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Regulations Menu

(<http://delaware.gov>)

[← Back \(../index.shtml\)](#)

Authenticated PDF Version  (25%20DE%20Reg%20350%2010-01-21.pdf)

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

Division of Health Care Quality

Statutory Authority: 16 Delaware Code, Section 1119C and 29 Delaware Code, Section 10119
(16 **Del.C.** §1119C & 29 **Del.C.** §10119)
16 **DE Admin. Code** 4407

EMERGENCY

EMERGENCY SECRETARY'S ORDER

Pursuant to 16 **Del.C.** §1119C and 29 **Del.C.** §10119

16 **DE Admin. Code** 4407 Hospital Standards (Construction, Maintenance, and Operation)

4407 Hospital Standards (Construction, Maintenance, and Operation)

AUTHORITY

Pursuant to 16 **Del.C.** §1119C and 29 **Del.C.** §10119, the Department of Health and Social Services ("Department") is adopting emergency regulatory amendments to 16 **DE Admin. Code** 4407 Hospital Standards (Construction, Maintenance, and Operation). Additionally, 29 **Del.C.** §10119 authorizes the Department to adopt emergency regulations where an agency determines that an imminent peril to the public health, safety or welfare requires the amendment of a regulation with less than the notice required by 29 **Del.C.** §10115. Moreover, 16 **Del.C.** §1119C authorizes the Department to adopt, amend, repeal, or issue regulations for hospitals.

REASON FOR THE EMERGENCY ORDER

Rapid and widespread transmission of COVID-19 has significantly impacted many vulnerable individuals receiving healthcare services throughout the community.

While the availability of COVID-19 vaccines has helped to mitigate some of the risk, health and safety protocols must continue. To protect our most vulnerable citizens from COVID-19, a comprehensive infection control and prevention program based upon guidance from the Centers for Disease Control and Prevention and other nationally recognized sources is imperative to prevent or significantly decrease transmission of COVID-19 and other infections. Emergency regulations to require this infection prevention and control program were published in the July 2021 *Register* at 25 DE Reg. 29 (07/01/21).

In addition, hospital staff must either provide evidence of COVID-19 vaccination, or undergo regular testing to prevent the transmission of COVID-19. While the state's requirements will offer employees the choice between getting vaccinated or getting tested, employers should encourage vaccination and federal guidance permits employers to require vaccinations. This emergency order adds language to the July amendment of Section 6.0.

EFFECTIVE DATE OF ORDER

It is hereby ordered, that 16 DE Admin. Code 4407 Hospital Standards (Construction, Maintenance, and Operation), specifically, Section 6.0 which expands the infection prevention and control program requirements, is temporarily modified as shown by underline as follows:

6.0 Infection Prevention and Control

6.4 Specific Requirements for COVID-19

6.4.1 Before their start date, all new staff, vendors and volunteers must be tested for COVID-19 in accordance with Delaware Division of Public Health Guidance.

6.4.2 All staff, vendors and volunteers must be tested for COVID -19 in a manner consistent with Division of Public Health Guidance.

6.4.3 Facilities must follow recommendations of the Centers for Disease Control and Prevention and the Division of Public Health regarding the provision of care or services to patients by staff, vendor or volunteer found to be positive for COVID-19 in an infectious stage.

6.5 Hospitals shall amend their policies and procedures to include:

6.5.1 Work exclusion and return to work protocols for staff tested positive for COVID-19.

6.5.2 Staff refusals to participate in COVID-19 testing;

6.5.3 Staff refusals to authorize release of testing results or vaccination status to the hospital;

6.5.4 Procedures to obtain staff authorizations for release of laboratory test results to the facility to inform infection control and prevention strategies; and

6.5.5 Plans to address staffing shortages and facility demands should a COVID-19 outbreak occur.

This Emergency Order shall take effect on September 30, 2021 and shall remain in effect for 120 days. At the expiration of 120 days, the Department may choose to renew this Emergency Order once for a period not exceeding 60 days, consistent with 29 **Del.C.** §10119(3).

PETITION FOR RECOMMENDATIONS

The Department will receive, consider, and respond to petitions by any interested person for recommendations or revisions of this Order. Petitions should be presented to the Division of Health Care Quality, 3 Mill Road, Suite 308, Wilmington, DE 19806, by email to Kathryn.Evinger@Delaware.gov (<mailto:Kathryn.Evinger@Delaware.gov>), or by fax to 302-421-7401.

ORDER

It is hereby ordered, this 10th day of September, 2021, that the above referenced amendment to 16 **DE Admin. Code** 4407 Hospital Standards (Construction, Maintenance, and Operation), a copy of which is hereby attached, is adopted, pursuant to 16 **Del.C.** §1119C and 29 **Del.C.** §10119, as referenced above, and supported by the evidence contained herein.

Molly K. Magarik, MS

Cabinet 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.

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

(<http://regulations.delaware.gov/register/november2014/final/18 DE Reg 390 11-01-14.htm>)

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.

6.0 Infection Prevention and Control

6.1 The hospital shall establish an infection prevention and control program which shall be based upon Centers for Disease Control and Prevention and other nationally recognized infection prevention and control guidelines.

6.1.1 The infection prevention and control program must include all services and all areas of the hospital, including provision of the appropriate personal protective equipment for all patients, staff, and visitors.

6.2 The individual designated to lead the hospital's infection prevention and control program must develop and implement a comprehensive plan that includes actions to prevent, identify, and manage infections and communicable diseases. The plan must include mechanisms that result in immediate action to take preventive or corrective measures that improve the hospital's infection control outcomes.

6.3 All hospital staff shall receive orientation at the time of employment and annual in-service education regarding the infection prevention and control program.

6.4 Specific Requirements for COVID-19

6.4.1 Before their start date, all new staff, vendors and volunteers must be tested for COVID-19 in accordance with Delaware Division of Public Health Guidance.

6.4.2 All staff, vendors and volunteers must be tested for COVID -19 in a manner consistent with Division of Public Health Guidance.

6.4.3 Facilities must follow recommendations of the Centers for Disease Control and Prevention and the Division of Public Health regarding the provision of care or services to patients by staff, vendor or volunteer found to be positive for COVID-19 in an infectious stage.

6.5 Hospitals shall amend their policies and procedures to include:

6.5.1 Work exclusion and return to work protocols for staff tested positive for COVID-19.

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6.5.3 Staff refusals to authorize release of testing results or vaccination status to the hospital;

6.5.4 Procedures to obtain staff authorizations for release of laboratory test results to the facility to inform infection control and prevention strategies; and

6.5.5 Plans to address staffing shortages and facility demands should a COVID-19 outbreak occur.

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

([http://regulations.delaware.gov/register/november2014/final/18 DE Reg 390 11-01-14.htm](http://regulations.delaware.gov/register/november2014/final/18%20DE%20Reg%20390%2011-01-14.htm))

25 DE Reg. 350 (10/01/21) (Emer.)

(/index.shtml)

Agency Information (/about.shtml)

Contact Information (/contact.shtml)

Register of Regulations (/register/current_issue.shtml)

Administrative Code (<http://regulations.delaware.gov/AdminCode>)

Delaware Code (<http://delcode.delaware.gov>)

Laws of Delaware (<http://delcode.delaware.gov/sessionlaws>)

City & Town Charters (<http://charters.delaware.gov/index.shtml>)

Delaware General Assembly (<http://legis.delaware.gov/>)

Style Manual (/style_manual.shtml)

Cumulative Table (/cumulative_table.shtml)

Citizen Participation (/citizen.shtml)

FOIA Request Form (http://delaware.gov/help/foia_request.shtml)