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Details: Emergency Rule extension requests by Department of Health Services.
(FORM UPDATED: 08/11/2010)

WISCONSIN STATE LEGISLATURE ... PUBLIC HEARING - COMMITTEE RECORDS

2009-10

(session year)

Joint

(Assembly, Senate or Joint)

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* Contents organized for archiving by: Stefanie Rose (LRB) (June 2012)



State of Wisconsin
Department of Health Services

Jim Doyle, Governor
Karen E. Timberlake, Secretary

July 21, 2010

The Honorable Jim Holperin, Co-Chairperson
JCRAR
Room 409 South, State Capitol
Madison, Wisconsin 53708

The Honorable Josh Zepnick, Co-Chairperson
JCRAR
Room 219 North, State Capitol
Madison, Wisconsin 53707

Re: Request for Extension of Emergency Rule

Dear Senator Holperin and Representative Zepnick:

The Department of Health Services (Department) under s. 227.24 (2), Stats., hereby requests, that the Joint Committee for Review of Administrative Rules extend the effective period of emergency rules order ch. DHS 137, relating to anatomical gifts and the Wisconsin Donor Registry. Pertinent information regarding this request is as follows:

Rule Subject:

- Chapter DHS 137, relating to anatomical gifts and the Wisconsin Donor Registry (Donor Registry)

Requested Extension Period:

- 60 days-August 26, 2010 to October 24, 2010

Date Rules Will Expire:

- August 25, 2010

Date Rules Became Effective:

- March 29, 2010

Extension Request Number:

- First request

Evidence that there is a threat to the public peace, health, safety or welfare that can be avoided only by extension of the emergency rule or part of the emergency rule:

- Existence of the Donor Registry may help to increase the availability of organs and tissue for use in transplantation, therapy, research or education. Donations received via the Donor Registry have exceeded Department projections.
- There is no existing permanent rule for the Donor Registry. The Donor Registry is operated only under emergency rule DHS 137.
- Section 157.06, (20) Stats., requires the Department to operate the Donor Registry under administrative rules. If the emergency rule expires, there would be no rules under which to operate the Donor Registry.

Evidence that it is impossible for the agency to promulgate a permanent rule prior to the expiration date of the emergency rule:

- The Department must modify the final proposed rules that were submitted to the Chief Clerks on June 2, 2010, because of an error in language use that has caused and may continue to cause confusion among the general public when making donations.
- The review periods of the Senate Committee on Health, Health Insurance, Privacy, Property Tax Relief, and Revenue and the Assembly Committee on Health and Healthcare Reform for DHS 137 is expired.
- Under s. 227.19 (4) (b) 4., Stats., in order to make the necessary modifications to ch. DHS 137, the Department's revised final proposed rules must be submitted and reviewed by the legislature under s. 227.19 (2), Stats.
- The new period of legislative committee assignment and review can take up to 40 days.
- An additional 40 days may pass before the rule can be published and become effective, once filed by the Department.
- The emergency rule, set to expire on August 25, 2010, will expire before the permanent rule can become effective.

Sincerely,

Rosie Greer
DHS Administrative Rules Manager

cc Senator Fred Risser
Speaker Michael Sheridan

**ADMINISTRATIVE RULES
ORDER OF THE
DEPARTMENT OF HEALTH SERVICES
ADOPTING EMERGENCY RULES**

The Wisconsin Department of Health Services hereby adopts emergency rules 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.

FINDING OF EMERGENCY

The Department of Health Services finds that an emergency exists and that the adoption of an emergency rule is necessary for the immediate preservation of the public health, safety and welfare. The facts constituting the emergency are as follows:

There are over 105,000 people in the United States on the national waiting list for organ transplants including 1,500 in Wisconsin. Due to the limited availability of organs for transplantation, 18 people die each day in the United States.

As part of Wisconsin's response to the need for increased organ and tissue donation, the department, as authorized under s. 157.06 (20), Stats., has established the Wisconsin Donor Registry (Donor Registry).

The Donor Registry will make it easier for Wisconsin residents to become donors and for procurement organizations to identify donors, and thus it should increase the supply of available organs and tissues, which may save the lives of persons awaiting transplant.

Promulgating the rules for the Donor Registry as emergency rules will enable department-authorized procurement organizations to quickly determine whether a person who is at or near death has a record of gift. In addition, the Donor Registry makes it possible for individuals to immediately make anatomical gifts.

The Donor Registry will become available for use by the public upon the effective date of these emergency rules and may be accessed by the public at yesIwillwisconsin.com. Substantially identical permanent rules are being proposed concurrent to this emergency order.

SUMMARY OF EMERGENCY 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 can amend or revoke his or her record of gift recorded in the Donor Registry.
- The conditions under which procurement organizations and their employees can receive department authorization to access the Donor Registry.
- The conditions of use of Donor Registry information.

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:

Martha Mallon
1 W. Wilson Street, room 233
PO Box 2659
Madison, WI 53701
608.261.6854
Martha.mallon@dhs.wisconsin.gov

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 EMERGENCY RULE

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

CHAPTER DHS 137 ANATOMICAL GIFTS

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

SUBCHAPTER I, THE WISCONSIN DONOR REGISTRY

SECTION 4. 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 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, 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 gifts 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 pars. (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 pars. (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, but is not limited to, 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 6. EFFECTIVE DATE: The rules contained in this order shall take effect as emergency rules on March 29, 2010.

Wisconsin Department of Health Services

Dated: March 22, 2010

Karen E. Timberlake, Department Secretary

SEAL:





State of Wisconsin
Department of Health Services

Jim Doyle, Governor
Karen E. Timberlake, Secretary

**Joint Committee for the Review of Administrative Rules
DHS 137: Organ Donor Registry Administrative Rule
Emergency Rule Extension Request**

**Carrie Kahn, Legislative Liaison
Martha Mallon, Program Director, Organ & Tissue Donation Program
August 24, 2010**

Good morning, Co-chairs Holperin and Zepnick and committee members. Thank you for taking time today to consider our request for a first extension of the emergency rule DHS 137 (CR 10-037). DHS requests an extension of 60 days to ensure that the permanent rule is in place before the emergency rule expires.

The need for organ and tissue donation nationwide is at an all-time high. Over 108,000 people in the United States are on the national waiting list for organ transplants, including 1,600 people in Wisconsin. Due to the limited availability of organs for transplantation, 18 people die each day in the United States.

Wisconsin's online Donor Registry went online March 29th, 2010 and has been well-received—more than 18,700 people have registered in the first four months.

The Wisconsin Donor Registry is an important part of increasing the donations that save and enhance people's lives. It provides access to information for medical professionals to quickly determine an individual's intention at the end of life. Families are typically relieved and comforted by having this information and by not having to make the decision during a very difficult time.

While residents will continue to have the option to make their decision to donate through applying for or renewing a driver's license, this process only occurs for most people every eight years. The online Registry provides an opportunity for residents to make this determination at any time, and the information is kept in a secure database that only authorized DHS employees and authorized medical professionals can access. This is not only more convenient for donors, but also increases the likelihood that people will make the decision to become donors.

The permanent rule received no objection during the legislative review period. The emergency rule only requires an extension at this time because technical language in the permanent rule required amendments to ensure clarity for the public.

Thank you for your consideration of this simple request. Please let me know if I can answer any questions.