

STATEMENT OF SCOPE
DEPARTMENT OF HEALTH SERVICES

The Governor approved this Statement of Scope on February 20, 2015.

Rule No.: DHS 124

Relating to: Hospitals

Rule Type: Permanent and Emergency

Type of Statement of Scope: Original

1. Finding/nature of emergency (Emergency Rule only):

The department finds that an emergency exists and that the adoption of an emergency rule may be necessary for the immediate preservation of the public health, safety and welfare. The facts constituting the emergency are as follows:

Beginning July 1, 2016, pursuant to s. 50.36 (1m) (a), (b), and (c), Stats., the department may not, except for s. DHS 124.24 (3), enforce any of the rules contained in s. DHS 124.40 or subch. II, III, or IV of ch. DHS 124. Under s. 50.36 (1), Stats., if additional rules are necessary to provide safe and adequate care and treatment of hospital patients and to protect the health and safety of the patients and employees, the department may promulgate those additional rules.

The department has determined that additional rules are necessary. The department has further determined that promulgating the rules may take at least 24 months to complete, or longer if the permanent rules are not able to be submitted to the legislature prior to its last general business floor period in 2016. The department has further determined that if the permitted rules cannot be promulgated by July 1, 2016, a regulatory gap will exist wherein, pursuant to s. 227.10 (2m), Stats., and 2011 Executive Order #50, agencies are prohibited from implementing or enforcing any standard requirement, or threshold, including as a term or condition of any license issued by the agency, unless that standard requirement, or threshold is explicitly required or explicitly permitted by statute or by a rule that has been promulgated. Thus, notwithstanding s. 50.36 (1m) (c), Stats., which requires the rules to be permanent rules in order to be enforceable, the department may promulgate emergency rules on or before July 1, 2016, to comply with s. 50.36 (1m) (a) 2. and (b), Stats., and to close any regulatory gap until the permanent rules become effective in the event that the department cannot promulgate permanent rules by July 1, 2016.

2. Detailed description of the objective of the proposed rule:

The objective of the proposed rule is to comply with s. 50.36 (1m) (a) 2., Stats., and as permitted by s. 50.36 (1), Stats., promulgate rules for maternity and neonatal care; physical environment; plan review; patient rights in critical access hospitals; satellite emergency locations; the granting of waivers and variances; and plans of correction of violations of ch. DHS 124 and ss. 50.32 to 50.39, Stats.

3a. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

Effective July 1, 2016, pursuant to s. 50.36 (1m) (a) and (b) Stats., the department may not, except for s. DHS 124.24 (3) enforce any of the rules contained in s. DHS 124.40 or subch. II, III, or IV of ch. DHS 124. Also effective July 1, 2016, s. 50.36 (1), Stats., requires the department to use and enforce the Medicare conditions of participation for hospitals as the minimum standards that apply to hospitals, and interpret the conditions for Medicare participation for hospitals using guidelines adopted by the federal Centers for Medicare and Medicaid Services unless the department determines that a different interpretation is reasonably necessary to protect public health and safety.

Section 50.36 (1), Stats., allows the department to promulgate, adopt, amend and enforce additional rules and standards for the construction, maintenance and operation of hospitals that the department determines are necessary to provide safe and adequate care and treatment of hospital patients and to protect the health and safety of the patients and employees.

Pursuant to ss. 50.36 (1) and (1m) (a), Stats., the department will promulgate rules for the following:

Plans of correction

Section 50.36 (4), Stats., requires the department to provide hospitals the opportunity to consult with the department concerning compliance and noncompliance with ch. DHS 124 and ss. 50.32 to 50.39, Stats. The department's current practice in addressing noncompliance is to issue the hospital a written statement of deficiency with a request that the hospital submit a written plan to the department describing how the hospital will correct the deficiency. Neither s. 50.36 (4), Stats., nor ch. DHS 124, explicitly address written statements of deficiencies or written plans of

correction. The department proposes to promulgate rules concerning the manner and method of communicating violations of ch. DHS 124 and ss. 50.32 to 50.39, Stats., to hospitals and to require hospitals to submit a written plan of correction to the department for a violation of ch. DHS 124 or ss. 50.32 to 50.39, Stats., for review and approval by the department.

Waivers and variances

Section DHS 124.04 establishes standards for granting waivers and variances by the department of a requirement of ch. DHS 124. These standards include the conditions under which the department may grant a waiver or a variance, application procedures for hospitals to make a request, conditions on granting the waiver or variance that may be added by the department, the ability of a hospital to contest the department's action on an application for a waiver or a variance and the conditions under which the department may revoke a waiver or a variance.

Section 50.36 (6m), Stats., establishes the ability of the department to grant a variance or a waiver of a requirement for hospitals. The provision includes the conditions for granting a request from the hospital and a stated term of the variance or waiver. The statute does not specify how such requests will be effectuated. The department intends to propose rules similar to the current provisions in s. DHS 124.04 to implement the provisions at s. 50.36 (6m), Stats.

Maternity and neonatal care

Section DHS 124.20 (5) establishes standards for the care and treatment of maternity patients and newborns. The department intends to propose rules for the care and treatment of maternity patients and newborns. Such rules may include, but may not be limited to, admissions, services for high-risk infants, institutional transfer of patients, infection control, labor and delivery, postpartum care, and neonatal care.

Patient rights and responsibilities in critical access hospitals

Section DHS 124.05 (3) (a) sets forth patient rights and hospitals' responsibilities to patients in hospitals, including critical access hospitals. These rights include, but are not limited to, the right to be treated with consideration, respect and recognition of their individuality, including the need for privacy in treatment, and confidentiality of their medical record. Every patient must also be given the opportunity to participate to the fullest extent possible in planning for his or her care and treatment.

The department is required under s. 50.36 (1), Stats., to use and enforce the conditions for Medicare participation for hospitals as the minimum standards that apply to hospitals. Because the conditions for Medicare participation under 42 CFR 485 for critical access hospitals do not contain standards for patient rights and responsibilities, the department intends to propose rules that would give patients in critical access hospitals patient rights similar to those afforded to patients in general hospitals.

Satellite emergency locations

Off-site emergency locations, also referred to as satellite emergency departments, freestanding emergency departments, emergency centers, or emergency care centers are a growing trend in emergency services across the nation, and in Wisconsin. Existing rules do not address the department's current policies and practices concerning emergency services provided at off-site emergency departments. Two hospitals in Wisconsin currently operate off-site emergency services under waiver of existing administrative rules which prohibit off-site emergency departments in part by requiring that emergency departments to be located in close proximity to an exterior entrance to a hospital. The department proposes to promulgate rules for the operation of off-site emergency departments to the extent deemed necessary to provide safe and adequate care and treatment of patients, and to protect the health and safety of the patients and employees. Proposed rules may include provisions relating to non-Medicare participating hospitals with emergency departments conducting medical screening examinations, stabilization, and treatment of persons with emergency medical conditions without regard to the person's ability to pay.

Physical environment

Existing rules under ch. DHS 124 subch. V, relating to the hospital's physical environment requires hospitals to design, construct, and operate their facilities in accordance with the Life Safety Code, national standards on construction and fire safety established by the National Fire Protection Association. The rules also require that patient rooms be of sufficient size, supported by sanitary support spaces, and afford the patient privacy and the means to contact staff, fire safe finishes, emergency procedures, and fire incident reporting to the department.

The department intends to propose rules relating to the physical environment of a hospital including patient rooms, additional patient care areas, walls, floors, carpeting and fire incident reporting to the department. The proposed rules may include requiring hospitals to be constructed and operated in accordance with applicable provisions of the 2014 edition of the Facilities Guidelines Institute (FGI) guidelines or other standards deemed appropriate. The FGI is a resource which provides a consensus technical design standard and basis for regulating the healthcare industry. The department also intends to propose that hospitals meet the provisions of the 2012 edition of the Life Safety Code (LSC) adopted into the federal Conditions of Participation.

Plan review and fee schedule

Section 50.36 (2) (a), Stats., requires the department to conduct plan reviews of all capital construction and remodeling projects of hospitals to ensure that the plans comply with applicable building code requirements under ch. 101, Stats., and with the physical plant requirements under Chapter 50, Stats., or department rules. Section 50.36 (2) (b), Stats., requires the department to promulgate rules that establish a fee schedule for its services in conducting plan reviews. Sections DHS 124.29, 124.30, and 124.31 establish plan review requirements and a fee schedule for plan reviews as authorized under s. 50.36 (2) (a) and (b), Stats. The department proposes to revise the requirements for plan reviews and prescribe a fee schedule for providing plan review services.

3b. Analysis of policy alternatives

There are no reasonable alternative to the proposed rulemaking.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

The department's authority to promulgate rules is as follows:

Section 50.36 (1), Stats., reads: The department may promulgate, adopt, amend and enforce additional rules and standards for the construction, maintenance and operation of hospitals that the department determines necessary to provide safe and adequate care and treatment of hospital patients and to protect the health and safety of the patients and employees. The building codes and construction standards of the department of safety and professional services shall apply to all hospitals to the extent they are not incompatible with any building codes or construction standards required by the conditions of Medicare participation for hospitals. Except for the construction codes and standards of the department of safety and professional services and except as provided in s. 50.39 (3), Stats., the department shall be the sole agency to adopt and enforce rules and standards pertaining to hospitals.

Section 50.36 (2) (a) and (b), Stats., reads: Notwithstanding sub. (3L), the department shall conduct plan reviews of all capital construction and remodeling projects of hospitals to ensure that the plans comply with any applicable building code requirements under ch. 101 and with any physical plant requirements under this chapter or under rules promulgated under this chapter.

(b) The department shall promulgate rules that establish a fee schedule for its services in conducting the plan reviews under par. (a).

Section 227.11 (2) (a), Stats, reads: 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.

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:

The department will spend approximately 1,500 staff hours for rulemaking. The department may form a committee to assist in developing the rule.

6. List with description of all entities that may be affected by the proposed rule:

The entities that may be affected by the proposed rule are hospitals, including critical access hospitals, patients, and the general public.

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:

There are no existing or proposed federal regulations that address the activities regulated by the proposed rule.

8. Anticipated economic impact of implementing the rule:

The department anticipates that the proposed rules would have little to no economic impact.

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