

June 30, 2023

The Honorable Ron Wyden
Chair
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Charles Grassley
Member
Senate Committee on Finance
135 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Bernard Sanders
Chair
Senate Committee on Health, Education,
Labor and Pensions
428 Senate Dirksen Office Building
Washington, D.C. 20510

The Honorable Bill Cassidy, M.D.
Ranking Member
Senate Committee on Health, Education,
Labor and Pensions
428 Senate Dirksen Office Building
Washington, D.C. 20510

VIA ELECTRONIC MAIL

Dear Senators Wyden, Grassley, Sanders, and Cassidy,

I write to thank you for your work and interest in improving the organ donation and transplant system. As you know, the United Network for Organ Sharing (UNOS) is the mission-driven, non-profit organization that serves as the nation's organ donation and transplant system—the Organ Procurement and Transplantation Network (OPTN)—under contract with and oversight by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS). We are committed to working with policymakers to help ensure that the United States continues to be the leader in successful organ donation and transplantation.

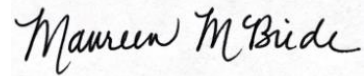
UNOS has always welcomed competition for the contract for the organ donation and transplant system and continues to do so. Therefore, we do not oppose S. 1668, *Securing the U.S. Organ Procurement and Transplantation Network Act*.

Given our intimate knowledge of the OPTN, UNOS respectfully suggests two technical edits to the legislation. We understand the intent of the legislation is to continue to have the governance of the system led by a private, nonprofit entity while other contract functions may be fulfilled by for-profit vendors. However, to ensure the intent of a nonprofit being responsible for the governance of the system, we believe clarifying language is needed. Given the complexity of the organ donation and transplant system, we also feel it is important that the entities eligible for the contract awards include those that have relevant expertise in the donation and transplant community.

The attached document includes the amendments, a redline of the changes to the legislation, and a redline of the bill's changes to the underlying statute with UNOS' amendments highlighted. This language would not in any way eliminate the competition sought by sponsors.

We sincerely appreciate the engagement with your offices, and we are ready to be a resource as Congress continues to evaluate ways to improve the organ donation and transplantation system.

Sincerely,

A handwritten signature in black ink that reads "Maureen McBride". The signature is written in a cursive style and is positioned above a light gray rectangular background.

Maureen McBride, Ph.D.
Chief Executive Officer, United Network for Organ Sharing

Enclosure:
Amendments to Securing the U.S. Organ Procurement and Transplantation Network Act

Recommended Amendments:

add in Section 2 (2)(b)(1)(A) behind “public or private entities” new language: "including those that have an expertise in organ procurement and transplantation"

add in Section 2:

(3) in subparagraph (N) of paragraph (2) by striking “and”.

(4) in subparagraph (O) of paragraph (2) –

(A) by striking “.” and inserting “, and” and

(B) inserting the following: “(P) be a private nonprofit entity that has an expertise in organ procurement and transplantation.”.

118th CONGRESS
1st Session

H. R. 2544

To improve the Organ Procurement and Transplantation Network, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

April 10, 2023

Mr. Bucshon (for himself and Ms. Kelly of Illinois) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To improve the Organ Procurement and Transplantation Network, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Securing the U.S. Organ Procurement and Transplantation Network Act”.

SEC. 2. ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK.

Section 372 of the Public Health Service Act (42 U.S.C. 274) is amended--

(1) in subsection (a)--

(A) by striking “The Secretary shall by contract” and inserting “In General--The Secretary shall”;

(B) by striking “establishment and” and inserting “continued”; and

(C) by striking the second and third sentences and inserting ``The Secretary may award grants, contracts, or cooperative agreements, as the Secretary determines appropriate, for purposes of carrying out this section.''; and

(2) in subsection (b), by striking ``(b) (1) The Organ Procurement'' and all that follows through the end of subparagraph (A) of paragraph (1) and inserting the following:
``(b) Composition.--

``(1) In general.--The Organ Procurement and Transplantation Network shall--

``(A) be operated through awards to public or private entities including those that have an expertise in organ procurement and transplantation 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''.

(3) in subparagraph (N) of paragraph (2) by striking "and".

(4) in subparagraph (O) of paragraph (2) -
(A) by striking "." and inserting ", and" and
(B) inserting the following: "(P) be a private nonprofit entity that has an expertise in organ procurement and transplantation.".

SEC. 3. TECHNICAL AMENDMENTS.

Title III of the Public Health Service Act is amended--

(1) in section 371(b) (1) (H) (i) (III) (42 U.S.C. 273(b) (1) (H) (i) (III)), by striking ``histocompatibility'' and inserting ``histocompatibility'';

(2) in section 374(c) (2) (42 U.S.C. 274b(c) (2)), by striking ``section 371 or 373'' each place it appears and inserting ``section 371, 372, or 373'';

(3) in section 375 (42 U.S.C. 274c)--

(A) by striking the comma at the end of each of paragraphs (1) and (2) and inserting a semicolon;

(B) in paragraph (3), by striking ``transplants, and'' and inserting ``transplants; and''; and

(C) in paragraph (4), by redesignating clauses (i) and (ii) as subparagraphs (A) and (B), respectively; and

(4) in section 376 (42 U.S.C. 274d)--

(A) by striking ``February 10 of 1991 and of each second year thereafter'' and inserting ``2 years after the date of enactment of the Securing the U.S. Organ Procurement and Transplantation Network Act and every second year thereafter''; and

(B) by striking ``Committee on Labor and Human Resources of the Senate.'' and inserting ``Committee on Health, Education, Labor, and Pensions of the Senate,''.

SEC. 4. GAO REVIEW.

Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall--

(1) to the extent data are available, conduct a review of the historical financing of the Organ Procurement and Transplantation Network described in section 372 of the Public Health Service Act (42 U.S.C. 274), including the utilization of registration fees among entities that have previously been awarded contracts under such section 372; and

(2) submit 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 a report on the review under paragraph (1),
including related recommendations, as applicable.

<all>

§274. Organ procurement and transplantation network

(a) Contract authority of Secretary; limitation; available appropriations

~~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.~~

(b) Functions

~~(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~~

~~“(b) COMPOSITION.—~~

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

~~“(A) be operated through awards to public or private entities including those that have an expertise in organ procurement and transplantation 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 273 of this title), 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, policies, 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, and

(P) be a private nonprofit entity that has an expertise in organ procurement and transplantation.

(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 274f-5 of this title](#); or

(ii) if the Secretary has determined under [section 274f-5\(c\) of this title](#) 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 274f-5\(c\) of this title](#).

(c) Consideration of critical comments

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.