



Exempt Action Final Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC5-410
Regulation title	Rules and Regulations for the Licensure of Hospitals
Action title	Update of the hospital building/construction regulations
Final agency action date	April 23, 2010
Document preparation date	May 18, 2010

When a regulatory action is exempt from executive branch review pursuant to § 2.2-4002 or § 2.2-4006 of the Virginia Administrative Process Act (APA), the agency is encouraged to provide information to the public on the Regulatory Town Hall using this form.

Note: While posting this form on the Town Hall is optional, the agency must comply with requirements of the Virginia Register Act, the *Virginia Register Form, Style, and Procedure Manual*, and Executive Orders 36 (06) and 58 (99).

Summary

Please provide a brief summary of all regulatory changes, including the rationale behind such changes. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

Chapter 177 of the 2005 Acts of Assembly requires that the physical plant standards for hospitals and outpatient surgery centers be consistent with the current edition of the “Guidelines for Design and Construction of Hospital and Health Care Facilities” (Guidelines) of the Facilities Guideline Institute (FGI), formerly of the American Institute of Architects. Therefore, the department is amending the *Rules and Regulations for the Licensure of Hospitals in Virginia* (12 VAC 5-410) pursuant to § 2.2-4006 A 4 a of the Code of Virginia (Code). The 2010 edition of the Guideline was released January 2010. This regulatory action adopts the 2010 edition of the Guideline as required by the 2005 legislation. The requirements of the Uniform Statewide Building Code take precedence as authorized by §36-98 of the Code.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

The Board of Health approved this non-discretionary action, and adopted the regulatory changes, at its April 23, 2010 meeting.

Family impact

Assess the impact of this regulatory action on the institution of the family and family stability.

There is no known direct impact on the institution of the family or family stability.

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Project 2340 - none

**DEPARTMENT OF HEALTH
Update of hospital building/construction regulations**

12VAC5-410-445. Newborn service design and equipment criteria.

A. Construction and renovation of a hospital's nursery shall be consistent with section ~~2.1-3.6~~ 2.2-2.12.1 through 2.2-2.12.6.6 of Part 2 of the ~~2006~~ 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute (formerly of the American Institute of Architects). Hospitals with higher-level nurseries shall comply with ~~section 2.1-3.4.6~~ sections 2.2-2.10.1 through 2.2-10.9.3 of Part 2 of the ~~2006~~ 2010 guideline as applicable.

B. The hospital shall provide the following equipment in the general level nursery and all higher level nurseries, unless additional equipment requirements are imposed for the higher level nurseries:

1. Resuscitation equipment as specified for the delivery room in 12VAC5-410-442 G 2 shall be available in the nursery at all times;
2. Equipment for the delivery of 100% oxygen concentration, properly heated, blended, and humidified, with the ability to measure oxygen delivery in fractional inspired concentration (FI02). The oxygen analyzer shall be calibrated every eight hours and serviced according to the manufacturer's recommendations by a member of the hospital's respiratory therapy department or other responsible personnel trained to perform the task;
3. Saturation monitor (pulse oximeter or equivalent);
4. Equipment for monitoring blood glucose;
5. Infant scales;
6. Intravenous therapy equipment;
7. Equipment and supplies for the insertion of umbilical arterial and venous catheters;
8. Open bassinets, self-contained incubators, open radiant heat infant care system or any combination thereof appropriate to the service level;
9. Equipment for stabilization of a sick infant prior to transfer that includes a radiant heat source capable of maintaining an infant's body temperature at 99°F;
10. Equipment for insertion of a thoracotomy tube; and
11. Equipment for proper administration and maintenance of phototherapy.

C. The additional equipment required for the intermediate level newborn service and for any higher service level is:

1. Pediatric infusion pumps accurate to plus or minus 1 milliliter (ml) per hour;
2. On-site supply of PgE1;

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3. Equipment for 24-hour cardiorespiratory monitoring for neonatal use available for every incubator or radiant warmer;
4. Saturation monitor (pulse oximeter or equivalent) available for every infant given supplemental oxygen;
5. Portable x-ray machine; and
6. If a mechanical ventilator is selected to provide assisted ventilation prior to transport, it shall be approved for the use of neonates.

D. The additional equipment required for the specialty level newborn service and a higher newborn service is as follows:

1. Equipment for 24-hour cardiorespiratory monitoring with central blood pressure capability for each neonate with an arterial line;
2. Equipment necessary for ongoing assisted ventilation approved for neonatal use with on-line capabilities for monitoring airway pressure and ventilation performance;
3. Equipment and supplies necessary for insertion and maintenance of chest tube for drainage;
4. On-site supply of surfactant;
5. Computed axial tomography equipment (CAT) or magnetic resonance imaging equipment (MRI);
6. Equipment necessary for initiation and maintenance of continuous positive airway pressure (CPAP) with ability to constantly measure delineated pressures and including alarm for abnormal pressure (i.e., vent with PAP mode); and
7. Cardioversion unit with appropriate neonatal paddles and ability to deliver appropriate small watt discharges.

E. The hospital shall document that it has the appropriate equipment necessary for any of the neonatal surgical and special procedures it provides that are specified in its medical protocol and that are required for the specialty level newborn service.

F. The additional equipment requirements for the subspecialty level newborn service are:

1. Equipment for emergency gastrointestinal, genitourinary, central nervous system, and sonographic studies available 24 hours a day;
2. Pediatric cardiac catheterization equipment;
3. Portable echocardiography equipment; and
4. Computed axial tomography equipment (CAT) and magnetic resonance imaging equipment (MRI).

G. The hospital shall document that it has the appropriate equipment necessary for any of the neonatal surgical and special procedures it provides that are specified in the medical protocol and are required for the subspecialty level newborn service.

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Part III

Standards and Design Criteria for New Buildings and Additions, Alterations and Conversion of Existing Buildings

12VAC5-410-650. General building and physical plant information.

A. All construction of new buildings and additions, renovations, alterations or repairs of existing buildings for occupancy as a hospital shall conform to state and local codes, zoning and building ordinances, and the Uniform Statewide Building Code.

In addition, hospitals shall be designed and constructed according to Part 1 and sections 2.1-1 through ~~2.1-4~~ 2.2-8 of Part 2 of the ~~2006~~ 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute (formerly of the American Institute of Architects). However, the requirements of the Uniform Statewide Building Code and local zoning and building ordinances shall take precedence.

B. All buildings shall be inspected and approved as required by the appropriate building regulatory entity. Approval shall be a Certificate of Use and Occupancy indicating the building is classified for its proposed licensed purpose.

Part V

Design Standards for New Outpatient Surgical Hospitals and Additions and Alterations to Existing Outpatient Surgical Hospitals

Article 1

General Considerations

12VAC5-410-1350. Codes; fire safety; zoning; construction standards.

A. All construction of new buildings and additions alterations or repairs to existing buildings for occupancy as a "free-standing" outpatient hospital shall conform to state and local codes, zoning and building ordinances, and the Statewide Uniform Building Code.

In addition, hospitals shall be designed and constructed according to Part 1 and sections 3.1-1 through ~~3.2-4~~ and 3.7 of Part 3 of the ~~2006~~ 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute (formerly of the American Institute of Architects). However, the requirements of the Uniform Statewide Building Code and local zoning and building ordinances shall take precedence.

B. All buildings shall be inspected and approved as required by the appropriate building regulatory entity. Approval shall be a Certificate of Use and Occupancy indicating the building is classified for its proposed licensed purpose.

C. The use of an incinerator shall require permitting from the nearest regional office of the Department of Environmental Quality.

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D. Water shall be obtained from an approved water supply system. Outpatient surgery centers shall be connected to sewage systems approved by the Department of Health or the Department of Environmental Quality.

E. Each outpatient surgery center shall establish a monitoring program for the internal enforcement of all applicable fire and safety laws and regulations.

F. All radiological machines shall be registered with the Office of Radiological Health of the Virginia Department of Health. Installation, calibration and testing of machines and storage facilities shall comply with 12VAC5-480, Radiation Protection Regulations.

G. Pharmacy services shall comply with Chapter 33 (§ 54.1-3300 et seq.) of Title 54.1 of the Code of Virginia and 18VAC110-20, Regulations Governing the Practice of Pharmacy.

DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-410)

Guidelines for Design and Construction of Health Care Facilities, Facilities Guidelines Institute (formerly of the American Institute of Architects), Washington, D.C., ~~2006~~ 2010 Edition.