PROPOSED ORDER OF DEPARTMENT OF HEALTH AND FAMILY SERVICES TO ADOPT RULES

The Wisconsin Department of Health and Family Services proposes to create chapter HFS 137, relating to prescribing forms for use by physicians, technicians, and tissue bank employees when removing organs and tissue, other than cardiovascular tissue from decedents.

SUMMARY OF PROPOSED RULE

Statute interpreted: Sections 157.06 (4m) (e), 157.06 (4r), and 157.06 (9m), 227.01 (13), 227.23, Stats.

Statutory authority: Sections 157.06 (9m) and 227.11 (2), Stats.

Explanation of agency authority:

Wisconsin Act 230, created s. 157.06 (9m), Stats., which requires the department to prescribe by rule, a form for use by physicians when removing an organ from a decedent under s. 157.06 (4m), Stats., and 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 (4m), Stats.

Related statute or rule: Section 157.06 (4m) and (9m), Stats.

Plain language analysis:

The department is required by 2005 Wisconsin Act 230 to appoint an advisory committee to assist the department in prescribing, by rule, a form for removal of organs and a form for removal of tissue, other than cardiovascular tissue, for use by physicians, technicians, and tissue bank employees under section 157.06 (4m) (e) of the statutes, as created by Act 230. Section 157.06 (4m) (e), Stats., requires a physician who removes tissue or an organ from a decedent or a technician or tissue bank employee who removes tissue from a decedent under s. 157.06 (4m), Stats., to complete the form created by the department and transmit the form to the coroner or medical examiner with jurisdiction over the decedent.

As required by section. 12. (1) (b) of Act 230, the department intends to promulgate emergency rules effective August 1, 2006 that are substantially identical to the proposed rules.

Because these rules only prescribe forms, the department will, as allowed under s. 227.23, Stats., promulgate these rules without adhering to the notice and public hearing requirements set forth under ch. 227, Stats. Also, as allowed under s. 227.23, Stats., the forms prescribed by the proposed rules will not be published in the code or register, but be listed by title and description with a statement as to how the forms may be obtained.

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

There is no known existing or proposed federal regulation that is comparable to the proposed rules.

Comparison with rules in adjacent states:

A search of the administrative codes in Minnesota, Iowa, Illinois, Indiana, and Michigan showed no comparable rules.

Summary of factual data and analytical methodologies:

The department relied on all of the following sources to draft the proposed rules or to determine the impact on small businesses:

- As required by 2005 Act 230, the forms prescribed by the proposed rule will be created with input from a department appointed advisory committee that is comprised of coroners, forensic pathologists, medical examiners, organ procurement organization personnel, tissue banks, and district attorneys.
- Department data on organ procurement organizations and tissue banks.
- Section 227.114 (1) (a), Stats., defines "small business" as a business entity, including its affiliates, which is independently owned and operated and not dominant in its field, and which employees 25 or fewer full-time employees or which has gross annual sales of less than \$5,000,000.

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

The proposed rules will have no effect on small businesses. The legislature by creation of s. 157.06 (4m), Stats., in 2005 Act 230, requires physicians, technicians, and tissue bank employees to complete the form prescribed by the proposed rules. The proposed rules will only list the number, title, and information on how the forms can be obtained. The proposed rules do not include any requirements independent of the requirements set forth in s. 157.06 (4m), Stats. The persons that are affected by the proposed rules are organ donor procurement organizations, hospitals, and tissue banks, physicians, technicians and tissue bank employees.

Effect on small business:

The proposed rules will not affect small businesses.

Agency contact person:

Martha Mallon Bureau of Community Health Promotion 1 West Wilson Street P.O. Box 2659 Madison, WI 53701-2659 (608) 261-6584 or, if you are hearing impaired, (608) 261-9314 (TTY) mallomi@dhfs.state.wi.us

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

Comments may be submitted to the agency contact person that is listed above and via the Wisconsin Administrative Rules Website at http://adminrules.wisconsin.gov until 4:30 p.m. on August 11, 2006.

TEXT OF PROPOSED RULE

SECTION 1. HFS 137 is created to read:

CHAPTER HFS 137

FORMS FOR USE WHEN REMOVING ORGANS AND TISSUES

HFS 137.01 Authority and purpose

HFS 137.02 Applicability

HFS 137.03 Form for use when removing tissue from a decedent

HFS 137.04 Form for use when removing organs from a decedent

HFS 137.01 Authority and purpose. (1) To prescribe by rule under the authority of s. 157.06 (9m), Stats., a form for use by physicians when removing an organ from a decedent under s. 157.06 (4m), Stats., and 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 (4m), Stats.

(2) Pursuant to s. 157.06 (4m) (e) 3., Stats., a physician, technician, or tissue bank employee shall complete the form prescribed under this chapter and transmit the completed form to the coroner or medical examiner with jurisdiction over the decedent.

HFS 137.02 Applicability. This chapter applies to physicians, technicians, and tissue bank employees, coroners and medical examiners.

HFS 137.03 Form for use when removing tissue from a decedent.

Form Number Title

DPH-137-02 Tissue recovery.

Note: Form HFS 137.02 can be obtained from the Department's website at <u>www.dhfs.state.wi.us</u>

HFS 137.04 Form for use when removing organs from a decedent.

Form Number Title

DPH-137-02 Organ recovery.

Note: Form HFS 137-02 can be obtained from the Department's website at <u>www.dhfs.state.wi.us</u>

SECTION 2. 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) (intro.), Stats.

Wisconsin Department of Health and Family Services

Dated:

Helene Nelson, Department Secretary

SEAL: