of the metrics that CMS uses to evaluate OPOs. This was an overly broad interpretation of a statutory requirement intended to encourage OPO facilitation of research on pancreatic islet cell transplantation, which is a potential treatment for Type 1 Diabetes. Many OPOs failed to evaluate or solicit research protocols from the entities to which they were sending pancreata to; therefore, it was impossible to evaluate whether pancreata were being used specifically for “islet cell transplantation research” as was the intent of statute. This section

mandates that any pancreas procured for research may only count as an organ procured under CMS metrics if such research is done under the standard federal requirements for sound scientific and medical studies found at 21 C.F.R. 58.120.

**Section 204. Conflicts of interest regarding Organ Procurement Organizations.** This section further reinforces government oversight by requiring the Secretary to promulgate regulations clarifying the requirements and expectations regarding conflicts of interest for OPOs. All OPOs will be required to establish conflict of interest policies that cover the scope and extent of actual and perceived conflicts of interest.

**Section 205. Funding for certification and recertification of Organ Procurement Organizations.** This section increases funding for the activities related to certifying and recertifying OPOs.

**Section 206. Conforming amendments.** This section aligns language in the PHSA with language in the SSA.

### **TITLE III - ENHANCING THE SECURING THE US OPTN ACT**

**Section 301. OPTN Board of Directors operations and duties.** The Securing the US OPTN Act made amendments to make clear that HHS has the authority to award multiple contracts to facilitate the various OPTN functions and to make clear that the OPTN Board of Directors operates independently of OPTN contractors. This section further clarifies the OPTN Board of Directors' responsibilities pertaining to establishment of OPTN membership criteria and policies describing medical criteria for allocating organs. This section also clarifies that the OPTN Board of Directors is not responsible for other OPTN functions, including IT systems, monitoring patient safety complaints and cases, and policy compliance, carried out by OPTN contractors. This section makes clear that the OPTN Board of Directors must make recommendations to the HHS Secretary as to which OPTN Board policies should be incorporated into regulation and made enforceable by the Secretary.

**Section 302. OPTN Board of Directors conflicts of interest.** This section further reinforces government oversight by requiring the OPTN to establish policies clarifying the requirements and expectations regarding conflicts of interest for members of the OPTN Board of Directors. The OPTN will be required to establish conflict of interest policies that cover the scope and extent of actual and perceived conflicts of interest. These policies include reporting requirements that will allow for future audits of any reported conflicts.

**Section 303. Organ Transplant Safety Taskforce.** This section strengthens oversight of the transplant network by creating a new entity called the Organ Transplant Safety Taskforce (OTST). This Taskforce will be distinct from the OPTN Board of Directors, will be operated under contract with HHS, and will be responsible for oversight compliance with OPTN policies,

the operating requirements of 42 CFR 121, and review of patient safety complaints and cases. This section tasks the HHS Secretary with establishing regulations for the operation of the OTST. These regulations regard monitoring the network for health and safety risks to patients, providing an appeals process for OPTN members found to be in noncompliance, and imposing sanctions for a finding of noncompliance. No individual may be a member of both the OPTN Board of Directors and the OTST. The OTST is intended to replace the current operations performed by the Membership and Professional Standards Committee.

**Section 304. Permanent OPTN Fee Authority Act.** This section provides the HHS Secretary authority to directly and permanently collect the fees that transplant hospitals pay each time they add a patient to the national organ waitlist. These fees are then used for the operation of the OPTN functions. Previously, only the United Network for Organ Sharing (UNOS) had the authority to collect these fees. The HHS Secretary would then be required to promptly post the amount of fees collected on the OPTN webpage for each quarter. Within 2 years of enactment of this section, the Government Accountability Office will be required to conduct a review of this fee collection and submit a report to the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate and the Committee on Energy and Commerce of the House of Representatives describing its review and any recommendations.

**Section 305. Ownership of OPTN source code and data.** This section extends the requirements of the SHARE IT Act to any software developed to operate the OPTN. This section mandates that, within 180 days of passage, the HHS Secretary must take steps to acquire HHS ownership of the underlying code that runs the software. It clarifies that any data or data sets created by the OPTN are the property of the Federal government. The Secretary is also tasked with making that data publicly available on HHS webpages, so long as it omits personally identifiable information. For data not made publicly available, entities with research or analysis purposes may request access to data or a data set and be granted access within 30 days of their request.