

**PROPOSED ORDER OF THE
DEPARTMENT OF HEALTH SERVICES
TO ADOPT RULES**

The Wisconsin Department of Health Services proposes to repeal and recreate ch. DHS 137 (title); to renumber DHS 137.01 to 137.04; and to create 137.01 to 137.08, Subchapter I, (title) and Subchapter II (title), relating to anatomical gifts and the Wisconsin Donor Registry.

SUMMARY OF PROPOSED RULE

Statutes interpreted:

Section 157.06, Stats.

Statutory authority:

Sections 157.06 (20) and 227.11 (2) (a), Stats.

Explanation of agency authority:

Section 157.06 (20), Stats., authorizes the department to establish an organ and tissue donor registry and directs the department to promulgate administrative rules to govern any registry it establishes.

Related statute or rule:

See the “Statutes interpreted” section.

Plain language analysis:

The rules under this order, as authorized under s. 157.06 (20), Stats., establish and govern the Wisconsin Donor Registry (Donor Registry).

The rules in this order prescribe:

- The conditions under which individuals may have a record of gift or record of intent to make an anatomical gift included in the Donor Registry.
- The conditions under which an individual may amend or revoke his or her record of gift recorded in the Donor Registry.
- The conditions under which procurement organizations and their employees may receive department authorization to access the Donor Registry.
- The conditions of use of Donor Registry information.

The department has adopted emergency rules, which will become effective on March 29, 2010, to govern the Donor Registry during the period it will take to promulgate permanent rules.

Summary of, and comparison with, existing or proposed federal regulations:

There appear to be no existing or proposed federal regulations that are comparable to the proposed rules.

Comparison with rules in adjacent states:

Illinois:

There appears to be no administrative code governing the Illinois donor registry.

Iowa:

Iowa has no administrative code governing its donor registry.

Michigan:

Michigan has no administrative code governing its donor registry.

Minnesota:

Minnesota has no administrative code regarding its donor registry.

Summary of factual data and analytical methodologies:

The department reviewed s. 157.06, Stats., worked with the Department of Transportation as required under s. 157.06 (20), Stats., and reviewed donor programs in other states. The department also received comments from its stakeholder advisory group which includes representatives from the following organizations:

1. University of Wisconsin Hospital and Clinics Organ Procurement Organization
2. University of Wisconsin Hospital and Clinics Transplant Program
3. Wisconsin Donor Network
4. Froedtert Memorial Lutheran Hospital
5. Children's Hospital of Wisconsin
6. Aurora Health Care
7. Life Source of Minnesota
8. American Tissue Services Foundation, Inc.
9. Musculoskeletal Transplant Foundation
10. RTI Donor Services
11. Wisconsin Tissue Bank
12. Lions Eye Bank of Wisconsin

Analysis and supporting documents used to determine effect on small business:

The rules do not affect small businesses.

Effect on small business:

The rules do not affect small businesses.

Agency contact person:

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Place where comments are to be submitted and deadline for submission:

Comments may be submitted to the agency contact person that is listed above until the deadline given in the upcoming notice of public hearing. The deadline for submitting comments and the notice of public hearing will be posted on the Wisconsin Administrative Rules Website at <http://adminrules.wisconsin.gov> after the hearing is scheduled.

TEXT OF PROPOSED RULE

SECTION 1. Chapter DHS 137 (title) is repealed and recreated to read:

CHAPTER DHS 137 ANATOMICAL GIFTS

SECTION 1m. Subchapter I (title) is created, for insertion above DHS 137.01, to read:

SUBCHAPTER I, THE WISCONSIN DONOR REGISTRY

SECTION 2. DHS 137.01 to 137.04 are renumbered DHS 137.30 to 137.33 and DHS 137.30, 137.31, 137.32 Note and 137.33 Note, as renumbered, are amended to read:

DHS 137.30 (1) This ~~chapter~~subchapter is established under the authority of s. 157.06 (26m), Stats., to create a form for use by physicians when removing an organ from a decedent under s. 157.06 (23m), Stats., and to create a form for use by physicians, technicians, and tissue bank employees when removing tissue, other than cardiovascular tissue, from a decedent under s. 157.06 (23m), Stats.

(2) Pursuant to s. 157.06 (23m) (e) 3., Stats., a physician, technician, or tissue bank employee shall complete the applicable form prescribed under this ~~chapter~~subchapter and transmit the completed form to the coroner or medical examiner with jurisdiction over the decedent.

137.31 **Applicability.** This ~~chapter~~subchapter applies to physicians, technicians, and tissue bank employees, coroners and medical examiners.

137.32 Note: Form DPH 43023 can be obtained from the Department's website at <http://dhs.wisconsin.gov/forms/DPH/dph43023.pdf>
<http://dhs.wisconsin.gov/forms/F4/F43023.pdf>

137.33 Note: Form DPH 43024 can be obtained from the Department's website at <http://dhs.wisconsin.gov/forms/DPH/dph43024.pdf>
<http://dhs.wisconsin.gov/forms/F4/F43024.pdf>

SECTION 5. DHS 137.01 to 137.08 are created to read:

DHS 137.01 Authority and purpose. This subchapter is promulgated under the authority of s. 157.06 (20), Stats., to establish and govern the operation of the Wisconsin donor registry as a means for individuals to make anatomical gifts in the manner provided under s. 157.06 (5) (a) 5, Stats., as a means for procurement organizations to determine whether individuals at or near death are donors, and as a means for the department to

obtain and analyze aggregate donor data for the purpose of encouraging and increasing organ, tissue and eye donation. The subchapter establishes the means by which individuals may authorize their inclusion in the registry when applying for a Wisconsin driver's license or identification card and the means by which individuals who have either a Wisconsin driver's license or identification card may authorize their inclusion in the registry by completing a form on the Wisconsin donor registry website. Under this subchapter, when an individual is at or near death, authorized procurement organizations may query the registry database to determine whether the individual has a record of gift or a record of intent.

DHS 137.02 Applicability. This subchapter applies to each procurement organization serving Wisconsin and to each person included or eligible for inclusion in the registry.

DHS 137.03 Definitions. Words, phrases, and terms used in this subchapter have the same meanings as are set forth in s. 157.06, Stats., except as defined in this subchapter or where the context clearly indicates a different meaning. In this subchapter:

- (1) "Department" means the department of health services.
- (2) "Donor question" means an inquiry made by the department of transportation pursuant to s. 343.50 (4m) or 343.75, Stats.
- (3) "Record of intent" means a statement or symbol in the department of transportation electronic database that indicates an individual responded affirmatively to the donor question when applying for a driver's license or identification card before March 29, 2010 or before the individual was at least 15 and one-half years of age.
- (4) "Wisconsin donor registry," or "registry," means the donor registry established by the department, pursuant to s. 157.06 (20), Stats., the operation of which is governed by this subchapter. It comprises records of anatomical gifts for the purpose of transplantation, therapy, research or education, which are maintained in the Wisconsin department of transportation driver license and identification card database, and any supplemental records of anatomical gifts maintained in a department database.
- (5) "Wisconsin donor registry website" or "registry website," means the website established by the department that an individual with a Wisconsin driver's license or identification card may access to make an anatomical gift by authorizing his or her inclusion in the Wisconsin donor registry or to revoke an anatomical gift the individual has recorded in the Wisconsin donor registry.

DHS 137.04 Registration in the Wisconsin Donor Registry. (1) RECORD OF GIFT. (a) Beginning March 29, 2010, an individual at least 15 and one-half years of age who indicates a desire to register as an organ, tissue, and eye donor when applying for or renewing a Wisconsin driver's license or identification card makes an anatomical gift of organs, tissues and eyes by authorizing his or her inclusion in the registry. The department

of transportation's inclusion of a statement or symbol in its database that the individual has indicated a desire to register as an organ, tissue, and eye donor constitutes a record of an anatomical gift for the purpose of transplantation or therapy under s. 157.06 (2) (t), Stats.

Note: Until January 2010, the application form for a Wisconsin driver's license or identification card included a statement that answering "yes" to the question whether the applicant wished to be an organ donor did not in itself authorize an anatomical gift. A record of intent will be noted for individuals who indicated they wanted to be organ donors using this application form. An individual who has indicated a desire to be a donor using this form may register as a donor in the manner described in par. (b) or when renewing his or her license.

(b) An individual who is at least 15 and one half years of age and has a Wisconsin driver's license or identification card may authorize his or her inclusion in the registry as a means of making an anatomical gift of organs, tissues and eyes by completing a form available on the Wisconsin donor registry website. The department shall forward the individual's authorization to the department of transportation, or the individual may write to the Wisconsin department of transportation. The department of transportation's entry of a statement or symbol in its database indicating that the individual has made an anatomical gift shall constitute a record of gift for the purpose of transplantation, therapy, research or education under s. 157.06 (2) (t), Stats.

Note: Requests may be mailed to the Wisconsin Department of Transportation, Division of Motor Vehicles, Qualifications and Issuance, Rm. 801, P.O. Box 7999, Madison, WI 53707-7999.

Note: Every time an individual renews his or her driver's license or identification card, the individual will be asked whether he or she wants to make an organ or tissue donation. If an individual who has authorized his or her inclusion in the registry under par. (a) or (b) wishes to remain in the registry, the individual must indicate this when renewing his or her driver's license or identification card. Individuals in the registry who do not renew their licenses will remain in the registry.

(c) An individual who authorizes his or her inclusion in the registry makes an anatomical gift of organs, tissues, and eyes, but does not make a gift of the entire body, unless the individual subsequently amends the gift under s. 157.06 (6) (a), Stats., to donate the entire body.

(d) An individual who authorizes his or her inclusion in the registry does not revoke a previously executed anatomical gift directed for the use of a particular person or purpose, limited to particular organs or tissues, or otherwise directed to a particular legal use.

(2) RECORD OF INTENT. (a) An individual who, before March 29, 2010, responded affirmatively to the donor question when applying for a driver's license or identification card, or communicated in writing to the department of transportation a desire to make an anatomical gift, has stated an intent to make an anatomical gift.

(b) An individual under 15 and one-half years of age, who indicates a desire to make an anatomical gift when applying for a Wisconsin driver's license or identification card, or who has a driver's license or identification card and communicates in writing to the department of transportation a desire to make an anatomical gift or indicates a desire to make an anatomical gift by completing the donor form on the registry website, has stated an intent to make an anatomical gift.

(c) The department of transportation's record of an individual's intent to make an anatomical gift is not a record of gift under s. 157.06 (2) (t), Stats., and does not by itself authorize an anatomical gift.

DHS 137.05 Amending an anatomical gift recorded in the Wisconsin Donor Registry. An individual who makes an anatomical gift by registering in the registry may amend his or her gift as provided in s. 157.06 (6) (a), Stats., in order to direct the gift for the use of a particular person, limit the gift, or otherwise specify a particular legal use of his or her gift, by executing another record of gift under s. 157.06 (5), Stats., such as a donor card, a statement in a power of attorney for health care document, advanced directive or will, or a statement on a driver's license or identification card, that identifies particular uses of the gift, consistent with s. 157.06 (11), Stats.

DHS 137.06 Revocation of an anatomical gift recorded in the Wisconsin Donor Registry. (1) In addition to using any of the means provided in s. 157.06 (6) (b), Stats., for revoking an anatomical gift, an individual who has made an anatomical gift by registering in the registry may revoke that gift as follows:

(a) The individual may ask that his or her name be removed from the registry by submitting the request through the Wisconsin donor registry website or by submitting the request to the department of transportation.

(b) The individual may decline to authorize inclusion of his or her name in the registry when applying for or renewing his or her driver's license or identification card.

(2) The revocation under par. (a) or (b) is effective when the department of transportation removes the statement or symbol in its database that indicated the individual had authorized his or her inclusion in the registry.

DHS 137.07 Authorization to access registry data. (1) Access to registry data requires authorization by the department.

(2) The department may authorize employees of procurement organizations that regularly serve Wisconsin citizens and are in compliance with federal and state law to access the registry solely for the purpose of determining whether an individual at or near death is included in the registry as having a record of gift or record of intent. As a condition for access to the registry, an employee of a procurement organization shall submit to a criminal background check through the Wisconsin department of justice.

(3) To obtain access to the registry for its employees, a procurement organization shall demonstrate to the department's satisfaction, in a manner prescribed by the department, that it has instituted effective procedures for assuring that access to the registry is not given to employees who are disqualified from accessing department of transportation records on the basis of a criminal background check, training its employees in the proper use of the registry, assuring that the registry is used only for appropriate purposes, and maintaining confidentiality of registry data. This may include submitting a signed use agreement prescribed by the department for the organization and each individual user.

Note: Forms for requesting authorization to use the registry may be obtained from the Organ & Tissue Donation Program and completed forms may be faxed to the program at 608-266-8925 or mailed to Organ & Tissue Donation Program, P.O. Box 2659, Madison, WI 53701-2659.

(4) A procurement organization shall remove registry access from users who are no longer employed by the organization or whose duties no longer include determining whether a person is included in the registry. In addition, a procurement organization shall remove registry access from employees at the request of the department.

(5) A procurement organization or authorized individual user of the registry shall report any suspected misuse of the registry to the department immediately.

(6) The department may authorize department employees or agents access to the registry for the purposes of monitoring the use of the registry and obtaining and analyzing aggregate donor data.

(7) The department may terminate an organization's or individual's access to the registry if the department reasonably suspects inappropriate access to or use of the registry.

DHS 137.08 Use of the registry by procurement organizations. (1) An authorized user may query the registry solely for the purpose of determining whether an individual who is near death or is recently deceased has a record of gift or record of intent recorded in the registry.

(2) Upon determining that a person is included in the registry, a procurement organization may print a registry certificate that shows the person's name, date of birth, and whether the person has a record of gift or record of intent. The certificate may be placed in the donor's file or shared with the donor's family.

(3) A procurement organization shall make a reasonable inquiry whether an individual who has a record of gift or record of intent has executed any other record of gift or intent that limits or extends the uses of the anatomical gift made by means of the registry, or has subsequently refused to make an anatomical gift, as provided under s. 157.06 (7), Stats., or revoked the anatomical gift as provided under s. 157.06 (6), Stats.

SECTION 5m. Subchapter II (title) is created, for insertion above DHS 137.30, to read:

SUBCHAPTER II, FORMS FOR USE WHEN REMOVING ORGANS AND TISSUES FROM A DECEDENT

SECTION 6. EFFECTIVE DATE: This rule shall take effect on the first day of the month following publication in the Wisconsin administrative register, as provided in s. 227.22 (2), Stats.

Wisconsin Department of Health Services

Dated:

Karen E. Timberlake, Department Secretary

SEAL: