

STATEMENT OF SCOPE
WISCONSIN DEPARTMENT OF HEALTH SERVICES

CHAPTER: DHS 137
RELATING TO: Anatomical Gifts
RULE TYPE: Permanent and emergency
SCOPE TYPE: Original

FINDING OF EMERGENCY: An emergency rule is necessary to protect the public peace, safety, and welfare. The rule governs the use of the Wisconsin Donor Registry, which is a lifesaving and time-sensitive registry. According to the Organ Procurement and Transplantation Network (OPTN), one donor can save the lives of up to eight people.¹ More than 100,000 people in the United States are waiting to receive an organ transplant, and, as of August 29, 2022, there are over 1,600 individuals on the waitlist from Wisconsin.² This rule seeks to lower the age requirement for registering as a potential anatomical donor, which would thereby expand the number of donors on the registry—which would further increase its potential to save lives. Promulgating an emergency rule would allow the Registry to expand sooner than if the agency had to comply with all the procedures in chapter 227 of the Wisconsin Statutes.

SUMMARY

1. Description of rule objective/s

The Wisconsin Department of Health Services (“the Department”) proposes to revise ch. DHS 137 to lower the age of individuals who may authorize their inclusion in the Wisconsin Donor Registry from 15 and one-half years to 15 years of age. 2021 Wisconsin Act 64 lowered the age requirement for a driver’s permit from 15 and one-half years to 15 years. Corresponding changes in s. 157.06, Stats., to lower the age requirement for making an anatomical gift were enacted by 2021 Wisconsin Act 220. The proposed rule will make ch. DHS 137 consistent with the statutes by replacing all references to “15 and one-half” in the rule with “15.”

2. Existing policies relevant to the rule

The current rule under ss. DHS 137.03 and 137.04 provide that a person applying for a driver’s license permit can add their name to the WI donor registry, making a record of anatomical gift. Currently, the individual needs to be 15 and one-half years to make an anatomical gift.

3. Policies proposed to be included in the rule

This rule change would lower the age that an individual could add their name to the Wisconsin Donor Registry to 15 years of age. Individuals of this age may now obtain a learners permit to drive and will be able to authorize adding their name to the donor registry. Individuals aged 15 to 19 register at a rate of 63%, which is among the highest statewide donor registration rate in the state.³ This policy would allow the Wisconsin Donor Registry to recognize these decisions.⁴

4. Analysis of policy alternative

¹ Organ Procurement & Transplant Network, *How organ allocation works* (last visited Aug. 23, 2022), <https://optn.transplant.hrsa.gov/patients/about-transplantation/how-organ-allocation-works/#:~:text=Every%2010%20minutes%20another%20person,donor%20can%20save%20eight%20lives.>

² Organ Procurement & Transplant Network, *State Data* (last visited August 29, 2022), <https://optn.transplant.hrsa.gov/data/view-data-reports/state-data/#>.

³ Wisconsin Department of Health Services Wisconsin Organ & Tissue Donor Program, *Donor Intent Query* (“Create Summary Report” - Run Date 6/27/2022) (last visited Aug. 29, 2022), <https://health.wisconsin.gov/donorRegistry/public/organDonor.html>.

⁴ The decision to make an anatomical gift made by anyone under the age of 18 can be overridden by parent or guardian unless said individual is an emancipated minor. See Wis. Stat. §§ 157.06(4)(c), and (8)(f) & (g).

There are no viable policy alternatives to the proposed rulemaking. The current rule is inconsistent with Wisconsin Statutes.

5. **Statutory authority for the rule**

a. **Explanation of authority to promulgate the proposed rule**

The Department is authorized to promulgate the rule based upon explicit statutory provisions identified below.

b. **Statute/s that authorize/s the promulgation of the proposed rule**

Section 157.06 (20), Stats.: DONOR REGISTRY. The department of health services may establish a donor registry. If the department of health services establishes a donor registry under this subsection, the department of transportation and department of natural resources shall cooperate with the department of health services in establishing the donor registry. The department of health services shall promulgate administrative rules governing any donor registry established under this subsection.

Sec. 227.11 (2)(a), Stats.: Rule-making authority is expressly conferred on an agency as follows:

(a) Each agency may promulgate rules interpreting the provisions of any statute enforced or administered by the agency, if the agency considers it necessary to effectuate the purpose of the statute, but a rule is not valid if the rule exceeds the bounds of correct interpretation. All of the following apply to the promulgation of a rule interpreting the provisions of a statute enforced or administered by an agency:

1. A statutory or nonstatutory provision containing a statement or declaration of legislative intent, purpose, findings, or policy does not confer rule-making authority on the agency or augment the agency's rule-making authority beyond the rule-making authority that is explicitly conferred on the agency by the legislature.
2. A statutory provision describing the agency's general powers or duties does not confer rule-making authority on the agency or augment the agency's rule-making authority beyond the rule-making authority that is explicitly conferred on the agency by the legislature.
3. A statutory provision containing a specific standard, requirement, or threshold does not confer on the agency the authority to promulgate, enforce, or administer a rule that contains a standard, requirement, or threshold that is more restrictive than the standard, requirement, or threshold contained in the statutory provision.

c. **Statute/s or rule/s that will affect the proposed rule or be affected by it**

Chapter DHS 137

Section 29.024, Stats.

Section 157.06, Stats.

6. **Estimates of the amount of time that state employees will spend to develop the rule and other necessary resources**

The estimated time for state employees to develop the rule is 2,080 hours. This includes the time required for research and analysis, drafting rule language, preparing related documents, holding a public hearing, and communicating with stakeholders and other affected parties.

7. **Description of all of the entities that may be affected by the rule, including any local governmental units, businesses, economic sectors, or public utility ratepayers who may reasonably be anticipated to be affected by the rule**

- Organ, tissue, and eye recovery organizations that work with people in Wisconsin.
- Hospitals; donation and transplantation professionals and advocates.
- Individuals and families waiting for lifesaving and healing procedures.

8. **Summary and preliminary comparison of any existing or proposed federal regulation that is intended to address the activities to be regulated by the rule**

There are federal regulations regarding the recovery and distribution of donated organs, tissues, and eyes. For organs, regulation includes the 1984 — National Organ Transplant Act (NOTA — P.L. 98-507). NOTA established the framework for the OPTN within the United States, the Scientific Registry of Transplant Recipients, a government unit within the Public Health Service (Division of Transplantation) to oversee contractual activities of the OPTN and prohibited the buying and selling of organs. The regulation and distribution of donated tissue is governed by the Food and Drug Administration. These rules and regulations govern the distribution of organs and tissues once recovered. Rules regarding registries and consent for donation are determined by states.

9. Anticipated economic impact, locally or statewide

The proposed rule is anticipated to have no economic impact.

10. Agency contacts

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