

RULEMAKING REPORT TO LEGISLATURE

CLEARINGHOUSE RULE 19-135

Ch. DHS 124

Basis and Purpose of Proposed Rule

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. Also effective July 1, 2016, s. 50.36 (1), Stats., requires the department to use and enforce 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. The department may promulgate additional rules if they 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, per s. 50.36 (1), Stats.

The department has determined that the following rule changes are necessary to ensure a safe and adequate environment for hospital patients and employees and to protect the health and welfare of the patients and employees. The rule would affect hospitals licensed by the State of Wisconsin.

The proposed rule also incorporates the NFPA Life Safety Code 101 - 2012 edition. Consent to incorporate the standards was given in writing by the Attorney General, pursuant to s. 227.21 (2) (a), Stats., on December 5, 2019.

Plans of correction

Section 50.36 (4), Stats., states that if the department takes enforcement action against a hospital for a violation of the requirements for hospitals, and the department subsequently conducts an on-site inspection of the hospital to review the hospital's action to correct the violation, the department may, unless the hospital is operated by the state, impose a \$200 inspection fee on the hospital. The proposed rules establish the manner in which violations of requirements stated in ch. DHS 124 and ss. 50.32 to 50.39, Stats., must be communicated to hospitals and the manner in which the hospital communicates its plan to correct the violation to the department.

Waivers and variances

Section 50.36 (6m), Stats., authorizes the department to grant a variance or a waiver of a requirement for hospitals. The proposed rule interprets the circumstances under which a waiver or variance would be seen to support the efficient and economic operation of the hospital.

Maternity and neonatal care

Section 50.36 (1), Stats., provides that the department must use and enforce the conditions for Medicare participation for hospitals as quality control measures, but may promulgate such additional rules as it deems necessary for safe and adequate care of hospital patients and to protect the health and safety of the patients and employees. The department has determined that additional rules are necessary to address the care and treatment of maternity patients and newborns regarding personnel, admission, patient placement and transfer, delivery, security, labor inducing medication and nursery.

Patient rights and responsibilities in critical access hospitals

Section 50.36 (1), Stats., provides that the department must use and enforce the conditions for Medicare participation for hospitals as quality control measures, but may promulgate such additional rules as it deems necessary for safe and adequate care of hospital patients and to protect the health and safety of the patients and employees. The conditions of participation for Medicare do not address patient rights in the critical access hospital setting. Proposed rules establish patient rights similar to the rights in the previous provisions contained in s. DHS 124.05 (3) (a).

Freestanding emergency departments

Section 50.36(1), Stats., provides that the department must use and enforce the conditions for Medicare participation for hospitals as quality control measures, but may promulgate such additional rules as it deems necessary for safe and adequate care of hospital patients and to protect the health and safety of the patients and employees. It was determined that additional rules were necessary to address physical environment, personnel, laboratory, and pharmacy and ambulance delivery in these settings.

Physical environment

Existing rules under ch. DHS 124, subch. V, relating to the hospital's physical environment, require 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. Proposed rules require hospitals to meet the provisions of the Life Safety Code (LSC) adopted into the federal Conditions of Participation.

Department Response to Legislative Council Rules Clearinghouse Recommendations

The Department accepted all of the recommendations from the Legislative Council Rules Clearinghouse.

Final Regulatory Flexibility Analysis

The issues raised by each small business during the public hearing(s).

N/A

Any changes in the rule as a result of an alternative suggested by a small business and the reasons for rejecting any of those alternatives.

N/A

The nature of any reports and estimated cost of their preparation by small businesses that must comply with the rule.

N/A

The nature and estimated costs of other measures and investments that will be required by small businesses in complying with the rule.

N/A

The reason for including or not including in the proposed rule any of the following methods for reducing the rule's impact on small businesses, including additional cost, if any, to the department for administering or enforcing a rule which includes methods for reducing the rule's impact on small businesses and the impact on public health, safety and welfare, if any, caused by including methods in rules

N/A

Changes to the Analysis or Fiscal Estimate/Economic Impact Analysis

Analysis

N/A

Fiscal Estimate/Economic Impact Analysis

N/A

Public Hearing Summary

The department began accepting public comments on the proposed rule via the Wisconsin Legislature Administrative Rules website, and through the Department's Administrative Rules Website on 11/25/19. A public hearing was held on 12/06/19, in Madison, WI. Public comments on the proposed rule were accepted until 12/06/19

List of the persons who appeared or registered for or against the Proposed Rule at the Public Hearing.

| Registrant | Position Taken (Support or Opposed) |
|-------------------|---|
| Matthew Stanford | Neither |

Summary of Public Comments to the Proposed Rule and the Agency's response to those comments, and an explanation of any modification made in the proposed rule as a result of public comments or testimony received at the Public Hearing.

| Rule Provision | Public Comment | Department Response |
|---|--|--|
| DHS 124.02 (10) DHS 124.124.04 (2) DHS 124.05 | The Wisconsin Hospital Association (WHA) proposed that the definitions of medical staff and network hospital, and the provisions related to statements of deficiency and plans of correction and waivers and variances be revised to provide clearer alignment with the Medicare Conditions of Participation and /or Chapter 50. | The Department of Health Services (DHS) accepted the proposed definitions of medical staff and network hospital and the proposed revisions related to waivers and variances and made the revision to the proposed rule. DHS did not accept the proposed language related to statements of deficiency and plans of correction. |
| | WHA recommended technical and clarifying revisions to the proposed rule to help address potential confusion or misinterpretation. | DHS accepted recommendations to clarify the proposed rule and made revisions to the proposed rule. |
| | WHA recommended technical and clarifying revisions to proposed rule to help address confusion or misinterpretation regarding the physical environment and plan review section of the proposed code. | DHS accepted recommendations to clarify revisions to the proposed rule regarding physical environment and plan review and made revisions to the proposed rule. |
| DHS 124.29 (9) | WHA recommended revisions to ensure a more efficient plan review and inspection process for hospitals. | DHS accepted the recommendations to ensure a more efficient plan review and inspection process and made revisions to the proposed rule. |

Summary of Items Submitted with this Report to the Legislature

Below is a checklist of the items that are attached to or included in this report to the legislature under s. 227.19 (3), Stats.

| Documents/Information | Included in Report | Attached | Not Applicable |
|---|--------------------|----------|----------------|
| Final proposed rule -- Rule Summary and Rule Text | | X | |
| Department response to Rules Clearinghouse recommendations | X | | |
| Final Regulatory Flexibility Analysis | | | X |
| Changes to the Analysis or Fiscal Estimate/Economic Impact Analysis | | | X |
| Public Hearing Summary | X | | |
| List of Public Hearing Attendees and Commenters | X | | |
| Summary of Public Comments and Department Responses | X | | |
| Fiscal Estimate/Economic Impact Analysis | | X | |
| Revised Fiscal Estimate/Economic Impact Analysis | | | X |
| Small Business Regulatory Review Board (SBRRB) statement, suggested changes, or other material, and reports made under s. 227.14 (2g), Stats. and Department's response | | | X |
| Department of Administration (DOA) report under s. 227.115 (2), Stats., on rules affecting housing | | | X |
| DOA report under s. 227.137 (6), Stats., on rules with economic impact of \$20 MM or more | | | X |
| Public Safety Commission (PSC) energy impact report under s. 227.117 (2), Stats. and the Department's response, including a description of changes made to the rule | | | X |