

Clearinghouse Rule 09-089

PROPOSED ORDER OF DEPARTMENT OF HEALTH SERVICES TO ADOPT RULES

The Wisconsin Department of Health Services proposes to repeal and create DHS 124.05 (3) (i); and to create DHS 124.05 (3) (j) and 124.24 (3), relating to forfeitures, anatomical gifts, and automated external defibrillator (AED) training for hospitals.

SUMMARY OF PROPOSED RULE

Statutes interpreted: Sections 50.36 (5), 50.375, 50.377 (1), (3), and (4), and 157.06 Stats.

Statutory authority: Sections 50.36 (1), 50.377 (2), and 227.11 (2) (a), Stats.

Explanation of agency authority:

Section 50.36 (1), Stats., requires the department to promulgate rules for the construction, maintenance and operation of hospitals deemed necessary to provide safe and adequate care and treatment of patients and to protect the health and safety of patients in a hospital. Section 50.377 (2), Stats., permits the department to directly assess forfeitures for violations of s. 50.375 (2) and (3), Stats., relating to emergency contraception for sexual assault victims. Section 227.11 (2) (a), Stats., provides state agencies with general rulemaking authority to 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.

Related statute or rule:

See the “Statutes interpreted” and “Statutory authority” sections.

Plain language analysis:

Section 157.06, Stats., specifies provisions relating to anatomical gifts. Under this proposed order, the department replaces the existing requirements under s. DHS 124.05 (3) (i), with a requirement for hospitals to comply with relevant provisions relating to anatomical gifts under s. 157.06, Stats. The proposed rule removes the more prescriptive requirements on the subject.

Section 50.36 (5), Stats., requires that before providing emergency services in a hospital, medical and nursing personnel have proficiency in the use of an automated external defibrillator (AED) achieved through instruction provided by an individual, organization or institution that is approved by the department. The proposed rule requires that before providing emergency services, hospital medical and nursing personnel be proficient in the use of automated external defibrillators.

Section 50.375, Stats., requires a hospital that provides emergency services to provide emergency contraception services to a female victim of sexual assault. Section 50.377, Stats., provides that “[w]hoever violates a requirement under s. 50.375 (2) or (3), Stats., may be required to forfeit not less than \$2,500 nor more than \$5,000 for each violation.” There are 3 separate requirements under s. 50.375 (2), Stats., and one requirement under s. 50.375 (3), Stats. The department, under s. 50.377, (2),

Stats., may directly assess the forfeitures for violations of these requirements. Under this proposed order, the department establishes forfeiture dollar amounts for violations of s. 50.375 (2) and (3), Stats., and the statutory requirements for notice of assessment and appeal rights relating to a forfeiture assessment. A hospital that violates all 4 requirements would be subject to a total forfeiture of \$10,000 for the first violation of those requirements, and a total forfeiture of \$20,000 for a subsequent violation of the same requirements.

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:

Emergency contraception: Illinois administrative code requires hospitals to provide medical and factually accurate written and oral information about emergency contraception and how and when victims may be provided emergency contraception. Hospitals that are found out of compliance with the code have 14 working days to submit a plan of correction to the state agency. If the hospital fails to submit an acceptable plan of correction or fails to implement the plan of correction within the time frames, the hospital is subject to the imposition of a fine of up to \$100 per day until the hospital complies with the requirement of the code. Administrative Code Section: 77 Ill. Adm. Code 545.95 and 545.67. The proposed rule establishes forfeiture amounts as permitted under s. 50.389, Stats., for violations of s. 50.375 (2) or (3), Stats., relating to emergency contraception for sexual assault victims.

Anatomical gifts: Illinois administrative code requires hospitals to have an agreement with its federally designated organ procurement agency providing for notification when potential organ donors become available and to provide access to the medical records of deceased patients. Administrative Code Section: 77 Ill. Adm. Code 250.280. The proposed rule requires hospitals to comply with relevant provisions under s.157.06, Stats., relating to anatomical gifts. The proposed rule removes the more prescriptive requirements on the subject.

Automated external defibrillators: Illinois administrative code requires users of AEDs to be trained. Administrative Code Section: 77 Ill. Adm. Code 525.400. The proposed rule requires that before providing emergency services, hospital medical and nursing personnel to be proficient in the use of automated external defibrillators.

Iowa:

Emergency contraception: Iowa has no administrative code regarding emergency contraception in hospitals. The proposed rule establishes forfeiture amounts as permitted under s. 50.389, Stats., for violations of s. 50.375 (2) or (3), Stats., relating to emergency contraception for sexual assault victims.

Anatomical gifts: Iowa has no administrative code regarding anatomical gifts in hospitals. The proposed rule requires hospitals to comply with relevant provisions under s.157.06, Stats., relating to anatomical gifts. The proposed rule removes the more prescriptive requirements on the subject.

Automated external defibrillators: Iowa has no administrative code regarding the use of automated external defibrillators in hospitals. The proposed rule requires that before providing emergency

services, hospital medical and nursing personnel be proficient in the use of automated external defibrillators.

Michigan:

Emergency contraception: Michigan has no administrative code regarding emergency contraception in hospitals. The proposed rule establishes forfeiture amounts as permitted under s. 50.389, Stats., for violations of s. 50.375 (2) or (3), Stats., relating to emergency contraception for sexual assault victims.

Anatomical gifts: Michigan has no administrative code regarding anatomical gifts in hospitals. The proposed rule requires hospitals to comply with relevant provisions under s.157.06, Stats., relating to anatomical gifts. The proposed rule removes the more prescriptive requirements on the subject.

Automated external defibrillators: Michigan has no administrative code regarding the use automated external defibrillators in hospitals. The proposed rule requires that before providing emergency services, hospital medical and nursing personnel be proficient in the use of automated external defibrillators.

Minnesota:

Emergency contraception: Minnesota has no administrative code regarding emergency contraception. The proposed rule establishes forfeiture amounts as permitted under s. 50.389, Stats., for violations of s. 50.375 (2) or (3), Stats., relating to emergency contraception for sexual assault victims.

Anatomical gifts: Minnesota has no administrative code regarding anatomical gifts in hospitals. The proposed rule requires hospitals to comply with relevant provisions under s.157.06, Stats., relating to anatomical gifts. The proposed rule removes the more prescriptive requirements on the subject.

Automated external defibrillators: Minnesota has no administrative code regarding the use automated external defibrillators in hospitals. The proposed rule requires that before providing emergency services, hospital medical and nursing personnel be proficient in the use of automated external defibrillators.

Summary of factual data and analytical methodologies:

The Department relied on all of the following sources to draft the proposed rule to determine the impact on small businesses.

- The Department solicited comments from representatives of the Wisconsin Hospital and Health Association, Wisconsin Public Psychiatric Hospital, Rural Wisconsin Health Cooperative and Planned Parenthood of Wisconsin. Representatives from these organizations reviewed the initial draft of the rule.
- The 2002 Economic Census – Wisconsin Geographic Series, compiled by the U.S. census bureau every 5 years for each year ending in “2” and “7” and contains the latest available economic data (2007 data is not yet published-August 2009) compiled on businesses located in Wisconsin.

- Criteria adopted by the Department and approved by the Wisconsin Small Business Regulatory Review Board to determine whether the Department's proposed rules have a significant economic impact on a substantial number of small businesses. Pursuant to the Department's criteria, a proposed rule will have a significant economic impact on a substantial number of small businesses if at least 10% of the businesses affected by the proposed rules are small businesses and if operating expenditures, including annualized capital expenditures, increase by more than the prior year's consumer price index or reduces revenues by more than the prior year's consumer price index. For the purposes of this rulemaking, 2008 is the index year. The consumer price index is compiled by the U.S. Department of Labor, Bureau of Labor Statistics; the preliminary rate for the Midwest in 2008 is currently estimated at 3.9 percent.
- Section 227.114 (1) (a), Wisconsin 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 employs 25 or fewer full-time employees or which has gross annual sales of less than \$5,000,000.
- DHS databases including the Aspen information System which contains demographic, licensing, program, and compliance history of hospitals in Wisconsin.

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

The North American Industry Classification System (NAICS) includes hospitals in the Health Care and Social Assistance sector, (sector 62) and further defined in sub-sector 622 hospitals. Industries in the hospitals subsector provide medical, diagnostic, and treatment services that include physician, nursing, and other health services to inpatients and the specialized accommodation services required by inpatients. Hospitals may also provide outpatient services as a secondary activity. Establishments in the Hospitals subsector provide inpatient health services, many of which can only be provided using the specialized facilities and equipment that form a significant and integral part of the production process. Employment statistics and revenue data from the 2002 NAICS dataset for Wisconsin report \$9.4 billion in revenue with over 103,000 employees receiving over \$3.5 billion in wages.

None of Wisconsin's hospitals meet the definition of a small business under s. 227.114 (1), Stats.

Effect on small business:

There is no fiscal impact on small business as defined in s. 227.114 (1), Stats., as none of Wisconsin's hospitals meet the definition of a small business.

Agency contact person:

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 Division of Quality Assurance
 1 West Wilson St., Room 1150
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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. DHS 124.05 (3) (i) is repealed and recreated to read:

DHS 124.05 (3) (i) *Anatomical gifts*. Every hospital shall comply with relevant provisions relating to anatomical gifts under s. 157.06, Stats.

SECTION 2. DHS 124.05 (3) (j) is created to read:

DHS 124.05 (3) (j) *Use of automated external defibrillators*. Before providing emergency services in a hospital, medical and nursing personnel shall have proficiency in the use of an automated external defibrillator as defined in s. 256.15 (1) (cr), Stats., achieved through instruction provided by an individual, organization, or institution of higher education that is approved under s. 46.03 (38), Stats., to provide such instruction.

SECTION 3. DHS 124.24 (3) is created to read:

DHS 124.24 (3) **FORFEITURE ASSESSMENT.**(a) In this subsection, “victim” means a female who alleges or for whom it is alleged that she suffered sexual assault and who, as a result of the sexual assault, presents as a patient at a hospital that provides emergency services.

(b) The department may directly assess a forfeiture for each violation of a requirement under s. 50.375 (2) or (3), Stats., for care of a victim by a hospital that provides emergency services. The department may assess the forfeitures as follows:

1. \$2,500 for a first violation of a requirement under s. 50.375 (2) or (3), Stats.
2. \$5,000 for a subsequent violation of a requirement under s. 50.375 (2) or (3), Stats.

Note: Section 50.375 (2), Stats., requires a hospital that provides emergency services to a victim to 1) provide the victim medically and factually accurate and unbiased written and oral information about emergency contraception and its use and efficacy; 2) orally inform the victim of her option to receive emergency contraception at the hospital, her option to report the sexual assault to a law enforcement agency, any available options for her to receive an examination to gather evidence regarding the sexual assault; and 3) except as specified in s. 50.375 (4), Stats., immediately provide to the victim upon her request emergency contraception, in accordance with instructions approved by the federal food and drug administration. If the medication is taken in more than one dosage, the hospital shall provide all subsequent dosages to the victim for later self administration.

Note: Section 50.375 (3), Stats., requires a hospital that provides emergency care to ensure that each hospital employee who provides care to a victim has available medically and factually accurate and unbiased information about emergency contraception.

(c) If the department determines that a forfeiture should be assessed for a particular violation, the department shall send a notice of assessment to the hospital. The notice shall specify the amount of the

forfeiture assessed, the violation and the statute or rule alleged to have been violated, and shall inform the hospital of the right to a hearing under par. (d) pursuant to s. 50.377 (3), Stats.

(d) Pursuant to 50.377 (3), Stats., a hospital may contest an assessment of a forfeiture by the department under par. (b) by sending, within 10 days after receipt of notice under par. (c), a written request for a hearing under s. 227.44, Stats., to the division of hearings and appeals. The administrator of the division may designate a hearing examiner to preside over the case and recommend a decision to the administrator under s. 227.46, Stats. The decision of the administrator of the division shall be the final administrative decision. The division shall commence the hearing within 30 days after receipt of the request for a hearing and shall issue a final decision within 15 days after the close of the hearing.

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: