

119TH CONGRESS
1ST SESSION

S.

To amend title XI of the Social Security Act and title III of the Public Health Service Act to improve the safety and fairness of the organ donation system, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. WYDEN introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend title XI of the Social Security Act and title III of the Public Health Service Act to improve the safety and fairness of the organ donation system, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*

2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the

5 “Organ Transplant System Improvement Act of 2025”.

6 (b) TABLE OF CONTENTS.—The table of contents for

7 this Act is as follows:

See. 1. Short title; table of contents.

TITLE I—ENSURING SAFETY AND FAIRNESS IN THE ORGAN DONATION SYSTEM

- Sec. 101. Ensuring standardization requirements.
- Sec. 102. HIPAA compliance.
- Sec. 103. Requiring clear protocol standards in organ donation recovery proceedings.
- Sec. 104. Organ recovery centers.
- Sec. 105. Regulations regarding organ recovery centers.
- Sec. 106. Intra-agency coordination.

TITLE II—STRENGTHENING THE QUALITY OF ORGAN PROCUREMENT ORGANIZATIONS

- Sec. 201. Allowing new organ procurement organizations.
- Sec. 202. Clarifying timelines for certification and recertification.
- Sec. 203. Clarification regarding research.
- Sec. 204. Conflicts of interest regarding organ procurement organizations.
- Sec. 205. Funding for certification and recertification of organ procurement organizations.
- Sec. 206. Conforming amendments.

TITLE III—ORGAN TRANSPLANTS

- Sec. 301. OPTN Board of Directors operations and duties.
- Sec. 302. OPTN Board of Directors conflicts of interest.
- Sec. 303. Organ Transplant Safety Taskforce.
- Sec. 304. Permanent OPTN Fee Authority Act.
- Sec. 305. Ownership of OPTN source code and data.

1 **TITLE I—ENSURING SAFETY AND 2 FAIRNESS IN THE ORGAN DO- 3 NATION SYSTEM**

4 **SEC. 101. ENSURING STANDARDIZATION REQUIREMENTS.**

5 (a) IN GENERAL.—Section 1138 of the Social Secu-
6 rity Act (42 U.S.C. 1320b–8) is amended—

7 (1) in the section heading, by striking “**ORGAN**
8 **PROCUREMENT AGENCIES**” and inserting
9 “**ORGAN PROCUREMENT ORGANIZATIONS**”;

10 (2) by striking “organ procurement agency”
11 each place it appears and inserting “organ procure-
12 ment organization”; and

1 (3) in subsection (b)(1)—

2 (A) in the matter preceding subparagraph
3 (A)(i), by striking “the agency” and inserting
4 “the organization”;

5 (B) in subparagraph (B), by striking
6 “organ procurement agencies” and inserting
7 “organ procurement organizations”;

8 (C) in subparagraph (D), by striking “the
9 rules and requirements” and inserting “each
10 rule and requirement”; and

11 (D) in subparagraph (E), by striking “the
12 policies” and inserting “each policy”.

13 (b) CIVIL MONETARY PENALTY.—Section 1138(b) of
14 the Social Security Act (42 U.S.C. 1320b-8(b)) is amend-
15 ed by adding at the end the following new paragraph:

16 “(3)(A) Any organ procurement organization that the
17 Secretary determines has violated the requirements de-
18 scribed in paragraph (1)(E) or hospital or critical access
19 hospital that the Secretary determines has violated the re-
20 quirements described in subsection (a)(1)(B) shall be sub-
21 ject to a civil monetary penalty equal to **【to be provided】**.

22 “(B) The provisions of section 1128A (other than
23 subsections (a) and (b)) shall apply to a civil monetary
24 penalty under this paragraph in the same manner as such

1 provisions apply to a penalty or proceeding under section
2 1128A(a).”.

3 **SEC. 102. HIPAA COMPLIANCE.**

4 (a) HOSPITALS.—Section 1138(a)(1)(C) of the Social
5 Security Act (42 U.S.C. 1320b-8(a)(1)(C)) is amended—

6 (1) by striking “hospital has” and inserting

7 “hospital—

8 “(i) has”;

9 (2) in clause (i), as added by paragraph (1), by
10 striking the period at the end and inserting “; and”;
11 and

12 (3) by adding at the end the following new
13 clause:

14 “(ii) enters into a business associate con-
15 tract with such organization.”.

16 (b) ORGAN PROCUREMENT ORGANIZATIONS.—Sec-
17 tion 1138(b)(1) of the Social Security Act (42 U.S.C.
18 1320b-8(b)(1)) is amended—

19 (1) in subparagraph (E), by striking “and” at
20 the end;

21 (2) in subparagraph (F), by striking the period
22 at the end and inserting a semicolon; and

23 (3) by adding at the end the following new sub-
24 paragraphs:

1 “(G) enters into business associate contracts
2 with each hospital within its service area; and

3 “(H) complies with all requirements of the reg-
4 ulations promulgated under the Health Insurance
5 Portability and Accountability Act of 1996.”.

6 **SEC. 103. REQUIRING CLEAR PROTOCOL STANDARDS IN**
7 **ORGAN DONATION RECOVERY PROCEEDINGS.**

8 (a) **HOSPITALS AND CRITICAL ACCESS HOSPITALS.**—
9 Section 1138(a) of the Social Security Act (42 U.S.C.
10 1320b-8(a)) is amended—

11 (1) in paragraph (1)—

12 (A) in subparagraph (A)—

13 (i) by redesignating clauses (i) through (iii) as subclauses (I) through
14 (III) and indenting appropriately;

15 (ii) in subclause (III), as so redesignated, by inserting “and” after the semi-
16 colon at the end; and

17 (iii) by striking “protocols for the
18 identification of potential organ donors
19 that” and inserting “protocols—

20 “(i) for the identification of potential
21 organ donors that”; and

22 (iv) by adding at the end the fol-
23 lowing:

1 “(ii) that describe that if there is any clin-
2 ical sign of life in an organ donor, staff of the
3 hospital or critical access hospital may pause
4 the organ procurement to reevaluate such do-
5 nor’s candidacy for organ donation;”;

6 (B) in subparagraph (B)—

7 (i) by striking “hospital in which” and
8 inserting “hospital or critical access hos-
9 pital in which”; and

10 (ii) by striking “and” at the end;

11 (C) in subparagraph (C), by striking the
12 period at the end and inserting “; and”; and

13 (D) by adding at the end the following new
14 subparagraph:

15 “(D) the hospital or critical access hospital edu-
16 cates the staff of the hospital regarding the written
17 protocols described in subparagraph (A)(ii).”; and

18 (2) in paragraph (2)(A), by striking “subpara-
19 graphs (A)(iii)” and inserting “subparagraphs
20 (A)(i)(III)”.

21 (b) ORGAN PROCUREMENT ORGANIZATIONS.—Sec-
22 tion 1138(b)(1) of the Social Security Act (42 U.S.C.
23 1320b-8(b)) of the Social Security Act, as amended by
24 section 102(b), is amended—

1 (1) in subparagraph (G), by striking “and” at
2 the end;

5 (3) by adding at the end the following new sub-
6 paragraph:

7 “(I) establishes written protocols that describe
8 if there is any clinical sign of life in an organ donor,
9 staff of the organization or any other person partici-
10 pating in organ procurement may pause the organ
11 procurement to reevaluate such donor’s candidacy
12 for organ donation.”.

13 SEC. 104. ORGAN RECOVERY CENTERS.

14 Section 1138 of the Social Security Act (42 U.S.C.
15 1320b-8), as amended by section 101(a), is amended—

16 (1) in subsection (a)(3)—

17 (A) in subparagraph (B), by striking
18 "and" at the end:

19 (B) in subparagraph (C), by striking the
20 period at the end and inserting “; and”; and

21 (C) by adding at the end the following new
22 subparagraph:

23 “(D) the term ‘organ recovery center’ means
24 any facility in which organ recovery is performed
25 that—

1 “(i) is owned or operated by an organ pro-
2 curement organization ; and

3 “(ii) is not under the control of a hospital
4 or critical access hospital.”.

5 (2) in subsection (b)(1), as amended by sections
6 102(b) and 103(b)—

7 (A) in subparagraph (H), by striking
8 “and” at the end;

9 (B) in subparagraph (I), by striking the
10 period at the end and inserting “; and”; and

11 (C) by adding at the end the following new
12 subparagraph:

13 “(J) ensures that any organ recovery center
14 that the organization uses to perform organ recov-
15 ery—

16 “(i) complies with the regulations promul-
17 gated by the Secretary under paragraph (4);
18 and

19 “(ii) is in good standing as determined by
20 the Secretary under subsection (c).”; and

21 (3) by adding at the end the following new sub-
22 section:

23 “(c) As part of the Secretary’s determination regard-
24 ing whether an organ procurement organization meets the
25 requirements described in subsection (b)(1)(A), the Sec-

7 SEC. 105. REGULATIONS REGARDING ORGAN RECOVERY
8 CENTERS.

9 Section 1138(b) of the Social Security Act (42 U.S.C.
10 1320b-8(b)), as amended by section 101(b) is amended
11 by adding at the end the following new paragraphs:

12 “(4) Not later than 1 year after the date of enact-
13 ment of this paragraph, the Secretary shall promulgate
14 regulations regarding the safe and appropriate operation
15 of an organ recovery center.

16 “(5) Beginning on the date that is 2 years after the
17 date the Secretary promulgates regulations under para-
18 graph (4), the Secretary shall consider each organ pro-
19 cured by an organ recovery center in good standing with
20 the Secretary (as determined under subsection (c)) as an
21 organ procured by a hospital or critical access hospital for
22 purposes of determining payment under title XVIII or
23 XIX with respect to organ procurement costs attributable
24 to payments made to an organ procurement organization
25 under this subsection.”.

1 **SEC. 106. INTRA-AGENCY COORDINATION.**

2 (a) IN GENERAL.—Not later than **【to be provided】**,
3 the Secretary of Health and Human Services (in this sec-
4 tion referred to as the “Secretary”) shall establish an
5 Intra-agency Coordinating Council (in this section re-
6 ferred to as the “Council”) for the purposes of—

7 (1) coordinating—

8 (A) improvements in—

9 (i) organ procurement;

10 (ii) clinical outcomes of organ trans-
11 plantation; and

12 (iii) **【the organ procurement and**
13 **transplantation system】;**

14 (B) transparency in data **【regarding organ**
15 **procurement and transplantation】; and**

16 (C) regulatory oversight regarding all as-
17 pects of the organ procurement and transplan-
18 tation system;

19 (2) facilitating coordination and communication
20 among **【agencies that are involved in the organ pro-**
21 **curement and transplantation system】; and**

22 (3) developing the action plan described in sub-
23 section (c).

24 (b) MEMBERS.—The Secretary shall appoint each
25 member of the Council. Such members shall be representa-
26 tives from—

1 (1) the Health Resources and Services Adminis-
2 tration;

3 (2) the Centers for Medicare & Medicaid Serv-
4 ices; and

8 (c) ACTION PLAN.—Not later than 2 years after the
9 Secretary establishes the Council, and every 2 years there-
10 after, the Council shall—

11 (1) develop an action plan regarding [how the
12 Council will accomplish the purposes described in
13 paragraphs (1) and (2) of subsection (a); and]

1 TITLE II—STRENGTHENING THE 2 QUALITY OF ORGAN PRO- 3 CUREMENT ORGANIZATIONS

4 SEC. 201. ALLOWING NEW ORGAN PROCUREMENT ORGANIZATIONS.

6 Section 1138(b)(1)(A)(ii)) of the Social Security Act
7 (42 U.S.C. 1320b-8(b)(1)(A)(ii)) is amended, by striking
8 “has been certified or recertified by the Secretary” and
9 inserting “is certified or has been certified or recertified
10 by the Secretary”.

11 SEC. 202. CLARIFYING TIMELINES FOR CERTIFICATION
12 AND RECERTIFICATION.

13 (a) NOTICE TO CONGRESS REGARDING HIGH-PER-

14 FORMING ORGAN PROCUREMENT ORGANIZATIONS.—Sec-
15 tion 1138(b) of the Social Security Act (42 U.S.C. 1320b-
16 8(b)), as amended by sections 101(b) and 105, is amend-
17 ed—

18 (1) in paragraph (1)(A)(ii), by inserting "or
19 subject to paragraph (6)," before "4 years"; and

20 (2) by adding at the end the following new
21 paragraph:

22 “(6) Not later than 1 year after the date of enact-
23 ment of this paragraph, and annually thereafter, the Sec-
24 retary shall submit to Congress a report describing—

1 “(A) each organ procurement organization that
2 the Secretary has determined is appropriate to be
3 recertified every 4 years based on its past practices
4 under paragraph (1)(A)(ii); and

5 “(B) justification for each such organization
6 being placed on the 4-year recertification cycle.”.

7 (b) DECERTIFICATION.—Section 1138(b) of the So-
8 cial Security Act (42 U.S.C. 1320b-8(b)), as amended by
9 sections 101(b) and section 105 and subsection (a) of this
10 section, is amended—

11 (1) in paragraph (2), by striking “The Sec-
12 retary” and inserting “Subject to paragraph (7), the
13 Secretary”; and

14 (2) by adding at the end the following new
15 paragraph:

16 “(7)(A) The Secretary may decertify an organ pro-
17 curement organization if —

18 “(i) the Secretary determines that decertifica-
19 tion is appropriate based on such organization’s per-
20 formance; and

21 “(ii) before decertifying such organization, the
22 Secretary formulates a transition plan for the service
23 area of such organization with a timeline to ensure
24 that organ procurement and transplants continue to
25 be furnished in such area and publishes a version of

1 such plan that contains information determined to
2 be appropriate by the Secretary on the Internet
3 website of the Centers for Medicare & Medicaid
4 Services;

5 “(B) In the event that the Secretary decertifies an
6 organ procurement organization under subparagraph (A),
7 the Secretary may certify a different organ procurement
8 organization to procure and allocate organs within the
9 service area of the decertified organ procurement organi-
10 zation.

11 “(C) For purposes of the next recertification of an
12 organ procurement organization following such organ pro-
13 curement organization taking over a service area under
14 subparagraph (B), the Secretary shall not take into con-
15 sideration the performance of the organ procurement or-
16 ganization within such service area.”.

17 **SEC. 203. CLARIFICATION REGARDING RESEARCH.**

18 Section 1138 of the Social Security Act (42 U.S.C.
19 1320b-8), as amended by section 101(a) and section 104,
20 is amended by adding at the end the following new sub-
21 section:

22 “(d) For purposes of certification or recertification
23 of an organ procurement organization under this section,
24 the Secretary shall count pancreata procured by an organ
25 procurement organization used for islet cell transplan-

1 tation or research, but only if such transplantation or re-
2 search is under a protocol approved pursuant to section
3 58.120 of title 21, Code of Federal Regulations (or suc-
4 cessor regulations).”.

5 **SEC. 204. CONFLICTS OF INTEREST REGARDING ORGAN**
6 **PROCUREMENT ORGANIZATIONS.**

7 Section 1138 of the Social Security Act (42 U.S.C.
8 1320b-8), as amended by sections 101(a), 104, and 203,
9 is amended—

10 (1) in subsection (b)(1)—

11 (A) in subparagraph (C), by inserting “and
12 conflicts-of-interest-related” after “perform-
13 ance-related”;

14 (B) in subparagraph (I), by striking “and”
15 at the end;

16 (C) in subparagraph (J), by striking the
17 period at the end and inserting “; and”; and

18 (D) by adding at the end the following new
19 subparagraph:

20 “(K) submits, at a time and in a form and
21 manner determined appropriate by the Secretary, a
22 report describing the conflicts of interest policies of
23 the organization, including how—

1 “(i) such policies comply with the conflicts
2 of interest regulations promulgated under sub-
3 section (e); and

4 “(ii) such organization discloses and re-
5 solves conflicts of interest, including what types
6 of, at what point, and to whom, conflicts of in-
7 terest are to be reported.”; and

8 (2) by adding at the end the following new sub-
9 section:

10 “(e) Not later than 1 year after the date of enactment
11 of this subsection, the Secretary shall promulgate regula-
12 tions—

13 “(1) clarifying the requirements and expecta-
14 tions for organ procurement organizations regarding
15 conflicts of interest, including conflicts of interest
16 within the Network;

17 “(2) mandating that the governing and medical
18 advisory board of each organ procurement organiza-
19 tion monitors actual and perceived conflicts of inter-
20 est within such organization; and

21 “(3) establishing uniform standards for organ
22 procurement organizations regarding what con-
23 stitutes a conflict of interest, the scope of potential
24 conflicts of interest, and procedures regarding the
25 disclosure of conflicts of interest.”.

1 **[SEC. 205. FUNDING FOR CERTIFICATION AND RECERTIFI-**
2 **CATION OF ORGAN PROCUREMENT ORGANI-**
3 **ZATIONS.]**

4 Section 1138 of the Social Security Act (42 U.S.C.
5 1320b-8), as amended by sections 101(a), 104, 203, and
6 204, is amended by adding at the end the following new
7 subsection:】

8 【“(f) 【In addition to amounts otherwise
9 available【*SLC Comment: This is a policy call. Without*
10 *this, the Secretary would only be able to use these funds*
11 *for purposes of certifying OPOs. With it, the Secretary*
12 *could use these funds and other funds made available for*
13 *certifying OPOs.]】*, there is appropriated to the Secretary
14 out of any funds in the Treasury not otherwise appro-
15 priated, 【*amount to be provided*】 for fiscal year 【*to be pro-*
16 *vided*】 【*and each subsequent fiscal year*】 for the purpose
17 of certifying and recertifying organ procurement organiza-
18 tions under subsection (b)(1)(A)(ii). 【*Amounts appro-*
19 *priated under the preceding sentence shall remain avail-*
20 *able until expended.]”】】*

21 **SEC. 206. CONFORMING AMENDMENTS.**

22 Section 371 of the Public Health Service Act (42
23 U.S.C. 273) is amended—

24 (1) in subsection (b)—
25 (A) in paragraph (1)—

1 (i) in the matter preceding subparagraph
2 graph (A), by striking “paragraph (2)”
3 and inserting “paragraph (3)”; and

4 (ii) in subparagraph (D), by striking
5 “has met” and all that follows through the
6 end of the subparagraph and inserting
7 “meets the other requirements of this sec-
8 tion;”;

12 (C) in paragraph (3)(H), by striking “par-
13 ticipate in” and inserting “be a member of”;
14 and

TITLE III—ORGAN TRANSPLANTS

22 SEC. 301. OPTN BOARD OF DIRECTORS OPERATIONS AND
23 DUTIES

24 (a) IN GENERAL.—Section 372(b) of the Public
25 Health Service Act (42 U.S.C. 274(b)) is amended—

1 (1) in paragraph (1)—

2 (A) in subparagraph (A), by striking “;
3 and” and inserting a period;

4 (B) by striking the paragraph designation
5 and heading and all that follows through “be
6 operated” in subparagraph (A) and inserting
7 the following:

8 “(1) OPERATION; BOARD OF DIRECTORS;
9 ORGAN TRANSPLANT SAFETY TASKFORCE.—

10 “(A) IN GENERAL.—The Organ Procure-
11 ment and Transplantation Network shall be op-
12 erated”; and

13 (C) by striking subparagraph (B) and in-
14 serting the following:

15 “(B) BOARD OF DIRECTORS.—

16 “(i) IN GENERAL.—The Organ Pro-
17 curement and Transplantation Network
18 shall have a board of directors (referred to
19 in this subsection as the ‘Board’) that has
20 a membership that includes—

21 “(I) representatives of transplant
22 coordinators, organ procurement orga-
23 nizations, and transplant hospitals;

24 “(II) at least one transplant can-
25 didate, transplant recipient, organ

1 donor, or family member of a trans-
2 plant candidate, transplant recipient,
3 or organ donor; and

1 are necessary, on the condition
2 that any committee so estab-
3 lished shall be approved by the
4 Secretary.

25 (2) in paragraph (2) —

5 “(2) DUTIES.—The Organ”;

6 (B) in subparagraph (A)—

7 (i) in clause (i), by striking “, and”
8 and inserting “; and”;

12 (iii) by moving the margins of clauses
13 (i) and (ii) 2 ems to the right;

14 (C) by striking subparagraph (B);

15 (D) in subparagraph (C), by striking
16 “twenty-four-hour telephone service” and in-
17 serting “24-hour telephone or information tech-
18 nology service”;

19 (E) by redesignating subparagraphs (C)
20 through (O) as subparagraphs (B) through (N),
21 respectively;

(F) by moving the margins of subparagraph (A) and subparagraphs (B) through (K) (as so redesignated) 2 ems to the right;

1 (G) in each of subparagraphs (B) through
2 (L) (as so redesignated), by striking the comma
3 at the end and inserting a semicolon;

4 (H) in subparagraph (M) (as so redesignated), by striking “transportation, and” and
5 inserting “transportation;”;
6

(I) in subparagraph (N) (as so redesignated), by striking the period at the end and inserting “; and”; and

10 (J) by adding at the end the following:

19 (b) CONFORMING AMENDMENTS.—

1 the matter preceding subparagraph (A), by striking
2 “paragraph (2)(E)” and inserting “paragraph
3 (2)(D)”.

4 (3) Section 377E of the Public Health Service
5 Act (42 U.S.C. 274f-5) is amended by striking “sec-
6 tion 372(b)(2)(E)” each place it appears and insert-
7 ing “section 372(b)(2)(D)”.

8 **SEC. 302. OPTN BOARD OF DIRECTORS CONFLICTS OF IN-
9 TEREST.**

10 Section 372(b) of the Public Health Service Act (42
11 U.S.C. 274(b)) is amended by adding at the end the fol-
12 lowing:

13 “(4) BOARD OF DIRECTORS CONFLICTS OF IN-
14 TEREST.—The Organ Procurement and Transplan-
15 tation Network shall establish a policy to ensure
16 that—

17 “(A) members of the Board are required to
18 submit conflict of interest disclosure forms that
19 include all material facts relating to an actual
20 or potential conflict of interest, including con-
21 flicts of interest relating to—

22 “(i) the functions of the Board; and
23 “(ii) the functions and members of
24 the Organ Procurement and Transplan-
25 tation Network;

1 “(B) each such reported conflict of interest
2 is recorded to allow for future audits; and

3 “(C) conflict of interest requirements for
4 Board members who also sit on other boards of
5 directors are clearly defined, including a re-
6 quirement that such outside board of director
7 membership is reported as a conflict of inter-
8 est.”.

9 **SEC. 303. ORGAN TRANSPLANT SAFETY TASKFORCE.**

10 Section 372(b)(1) of the Public Health Service Act
11 (42 U.S.C. 274(b)(1)) (as amended by section 301(1)) is
12 amended by adding at the end the following:

13 “(C) ORGAN TRANSPLANT SAFETY
14 TASKFORCE.—

15 “(i) IN GENERAL.—The Secretary
16 shall establish a taskforce, to be known as
17 the ‘Organ Transplant Safety Taskforce’
18 (referred to in this subparagraph as the
19 ‘Taskforce’), which shall—

20 “(I) be operated through an
21 award described in subparagraph (A);
22 and

23 “(II) be independent of, but co-
24 ordinate with, the Board and other

1 entities receiving an award under sub-
2 paragraph (A).

3 “(ii) DUTIES.—The Taskforce shall be
4 responsible for overseeing the members of
5 the Organ Procurement and Transplan-
6 tation Network, including by conducting
7 ongoing and periodic reviews, complaint
8 surveys, and evaluations of the compliance
9 of members of the Organ Procurement and
10 Transplantation Network with Organ Pro-
11 curement and Transplantation Network
12 policies, patient safety requirements, and
13 part 121 of title 42, Code of Federal Regu-
14 lations (or successor regulations), in order
15 to monitor risks to the health of patients
16 or to public safety.

17 “(iii) REGULATIONS.—The Secretary
18 shall promulgate regulations—

19 “(I) to establish appropriate
20 plans and procedures for the
21 Taskforce to carry out the duties de-
22 scribed in clause (ii);

23 “(II) to provide for appeals proc-
24 esses for members of the Organ Pro-
25 curement and Transplantation Net-

1 work found to be in noncompliance by
2 the Taskforce under such clause; and

3 “(III) to establish sanctions for
4 such noncompliance, which may in-
5 clude—

6 “(aa) removal of designation
7 as a transplant program under
8 section 121.9 of title 42, Code of
9 Federal Regulations (or successor
10 regulations);

11 “(bb) termination of a
12 transplant hospital’s enrollment
13 under title XVIII of the Social
14 Security Act or under a State
15 plan under title XIX of such Act
16 (or a waiver of such plan);

17 “(cc) termination of an
18 organ procurement organization’s
19 certification under section
20 1138B(b) of the Social Security
21 Act; and

22 “(dd) termination of an
23 organ procurement organization’s
24 reimbursement under title XVIII
25 of the Social Security Act or

1 **SEC. 304. PERMANENT OPTN FEE AUTHORITY ACT.**

2 Section 372 of the Public Health Service Act (42
3 U.S.C. 274) is amended by adding at the end the fol-
4 lowing:

5 “(d) REGISTRATION FEES.—

6 “(1) IN GENERAL.—The Secretary shall collect
7 registration fees from each member of the Organ
8 Procurement and Transplantation Network for each
9 transplant candidate such member places on the list
10 described in subsection (b)(2)(A)(i). Such regis-
11 tration fees shall be collected and distributed only to
12 support the operation of the Organ Procurement
13 and Transplantation Network. Such registration fees
14 are authorized to remain available until expended.

15 “(2) COLLECTION.—The Secretary may collect
16 the registration fees under paragraph (1) directly or
17 through awards made under subsection (b)(1)(A).

18 “(3) DISTRIBUTION.—Any amounts collected
19 under this subsection shall—

20 “(A) be credited to the ‘Department of
21 Health and Human Services – Health Re-
22 sources and Services Administration – Heath
23 Systems’ account; and

24 “(B) be available, without further appro-
25 priation, to distribute such fees among award-
26 ees described in subsection (b)(1)(A).

2 “(A) promptly post on the website of the
3 Organ Procurement and Transplantation Net-
4 work—

11 “(B) update the information posted pursu-
12 ant to subparagraph (A), as applicable for each
13 calendar quarter for which fees are collected
14 under paragraph (1).

15 “(5) GAO REVIEW.—Not later than 2 years
16 after the date of enactment of this subsection, the
17 Comptroller General of the United States shall, to
18 the extent data are available—

19 “(A) conduct a review concerning the ac-
20 tivities under this subsection; and

21 “(B) submit to the Committee on Health,
22 Education, Labor, and Pensions and the Com-
23 mittee on Finance of the Senate and the Com-
24 mittee on Energy and Commerce of the House
25 of Representatives, a report on such review, in-

1 cluding related recommendations, as applica-
2 ble.”.

3 **SEC. 305. OWNERSHIP OF OPTN SOURCE CODE AND DATA.**

4 Section 372 of the Public Health Service Act (42
5 U.S.C. 274) (as amended by section 304) is amended by
6 adding at the end the following:

7 “(e) OWNERSHIP OF OPTN SOURCE CODE AND
8 DATA; ACCESS.—

9 “(1) IN GENERAL.—The requirements of the
10 SHARE IT Act shall apply to any software (as de-
11 fined in section 2 of such Act) developed to operate
12 and maintain the Organ Procurement and Trans-
13 plantation Network.

14 “(2) OWNERSHIP.—Not later than **【180】** days
15 after the date of enactment of the Organ Transplant
16 System Improvement Act of 2025, the Secretary
17 shall **【take such measures as are necessary to】** en-
18 sure that the Department of Health and Human
19 Services—

20 “(A) owns the source code and other key
21 technical components of the code, including doc-
22 umentation, data models, schemas, metadata,
23 architecture designs, configuration scripts, and
24 artifacts required to develop, build, test, and

1 deploy the code, for any software described in
2 paragraph (1); and

3 “(B) acquires and exercises rights suffi-
4 cient to enable the government-wide access to,
5 sharing of, use of, and modification of any
6 source code created in the development of soft-
7 ware described in paragraph (1).

8 “(3) DATA.—

9 “(A) IN GENERAL.—Any data and data
10 sets produced by the Organ Procurement and
11 Transplantation Network shall be owned by the
12 Federal Government.

13 “(B) ACCESS.—Any entity that submits
14 data to the Organ Procurement and Transplan-
15 tation Network pursuant to subsection (b)(2)
16 shall be granted access to any data sets pro-
17 duced by the Organ Procurement and Trans-
18 plantation Network without charge.

19 “(C) PUBLIC ACCESS.—

20 “(i) IN GENERAL.—The Secretary
21 may make the data and data sets produced
22 by the Organ Procurement and Transplan-
23 tation Network publicly available on a
24 website of the Department of Health and
25 Human Services.

1 “(ii) ACCESS FOR RESEARCHERS.—

2 “(I) IN GENERAL.—If the Sec-
3 retary does not make the data and
4 data sets produced by the Organ Pro-
5 curement and Transplantation Net-
6 work publicly available pursuant to
7 clause (i), an entity with a bona fide
8 research or analysis purpose may sub-
9 mit to the Organ Procurement and
10 Transplantation a request for access
11 to data or a data set, and the Organ
12 Procurement and Transplantation
13 Network shall grant access to such
14 data or data set to such entity within
15 30 days of such request.

16 “(II) EFFECT.—Nothing in this
17 clause restricts any written data shar-
18 ing agreement with the Secretary that
19 supports research and statistical ac-
20 tivities for the benefit of the organ
21 transplant system, consistent with ap-
22 plicable privacy, security, and disclo-
23 sure laws and any additional require-
24 ments for privacy and security estab-
25 lished by the Secretary.

1 “(iii) REQUIREMENT.—Any data or
2 data sets made available under clause (i)
3 or (ii) may not contain data that would
4 make a donor or recipient personally iden-
5 tifiable.”.