118TH CONGRESS
*1st Session*
HOUSE OF REPRESENTATIVES
REPORT
118–140

# SECURING THE U.S. ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK ACT

JULY 11, 2023.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mrs. RODGERS of Washington, from the Committee on Energy and Commerce, submitted the following

# R E P O R T

[To accompany H.R. 2544]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 2544) to improve the Organ Procurement and Transplantation Network, and for other purposes, having considered the same, reports favorably thereon without amendment and recommends that the bill do pass.

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## PURPOSE AND SUMMARY

H.R. 2544, the "Securing the U.S. Organ Procurement and Transplantation Network Act." introduced by Representatives Larry Bucshon (R–IN) and Robin Kelly (D–IL), amends the Public

Health Service Act to allow for competition within the Organ Procurement and Transplantation Network (OPTN) contract process. The legislation also makes technical changes and requires the Comptroller General to conduct a review of the OPTN and submit its findings to the House Energy and Commerce Committee and the Senate Health, Education, Labor, and Pensions committee.

## BACKGROUND AND NEED FOR LEGISLATION

Close to 104,000 people are on the national organ transplant wait list.[1] Around 41,000 patients in need of an organ received a transplant from either a living or deceased donor in 2022, which is just a fraction of the total organ transplant waitlist.[2] The National Academy of Sciences issued a report in 2022 that found that the current U.S. organ transplant system is demonstrably inequitable, with wide variation in performance across the system.[3] The report found that approximately one in five kidneys from deceased donors are not used, and at least 17 people a day die waiting for an organ transplant.

In the U.S., procurement of organs from deceased donors for transplantation is done by organ procurement organizations (OPOs). OPOs are responsible for working with donor hospitals to identify opportunities for organ donation, working with donor families to obtain consent for organ donation, when necessary, conducting testing to identify potential for disease transmission or other safety issues, and safely procuring and transporting all transplantable organs based on OPTN policies.[4] There are currently 57 OPOs with each assigned to their own donation service area (DSA). The Social Security Act requires than an OPO be a member of the OPTN, a membership organization that links all professionals in the U.S. organ donation and transplantation system. The OPTN is responsible for governing how deceased donor organs are allocated to individuals on the waiting list.

A single contractor has operated the OPTN since it was created, and there has been little to no competition for the contract. This has stifled innovation and hindered efforts to increase equity in organ allocation, according to a review by the U.S. Digital Service.[5] Additionally, this contractor has been the subject of Congressional investigations and allegations from patients, families, transplant centers, and others, of consistent mismanagement, lack of technical expertise, failure to provide adequate oversight of OPOs, and risks to patient safety.[6] In fact, the Centers for Medicare and Medicaid Services (CMS) has estimated that if OPOs increased their performance, approximately 5,6000 more organs per year could be transplanted.[7]

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[1] Organ Procurement and Transplantation Network Modernization Initiative, Health Resources and Service Administration (HRSA).

[2] Id.

[3] National Academies of Sciences, Engineering, and Medicine, *Realizing the Promise of Equity in the Organ Transplantation System,* (Feb. 2022).

[4] U.S. Centers for Medicare and Medicaid Services, *Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS–3380–F,* (Nov. 20, 2020).

[5] The Washington Post, *Thousands of Lives Depend on a Transplant Network in Need of "Vast Restructuring,"* (July 31, 2022).

[6] Senate Finance Committee, Memo on "A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network," (Aug. 3, 2022).

[7] Id.

The management of the organ transplant system in the U.S. needs reform. H.R. 2544 is necessary to increase competition within the OPTN with the ultimate goal of improving OPO performance and patient outcomes.

## COMMITTEE ACTION

On April 19, 2023, the Subcommittee on Health held a hearing on H.R. 2544. The Subcommittee received testimony from:

- Carole Johnson, Administrator, Health Resources and Services Administration

On May 17, 2023, the Subcommittee on Health met in open markup session and forwarded H.R. 2544, without amendment, to the full Committee by a record vote of 28 yeas and 0 nays. On May 24, 2023, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 2544, without amendment, favorably reported to the House by a record vote of 49 yeas and 0 nays.

## COMMITTEE VOTES

Clause 3(b) of rule XIII requires the Committee to list the record votes on the motion to report legislation and amendments thereto. The following reflects the record votes taken during the Committee consideration:

**COMMITTEE ON ENERGY AND COMMERCE**
**118TH CONGRESS**
**ROLL CALL VOTE # 2**

**BILL:** H.R. 2544, the Securing the U.S. Organ Procurement and Transplantation Network Act

**AMENDMENT:** A motion by Chair Rodgers to order H.R. 2544 favorably reported to the House, as amended. (Final Passage)

**DISPOSITION: AGREED TO,** by a roll call vote of 49 yeas and 0 nays.

| REPRESENTATIVE | YEAS | NAYS | PRESENT | REPRESENTATIVE | YEAS | NAYS | PRESENT |
|---|---|---|---|---|---|---|---|
| Rep. Rodgers | X | | | Rep. Pallone | X | | |
| Rep. Burgess | X | | | Rep. Eshoo | X | | |
| Rep. Latta | X | | | Rep. DeGette | X | | |
| Rep. Guthrie | X | | | Rep. Schakowsky | X | | |
| Rep. Griffith | X | | | Rep. Matsui | X | | |
| Rep. Bilirakis | X | | | Rep. Castor | X | | |
| Rep. Johnson | X | | | Rep. Sarbanes | | | |
| Rep. Bucshon | X | | | Rep. Tonko | X | | |
| Rep. Hudson | X | | | Rep. Clarke | X | | |
| Rep. Walberg | X | | | Rep. Cárdenas | X | | |
| Rep. Carter | X | | | Rep. Ruiz | X | | |
| Rep. Duncan | X | | | Rep. Peters | X | | |
| Rep. Palmer | X | | | Rep. Dingell | X | | |
| Rep. Dunn | X | | | Rep. Veasey | X | | |
| Rep. Curtis | X | | | Rep. Kuster | X | | |
| Rep. Lesko | X | | | Rep. Kelly | X | | |
| Rep. Pence | X | | | Rep. Barragán | | | |
| Rep. Crenshaw | X | | | Rep. Blunt Rochester | X | | |
| Rep. Joyce | X | | | Rep. Soto | X | | |
| Rep. Armstrong | X | | | Rep. Craig | X | | |
| Rep. Weber | X | | | Rep. Schrier | X | | |
| Rep. Allen | X | | | Rep. Trahan | X | | |
| Rep. Balderson | X | | | Rep. Fletcher | X | | |
| Rep. Fulcher | X | | | | | | |
| Rep. Pfluger | X | | | | | | |
| Rep. Harshbarger | X | | | | | | |
| Rep. Miller-Meeks | X | | | | | | |
| Rep. Cammack | X | | | | | | |
| Rep. Obernolte | | | | | | | |

05/24/2023

## OVERSIGHT FINDINGS AND RECOMMENDATIONS

Pursuant to clause 2(b)(1) of rule X and clause 3(c)(1) of rule XIII, the Committee held a hearing and made findings that are reflected in this report.

## NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to clause 3(c)(2) of rule XIII, the Committee finds that H.R. 2544 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

## CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII, at the time this report was filed, the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974 was not available.

## FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

## STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to allow for competition within the OPTN contracting process to improve the United States' organ transplantation system and improve health outcomes for patients.

## DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 2544 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111–139 or the most recent Catalog of Federal Domestic Assistance.

## RELATED COMMITTEE AND SUBCOMMITTEE HEARINGS

Pursuant to clause 3(c)(6) of rule XIII, the following related hearing was used to develop or consider H.R. 2544: "Examining Existing Federal Programs to Build a Stronger Health Workforce and Improve Primary Care," held on April 19, 2023. Witness was HRSA Administrator, Carole Johnson.

## COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974. At the time this report was filed, the estimate was not available.

## EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 2544 contains no earmarks, limited tax benefits, or limited tariff benefits.

## ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

## APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

## SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

*Section 1. Short title*

Section 1 provides the short title of "Securing the U.S. Organ Procurement and Transplantation Network Act."

*Section 2. Organ procurement and transplantation network*

Section 2 amends section 372 of the Public Health Service Act (PHSA) to clarify HRSA's authority to award grants, contracts, or cooperative agreements, as the Secretary determines appropriate, for the purpose of carrying out the functions of the OPTN. The section also requires that the OPTN contacting process to be competitive and to be operated through awards to public or private entities made by the Secretary that are distinct from the awards made to support the organization tasked with supporting the board of directors.

*Section 3. Technical amendments*

Section 3 makes technical changes to Title III of the PHSA.

*Section 4. GAO review*

Section 4 requires the Comptroller General to conduct a review of the historical financing of OPTN, including the utilization of registration fees among entities that have previously been awarded contracts; and to report its finding and recommendations to Congress.

## CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, and existing law in which no change is proposed is shown in roman):

## PUBLIC HEALTH SERVICE ACT

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# TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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## PART H—ORGAN TRANSPLANTS

### ORGAN PROCUREMENT ORGANIZATIONS

SEC. 371. (a)(1) The Secretary may make grants for the planning of qualified organ procurement organizations described in subsection (b).

(2) The Secretary may make grants for the establishment, initial operation, consolidation, and expansion of qualified organ procurement organizations described in subsection (b).

(b)(1) A qualified organ procurement organization for which grants may be made under subsection (a) is an organization which, as determined by the Secretary, will carry out the functions described in paragraph (2) and—

(A) is a nonprofit entity,

(B) has accounting and other fiscal procedures (as specified by the Secretary) necessary to assure the fiscal stability of the organization,

(C) has an agreement with the Secretary to be reimbursed under title XVIII of the Social Security Act for the procurement of kidneys,

(D) notwithstanding any other provision of law, has met the other requirements of this section and has been certified or recertified by the Secretary within the previous 4-year period as meeting the performance standards to be a qualified organ procurement organization through a process that either—

(i) granted certification or recertification within such 4-year period with such certification or recertification in effect as of January 1, 2000, and remaining in effect through the earlier of—

(I) January 1, 2002; or

(II) the completion of recertification under the requirements of clause (ii); or

(ii) is defined through regulations that are promulgated by the Secretary by not later than January 1, 2002, that—

(I) require recertifications of qualified organ procurement organizations not more frequently than once every 4 years;

(II) rely on outcome and process performance measures that are based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified organ procurement organizations;

(III) use multiple outcome measures as part of the certification process; and

(IV) provide for a qualified organ procurement organization to appeal a decertification to the Secretary on substantive and procedural grounds;

(E) has procedures to obtain payment for non-renal organs provided to transplant centers,

(F) has a defined service area that is of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs, and that either includes an entire metropolitan statistical area (as specified by the Director of the Office of Management and Budget) or does not include any part of the area,

(G) has a director and such other staff, including the organ donation coordinators and organ procurement specialists necessary to effectively obtain organs from donors in its service area, and

(H) has a board of directors or an advisory board which—

(i) is composed of—

(I) members who represent hospital administrators, intensive care or emergency room personnel, tissue banks, and voluntary health associations in its service area,

(II) members who represent the public residing in such area,

(III) a physician with knowledge, experience, or skill in the field of [histocompatability] *histocompatibility* or an individual with a doctorate degree in a biological science with knowledge, experience, or skill in the field of histocompatibility,

(IV) a physician with knowledge or skill in the field of neurology, and

(V) from each transplant center in its service area which has arrangements described in paragraph (3)(G) with the organization, a member who is a surgeon who has practicing privileges in such center and who performs organ transplant surgery,

(ii) has the authority to recommend policies for the procurement of organs and the other functions described in paragraph (3), and

(iii) has no authority over any other activity of the organization.

(2)(A) Not later than 90 days after the date of the enactment of this paragraph, the Secretary shall publish in the Federal Register a notice of proposed rulemaking to establish criteria for determining whether an entity meets the requirement established in paragraph (1)(E).

(B) Not later than 1 year after the date of enactment of this paragraph, the Secretary shall publish in the Federal Register a final rule to establish the criteria described in subparagraph (A).

(3) An organ procurement organization shall—

(A) have effective agreements, to identify potential organ donors, with a substantial majority of the hospitals and other health care entities in its service area which have facilities for organ donations,

(B) conduct and participate in systematic efforts, including professional education, to acquire all usable organs from potential donors,

(C) arrange for the acquisition and preservation of donated organs and provide quality standards for the acquisition of organs which are consistent with the standards adopted by the Organ Procurement and Transplantation Network under sec-

tion 372(b)(2)(E), including arranging for testing with respect to identifying organs that are infected with human immunodeficiency virus (HIV),

(D) arrange for the appropriate tissue typing of donated organs,

(E) have a system to allocate donated organs equitably among transplant patients according to established medical criteria,

(F) provide or arrange for the transportation of donated organs to transplant centers,

(G) have arrangements to coordinate its activities with transplant centers in its service area,

(H) participate in the Organ Procurement Transplantation Network established under section 372,

(I) have arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all usable tissues are obtained from potential donors,

(J) evaluate annually the effectiveness of the organization in acquiring potentially available organs, and

(K) assist hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors.

(c) Pancreata procured by an organ procurement organization and used for islet cell transplantation or research shall be counted for purposes of certification or recertification under subsection (b).

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ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

SEC. 372. (a) [The Secretary shall by contract] *IN GENERAL—The Secretary shall* provide for the [establishment and] *continued* operation of an Organ Procurement and Transplantation Network which meets the requirements of subsection (b). [The amount provided under such contract in any fiscal year may not exceed $7,000,000. Funds for such contracts shall be made available from funds available to the Public Health Service from appropriations for fiscal years beginning after fiscal year 1984.] *The Secretary may award grants, contracts, or cooperative agreements, as the Secretary determines appropriate, for purposes of carrying out this section.*

(b) *COMPOSITION.*—[(1) THE ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK SHALL CARRY OUT THE FUNCTIONS DESCRIBED IN PARAGRAPH (2) AND SHALL—]

[(A) be a private nonprofit entity that has an expertise in organ procurement and transplantation, and]

*(1) IN GENERAL.—The Organ Procurement and Transplantation Network shall—*

*(A) be operated through awards to public or private entities made by the Secretary that are distinct from the awards made to support the organization tasked with supporting the board of directors described in subparagraph (B); and*

(B) have a board of directors—

(i) that includes representatives of organ procurement organizations (including organizations that have received grants under section 371), transplant centers, voluntary health associations, and the general public; and

(ii) that shall establish an executive committee and other committees, whose chairpersons shall be selected to ensure continuity of leadership for the board.

(2) The Organ Procurement and Transplantation Network shall—

(A) establish in one location or through regional centers—

(i) a national list of individuals who need organs, and

(ii) a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list, especially individuals whose immune system makes it difficult for them to receive organs,

(B) establish membership criteria and medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria,

(C) maintain a twenty-four-hour telephone service to facilitate matching organs with individuals included in the list,

(D) assist organ procurement organizations in the nationwide distribution of organs equitably among transplant patients,

(E) adopt and use standards of quality for the acquisition and transportation of donated organs,

(F) prepare and distribute, on a regionalized basis (and, to the extent practicable, among regions or on a national basis), samples of blood sera from individuals who are included on the list and whose immune system makes it difficult for them to receive organs, in order to facilitate matching the compatibility of such individuals with organ donors,

(G) coordinate, as appropriate, the transportation of organs from organ procurement organizations to transplant centers,

(H) provide information to physicians and other health professionals regarding organ donation,

(I) collect, analyze, and publish data concerning organ donation and transplants,

(J) carry out studies and demonstration projects for the purpose of improving procedures for organ procurement and allocation,

(K) work actively to increase the supply of donated organs,

(L) submit to the Secretary an annual report containing information on the comparative costs and patient outcomes at each transplant center affiliated with the organ procurement and transplantation network,

(M) recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, polices, and procedures that address the unique health care needs of children,

(N) carry out studies and demonstration projects for the purpose of improving procedures for organ donation procurement and allocation, including but not limited to projects to examine and attempt to increase transplantation among populations with special needs, including children and individuals who are

members of racial or ethnic minority groups, and among populations with limited access to transportation, and

(O) provide that for purposes of this paragraph, the term "children" refers to individuals who are under the age of 18.

(3) CLARIFICATION.—In adopting and using standards of quality under paragraph (2)(E), the Organ Procurement and Transplantation Network may adopt and use such standards with respect to organs infected with human immunodeficiency virus (in this paragraph referred to as "HIV"), provided that any such standards ensure that organs infected with HIV may be transplanted only into individuals who—

(A) are infected with HIV before receiving such organ; and

(B)(i) are participating in clinical research approved by an institutional review board under the criteria, standards, and regulations described in subsections (a) and (b) of section 377E; or

(ii) if the Secretary has determined under section 377E(c) that participation in such clinical research, as a requirement for such transplants, is no longer warranted, are receiving a transplant under the standards and regulations under section 377E(c).

(c) The Secretary shall establish procedures for—

(1) receiving from interested persons critical comments relating to the manner in which the Organ Procurement and Transplantation Network is carrying out the duties of the Network under subsection (b); and

(2) the consideration by the Secretary of such critical comments.

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GENERAL PROVISIONS RESPECTING GRANTS AND CONTRACTS

SEC. 374. (a) No grant may be made under this part or contract entered into under section 372 or 373 unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be in such form and shall be submitted in such manner as the Secretary shall by regulation prescribe.

(b)(1) A grant for planning under section 371(a)(1) may be made for one year with respect to any organ procurement organization and may not exceed $100,000.

(2) Grants under section 371(a)(2) may be made for two years. No such grant may exceed $500,000 for any year and no organ procurement organization may receive more than $800,000 for initial operation or expansion.

(3) Grants or contracts under section 371(a)(3) may be made for not more than 3 years.

(c)(1) The Secretary shall determine the amount of a grant or contract made under section 371 or 373. Payments under such grants and contracts may be made in advance on the basis of estimates or by the way of reimbursement, with necessary adjustments on account of underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants and contracts.

(2)(A) Each recipient of a grant or contract under [section 371 or 373] *section 371, 372, or 373* shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant or contract, the total cost of the undertaking in connection with which such grant or contract was made, and the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(B) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of a grant or contract under [section 371 or 373] *section 371, 372, or 373* that are pertinent to such grant or contract.

(d) For purposes of this part:

(1) The term "transplant center" means a health care facility in which transplants of organs are performed.

(2) The term "organ" means the human kidney, liver, heart, lung, pancreas, and any other human organ (other than corneas and eyes) specified by the Secretary by regulation and for purposes of section 373, such term includes bone marrow.

ADMINISTRATION

SEC. 375. The Secretary shall designate and maintain an identifiable administrative unit in the Public Health Service to—

(1) administer this part and coordinate with the organ procurement activities under title XVIII of the Social Security Act[,]*;*

(2) conduct a program of public information to inform the public of the need for organ donations[,]*;*

(3) provide technical assistance to organ procurement organizations, the Organ Procurement and Transplantation Network established under section 372, and other entities in the health care system involved in organ donations, procurement, and [transplants, and] *transplants; and*

(4) provide information—

[(i)] *(A)* to patients, their families, and their physicians about transplantation; and

[(ii)] *(B)* to patients and their families about the resources available nationally and in each State, and the comparative costs and patient outcomes at each transplant center affiliated with the organ procurement and transplantation network, in order to assist the patients and families with the costs associated with transplantation.

REPORT

SEC. 376. Not later than [February 10 of 1991 and of each second year thereafter] *2 years after the date of enactment of the Securing the U.S. Organ Procurement and Transplantation Network Act and every second year thereafter*, the Secretary shall publish, and submit to the Committee on Energy and Commerce of the House of Representatives and the [Committee on Labor and Human Resources of the Senate.] *Committee on Health, Education,*

*Labor, and Pensions of the Senate,* a report on the scientific and clinical status of organ transplantation. The Secretary shall consult with the Director of the National Institutes of Health and the Commissioner of the Food and Drug Administration in the preparation of the report.

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