

116TH CONGRESS
1ST SESSION

H. R. 1835

To amend the Public Health Service Act to ensure the consensual donation and respectful disposition of human bodies and human body parts donated or transferred for education, research, or the advancement of medical, dental, or mortuary science and not for use in human transplantation, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 18, 2019

Mr. RUSH (for himself and Mr. BILIRAKIS) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to ensure the consensual donation and respectful disposition of human bodies and human body parts donated or transferred for education, research, or the advancement of medical, dental, or mortuary science and not for use in human transplantation, 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.**

4 This Act may be cited as the “Consensual Donation
5 and Research Integrity Act of 2019”.

1 **SEC. 2. HUMAN BODIES AND HUMAN BODY PARTS DO-**
2 **NATED OR TRANSFERRED FOR EDUCATION,**
3 **RESEARCH, OR THE ADVANCEMENT OF MED-**
4 **ICAL, DENTAL, OR MORTUARY SCIENCE AND**
5 **NOT FOR USE IN HUMAN TRANSPLANTATION.**

6 (a) IN GENERAL.—Title III of the Public Health
7 Service Act (42 U.S.C. 241 et seq.) is amended by insert-
8 ing after section 373 the following new section:

9 **“SEC. 373A. HUMAN BODIES AND HUMAN BODY PARTS DO-**
10 **NATED OR TRANSFERRED FOR EDUCATION,**
11 **RESEARCH, OR THE ADVANCEMENT OF MED-**
12 **ICAL, DENTAL, OR MORTUARY SCIENCE AND**
13 **NOT FOR USE IN HUMAN TRANSPLANTATION.**

14 “(a) REGISTRATION.—

15 “(1) IN GENERAL.—A person who acquires or
16 transfers in or affecting interstate commerce a
17 human body or human body part for education, re-
18 search, or the advancement of medical, dental, or
19 mortuary science (and not for use in human trans-
20 plantation) shall register with the Secretary at such
21 time and in such manner as the Secretary may re-
22 quire.

23 “(2) CONTENTS OF APPLICATION.—An appli-
24 cant for registration or renewal of registration under
25 this section shall submit an application to the Sec-
26 retary containing such information as the Secretary

1 may by regulation require on the activities to be car-
2 ried out pursuant to the registration. Unless the
3 Secretary specifies otherwise by regulation, an appli-
4 cation shall include—

5 “(A) the name of the applicant, including
6 all trade names under which the applicant con-
7 ducts business;

8 “(B) the date on which the applicant first
9 began or will begin commencing activities de-
10 scribed in paragraph (1);

11 “(C) a list of all addresses at which the
12 applicant conducts business;

13 “(D) a description of the premises and
14 equipment used by the applicant;

15 “(E) a description of the types of service
16 provided by the applicant;

17 “(F) an identification of a representative
18 of the applicant who has attained the age of 18
19 and has the authority to ensure that the appli-
20 cant complies with this section;

21 “(G) an assurance that the applicant will
22 keep records in accordance with subsection (c);

23 “(H) an assurance that the applicant will
24 label and package all human bodies or human

1 body parts in accordance with subsection (d);
2 and

3 “(I) an assurance that the Secretary will
4 be permitted to inspect the premises and
5 records of the applicant at the times and in the
6 manners prescribed under subsection (b).

7 “(3) FEES.—

8 “(A) AUTHORITY.—The Secretary shall es-
9 tablish a fee for registration under paragraph
10 (1) and renewal under paragraph (4) in an
11 amount in accordance with subparagraph (B).

12 “(B) AMOUNT.—The Secretary shall deter-
13 mine the amount of the fees authorized by sub-
14 paragraph (A) on an annual basis based on the
15 projected cost of implementing and enforcing
16 this section, including the cost of inspections
17 under subsection (b).

18 “(C) COLLECTIONS AND APPROPRIATIONS
19 ACTS.—The fees authorized by subparagraph
20 (A) shall be available for obligation only to the
21 extent and in the amounts provided in advance
22 in appropriations Acts.

23 “(4) REGISTRATION RENEWAL.—The Secretary
24 shall require that the registration of a registrant be

1 renewed by such registrant at such intervals as the
2 Secretary determines appropriate.

3 “(5) CHANGE OF INFORMATION.—Not later
4 than 30 days after any change of any information
5 listed in paragraph (2), an applicant or registrant
6 shall notify the Secretary of such change in writing
7 as prescribed by regulation by the Secretary.

8 “(b) INSPECTIONS.—The Secretary shall inspect at
9 regular intervals (to be prescribed by the Secretary) the
10 premises described in subsection (a)(2)(D).

11 “(c) RECORD KEEPING.—

12 “(1) IN GENERAL.—A registrant shall compile
13 or maintain a record for each case in which the reg-
14 istrant acquires a human body or human body part.

15 “(2) RECORD REQUIREMENTS.—A record under
16 paragraph (1) shall contain such information as the
17 Secretary may by regulation require. Unless the Sec-
18 retary specifies otherwise by regulation, a record
19 under paragraph (1) shall include the following:

20 “(A) Documentation that the donor has
21 knowingly consented to the transfer of the
22 human body or human body part (not for use
23 in transplantation) involved for education, re-
24 search, or the advancement of medical, dental,
25 or mortuary science in accordance with all ap-

1 plicable laws pertaining to the disposition of
2 human remains.

3 “(B) Documentation that the donor has
4 been informed of the obligation of the reg-
5 istrant under subsection (e) to dispose of the
6 human body or human body part.

7 “(C) The date and time of the donation or
8 transfer from the donor.

9 “(D) The name of the person, including
10 any trade or business name, who transferred
11 the human body or human body part to the reg-
12 istrant, if applicable.

13 “(E) The full name and most recent ad-
14 dress of the donor.

15 “(F) A description of the human body or
16 human body part being acquired or transferred.

17 “(G) The medical history of the donor, in-
18 cluding the autopsy report if an autopsy was
19 conducted.

20 “(H) The identity and address of each per-
21 son that has been in possession of the human
22 body or human body part prior to the reg-
23 istrant, including any funeral home, coroner,
24 hospital, organ procurement organization, or
25 tissue bank.

1 “(I) Documentation of the use and disposi-
2 tion of each human body or human body part
3 by the registrant.

4 “(J) Documentation of the name and ad-
5 dress of each person to whom the registrant
6 transfers such human body or human body
7 part.

8 “(d) LABELING AND PACKAGING.—

9 “(1) IN GENERAL.—A registrant shall ensure
10 that all human bodies and human body parts in the
11 possession of, or transferred by, a registrant are la-
12 beled and packaged in accordance with paragraphs
13 (2) and (3).

14 “(2) LABELING REQUIREMENTS.—A label
15 under paragraph (1) shall contain such information
16 as the Secretary may by regulation require con-
17 sistent with any applicable Federal privacy provi-
18 sions. Unless the Secretary specifies otherwise by
19 regulation, a label under paragraph (1) shall include
20 the following:

21 “(A) The proper name of the donor.

22 “(B) A description of the contents of the
23 package, indicating whether it is a human body
24 or human body parts, including a list of all
25 such parts.

1 “(C) The name, address, and any applica-
2 ble license or registration number of the person
3 transferring the human body or human body
4 part.

5 “(D) The tissue types of the human body
6 or human body part.

7 “(E) The cause of death of the donor, if
8 applicable and known.

9 “(F) Serological test results, if any such
10 results exist.

11 “(G) Any known infectious disease agents
12 of such human body or human body part.

13 “(H) A statement about the use of per-
14 sonal protective equipment and universal pre-
15 cautions when handling a human body or
16 human body part as required by law.

17 “(I) The statement ‘not for transplan-
18 tation.’.

19 “(3) PACKAGING REQUIREMENTS.—Each
20 human body or human body part described in para-
21 graph (1) shall be wrapped and packaged in such
22 manner as the Secretary may by regulation require.
23 Unless the Secretary specifies otherwise by regula-
24 tion, each such human body or human body part
25 shall be wrapped and packaged in a manner that—

1 “(A) mitigates potential contamination and
2 cross contamination;

3 “(B) mitigates potential safety hazards;

4 “(C) is sealed to prevent leakage; and

5 “(D) ensures the integrity of the human
6 body or human body part.

7 “(e) DISPOSITION.—The registrant shall ensure the
8 proper disposition of a human body or human body part,
9 in accordance with applicable Federal and State law, by—

10 “(1) returning the human body or human body
11 part to a relative or personal representative of the
12 donor or carrying out the disposition of such human
13 body or human body part; or

14 “(2) if the registrant is transferring the human
15 body or human body part to another person, con-
16 tracting with such person to assume the obligation
17 described in paragraph (1).

18 “(f) VIOLATIONS.—

19 “(1) IN GENERAL.—Any person who violates a
20 requirement of this section shall be fined in accord-
21 ance with title 18, United States Code.

22 “(2) REVOCATION OF REGISTRATION.—The
23 Secretary may suspend or revoke the registration of
24 any registrant found to be in violation of this sec-
25 tion.

1 “(3) ALTERATION OR FALSIFICATION OF
2 LABEL.—It shall be a violation of this section for
3 any person to alter or falsify any information in a
4 label required by subsection (d).

5 “(g) DEFINITIONS.—In this section:

6 “(1) DONOR.—The term ‘donor’ means a per-
7 son who has knowingly consented in accordance with
8 applicable law to the transfer of such person’s de-
9 ceased body or deceased or living body part (not for
10 use in transplantation) for education, research, or
11 the advancement of medical, dental, or mortuary
12 science.

13 “(2) EDUCATION.—The term ‘education’ means
14 the use of a human body or body parts for teaching
15 or training individuals, including medical, dental, or
16 mortuary science students or professionals, with re-
17 gard to the anatomy and characteristics of the
18 human body, disease detection, and such other uses
19 as may be specified by the Secretary by regulation.

20 “(3) HUMAN BODY.—The term ‘human body’
21 means a deceased human body.

22 “(4) HUMAN BODY PART.—The terms ‘human
23 body part’ or ‘body part’ mean an organ, tissue, eye,
24 bone, blood vessel or any other portion of a deceased
25 or living human body that is subject to an anatom-

1 ical gift or other transfer made pursuant to State
2 law, but do not include—

3 “(A) blood drawn for medical purposes; or

4 “(B) a growing cell line.

5 “(5) RESEARCH.—The term ‘research’ does not
6 include an autopsy or examination, conducted as
7 part of a criminal investigation.”.

8 (b) RULE OF APPLICABILITY.—The amendments
9 made by this section shall apply with respect to any acqui-
10 sition or transfer of a human body or human body parts
11 after the date that is 2 years after the date of the enact-
12 ment of this Act.

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