

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code, Section 1007 (16 Del.C. §1007)

16 DE Admin. Code 4407

FINAL

ORDER

4407 Hospital Standards (Construction, Maintenance, and Operation)

NATURE OF THE PROCEEDINGS:

The Delaware Department of Health and Social Services ("DHSS") initiated proceedings to adopt the State of Delaware Regulations Governing Hospital Standards (Construction, Maintenance, and Operation). The DHSS proceedings to adopt regulations were initiated pursuant to 29 Delaware Code Chapter 101 and authority as prescribed by 16 Del.C. §1007.

On August 1, 2014 (Volume 18, Issue 2), DHSS published in the Delaware *Register of Regulations* its notice of proposed regulations, pursuant to 29 Del.C. §10115. It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by September 2, 2014, after which time the DHSS would review information, factual evidence and public comment to the said proposed regulations.

Written comments were received during the public comment period and evaluated. The results of that evaluation are summarized in the accompanying "Summary of Evidence."

SUMMARY OF EVIDENCE

In accordance with Delaware Law, public notices regarding proposed Department of Health and Social Services (DHSS) Regulations Governing Hospital Standards (Construction, Maintenance, and Operation) were published in the *Delaware State News*, the *News Journal* and the *Delaware Register of Regulations*.

Entities offering written comments include:

- State Council for Persons with Disabilities, Denise McMullin-Powell, Chairperson
- Governor's Advisory Council for Exceptional Citizens, Robert D. Overmiller, Chairperson

Public comments and the DHSS (Agency) responses are as follows:

State Council for Persons with Disabilities, Denise McMullin-Powell, Chairperson:

The State Council for Persons with Disabilities (SCPD) has reviewed the Department of Health and Social Services/ Division of Public Health's (DPH's) proposal to amend its hospital standards to ensure that hospital staff have ready access to a locked hospital bathroom in the event of an emergency. This is a result of enactment of H.B. 129 ("Christina's Law") which the Governor signed on June 10, 2014. DPH is implementing the statutory mandate by proposing the addition of the following subsection to its regulations covering hospital construction, maintenance, and operation:

4.4. Hospitals must develop and implement policies and procedures for hospital staff to have ready access to a locked hospital bathroom in the event of an emergency.

The proposed regulation was published as 18 DE Reg. 119 in the August 1, 2014 issue of the *Register of Regulations*. SCPD has the following observations.

First, placement of this sentence in the personnel-related "§4.0 Governing Body, Organization and Staff" regulation is counterintuitive. If someone were looking for a standard on bathroom access, it may be more logical to place the sentence in "§3.0 Physical Environment".

Agency Response: The Agency appreciates and acknowledges these comments. The hospital's governing body is responsible for all hospital operations; therefore, the regulations will remain as written.

Second, it's unclear what process will be used to alert hospitals of the new regulation and what time line applies to "development and implementation" of the policies and procedures. Are hospitals out of compliance if a policy is not operational on the effective date of the regulation (e.g. October 1, 2014) or do they enjoy some time to develop and implement the policies and procedures? DPH may wish to consider either inserting a firm effective date (e.g. December 1, 2014) or communicating an expectation through a sub-regulatory letter or guidance document.

Agency Response: The Agency appreciates and acknowledges these comments. The Agency has developed a plan to notify all licensed hospitals and ensure the implementation of the new regulations.

Third, in reviewing the regulation, SCPD noted that 1977 and 1981 versions of national standards are incorporated by reference. See §§3.1 and 4.1. DPH may wish to review these references to determine if they should be updated. Literally, the 1977 and 1981 versions of standards are binding.

Agency Response: The Agency appreciates and acknowledges these comments. The Agency intends to review and

update the hospital regulations in the near future.

Governor's Advisory Council for Exceptional Citizens, Robert D. Overmiller, Chairperson:

The Governor's Advisory Council for Exceptional Citizen's (GACEC) has reviewed the Division of Public Health (DPH) proposal to implement the requirements of House Bill No. 129 which was signed by Governor Markell on June 10, 2014.

As background, a 14 year old girl experienced a medical emergency while locked in a hospital bathroom and staff was unable to unlock the door prior to her death. This prompted the introduction and eventual enactment of House Bill No. 129, labeled "Christina's Law". The preamble to House Amendment No. 1 to House Bill No. 129 provides details on the inability of hospital staff to reach Christina without undue delay.

The legislation requires the Department of Health and Social Services to "adopt regulations to ensure that hospital staff persons have ready access to a locked hospital bathroom in the event of an emergency." The Division of Public Health is implementing the statutory mandate by proposing the addition of the following subsection to its regulations covering hospital construction, maintenance, and operation:

- 4.4. Hospitals must develop and implement policies and procedures for hospital staff to have ready access to a locked hospital bathroom in the event of an emergency.

Council would like to share a few observations.

First, placement of this sentence in the personnel-related "§4.0 Governing Body, Organization and Staff" regulation is unexpected. If someone were looking for a standard on bathroom access, it may be more logical to place the sentence in "§3.0 Physical Environment".

Agency Response: The Agency appreciates and acknowledges these comments. The hospital's governing body is responsible for all hospital operations; therefore, the regulations will remain as written.

Second, the process that will be used to alert hospitals of the new regulation and what time line applies to "development and implementation" of the policies and procedures is not clear in the proposed regulations. Are hospitals out of compliance if a policy is not operational on the effective date of the regulation (e.g. October 1, 2014) or do they enjoy some time to develop and implement the policies and procedures? The Department of Health and Social Services (DHSS) may wish to consider either inserting a firm effective date (e.g. December 1, 2014) or communicating an expectation through a sub-regulatory letter or guidance document.

Agency Response: The Agency appreciates and acknowledges these comments. The Agency has developed a plan to notify all licensed hospitals and ensure the implementation of the new regulations.

Third, in reviewing the regulation, it was noted that versions of national standards from 1977 and 1981 are incorporated by reference. See §§3.1 and 4.1. DPH may wish to review these references to determine if they should be updated. The 1977 and 1981 versions of standards appear to be binding.

Agency Response: The Agency appreciates and acknowledges these comments. The Agency intends to review and update the hospital regulations in the near future.

The public comment period was open from August 1, 2014 through September 2, 2014.

Based on comments received during the public comment period, no changes have been made to the proposed regulations. The regulations have been approved by the Delaware Attorney General's office and the Cabinet Secretary of DHSS.

FINDINGS OF FACT:

Based on public comments received, no changes were made to the proposed regulation. The Department finds that the proposed regulations, as set forth in the attached copy should be adopted in the best interest of the general public of the State of Delaware.

THEREFORE, IT IS ORDERED, that the proposed State of Delaware Regulations Governing Hospital Standards (Construction, Maintenance, and Operation) are adopted and shall become effective November 11, 2014, after publication of the final regulation in the Delaware *Register of Regulations*.

Rita M. Landgraf, Secretary

4407 Hospital Standards (Construction, Maintenance, and Operation)

1.0 General Licensing Requirements and Procedures

- 1.1 Definitions: The definitions as contained in 16 **Del.C.** 1001 of the Hospital Licensure Law shall apply to these rules and regulations.
- 1.2 Purpose: The purpose of these regulations is to establish reasonable standards of equipment, capacity, sanitation, and any conditions which might influence the health care received by patients or promote the purposes of the Hospital Licensure Law.
- 1.3 Application: These rules and regulations apply to all health facilities that meet the criteria for a hospital as defined under 16 **Del.C.** 1001 of the Hospital Licensure Law. The Department of Health and Social Services in

these regulations officially adopts certain National Standards for hospital licensure inspections and procedures. Nothing stated in these rules and regulations shall relieve a hospital from complying with local, city, county ordinances, codes, laws, regulations or relieve the hospital from compliance with other State or Federal requirements.

- 1.4 Issuance and Renewal of License. Upon receipt and approval of a complete application the Department of Health and Social Services shall issue or renew a license in accordance with one of the following categories:
 - 1.4.1 Annual License: An annual license shall be issued or renewed on a calendar year basis if the applying hospital is in substantial compliance with the provisions of these rules and regulations:
 - 1.4.2 Provisional License: A provisional license for a term not to exceed six (6) calendar months may be granted only to an applying hospital which, although not in substantial compliance, is demonstrating satisfactory evidence to meet the provisions of these rules and regulations.

2.0 New Construction, Additions and Alterations

- 2.1 Definition: **"New construction, additions, and alterations"** means new buildings to be used as hospitals, additions to existing buildings to be used as hospitals, conversion of existing buildings or portions thereof for use as hospitals, alterations other than minor alterations to existing hospitals.
- 2.2 A person desiring to establish a new hospital or a new addition or alteration to a licensed hospital must apply to the Department of Health and Social Services prior to establishing or beginning construction. The person must demonstrate that the new facility will meet the standards of these rules and regulations. A letter of approval to proceed with the development of plans and specifications will be issued by the Department of Health and Social Services to any person or hospital which demonstrates that the new facility will be in accordance with these rules and regulations. Plans and specifications for new construction, additions, or alterations, other than minor alterations must be prepared by or under the direction of an architect or engineer duly registered in the State of Delaware. A narrative description must be submitted with or prior to the submission of preliminary drawings. Final working drawings and specifications must be submitted to and approved by the Department of Health and Social Services prior to the beginning of actual construction.
- 2.3 Under the authority of 16 **Del.C.** Ch. 10 as amended, the Department of Health and Social Services adopts as the official standards for new construction, additions and alterations of hospitals, where applicable, the "Guidelines for Construction and Equipment of Hospital and Medical Facilities". U.S. Department of Health and Human Services, Public Health Service Publication Number (HRS-M-HF), 84-1 and all codes or standards referred under these adopted parts. When a hospital that is required to be licensed under these rules and regulations does not normally provide a particular service or department the parts of the following which relate to such service or department shall not be applicable. This Section of rules and regulations shall apply to new construction, additions, or alterations of hospitals only and not to existing facilities.

3.0 Physical Environment

- 3.1 Under the authority of 16 **Del.C.** Ch. 10, as amended, the Department of Health and Social Services adopts as the official standards for the physical environment in hospitals the following parts of the regulations, Medicare Program Regulations, 42 CFR Part 405, Subpart J, U.S. Department of Health and Human Services, Social Security Administration, dated October, 1977, Sections 405.1020 - 405.1034 inclusive, and all codes and standards referred to under these adopted parts. If any part of this section is in conflict with Section 50.1, "New Construction, Additions, and Alterations" this part shall be void and the preceding section shall apply. When a hospital that is required to be licensed under these rules and regulations does not normally provide a particular service or department, the parts of the following which relate to such service or department shall not be applicable.
- 3.2 Physical Environment. Section 405.1022 and subsection b of Section 405.1025 shall apply. The Department of Health and Social Services' regulation governing the sanitation of eating places shall also apply to the dietary department. The radiation control regulations adopted by the Authority on Radiation Protection shall govern the hospital's radiological department.

4.0 Governing Body, Organization and Staff

- 4.1 Under the authority of 16 **Del.C.** Ch. 10, as amended, the Department of Health and Social Services adopts as the official standards for the governing body, organization, and staff of hospitals the following parts of "Standards for Accreditation of Hospitals Plus Provisional Interpretations", published by the Joint Commission on Accreditation of Hospitals, dated 1981 Edition, and the "Requirements and Interpretative Guide for Accredited Hospitals", by the American Osteopathic Hospital Association, and all codes or standards referred to under these adopted parts. If any part of this section is in conflict with Section 2.0 "New Construction.

Additions, and Alterations" or Section 3.0 "Physical Environment", this part shall be void and the preceding Sections shall apply. When a hospital that is required to be licensed under these rules and regulations does not normally provide a particular service or department the parts of the following which relate to such service or department shall not be applicable.

- 4.2 Allopathic Hospitals. Pages 1 through 107 inclusive of the Standards for Accreditation of Hospitals Plus Provisional Interpretations by the Joint Commission on Accreditation of Hospitals, shall apply to the governing body, organization and staff of all allopathic hospitals.
- 4.3 Osteopathic Hospitals. Pages 7 through 93 inclusive of the Requirements and Interpretative Guide for Accredited Hospitals by the American Osteopathic Association shall apply to the governing body, organization and staff of all osteopathic hospitals.
- 4.4 Hospitals must develop and implement policies and procedures for hospital staff to have ready access to a locked hospital bathroom in the event of an emergency.

5.0 Fire Safety

Fire safety in hospitals shall comply with the adopted rules and regulations of the State Fire Prevention Commission. Enforcement of the fire requirements is the responsibility of the State Fire Prevention Commission. All applications for license must include, with the application, a letter certifying compliance by the Fire Marshall having jurisdiction. Notification of non-compliance with the rules and regulations of the State Fire Prevention Commission may be grounds for revocation of license.

18 DE Reg. 390 (11/01/14) (Final)