

State Board of Health

12 VAC 5-410

**Rules and Regulations for the Licensure
of Hospitals in Virginia**



Office of Licensure and Certification
Virginia Department of Health
9960 Mayland Drive, Ste. 401
Richmond, VA 23233

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Office of Licensure and Certification**

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**CHAPTER 410.
REGULATIONS FOR THE LICENSURE OF HOSPITALS IN VIRGINIA**

**PART I.
Definitions and General Information and Procedures.**

**Article 1.
Definitions.**

12 VAC 5-410-10. Definitions. (revised 3/1/2007)

As used in this chapter, the following words and terms shall have the following meanings unless the context clearly indicates otherwise:

"Board" means the State Board of Health.

"Chief executive officer" means a job descriptive term used to identify the individual appointed by the governing body to act in its behalf in the overall management of the hospital. Job titles may include administrator, superintendent, director, executive director, president, vice-president, and executive vice-president.

"Commissioner" means the State Health Commissioner.

"Consultant" means one who provides services or advice upon request.

"Department" means an organized section of the hospital.

"Direction" means authoritative policy or procedural guidance for the accomplishment of a function or activity.

"Facilities" means building(s), equipment, and supplies necessary for implementation of services by personnel.

"Full-time" means a 37-1/2 to 40 hour work week.

"General hospital" means institutions as defined by § 32.1-123 of the Code of Virginia with an organized medical staff; with permanent facilities that include inpatient beds; and with medical services, including physician services, dentist services and continuous nursing services, to provide diagnosis and treatment for patients who have a variety of medical and dental conditions that may require various types of care, such as medical, surgical, and maternity.

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"Home health care department/service/program" means a formally structured organizational unit of the hospital that is designed to provide health services to patients in their place of residence and meets Part II (12 VAC 5-381-150 et seq.) of the regulations adopted by the board for the licensure of home care organizations in Virginia.

"Medical" means pertaining to or dealing with the healing art and the science of medicine.

"Nursing care unit" means an organized jurisdiction of nursing service in which nursing services are provided on a continuous basis.

"Nursing home" means an institution or any identifiable component of any institution as defined by § 32.1-123 of the Code of Virginia with permanent facilities that include inpatient beds and whose primary function is the provision, on a continuing basis, of nursing and health related services for the treatment of patients who may require various types of long term care, such as skilled care and intermediate care.

"Nursing services" means patient care services pertaining to the curative, palliative, restorative, or preventive aspects of nursing that are prepared or supervised by a registered nurse.

"Office of Licensure and Certification" or "OLC" means the Office of Licensure and Certification of the Virginia Department of Health.

"Organized" means administratively and functionally structured.

"Organized medical staff" means a formal organization of physicians and dentists with the delegated responsibility and authority to maintain proper standards of medical care and to plan for continued betterment of that care.

"Outpatient hospital" means institutions as defined by §32.1-123 of the Code of Virginia that primarily provide facilities for the performance of surgical procedures on outpatients. Such patients may require treatment in a medical environment exceeding the normal capability found in a physician's office, but do not require inpatient hospitalization. Outpatient abortion clinics are deemed a category of outpatient hospitals.

"Ownership/person" means any individual, partnership, association, trust, corporation, municipality, county, governmental agency, or any other legal or commercial entity that owns or controls the physical facilities and/or manages or operates a hospital.

"Rural hospital" means any general hospital in a county classified by the federal Office of Management and Budget (OMB) as rural, any hospital designated as a critical access

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hospital, any general hospital that is eligible to receive funds under the federal Small Rural Hospital Improvement Grant Program, or any general hospital that notifies the commissioner of its desire to retain its rural status when that hospital is in a county reclassified by the OMB as a metropolitan statistical area as of June 6, 2003.

"Service" means a functional division of the hospital. Also used to indicate the delivery of care.

"Special hospital" means institutions as defined by §32.1-123 of the Code of Virginia that provide care for a specialized group of patients or limit admissions to provide diagnosis and treatment for patients who have specific conditions (e.g., tuberculosis, orthopedic, pediatric, maternity).

"Special care unit" means an appropriately equipped area of the hospital where there is a concentration of physicians, nurses, and others who have special skills and experience to provide optimal medical care for patients assigned to the unit.

"Staff privileges" means authority to render medical care in the granting institution within well-defined limits, based on the individual's professional license and the individual's experience, competence, ability and judgment.

"Unit" means a functional division or facility of the hospital.

**Article 2.
General Information.**

12 VAC 5-410-20. Exceptions; variances.

A. In accordance with the §32.1-124 of the Code of Virginia the provisions of this chapter shall not be applicable to:

1. A dispensary or first aid facility maintained by any commercial or industrial plant, educational institution or convent;
2. An institution licensed by the State Mental Health, Mental Retardation and Substance Abuse Services Board;
3. An institution or portion thereof licensed by the State Board of Social Services;
4. A hospital owned or operated by an agency of the Commonwealth or of the United States government; or
5. An office of one or more physicians or surgeons unless such office is used principally for performing surgery as defined in 12VAC5-410-10 of this chapter.

B. In accordance with §32.1-128 of the Code of Virginia nothing in these rules and regulations shall be construed to authorize or require the interference with the

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supervision, regulation, or treatment of residents, patients, or personnel of any institution operated by and for the adherents of any well-recognized church or denomination who rely upon treatment by mental or spiritual means without the use of any drug or material remedy, provided such institution complies with applicable statutes and regulations on sanitation, life safety and construction design.

12 VAC 5-410-30. Allowable variances.

A. Upon the finding that the enforcement of one or more of these regulations would be clearly impractical, the commissioner shall have the authority to waive, either temporarily or permanently, the enforcement of one or more of these regulations, provided safety and patient care and services are not adversely affected.

B. Modification of any individual standard herein, for experimental or demonstrative purposes, or any other purposes, shall require advance written approval from the OLC.

**Article 3.
Procedures for Licensure or License Renewal.**

12 VAC 5-410-40. General.

No person, as defined in 12VAC5-410-10, shall establish, conduct, maintain, or operate in this State any hospital as defined and included within provisions of this chapter without having obtained a license. Any person establishing, conducting, maintaining, or operating a hospital without a license shall be guilty of a Class 6 felony.

12 VAC 5-410-50. Classification.

Hospitals to be licensed shall be classified as general hospitals, special hospitals or outpatient hospitals defined by 12VAC5-410-10.

12 VAC 5-410-60. Separate license.

A. A separate license shall be required by hospitals maintained on separate premises even though they are operated under the same management. Separate license is not required for separate buildings on the same grounds or within the same complex of buildings.

B. Hospitals which have separate organized sections, units, or buildings to provide services of a classification covered by provisions of other state statutes or regulations may be required to have an additional applicable license for that type or classification of service (e.g., psychiatric, nursing home, home health services, outpatient surgery, outpatient abortions).

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12 VAC 5-410-70. Request for issuance.

A. Hospital licenses shall be issued by the commissioner, but all requests for licensing shall be submitted initially to the OLC. The procedure for obtaining the license shall include the following steps:

1. Request for application forms shall be made in writing to the OLC;
2. Application for license or license renewal to establish or maintain a hospital shall be made and submitted to the OLC;
3. All categories of inpatient beds shall be included on the hospital application for licensure in order for the OLC to have an accurate and complete record of the total bed capacity of the facility;
4. Application for initial license, change in license, or license renewal shall be accompanied by a check or money order for the service charge, payable to the OLC; and
5. Application for initial license of a hospital or for additions to an existing licensed hospital must be accompanied by evidence of approval from a representative of the State Fire Marshal and a copy of the occupancy permit issued by the local building official.
6. Application for initial license of a hospital shall include a statement of any agreement made with the commissioner as a condition for Certificate of Public Need approval to provide a level of care at a reduced rate to indigents or accept patients requiring specialized care.

Any initial license issued to any hospital that made such agreement as a condition of its Certificate of Public Need approval shall not be renewed without demonstrating prior to or at the time of applying for license renewal that it is substantially complying with its agreement.

B. The renewal of a hospital license shall be conditioned upon the up-to-date payment of any civil penalties owed as a result of willful refusal, failure, or neglect to honor certain conditions established in their award of a Certificate of Public Need pursuant to §32.1-102.4 F of the Code of Virginia.

12 VAC 5-410-80. Service charge.

A. In accordance with §32.1-130 of the Code of Virginia, the following service charge shall be made:

- 0 to 50 beds - \$75
- 51 to 333 beds - \$1.50 per bed
- 334 or more - \$500

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B. The hospital shall not be required to pay a service charge on hospital beds in a category that requires separate license by the OLC or another state agency (i.e., psychiatric, nursing home).

12 VAC 5-410-90. License expiration.

Licenses shall expire as specified or at midnight December 31 following date of issue, whichever is first, and shall be renewable annually, upon filing of application and payment of service charge, unless cause appears to the contrary.

12 VAC 5-410-100. Name.

Every hospital shall be designated by a permanent and appropriate name which shall appear on the application for license. Any change of name shall be reported to the OLC within 30 days.

12 VAC 5-410-110. Bed capacity.

A. Each license issued by the commissioner shall specify the maximum allowable number of beds. The number of beds allowed shall be determined by the OLC and shall so appear on the license issued by the OLC.

B. Request for licensed bed increase or decrease shall be made in writing to the OLC. No increase will be granted without an approved Certificate of Public Need.

12 VAC 5-410-120. Posting of license.

The hospital license issued by the commissioner shall be framed and posted conspicuously on the premises either in the main entrance to the hospital or in a place visible from that main entrance.

12 VAC 5-410-130. Return of license.

The OLC shall be notified in writing at least within 30 working days in advance of any proposed change in location or ownership of the facility. A license shall not be transferred from one owner to another or from one location to another. The license issued by the commissioner shall be returned to the OLC for correction or reissuance when any of the following changes occur during the licensing year:

1. Revocation;
2. Change of location;
3. Change of ownership;
4. Change of name;

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5. Change of bed capacity; or
6. Voluntary closure.

12 VAC 5-410-140. Inspection procedure.

A. The OLC may presume that a hospital accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and certified for participation in Title XVIII of the Social Security Act (Medicare) generally meets the requirements of Part II (12 VAC 5-410-170 et seq.) of this chapter provided the following conditions are met:

1. The hospital provides to the OLC, upon request, a copy of the most current accreditation survey findings made by the Joint Commission on Accreditation of Healthcare Organizations; and
2. The hospital notifies the OLC within 10 days after receipt of any notice of revocation or denial of accreditation by the Joint Commission on Accreditation of Healthcare Organizations.

B. The OLC may presume that a unit or part of a hospital licensed or certified by another state agency, or another section, bureau or division of the OLC meets the requirements of Part II of this chapter for that specific unit or part provided the following conditions are met:

1. The hospital provides the OLC, upon request, a copy of the most current inspection report made by the other state agency; and
2. The hospital notifies the OLC within 10 days after receipt of any notice of revocation or suspension by the other state agency.

C. Notwithstanding any other provision of this chapter to the contrary, if the licensing agency finds, after inspection, violations pertaining to environmental health or life safety, the hospital shall receive a written licensing report of such findings. The hospital shall be required to submit a plan of correction in accordance with provisions of 12 VAC 5-410-150.

12 VAC 5-410-150. Plan of correction.

A. Upon receipt of a written licensing report each hospital shall prepare a plan for correcting any licensing violations cited at the time of inspection. The plan of correction shall be to the OLC within the specified time limit set forth in the licensing report. The plan of correction shall contain at least the following information:

1. The methods implemented to correct any violations of this chapter; and
2. The date on which such corrections are expected to be completed.

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B. The OLC shall notify the hospital, in writing, whenever any item in the plan of correction is determined to be unacceptable.

12 VAC 5-410-160. Revocation of license.

The commissioner may revoke or suspend the license to operate a hospital in accordance with §32.1-135 of the Code of Virginia for the following reasons:

1. Violation of any provision of these rules and regulations. Violations which in the judgment of the commissioner jeopardize the health or safety of patients shall be sufficient cause for immediate revocation or suspension; or
2. Willfully permitting, aiding, or abetting the commission of any illegal act in the hospital.

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PART II.

Organization and Operation of General and Special Hospitals.

Article 1.

Organization and Management.

12 VAC 5-410-170. Ownership.

A. There shall be disclosure of hospital ownership. In the case of corporations, all individuals or entities holding 5.0% or more of the total ownership shall be identified by name and address.

B. When the owner delegates the operation of a hospital to an individual, corporation or other legal entity by management contract or lease agreement, subsection A shall also be applicable to the operator.

12 VAC 5-410-180. Governing body.

A. Each hospital shall have an organized governing body or other legal entity responsible for the management and control of the operation. The governing body or other legal entity may be an individual, group, corporation or governmental agency.

B. The governing body shall be responsible for insuring compliance with these rules and regulations.

C. The governing body shall provide facilities, personnel and other resources necessary to meet patient and program needs.

D. The governing body shall adopt and maintain written bylaws, rules and regulations in accordance with legal requirements. A copy of said bylaws, rules and regulations including amendments or revisions thereto, shall be made available to the OLC on request.

E. The bylaws, rules and regulations shall include:

1. A statement of purpose;
2. A statement of qualifications for membership and method of selecting members of the governing body;
3. Provisions for the establishment, selection, term of office of committee members and officers;
4. Description of the functions and duties of the governing body, officers, and committees;
5. Specifications for the frequency of meetings, attendance requirements, provision

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for the order of business and the maintenance of written minutes;

6. A statement of the authority and responsibility delegated to the chief executive officer and to the medical staff;

7. Provision for the selection and appointment of medical staff and the granting of clinical privileges including the provision for current license to practice in Virginia.

8. Provision for the adoption of the medical staff bylaws, rules and regulations;

9. Provision of guidelines for the relationships among the governing body, the chief executive officers, and the medical staff.

10. A policy statement concerning the development and implementation of short- and long-range plans in accordance with Part III (12 VAC 5-410-650 et seq.) of this chapter.

11. A policy statement relating to conflict of interest on the part of members of the governing body, medical staff and employees who may influence corporate decisions.

12 VAC 5-410-190. Chief executive officer.

A. The chief executive officer shall be directly responsible to the governing body for the management and operation of the hospital and shall provide liaison between the governing body and the medical staff.

B. The chief executive officer, or his designee, shall ensure that families of patients who are potential donors are informed of the option of organ, tissue, and eye donation.

12 VAC 5-410-200. Organization. (revised 11/2011)

A. The internal hospital organization shall be structured to include appropriate departments and services consonant with its statement of purpose.

B. Each hospital shall maintain clearly written definitions of its organization, authority, responsibility, and relationships.

C. Each hospital department and service shall maintain:

1. Clearly written definitions of its organization, authority, responsibility, and relationships; and

2. Written policies and procedures including:

a. Patient care where applicable;

b. Infection prevention;

c. Disaster preparedness; and

d. Facility security.

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12 VAC 5-410-210. Medical staff.

A. Each hospital shall have an organized medical staff responsible to the governing body of the hospital for its own organized governance and all medical care provided to patients.

B. The medical staff shall be responsible to the hospital governing board and maintain appropriate standards of professional performance through staff appointment criteria, delineation of staff privileges, continuing peer review and other appropriate mechanisms.

C. The medical staff, subject to approval by the governing body, shall develop bylaws incorporating details of the medical staff organization and governance, giving effect to its general powers, duties, and responsibilities including:

1. Methods of selection, election, or appointment of all officers and other executive committee members and officers;
2. Provisions for the selection and appointment of officers of departments or services specifying required qualifications;
3. The type, purpose, composition and organization of standing committees;
4. Frequency and requirements for attendance at staff and departmental meetings;
5. An appeal mechanism for denial, revocation, or limitation of staff appointments, reappointments and privileges;
6. Delineation of clinical privileges in accordance with the requirements of §32.1-134.2 of the Code of Virginia;
7. Requirements regarding medical records;
8. A mechanism for utilization and medical care review; and
9. Such other provisions as shall be required by hospital or governmental rules and regulations.

D. A copy of approved medical staff bylaws and regulations and revisions thereto, shall be made available to the OLC on request.

12 VAC 5-410-220. Organ donation.

A. The hospital shall develop and implement a routine contact protocol for organ, tissue and eye donation in compliance with federal law and the regulations of the Centers for Medicare and Medicaid (CMS), particularly 42 CFR 482.45.

B. The protocol shall:

1. Ensure that the hospital collaborates with its designated organ procurement organization (OPO) to inform the family of each potential donor of the option of organ, tissue, and eye donation as well as the option to decline to donate;
2. Recite provisions of §32.1-290.1 of the Code of Virginia specifying family

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members who are authorized to make an anatomical gift of all or part of the decedent's body for an authorized purpose and the order of priority of those family members who may make such gift; and

3. Include written procedures for organ, tissue, and eye donation. The procedures shall include:

- a. Training of staff in organ, tissue, or eye donation;
- b. A mechanism for informing the next of kin of the organ, tissue, and eye donation option;
- c. Procedures to be employed when the hospital, consistent with the authority granted by §32.1-292.1 of the Code of Virginia, deems it appropriate to conduct a reasonable search for a document of gift or other information identifying the bearer as a donor or as an individual who has refused to make an anatomical gift;
- d. Provisions for the procurement and maintenance of donated organs, tissues, and eyes;
- e. The name and telephone number of the local organ procurement agency, tissue or eye bank to be notified of potential donors; and
- f. Documentation of the donation request in the patient's medical record.

C. The hospital shall have an agreement with an OPO certified by CMS:

1. To notify the OPO in a timely manner of all deaths or imminent deaths of patients in the hospital; and
2. Authorizing the OPO to determine the suitability of the decedent or patient for organ donation and the suitability for tissue and eye donation in the absence of a similar arrangement with any eye bank or tissue bank in Virginia certified by the Eye Bank Association of America or the American Association of Tissue Banks.

D. The hospital shall have an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage, and distribution of tissues and eyes to ensure that all usable tissues and eyes are obtained from potential donors and to avoid interference with organ procurement.

E. The individual making contact with the family shall have completed a course in the methodology for approaching potential donor families and requesting organ or tissue donation that:

1. Is offered or approved by the OPO and designed in conjunction with the tissue and eye bank community; and
2. Encourages discretion and sensitivity according to the specific circumstances, views, and beliefs of the relevant family.

F. The hospital shall work cooperatively with its designated OPO in educating its staff on:

1. Donation issues;

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2. The proper review of death records to improve identification of potential donors; and
3. The proper procedures for maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

G. The protocol shall be followed, without exception, unless the family of the relevant decedent or patient expresses opposition to organ donation, the chief administrative officer of the hospital or his designee knows of such opposition, and no donor card or other relevant document, such as an advance directive, can be found.

**Article 2.
Patient Care Services.**

12 VAC 5-410-230. Patient care management.

- A. All patients shall be under the care of a member of the medical staff.
- B. Each hospital shall have a plan that includes effective mechanisms for the periodic review and revision of patient care policies and procedures.
- C. Each hospital shall establish a protocol relating to the rights and responsibilities of patients based on Joint Commission on Accreditation of Healthcare Organizations' 2000 Hospital Accreditation Standards, January 2000. The protocol shall include a process reasonably designed to inform patients of their rights and responsibilities. Patients shall be given a copy of their rights and responsibilities upon admission.
- D. No medication or treatment shall be given except on the signed order of a person lawfully authorized by state statutes.
 1. Hospital personnel, as designated in medical staff bylaws, rules and regulations, or hospital policies and procedures, may accept emergency telephone and other verbal orders for medication or treatment for hospital patients from physicians and other persons lawfully authorized by state statute to give patient orders.
 3. As specified in the hospital's medical staff bylaws, rules and regulations, or hospital policies and procedures, emergency telephone and other verbal orders shall be signed within a reasonable period of time not to exceed 72 hours, by the person giving the order, or, when such person is not available, cosigned by another physician or other person authorized to give the order.
- E. Each hospital shall have a reliable method for identification of each patient, including newborn infants.

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F. Each hospital shall include in its visitation policy a provision allowing each adult patient to receive visits from any individual from whom the patient desires to receive visits, subject to other restrictions contained in the visitation policy including, but not limited to the patient's medical condition and the number of visitors permitted in the patient's room simultaneously.

12 VAC 5-410-240. Anesthesia service.

A. Each hospital which provides surgical or obstetrical services shall have an organized anesthesia department/service.

The anesthesia department/service shall be directed by a physician member of the medical staff.

B. The anesthesia department/service shall be organized under written policies and procedures regarding staff privileges, the administration of anesthetics, the maintenance of safety controls and qualifications, and supervision of anesthesiologists and trainees.

C. Policies shall include provisions in addition to the above, for at least:

1. Pre-anesthesia evaluation by a medical staff member;
2. Safety of the patient during the anesthesia period;
3. Review of patient's condition prior to induction of anesthesia and post anesthetic evaluation; and
4. Recording of all events related to each phase of anesthesia care.

12 VAC 5-410-250. Sterile supply service.

A. Each hospital shall operate a sterile supply service or provide for the processing, sterilizing, storing, and dispensing of clean and sterile supplies and equipment.

B. Facilities shall be provided for the cleaning, preparation, sterilizing, aeration, storage and dispensing of supplies and equipment for patient care.

C. Areas for the processing of clean and soiled supplies and equipment shall be separated by physical barriers.

D. Written procedures shall be established subject to the approval of the Infection Control Committee for all sterile supply service functions including:

1. Procedures for all sterilizing and for the disposal of wastes and contaminated supplies; and
2. Procedures for the safety of personnel and patients.

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12 VAC 5-410-260. Dietary service. (revised 1/25/2006)

- A. Each hospital shall maintain a dietary service directed by a full-time person, qualified as allowed in 12VAC5-421.
- B. Each hospital shall have at least one dietitian, meeting the criteria of §54.1-2731 of the Code of Virginia, employed on either a full-time, part-time or on a consultative basis, to direct nutritional aspects of patient care and to advise on food preparation and service.
- C. Space, equipment and supplies shall be provided for the efficient, safe and sanitary receiving, storage, refrigeration, preparation and serving of food.
- D. The hospital food service operation shall comply with applicable standards in 12VAC5-421.
- E. A diet manual, approved by the medical staff shall be maintained by the dietary service. Diets served to patients shall comply with the principles set forth in the diet manual.
- F. All patient diets shall be ordered in writing by a member of the medical staff.
- G. Pertinent observations and information relative to the special diets and to dietetic treatment shall be recorded in the patient's medical record.
A hospital contracting for food service shall require, as part of the contract, that the contractor comply with the provisions of this section.

12 VAC 5-410-270. Disaster and mass casualty programs. (revised 1/25/2006)

- A. Each hospital shall develop and maintain a written disaster plan that includes provisions for complete evacuation of the facility and care of mass casualties.
- B. The plan shall provide for widespread disasters as well as for disaster occurring within the local community and hospital facility.
- C. The disaster plan shall be rehearsed at least twice a year preferably as part of a coordinated drill in which other community emergency service agencies participate. Written reports and evaluation of all drills shall be maintained for at least two years.
- D. A copy of the plan and any revision thereto shall be made available to the OLC upon request.

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12 VAC 5-410-280. Emergency service. (revised 1/25/2006)

A. Hospitals with an emergency department/service shall have 24-hour staff coverage and shall have at least one physician on call at all times. Hospitals without emergency service shall have written policies governing the handling of emergencies.

B. No less than one registered nurse shall be assigned to the emergency service on each shift. Such assignment need not be exclusive of other duties, but must have priority over all other assignments.

C. Those hospitals that provide ambulance services shall comply with Article 2.1 (§32.1-111.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia and 12VAC5-31.

D. The hospital shall provide equipment, drugs, supplies, and ancillary services commensurate with the scope of anticipated needs, including radiology and laboratory services and facilities for handling and administering of blood and blood products. Emergency drugs and equipment shall remain accessible in the emergency department at all times.

E. Current roster of medical staff members on emergency call, including alternates and medical specialists or consultants shall be posted in the emergency department.

F. Hospitals shall make special training available, as required, for emergency department personnel.

G. Toxicology reference material and poison antidote information shall be available along with telephone numbers of the nearest poison control centers.

12 VAC 5-410-290. Laboratory service; general. (revised 1/25/2006)

A. The director of laboratory service shall be a physician member of the medical staff. If the physician director of laboratory service is not a pathologist, a pathologist shall be retained on a consultant basis.

When the pathologist provides services only on a consultative basis, these services shall be provided at least on a monthly basis. A written evaluation report with recommendations to the medical staff and administration shall be provided by the consultant pathologist on a monthly basis.

B. Laboratories shall have adequate space, equipment, and supplies and shall be operated according to 42 CFR Part 493.

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C. Provisions shall be made to assure continuous availability of emergency laboratory services.

12 VAC 5-410-300. Clinical laboratory services.

Examination in the fields of hematology, chemistry, microbiology, seroimmunology, clinical microscopy and other services necessary to meet patient care needs shall be provided directly or shall be provided through a contractual arrangement with a reference laboratory.

12 VAC 5-410-310. Tissue pathology.

A. Tissue pathology services shall be provided either by the hospital or pursuant to contractual arrangements with a laboratory. In the latter instance, written policies and procedures shall be established governing prompt transportation of specimens and submission of reports.

B. In accordance with medical staff bylaws, surgically removed tissues shall be examined by a pathologist and findings shall be included in the patient's medical record.

12 VAC 5-410-320. Quality control.

There shall be a quality control program designed to ensure reliability of the laboratory data and shall include provisions for no less than:

1. Frequency and method of work performance evaluation;
2. Frequency and method of performance testing of instruments and equipment;
3. A preventive and corrective maintenance program;
4. Participation in appropriate external proficiency testing programs for the services provided.
5. Maintenance for at least two years of records documenting quality control activities.

12 VAC 5-410-330. Autopsy service.

An autopsy service shall be provided either directly by the hospital or written contractual agreement with another institution.

12 VAC 5-410-340. Blood banks and transfusion services. (revised 1/25/2006)

A. If the hospital provides facilities for the procurement, extraction and collection of blood and blood products, written policies and procedures for all phases of operation of

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blood banks and transfusion services shall be established and periodically revised to comply with 42 CFR Part 493, 42 CFR 482.27 and 21 CFR Part 606.

B. Each hospital shall provide appropriate facilities and equipment for the storage and administration of whole blood and blood products.

C. For emergency situations, the hospital shall:

1. Make arrangements by which blood can be quickly obtained from community blood sources, or maintain an up-to-date list of available donors, as well as provide the equipment and personnel and obtain blood from the donor; or

2. Maintain a minimum supply of O negative blood, if the hospital provides obstetrical services.

12 VAC 5-410-350. Isolation of special microorganisms. (revised 1/25/2006)

When a hospital diagnostic laboratory isolates from clinical, pathological or environmental specimens, any one of the special micro-organisms listed in 12VAC5-90-80, it shall be reported as required pursuant to 12VAC5-90.

12 VAC 5-410-360. Nuclear medicine. (revised 1/25/2006)

Every hospital that maintains a nuclear medicine service within the institution or through contractual arrangements shall ensure that it is under the medical supervision of a physician who is a designated authorized user of isotopes licensed by the Nuclear Regulatory Commission or the Office of Radiologic Health of the Department of Health as required by 12VAC5-480.

1. There shall be quality control procedures governing nuclear medicine services to ensure diagnostic reliability and therapeutic effectiveness.

2. Records of diagnostic or therapeutic services shall be incorporated in the patient's medical record.

12 VAC 5-410-370. Medical records. (revised 1/25/2006)

A. The medical record department shall be staffed and equipped to facilitate the accurate processing, checking, indexing, filing and retrieval of all medical records.

B. A medical record shall be established and maintained for every person treated on an inpatient, outpatient (ambulatory) or emergency basis, in any unit of the hospital. The record shall be available to all other units.

A separate medical record shall be maintained for each newborn infant. Entered on the chart of the newborn shall be notes of gestational history, including any pathology

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and information regarding complications of delivery and mother's medication during labor and delivery.

C. Written policies and procedures shall be established regarding content and completion of medical records.

D. Entries in the medical record shall be made by the responsible person in accordance with hospital policies and procedures.

E. Provisions shall be made for the safe storage of medical records or accurate and legible reproductions thereof according to §32.1-127.1:03 of the Code of Virginia and the Health Insurance Portability and Accountability Act, or HIPPA (42 USC §1320d et seq.).

F. All medical records either original or accurate reproductions shall be preserved for a minimum of five years following discharge of the patient.

1. Records of minors shall be kept for at least five years after such minor has reached the age of 18 years.

2. Birth and death information shall be retained for 10 years in accordance with §32.1-274 of the Code of Virginia.

12 VAC 5-410-380. Nursing service. (revised 1/25/2006)

A. Each hospital shall have an organized nursing department. A registered nurse qualified on the basis of education, experience and clinical ability shall be responsible for the direction of nursing care provided the patients.

B. The number and type of nursing personnel on all shifts shall be based upon the needs of the patients and the capabilities of the nursing staff assigned to the patient care unit. All registered nurses and licensed practical nurses shall hold a current license issued by the Virginia Board of Nursing or a current multistate licensure privilege to practice nursing in Virginia.

C. All nursing services shall be directly provided by an appropriately qualified registered nurse or licensed practical nurse, except for those nursing tasks that may be delegated by a registered nurse according to 18VAC90-20-420 through 18VAC90-20-460 of the regulation of the Virginia Board of Nursing with a plan developed and implemented by the hospital.

D. Nursing personnel shall be assigned to patient care units in a manner that minimizes the risk of cross infection and accidental contamination.

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12 VAC 5-410-390. Pharmaceutical service. (revised 1/25/2006)

- A. Each hospital shall provide pharmaceutical services under the direction of a pharmacist licensed by the Virginia Board of Pharmacy.
- B. There shall be evidence of a current pharmacy license pursuant to Chapter 33 (§54.1-3300 et seq.) of Title 54.1 of the Code of Virginia and 18VAC110-20.
- C. Each hospital shall obtain a criminal history record check pursuant to §32.1-126.02 of the Code of Virginia on any compensated employee, not licensed by the Board of Pharmacy, whose job duties provide access to controlled substances with the hospital pharmacy.

12 VAC 5-410-400. Radiology service.

- A. Each hospital shall maintain radiology services which are under the medical supervision of a physician who meets the qualifications of the medical staff bylaws.
- B. Hospitals maintaining radiotherapy services shall provide for their safe and effective operation under a director qualified by training and experience in therapeutic radiology.
- C. Sufficient technical personnel shall be available, consistent with the scope of services provided.
- D. Space and equipment shall be provided for radiographic and fluoroscopic X-ray services including facilities for processing and storage of radiographic films and records.
- E. Reports of radiological interpretations, consultations and therapy shall be part of the patient's medical record.
- F. Reports shall be preserved in accordance with 12VAC5-410-370 H.

12 VAC 5-410-410. Social service.

- A. Every hospital shall have a plan for the provision of social services to the patient and the patient's family.
- B. An employee of the hospital with knowledge of community agencies and other social service resources shall be designated to assume responsibility for said service.
- C. Appropriate records shall be maintained.

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12 VAC 5-410-420. Surgical service.

- A. The surgical department/service shall have a defined organization and shall be governed by written policies and procedures.
- B. The surgical department/service shall be under the medical supervision of a physician who meets the requirements of the medical staff bylaws.
- C. The operating suite shall be:
1. Under the supervision of a registered professional nurse.
 2. Designed to include operating and recovery rooms, proper scrubbing, sterilizing and dressing room facilities, storage for anesthetic agents and shall be equipped as required by the scope and complexity of the services.
 3. Provided with prominently posted safety policies and procedures.
- D. A roster of current surgical privileges of every surgical staff member shall be maintained on file in the operating suite.
- E. An operating room register shall be maintained which shall include as a minimum:
1. Patient's name and hospital number;
 2. Pre- and post-operative diagnosis;
 3. Complications, if any;
 3. Name of surgeon, first assistant, anesthesiologist or anesthesiologist, scrub nurse and circulating nurse;
 5. Operation performed; and
 6. Type of anesthesia.
- F. Policies and procedures governing infection control and reporting techniques shall be established in accordance with 12VAC5-410-490.
- G. The patient's medical chart shall be available in the surgical suite at time of surgery and shall contain no less than the following information:
1. A medical history and physical examination;
 2. Evidence of appropriate informed consent; and
 3. A pre-operative diagnosis.
- H. An accurate and complete description of operative procedure shall be recorded by the operating surgeon within 48 hours following completion of surgery and made part of the patient's clinical record.

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**Article 3.
Special Services.**

12 VAC 5-410-430. Applicability.

If a hospital provides any of the services in this article, the requirements of the specific service shall apply.

12 VAC 5-410-440. Obstetric and newborn services general requirements. (revised 11/2011)

A. Hospitals with licensed obstetric and newborn services in operation prior to August 10, 1995, or revisions to thereof shall comply with all of the requirements of this section with the exception of specified sections of 12VAC5-410-442. Hospitals that establish and organize obstetric and newborn services after August 10, 1995, shall comply with all requirements of this section and 12VAC5-410-441 through 12VAC5-410-447 before licensure approval is granted.

B. A hospital with organized obstetric and newborn services shall comply with the following general requirements:

1. The governing body of the hospital or the chief executive officer shall appoint an administrative manager for the obstetric and newborn services. The administrative manager may serve as an administrator of another hospital service but must be available to the obstetric and newborn services. The chief executive officer shall designate, in writing, an individual to act in the administrative manager's behalf during a temporary absence of the administrative manager.

2. The hospital is responsible for the development, periodic review and revision of a service management plan. The plan must include provisions to assure that the hospital complies with all state and federal regulations and guidelines applicable to obstetric and newborn care as well as the policies and procedures for obstetric and newborn care adopted by the hospital's governing body and medical staff. The plan is to be developed and maintained as follows:

a. The plan shall be developed in cooperation with the medical directors and nursing staffs assigned to each of the services.

b. The plan shall include the protocol, required by §32.1-127 of the Code of Virginia, for the admission or transfer of any pregnant woman who presents in labor.

c. The plan shall be the responsibility of the administrative manager who is to assure that the plan is developed, that it complies with state and federal requirements and the hospital's policies and procedures, and that it is periodically reviewed and revised.

d. A copy of the plan shall be readily available at each nursing station within the obstetric and newborn services for staff reference.

e. A copy of the plan shall be made available, upon request, to the licensing

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inspector for review.

3. The hospital shall provide the following services in support of the obstetric and newborn services units:

a. Clinical laboratory services and blood bank services shall be available in the hospital on a 24-hour basis. Laboratory and blood bank personnel shall be available on-site or on-call on a 24-hour basis. The blood bank shall have group O Rh negative blood available at all times and be able to provide correctly matched blood in 45 minutes from request. The hospital's laboratory and blood bank personnel must be capable of performing the following tests with less than 1.0 ml of blood within one hour of request or less if specified:

- (1) Blood group and Rh type determination/cross matching
- (2) Arterial blood gases within 20 minutes
- (3) Blood glucose within 20 minutes
- (4) Complete blood count
- (5) Total protein
- (6) Total bilirubin
- (7) Direct Coombs test
- (8) Electrolytes
- (9) Blood urea nitrogen
- (10) Clotting profile (may require more than one cc of blood)

b. Portable radiological services for basic radiologic studies in each labor room, delivery room, and nursery shall be available on call on a 24-hour basis.

c. In addition to the requirements specified in 12VAC5-410-240 anesthesia service personnel shall be available on-site or on-call to begin anesthesia within 30 minutes of notification.

C. Beginning July 1, 2012, hospitals providing maternity care shall offer to obtain a sample of blood from an infant born at the hospital and provide that sample to the mother of the infant.

12 VAC 5-410-441. Obstetric service requirements; medical direction; physician consultation and coverage; nurse staffing and coverage; policies and procedures.

A. The governing body shall appoint a physician as medical director of the organized obstetric service who meets the qualifications specified in the medical staff bylaws.

1. If the medical director is not a board certified obstetrician or board eligible in obstetrics, the hospital shall have a written agreement with one or more board-certified or board-eligible obstetricians to provide consultation on a 24-hour basis. Consultation may be by telephone.

2. The duties and responsibilities of the medical director of obstetric services shall include but not be limited to:

a. The general supervision of the quality of care provided patients admitted to the

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service;

- b. The establishment of criteria for admission to the service;
- c. The adherence to standards of professional practices and policies and procedures adopted by the medical staff and governing body;
- d. The development of recommendations to the medical staff on standards of professional practice and staff privileges;
- e. The identification of clinical conditions and medical or surgical procedures that require physician consultation; and
- f. Arranging conferences, at least quarterly, to review obstetrical surgical procedures, complications and infant and maternal mortality and morbidity. Infant mortality and morbidity shall be discussed jointly between the obstetric and newborn service staffs.

B. A physician with obstetrical privileges capable of arriving on-site within 30 minutes of notification shall be on a 24-hour on-call duty roster.

C. A physician with obstetrical privileges shall be accessible for patient treatment within 10 minutes during the administration of an oxytocic agent to an antepartum patient.

D. A physician or a certified nurse-midwife, under the supervision of a physician with obstetrical privileges, shall be in attendance for each delivery. Physician supervision of the nurse-midwife shall be in compliance with the regulations of the Boards of Nursing and Medicine.

E. A physician shall be in attendance during all high-risk deliveries. High-risk deliveries shall be defined by the obstetric service medical staff.

F. A physician or a nurse skilled in neonatal cardiopulmonary resuscitation (CPR) shall be available in the hospital at all times.

G. A current roster of physicians, with a delineation of their obstetrical, newborn, pediatric, medical and surgical staff privileges, shall be posted at each nurses' station in the obstetric suite and in the emergency room.

H. A copy of the 24-hour on-call duty schedule, including the list of on-call consulting physicians, shall be posted at each nurses' station in the obstetric suite and in the emergency room.

I. An occupied unit of the obstetrics service shall be supervised by a registered nurse 24 hours a day.

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J. If the postpartum unit is organized as a separate nursing unit, staffing shall be based on a formula of one nursing personnel for every six to eight obstetric patients. Staffing shall include at least one registered nurse for the unit for each duty shift.

K. If the postpartum and general care newborn units are organized as combined rooming-in or modified rooming-in units, staffing shall be based on a formula of one nursing personnel for every four mother-baby units. The rooming-in units shall be staffed at all times with no less than two nursing personnel each shift. At least one of the two nursing personnel on each shift shall be a registered nurse.

L. A registered nurse shall be in attendance at all deliveries. The nurse shall be available on-site to monitor the mother's general condition and that of the fetus during labor, at least one hour after delivery, and longer if complications occur.

M. Nurse staffing of the labor and delivery unit shall be scheduled to ensure that the total number of nursing personnel available on each shift is equal to one half of the average number of deliveries in the hospital during a 24-hour period.

N. At least one of the personnel assigned to each shift on the obstetrics unit shall be a registered nurse. At no time when the unit is occupied shall the nursing staff on any shift be less than two staff members.

O. Patients placed under analgesia or anesthesia during labor or delivery shall be under continuous observation by a registered nurse or a licensed practical nurse for at least one hour after delivery.

P. To ensure adequate nursing staff for labor, delivery, and postpartum units during busy or crisis periods, duty schedules shall be developed in accordance with the following nurse/patient ratios:

1. 1:1 to 2 Antepartum testing
2. 1:2 Laboring patients
3. 1:1 Patients in second stage of labor
4. 1:1 Ill patients with complications
5. 1:2 Oxytocin induction or augmentation of labor
6. 1:2 Coverage of epidural anesthesia
7. 1:1 Circulation for cesarean delivery
8. 1:6 to 8 Antepartum/postpartum patients without complications
9. 1:2 Postoperative recovery
10. 1:3 Patients with complications, but in stable condition
11. 1:4 Mother-newborn care

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Q. Student nurses, licensed practical nurses and nursing aides who assist in the nursing care of obstetric patients shall be under the supervision of a registered nurse.

R. At least one registered nurse trained in obstetric and neonatal care shall be assigned to the care of mothers and infants at all times.

S. At least one member of the nursing staff on each shift who is skilled in cardiopulmonary resuscitation of the newborn must be immediately available to the delivery suite.

T. All nursing personnel assigned to the obstetric service shall have orientation to the obstetrical unit.

U. The governing body shall adopt written policies and procedures for the management of obstetric patients approved by the medical and nursing staff assigned to the service.

1. The policies and procedures shall include, but not be limited to, the following:
 - a. Criteria for the identification and referral of high-risk obstetric patients;
 - b. The types of birthing alternatives, if offered, by the hospital;
 - c. The monitoring of patients during antepartum, labor, delivery, recovery and postpartum periods with or without the use of electronic equipment;
 - d. The use of equipment and personnel required for high-risk deliveries, including multiple births;
 - e. The presence of family members or chosen companions during labor, delivery, recovery, and postpartum periods;
 - f. The reporting, to the Department of Health, of all congenital defects;
 - g. The care of patients during labor and delivery to include the administration of Rh O(D) immunoglobulin to Rh negative mothers who have met eligibility criteria. Administration of RH O(D) immunoglobulin shall be documented in the patient's medical record;
 - h. The provision of family planning information, to each obstetric patient at time of discharge, in accordance with §32.1-134 of the Code of Virginia;
 - i. The use of specially trained paramedical and nursing personnel by the obstetrics and newborn service units;
 - j. A protocol for hospital personnel to use to assist them in obtaining public health, nutrition, genetic and social services for patients who need those services;
 - k. The use of anesthesia with obstetric patients;
 - l. The use of radiological and electronic services, including safety precautions, for obstetric patients;
 - m. The management of mothers who utilize breast milk with their newborns.

Breast milk shall be collected in aseptic containers, dated, stored under refrigeration and consumed or disposed of within 24 48 hours of collection if the breast milk has not been

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frozen. This policy pertains to breast milk collected while in the hospital or at home for hospital use;

- n. Staff capability to perform cesarean sections within 30 minutes of notice;
- o. Emergency resuscitation procedures for mothers and infants;
- p. The treatment of volume shock in mothers;
- q. Training of hospital staff in discharge planning for identified substance abusing, postpartum women and their infants; and
- r. Written discharge planning for identified substance abusing, postpartum women and their infants. The discharge plans shall include appropriate referral sources available in the community or locality for mother and infants such as:
 - (1) Substance abuse treatment services; and
 - (2) Comprehensive early intervention services for infants and toddlers with disabilities and their families pursuant to Part H of the Individuals with Disabilities Education Act, 20 USC §1471 et seq.
 - (3) The discharge planning process shall be coordinated by a health care professional and shall include, to the extent possible:
 - (a) The father of the infant; and
 - (b) Any family members who may participate in the follow-up care of the mother or infant.

The discharge plan shall be discussed with the mother and documented in the medical record.

2. The obstetric service shall adopt written policies and procedures for the use of the labor, delivery and recovery rooms (LDR)/Labor, delivery, recovery and postpartum rooms (LDRP) that include, but are not limited to the following:
- a. The philosophy, goals and objectives for the use of the LDR/LDRP rooms;
 - b. Criteria for patient eligibility to use the LDR/LDRP rooms;
 - c. Identification of high-risk conditions which disqualify patients from use of the LDR/LDRP rooms;
 - d. Patient care in LDR/LDRP rooms, including but not limited to, the following:
 - (1) Defining vital signs, the intervals at which they shall be taken, and requirements for documentation; and
 - (2) Observing, monitoring, and assessing the patient by a registered nurse, certified nurse midwife, or physician;
 - e. The types of analgesia and anesthesia to be used in LDR/LDRP rooms;
 - f. Specifications of conditions of labor or delivery requiring transfer of the patient from LDR/LDRP rooms to the delivery room;
 - g. Specification of conditions requiring the transfer of the mother to the postpartum unit or the newborn to the nursery;
 - h. Criteria for early or routine discharge of the mother and newborn;
 - i. The completion of medical records;
 - j. The presence of family members or chosen companions in the delivery room or

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operating room in the event that the patient is transferred to the delivery room or operating room;

k. The number of visitors allowed in the LDR/LDRP room, and their relationship to the mother; and

l. Infection control, including, but not limited to, gowning and attire to be worn by persons in the LDR/LDRP room, upon leaving it, and upon returning.

12 VAC 5-410-442. Obstetric service design and equipment criteria. (revised 3/1/2007)

A. Renovation or construction of a hospital's obstetric unit shall be consistent with section 2.1-4 of Part 2 of the 2006 Guidelines for Design and Construction of Health Care Facilities of the American Institute of Architects.

B. Delivery rooms, LDR/LDRP rooms, and nurseries shall be equipped to provide emergency resuscitation for mothers and infants.

C. Equipment and supplies shall be assigned for exclusive use in the obstetric and newborn units.

D. The same equipment and supplies required for the labor room and delivery room shall be available for use in the LDR/LDRP rooms during periods of labor, delivery, and recovery.

E. Sterilizing equipment shall be available in the obstetric unit or in a central sterilizing department. Flash sterilizing equipment or sterile supplies and instruments shall be provided in the obstetric unit.

F. Daily monitoring is required of the stock of necessary equipment in the labor, delivery, and recovery rooms (LDR) and labor, delivery, recovery and postpartum (LDRP) rooms and nursery.

G. The hospital shall provide the following equipment in the labor, delivery and recovery rooms and, except where noted, in the LDR/LDRP rooms:

1. Labor rooms.

- a. A labor or birthing bed with adjustable side rails.
- b. Adjustable lighting adequate for the examination of patients.
- c. An emergency signal and intercommunication system.
- d. A sphygmomanometer, stethoscope and fetoscope or doppler.
- e. Fetal monitoring equipment with internal and external attachments.
- f. Mechanical infusion equipment.
- g. Wall-mounted oxygen and suction outlets.
- h. Storage equipment.

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- i. Sterile equipment for emergency delivery to include at least one clamp and suction bulb.
- j. Neonatal resuscitation cart.
- 2. Delivery rooms.
 - a. A delivery room table that allows variation in positions for delivery. This equipment is not required for the LDR/LDRP rooms.
 - b. Adequate lighting for vaginal deliveries or cesarean deliveries.
 - c. Sterile instruments, equipment, and supplies to include sterile uterine packs for vaginal deliveries or cesarean deliveries, episiotomies or laceration repairs, postpartum sterilizations and cesarean hysterectomies.
 - d. Continuous in-wall oxygen source and suction outlets for both mother and infant.
 - e. Equipment for inhalation and regional anesthesia. This equipment is not required for LDR/LDRP rooms.
 - f. A heated, temperature-controlled infant examination and resuscitation unit.
 - g. An emergency call system.
 - h. Plastic pharyngeal airways, adult and newborn sizes.
 - i. Laryngoscope and endotracheal tubes, adult and newborn sizes.
 - j. A self-inflating bag with manometer and adult and newborn masks that can deliver 100% oxygen.
 - k. Separate cardiopulmonary crash carts for mothers and infants.
 - l. Sphygmomanometer.
 - m. Cardiac monitor. This equipment is not required for the LDR/LDRP rooms.
 - n. Gavage tubes.
 - o. Umbilical vessel catheterization trays. This equipment is not required for LDR/LDRP rooms.
 - p. Equipment that provides a source of continuous suction for aspiration of the pharynx and stomach.
 - q. Stethoscope.
 - r. Fetoscope.
 - s. Intravenous solutions and equipment.
 - t. Wall clock with a second hand.
 - u. Heated bassinets equipped with oxygen and transport incubator.
 - v. Neonatal resuscitation cart.
- 3. Recovery rooms.
 - a. Beds with side rails.
 - b. Adequate lighting.
 - c. Bedside stands, overbed tables, or fixed shelving.
 - d. An emergency call signal.
 - e. Equipment necessary for a complete physical examination.
 - f. Accessible oxygen and suction equipment.

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12 VAC 5-410-443. Newborn service requirements; designation of newborn service levels, service levels.

A. If a hospital intends to provide newborn services, it shall make application to the department requesting approval for a level of newborn service as specified in subsection B of this section. Application shall be made at least 60 days prior to the desired date of approval. Approval is required to be renewed annually. Newborn service level approval shall be based upon the hospital's certification and the department's verification that the hospital meets the requirements of this section for the level requested.

1. No approval for a general level newborn service designation will be granted without a Certificate of Public Need (COPN) or without documentation by the applicant that it provided general level newborn services prior to July 1, 1992, or that the provision of general level newborn services was found to be exempt from Certificate of Public Need review pursuant to §32.1-102.11 of the Code of Virginia.

2. No approval for a newborn service level designation higher than general level will be granted without a Certificate of Public Need or without documentation by the applicant that it provided a newborn service level higher than general level prior to July 1, 1992, or that the provision of a newborn service level higher than general level was found to be exempt from Certificate of Public Need review pursuant to §32.1-102.11 of the Code of Virginia.

B. A hospital's newborn service shall be designated as a general level, intermediate level, specialty level, or subspecialty level newborn service. The newborn service levels are designated as follows:

1. A general level newborn service shall provide care to newborns of low risk as specified within the service's medical protocol. A general level newborn nursery shall have the capability to care for newborns who weigh at least 2000 grams at birth or who have completed 34 weeks gestation. Risk assessment shall be provided to identify all high-risk neonates and ensure appropriate consultation. A general level newborn nursery shall have the equipment and staff capabilities to immediately stabilize a sick newborn prior to transporting the newborn to an appropriate higher level nursery. The equipment and staff to receive convalescing neonates from higher level nurseries shall also be provided.

2. An intermediate level newborn service shall provide care as specified within the service's medical protocol to moderately ill neonates or stable-growing low birthweight neonates who require only a weight increase to be ready for discharge. In addition to the capabilities required of the general level newborn nursery, the intermediate level nursery shall have the equipment and staff capabilities to provide controlled temperature environments for each neonate, the insertion and maintenance of umbilical arterial lines, hood oxygen to 40%, continuous monitoring of blood oxygen, and assisted ventilation of a neonate in preparation for transport utilizing a mechanical ventilator or an ambu bag.

3. A specialty level newborn service shall provide intensive care to high-risk neonates

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with neonatal illnesses as specified in the service's medical protocol. In addition to the capabilities required of the lower level nurseries, the specialty level nursery shall have the equipment and staff capabilities to provide the following: maintenance of central arterial umbilical catheters or peripheral arterial lines with constant pressure monitoring, insertion and maintenance of chest tubes for drainage, administration of total parenteral nutrition (TPN), the maintenance of pressor medications, the administration of surfactant and respiratory support to include the maintenance of hood oxygen, continuous positive airway pressure (CPAP), and neonatal mechanical ventilation beyond the immediate stabilization period.

4. A subspecialty level newborn service shall provide intensive care for high-risk, critically ill neonates with complex neonatal illnesses. The subspecialty level newborn service shall provide, in-house, a full range of pediatric medical and surgical subspecialists to care for critically ill neonates. The pediatric subspecialists required as members of the hospital's staff are those subspecialists required of a Subspecialty Perinatal Center as referenced within the 1993 edition of *Toward Improving the Outcome of Pregnancy*, March of Dimes Birth Defects Foundation, Appendix 6, Pages 114 and 115. Rarely, the availability of highly technical expertise and specialized physicians at another subspecialty center will indicate consultation and possibly transfer. The subspecialty level nursery shall have the capability to care for neonates born in its facility as well as those referred from lower level nurseries. The subspecialty level nursery shall have all of the technical capabilities required of the lower level nurseries as well as the equipment and staff capabilities to maintain a neonate on prostaglandin E1 (PgE1) and the ability to perform echocardiography evaluations.

C. The hospital shall establish a written medical protocol, approved by the governing body, that specifies all neonatal conditions routinely managed by the newborn service as well as protocols for those medical conditions which require consultation and may necessitate transfer to a higher level of newborn service.

D. Physician consultation shall occur between physicians at the birth hospital and at the referral hospital to which the newborn may be referred.

E. The physician at the birth hospital shall document in the newborn's medical record any physician's consultation and any agreement to manage the newborn at the birth hospital or to stabilize and then transfer the newborn according to the hospital's collaboration agreement. In the event of disagreement, the attending physician at the birth hospital shall be responsible for the management and care of the newborn and shall document the consultation and results of consultation in the newborn's medical record.

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12 VAC 5-410-444. Newborn service medical direction; physician consultation and coverage; nursing direction, nurse staffing and coverage; policies and procedures.
(revised 1/25/2006)

A. The governing body shall appoint a physician as medical director of the organized newborn service who meets the qualifications specified in the medical staff bylaws. In addition, the medical director must meet the qualifications specified for the medical direction of the highest level of newborn service provided by the hospital.

1. If a hospital offers only general level newborn services, the medical director shall be a physician qualified to provide normal newborn care, including the ability to immediately resuscitate and stabilize a sick newborn for transfer to a higher level of service.

2. If a hospital offers intermediate level newborn services, the medical director shall be a board-certified or board-eligible pediatrician with training and experience in the care of preterm neonates, including stabilization and ventilation management.

3. If a hospital offers specialty level newborn services, the medical director shall be a board-certified or board-eligible neonatologist.

4. If a hospital offers subspecialty level newborn services, the medical director shall be a board-certified or board-eligible neonatologist.

B. The duties and responsibilities of the medical directors of all levels of newborn service shall include, but not be limited to the:

1. General supervision of the quality of care provided patients admitted to the service;

2. Establishment of criteria for admission to the service;

3. Adherence of the service to standards of professional practices, policies and procedures, the medical protocol, and the hospital's collaboration agreements adopted by the medical staff and governing body applicable to the service;

4. Development of recommendations to the medical staff on standards of professional practice and staff privileges applicable to the service;

5. Identification of clinical conditions and medical and surgical procedures that require physician consultation;

6. Conducting conferences, at least quarterly, to review routine and emergency surgical procedures, complications and infant and maternal mortality and morbidity. Infant mortality and morbidity shall be discussed with the obstetric service staff; and

7. Active participation in the service's quality assurance program.

C. The hospital shall provide the following physician consultation and coverage in the general level newborn nursery service and all higher level nursery services unless unique requirements are specifically imposed for the higher level nursery services:

1. A physician with pediatric privileges capable of arriving on-site within 30 minutes of notification shall be on the 24-hour on-call duty roster;

2. A physician or nurse skilled in neonatal cardiopulmonary resuscitation (CPR) shall

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be available in the hospital at all times.

3. A current roster of physicians, with a delineation of their newborn, pediatric, medical and surgical privileges shall be posted at each nurses' station in the newborn service unit.

4. A copy of the 24-hour on-call duty schedule, including a list of on-call consulting physicians, shall be posted at each nurses' station in the newborn service unit.

5. If the medical director is not a board-certified or board-eligible pediatrician, the hospital shall have a written agreement with one or more board-certified or board-eligible pediatricians to be available to provide consultation on a 24-hour basis. Consultation may be by telephone.

6. If a hospital does not have a neonatologist on staff available on a 24-hour basis, it shall have a written agreement with another hospital to provide consultation, at least by telephone, on a 24-hour basis, by a board-certified or board-eligible neonatologist. The consultant shall be available to advise on the development of a protocol for the care and transport of sick newborns.

D. The physician consultation and coverage for the intermediate level newborn nursery service shall be the same as the general level newborn service with the following exceptions:

1. Subdivision C 1 of this section shall not apply.
2. Physician coverage shall be provided on a 24-hour on-call basis by a board-certified or board-eligible pediatrician or pediatricians capable of arriving on-site within 30 minutes of notification.

E. The physician consultation and coverage for the specialty level and the subspecialty level newborn services shall be the same as for the lower level newborn services with the following exceptions:

1. Subdivision C 1 of this section shall not apply.
2. In-house physician consultation and coverage shall be provided 24 hours a day by a:
 - a. Board-certified or board-eligible neonatologist;
 - b. Board-certified or board-eligible pediatrician;
 - c. Second year or higher level pediatric resident; or
 - d. Neonatal nurse practitioner.

3. Whenever in-house coverage is provided as stated in subdivision 2 b, c, or d of this subsection, a board-certified or board-eligible neonatologist shall be on-call and available to be on-site within 20 minutes of request.

F. The nursing direction, staff and coverage required for the general level newborn service shall be as follows:

1. The neonatal nursing program shall be under the direction of a registered nurse.
2. The nursing director's responsibilities shall include, but not be limited to:

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- a. Directing neonatal nursing services;
- b. Guiding the development and implementation of neonatal nursing policies and procedures;
- c. Collaborating with the medical staff; and
- d. Consulting with referral hospitals with which a hospital has transfer agreements applicable to the service or services.

3. Each occupied unit of the newborn service shall be under the direct supervision of a registered nurse 24 hours a day. The registered nurse shall have documented competence in neonatal nursing appropriate to the level of service provided.

4. If a general level newborn nursery is organized as a separate nursing unit, staffing shall be based on a formula of a minimum of one nursing personnel to every eight newborns. Staffing shall include at least one registered nurse for the unit for each duty shift to provide direct supervision for nursing care.

5. If the postpartum and general level newborn units are organized as combined rooming-in or modified rooming-in units, staffing shall be based on a formula of one nursing personnel for every four mother-baby units. The rooming-in units shall always be staffed with no less than two nursing personnel assigned to each shift. One of the two nursing personnel shall be a registered nurse to provide direct supervision of nursing care.

6. When infants are present in the nursery, at least one nursing personnel trained in the care of newborn infants, with duties restricted to the care of the infants, shall be assigned to the nursery at all times. This nursing personnel is in addition to the registered nurse who is required to provide supervision.

7. To ensure adequate nursing staff for the nursery for normal newborns, duty schedules shall be developed and actual shift staffing shall occur according to the following minimum nurse to patient ratios:

- a. 1:4 Recently born infants and those needing close observation.
- b. 1:8 Newborns needing only routine care.
- c. 1:4 Mother-newborn routine care.

8. Student nurses, licensed practical nurses and nursing aides who assist in the nursing care of newborn infants shall be under the direct supervision of a registered nurse.

9. At least one nurse on each shift who is skilled in neonatal cardiopulmonary resuscitation must be immediately available to the nursery.

10. All nursing personnel assigned to the newborn service shall have orientation to the nursery, including orientation to patient care appropriate for the service level provided.

G. The nursing direction, staff and coverage required of the intermediate level newborn service shall be the same as required of the general level newborn service with the following exceptions:

- 1. To ensure adequate nursing staff for the nursery, duty schedules shall be developed

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and actual shift staffing shall occur according to a ratio of at least one nurse to four neonates.

2. All registered nurses assigned to the newborn service shall be trained in neonatal cardiopulmonary resuscitation (CPR).

H. The nursing direction, staff and coverage for the specialty level newborn service shall be the same as the lower level newborn service levels with the following exceptions:

1. The newborn nursery service shall have a nurse manager. The nurse manager shall be a registered nurse with advanced training and experience in the nursing management of high-risk neonates and their families. The responsibilities of the nurse manager shall include, but not be limited to:

- a. Daily management of the nursery;
- b. Supervision and evaluation of nursing personnel assigned to the nursery;
- c. Assuring nursing coverage 24 hours a day; and
- d. Implementing nursing policies and procedures at the service level.

2. All registered nurses shall have advanced training and experience in the management of neonatal patients, including specialized care technology and ventilator care for neonates. Only registered nurses with this advanced training and experience shall be assigned to care for neonates on ventilators.

3. To ensure adequate nursing staff for the nursery, duty schedules shall be developed and actual shift staffing shall occur according to a ratio of at least one nurse to three patients for neonates requiring specialty level care. For those neonates who have been assessed as no longer needing specialty level care, nurse to patient ratios shall be according to the neonate's appropriate level of service.

I. The nursing direction, staff and coverage for the subspecialty level newborn service shall be the same as all lower levels of newborn services with the following exceptions:

1. A neonatal clinical nurse specialist shall be assigned to the nursery, duties and responsibilities shall include staff consultation, collaboration, and teaching.

2. All registered nurses shall have advanced training and experience, beyond what is required of nurses in the lower level nurseries, in the management of high-risk neonates, including the care of unstable neonates with multisystem problems.

3. To ensure adequate nursing staff for the nursery, duty schedules shall be developed and actual shift staffing shall occur according to the following minimum nurse to patient ratios for neonates requiring subspecialty level care:

- a. 1:2 Neonates requiring subspecialty level care; and
- b. 1:1 Neonates requiring multisystem support.

For those neonates who have been assessed as no longer needing subspecialty level care, nurse to patient ratios shall be according to the neonate's appropriate level of service.

4. All nursing patient care shall be provided by registered nurses assigned to the subspecialty level nursery.

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J. The governing body shall adopt written policies and procedures approved by the medical and nursing staff of the service, for the medical care of newborns.

K. The policies and procedures for the general level nursery and all higher levels of newborn services shall include, but not be limited to:

1. Medical criteria for the identification of high-risk neonatal patients.

2. Protocols for the management of all neonatal medical conditions that are routinely managed by the service as well as protocols for the stabilization and transfer of neonates that require a higher level of newborn service. These protocols shall be maintained in the nursery in addition to the telephone numbers of each nursery and the names of each referral newborn service medical director.

3. Written collaboration agreements with hospitals with higher levels of newborn services. A hospital may enter into more than one collaboration agreement. The collaboration agreements shall specifically identify those medical conditions that require consultation and may necessitate a neonatal transfer as well as the interim treatment required prior to transfer. Nothing in the regulation shall require a birth hospital to enter into a collaboration agreement with a referral hospital that disagrees with the medical, consultation and transfer protocols adopted by the birth hospital. All neonatal transfers shall conform with Section 1867 of the Social Security Act, its amendments in force to date and implementing regulations. At the time of any transfer, the medical treatment at the referral hospital shall outweigh the risks to the neonate from affecting the transfer. The collaboration agreements shall include, but not be limited to:

a. Criteria for neonatal transfer to the referral nursery;

b. Procedures for neonatal transport;

c. Back transfer criteria which provides for the return of the neonate to the referring hospital when medically appropriate;

d. Annual review by both parties of all cases of neonatal transfer;

e. Annual review by both parties of the collaboration agreements; and

f. Annual evaluation by both parties of the collaboration agreement and modification of the agreement, as necessary, as indicated by the evaluation results.

4. Establishment and maintenance of an ongoing, documented quality assurance program by the service that utilizes a multidisciplinary team of health practitioners and administrators for review and is integrated with the hospital's overall quality assurance program.

a. The quality assurance program shall include:

(1) Problem identification;

(2) Action plans;

(3) Evaluation; and

(4) Follow-up.

b. The quality assurance program shall include an annual review of the following:

(1) Neonatal transfer cases;

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- (2) Management of in-house neonatal cases; and
- (3) Staff in-house inservice programs.
- d. Outcome statistics, including morbidity, mortality, and the appropriateness of neonatal transfers, shall be compiled in a standardized manner and reviewed quarterly by a multidisciplinary committee.
- 5. Immediate resuscitation and stabilization of the sick neonate in accordance with current cardiopulmonary resuscitation (CPR) standards of the American Heart Association and the American Academy of Pediatrics.
- 6. Care of newborns after delivery to include the following:
 - a. Care of eyes, skin and umbilical cord and the provision of a single parenteral dose of Vitamin K-1, water soluble, as a prophylaxis against hemorrhagic disorder;
 - b. Maintenance of the newborn's airway, respiration, and body temperature; and
 - c. Assessment of the newborn and recording of the one-minute and five-minute Apgar scores.
- 7. Performance of prophylaxis against ophthalmia neonatorum by the administration of a 1.0% solution of silver nitrate aqueous solution, erythromycin, or tetracycline ointment or solution. This process is to be performed within one hour of delivery with documentation entered in the newborn's medical record. The process may be performed in the nursery.
- 8. Clamping or tying of the umbilical cord and, when indicated, collecting a sample of cord blood.
- 9. Performance of Rh type and Coombs' test for every newborn born to a Rh negative mother and performing major blood grouping and Coombs' tests when indicated for every newborn born to an O blood group mother or a mother with a family history of blood incompatibility. If such qualitative tests are performed, the results shall be documented in the newborn's medical record.
- 10. Identification and treatment of hyperbilirubinemia and hypoglycemia.
- 11. Identification of each newborn, prior to leaving the delivery room, with two identification bands fastened on the newborn and one identification band fastened on the mother. The newborn's medical record shall accompany the infant from the delivery room.
- 12. Newborn transport, within the hospital, of all newborns who are either premature or compromised by using a heated bassinet equipped with oxygen, a transport incubator or other similar equipment.
- 13. Registered nurse or physician assessment of a newborn within one hour after delivery and documentation of the assessment in the newborn's medical record. Assessment in the delivery area is permitted if the hospital permits a newborn and its mother to remain together during the immediate post-delivery period.
- 14. Delineation of how infants are to be monitored during stays with their mothers and under what circumstances infants must be taken to the nursery immediately after delivery and not allowed to remain with their mothers.
- 15. Physician examination of the newborn consistent with guidelines of the American

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Academy of Pediatrics. A high-risk newborn shall be examined upon admission to the nursery.

16. Ensuring that every bassinet and incubator in the nursery bears the identification of the newborn's last name, sex, date and time of birth, the mother's last name, and the attending physician's name.

17. The management of mothers who utilize breast milk with their newborns. Breast milk shall be collected in aseptic containers, dated, stored under refrigeration and consumed or disposed of within 24-48 hours of collection if the breast milk has not been frozen. This policy pertains to breast milk collected while in the hospital or at home for hospital use.

18. Preparation and use of formula including, but not limited to:

- a. The distribution of feeding units immediately after assembly;
- d. The use of prepared formula only within the time period designated on the package; and
- e. The use of presterilized formula only, except in the case of facility-defined emergencies.

19. Screening newborns for risk factors associated with hearing impairment as required in §§32.1-64.1 and 32.1-64.2 of the Code of Virginia and in accordance with the regulations of the Board of Health governing the Virginia Hearing Impairment Identification and Monitoring System (12VAC5-80).

20. Screening and treatment of genetic, metabolic, and other diseases identifiable in the newborn period as specified in §32.1-65 of the Code of Virginia and in accordance with the Regulations Governing the Newborn Screening and Treatment Program (12VAC5-70).

21. Reporting to the Department of Health all required reportable congenital defects.

22. Visitor contact with the newborn, including newborns delivered by cesarean section, and premature, sick, congenitally malformed, and dying newborns.

23. Completion of birth certificates.

24. Discharge planning appropriate for the needs of the patient for at-risk infants.

L. The additional policies and procedures required for the intermediate level newborn service shall include, but not be limited to:

1. Insertion and maintenance of peripheral intravenous lines and use of pediatric infusion pumps that are accurate to plus or minus one milliliter an hour;

2. Insertion and maintenance of umbilical arterial lines and the use of pediatric infusion pumps accurate to plus or minus one milliliter an hour;

3. Use of heated, humidified, and blended supplemental oxygen by hood with a recording of oxygen levels every hour using a calibrated constant oxygen analyzer. The policy shall address consultation with a higher level nursery identified in the collaboration agreement when oxygen levels exceed 40% and remain at 40% or greater for a period of four hours or more;

4. Administration of nasogastric or orogastric feedings;

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5. Use of saturation monitor (pulse oximeter or equivalent) for any newborn requiring supplemental oxygen;
6. Use of assisted ventilation in preparation for transport;
7. Initiation of PgE1 prior to transport; and
8. Administration of blood components and a policy for provision of partial and total exchange transfusions.

M. The additional policies and procedures required for the specialty level newborn service shall include, but not be limited to:

1. Provision of ongoing assisted ventilation;
2. Administration of surfactant;
3. Preparation and administration of total parenteral nutrition (TPN);
4. Initiation and maintenance of pressor medications;
5. Provision for developmental follow up;
9. Insertion and maintenance of central umbilical arterial catheters or peripheral arterial lines with constant pressure monitoring;
10. Placement of chest tubes with water seal on an emergency basis;
11. Use of heated, humidified, and blended supplemental oxygen by hood with a recording of oxygen levels every hour using a calibrated constant oxygen analyzer;
9. Administration and maintenance of CPAP including the requirement for in-house physician coverage;
10. Daily availability of appropriate drug peak and trough assays on one milliliter or less of blood;
11. Cardioversion capability specific for newborns; and
12. Provision for ophthalmology consult and requirements regarding the examination of high-risk newborns.

N. The additional policies and procedures required for the subspecialty level newborn service shall include, but not be limited to:

1. Provision for returning patients to the operating room within 30 minutes, if indicated;
3. Provision for echocardiography evaluation;
4. Provision for patient treatment on an extracorporeal membrane oxygenator (ECMO) or a written collaboration agreement with a hospital with this capability;
4. Provision for maintenance of central venous pressure monitoring; and
5. Provision for the maintenance of neonates on prostaglandin E1 (PgE1).

12 VAC 5-410-445. Newborn service design and equipment criteria. (revised 8/2010)

A. Construction and renovation of a hospital's nursery shall be consistent with section 2.2-2.12.1 through 2.2-2.12.6.6 of Part 2 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute (formerly of

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the American Institute of Architects). Hospitals with higher-level nurseries shall comply with sections 2.2-2.10.1 through 2.2-10.9.3 of Part 2 of the 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 (FI_{O2}). 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;
7. 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;
3. On-site supply of PgE1;
4. 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;

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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.

12 VAC 5-410-446. Newborn support services and other resources.

A. The support services and other resources required for the general level newborn service and all higher levels of newborn services shall be as follows:

1. Clinical laboratory services and blood bank services available in the hospital on a 24-hour basis. Laboratory and blood bank personnel available on-site or on-call on a 24-hour basis;
2. Group O Rh negative blood available from the blood bank at all times and the blood bank's ability to provide correctly matched blood within 45 minutes of request;
3. Hospital laboratory and blood bank personnel capability to perform the following tests with less than 1.0 ml of blood within one hour or less of request if specified: (i) blood group and Rh type determination/cross-matching, (ii) arterial blood gases within 20 minutes, (iii) blood glucose within 20 minutes, (iv) complete blood count, (v) total

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protein and albumin, (vi) total and direct bilirubin, (vii) direct Coombs' test, (viii) electrolytes, (ix) blood urea nitrogen, (x) clotting profile (may require more than one ml of blood); and

4. Portable radiological services for basic radiologic studies in the nursery available on-call, within 30 minutes of request, on a 24-hour basis.

B. The additional support services and resources required of the intermediate level newborn service shall be as follows:

1. A respiratory therapist in-house 24 hours a day. The therapist shall have orientation to the neonatal nursery, including orientation to the appropriate level of care. The therapist shall have documented competence in neonatal respiratory care;

2. A radiology technician in-house 24 hours a day;

3. An ultrasound technician available on-call 24 hours a day;

4. A laboratory technician in-house 24 hours a day;

5. A blood bank technician available on call within 30 minutes of request;

6. A licensed physical therapist or certified occupational therapist available for consultation;

7. A registered dietitian with documented competence in neonatal nutrition available for consultation;

8. A biomedical technician, available to the nursery, responsible for the maintenance and safe functioning of specialized medical equipment;

9. Microvolume assays for xanthines and aminoglycosides available within 12 hours of request;

10. Blood gases to be performed on 0.25 ml or less heparinized blood within 20 minutes of request;

11. Blood components available within two hours of request; and

12. Portable chest x-ray within 20 minutes of request.

C. The specialty level support services and resources that are required in addition to the requirements for the lower level nurseries are as follows:

1. A blood bank technician in-house 24 hours a day;

2. A pharmacist with documented competence in neonatal pharmacology on staff;

3. A licensed physical therapist or certified occupational therapist with documented competence in neonatal care;

4. A medical social worker as a participating member of the service;

5. An ultrasound technician on-call 24 hours a day; and

6. A registered dietitian with documented competence in neonatal nutrition as a participating member of the service.

D. The subspecialty level support services and resources that are required in addition to the requirements of the lower level nurseries are as follows:

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1. A radiologist with documented competence in the interpretation of pediatric and neonatal films readily available for providing pediatric and neonatal x-ray procedures and ultrasound interpretation;
2. A developmental pediatrician on staff;
3. A cardiothoracic surgeon with documented competence in pediatric surgical procedures on staff and on-call 24 hours a day;
4. A pediatric surgeon on staff and on-call 24 hours a day;
5. An anesthesiologist with documented competence in neonatal anesthesiology on-call 24 hours a day;
6. The following pediatric subspecialists on staff available to be on-site within 30 minutes of request 24 hours a day:
 - a. Cardiology;
 - b. Endocrinology;
 - c. Gastroenterology;
 - d. Genetics;
 - e. Hematology;
 - f. Immunology;
 - g. Infectious diseases;
 - h. Metabolism;
 - i. Nephrology;
 - j. Neurology;
 - k. Nutrition;
 - l. Pharmacology; and
 - m. Pulmonology;
7. The following pediatric surgical subspecialists on staff available to be on-site within 30 minutes of request 24 hours a day:
 - a. Neurosurgeon;
 - b. Ophthalmologist;
 - c. Orthopedic surgeon;
 - d. Otolaryngologic surgeon; and
 - e. Urologic surgeon;
8. An echocardiography technician on staff;
9. An American College of Medical Genetics certified or eligible genetics counselor on staff;
10. In-house 24-hour capability for microchemistries;
11. Hospital resources to provide for the medical follow up of discharged, high-risk neonates that incorporate a parent education program that includes, but is not limited to, the following:
 - a. Pediatric cardiopulmonary resuscitation training;
 - b. Home cardiopulmonary monitoring;
 - c. Home oxygen monitoring; and
 - d. Lactation instruction;

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12. Hospital resources to provide comprehensive, neonatal continuing education to health professionals external to the hospital;

13. A referral network for cardiovascular surgical consultation; and

14. The operation of a neonatal transport system on a 24-hour basis. Transports shall be initiated within 30 minutes of request. The neonatal transport system shall operate in accordance with the most current editions of the Guidelines for Air and Ground Transport of Neonatal and Pediatric Patients published by the American Academy of Pediatrics and the Neonatal Transport Standards and Guidelines published by the National Association of Neonatal Nurses.

12 VAC 5-410-447. Combined obstetric and clean gynecological service; infection control.

A. A hospital may combine obstetric and clean gynecological services. The hospital shall define clean gynecological cases in written hospital policy. A combined obstetric and clean gynecologic service shall be organized under written policies and procedures. The policies and procedures shall be approved by the medical and nursing staff of these services and adopted by the governing body and shall include, but not limited to the following requirements:

1. Cesarean section and obstetrically related surgery, other than vaginal delivery, shall be carried out in designated operating or delivery rooms. Vaginal deliveries may be performed in designated delivery or operating rooms that are used solely for obstetric or clean gynecologic procedures.

2. Clean gynecological cases may be admitted to the postpartum nursing unit of the obstetric service according to procedures determined by the obstetrics and gynecologic staff and the hospital's infection control committee.

3. Only members of the medical staff with approved privileges shall admit and care for patients in the combined service area. These admissions shall be subject to the medical staff bylaws.

4. Hospitals with a combined service shall limit admission to the service to those patients allowed by policies adopted by the obstetric and gynecological medical staff and the hospital's infection control committee.

5. Unoccupied beds shall be reserved daily in a combined service ready for use by obstetric patients.

6. Patients admitted to the combined service may be taken to radiology or other hospital departments for diagnostic procedures, before or after surgery, if it is not evident that these procedures may be hazardous to the patients or to other patients on the combined service.

7. Patients may receive postpartum or immediate postoperative care in the general recovery room prior to being returned to the combined service area if the following conditions prevail:

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a. The recovery room or intensive care unit is a separate unit adjacent to or part of the general surgical operating suite or delivery suite; and

b. The recovery room is under the direct supervision of the chairman of the anesthesiology department of the hospital.

In separate obstetric recovery rooms, supervision shall be provided by the obstetrician in charge or by physicians approved by the medical staff of the combined service.

8. Nursing care of all patients shall be supervised by a registered nurse.

9. Nursing care of both obstetrical and gynecological patients may be given by the same nursing personnel.

10. Visitor regulations applicable to visitors of obstetric patients shall also apply to visitors of other patients admitted to the combined service.

B. In addition to the infection control requirements specified in 12VAC5-410-490, the hospital's infection control committee, in cooperation with the obstetric and newborn medical and nursing staff, shall establish written policies and procedures for infection control within the obstetric and newborn services. The policies and procedures shall be adopted by the governing body and shall include, but not be limited to, the following:

1. The establishment of criteria for determining infection-related maternal and newborn morbidity;

2. Written criteria for the isolation or segregation of mothers and newborns, in accordance with Guidelines for Perinatal Care (American Academy of Pediatrics/American College of Obstetricians and Gynecologists) and Control of Communicable Diseases in Man (American Public Health Association) to include at least the following categories:

a. Birth prior to admission to the facility;

b. Birth within the facility but prior to admission to the labor and delivery area;

c. Readmission to the service after transfer or discharge;

d. Presence of infection;

e. Elevated temperature; and

f. Presence of rash, diarrhea, or discharging skin lesions;

3. Written policies and procedures for the isolation of patients in accordance with Guidelines for Perinatal Care (AAP/ACOG) and Control of Communicable Diseases in Man (American Public Health Association) including, but not limited to, the following:

a. Ensuring that a physician orders and documents in the patient's medical record the placement of a mother or newborn in isolation;

b. Ensuring that at least one labor room is available for use by a patient requiring isolation;

c. Provisions for the isolation of a mother and newborn together (rooming-in) or separately; and

d. Policies and procedures for assigning nursing personnel to care for patients in isolation;

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4. Control of traffic, including personnel and visitors. Policies and procedures shall be established in the event that personnel from other services must work in the obstetric and newborn services or personnel from the obstetric and newborn services must work on other services. Appropriate clothing changes and handwashing shall be required of any individual prior to assuming temporary assignments or substitution from any other area or service in the hospital;

5. Determination of the health status of personnel, and control of personnel with symptoms of communicable infectious disease;

6. Review of cleaning procedures, agents, and schedules in use in the obstetric and newborn services. Incubators or bassinets shall be cleaned with detergent and disinfectant registered by the U.S. Environmental Protection Agency each time a newborn occupying it is discharged or at least every seven days;

7. Techniques of patient care, including handwashing and the use of protective clothing such as gowns, masks, and gloves; and

8. Infection control in the nursery, including but not limited to:

a. Closing of the nursery immediately in the event of an epidemic, as determined by the infection control director in consultation with the medical director and the Department of Health;

b. Assigning a newborn to a clean incubator or bassinet at least every seven days;

c. Using an impervious cover that completely covers the surface of the scale pan if newborns are weighed on a common scale, and changing the cover after each newborn is weighed;

d. Gowning in isolation cases; and

e. Requiring nursery personnel wear clean scrub attire in the nursery when they are handling infants. Appropriate cover garments shall be worn over scrub attire when personnel are holding infants. Personnel shall wash their hands after contact with each patient and upon entering or leaving the nursery.

12 VAC 5-410-450. Psychiatric service. (revised 1/25/2006)

A. The psychiatric service shall be under the supervision of a physician, licensed by the Board of Medicine, who meets the qualifications of the medical staff bylaws.

B. Psychiatric units shall conform to the applicable licensure requirements pursuant to 12VAC35-105.

12 VAC 5-410-460. Special care units.

A. As used in this section, special care units may be multipurpose or include but not be limited to units for: intensive care, burn care, coronary care, pulmonary care, rehabilitation, and hemodialysis.

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B. Special care units shall have a defined organization. Each unit shall be designed and equipped for the defined special functions. Each special care unit shall be governed by written policies and procedures specifically relating to utilization of the service.

C. Each unit shall be under the direction of a physician qualified by training and experience in the specialty care in accordance with medical staff bylaws.

D. Personnel shall be provided based on the scope and complexity of the services provided.

E. The hospital shall have a written plan for a continuing education program developed specifically for personnel of special care units.

12 VAC 5-410-470. Outpatient (ambulatory care).

A. All hospital outpatient (ambulatory care) services shall conform to all applicable rules and regulations herein, since such services are an integral part of the hospital and covered by its licensure.

B. Freestanding outpatient surgical hospitals shall comply with the provisions of Part IV of this chapter.

**Article 4.
Environmental and Maintenance Services.**

12 VAC 5-410-480. Housekeeping service. (revised 1/25/2006)

A. Written housekeeping procedures shall be established for the cleaning of all areas in the hospital and copies posted in appropriate areas.

B. All parts of the hospital and its premises shall be kept clean, neat, and free of litter and rubbish.

C. Equipment and supplies shall be provided for cleaning of all surfaces. Such equipment shall be maintained in a safe and sanitary condition.

D. Cleaning solutions and substances shall be labeled, stored in a safe place, and kept separate from food storage and patient care supplies.

E. Cleaning shall be performed in a manner which will minimize the spread of pathogenic organisms in the hospital atmosphere.

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12 VAC 5-410-490. Infection control. (revised 1/25/2006)

A. Each hospital shall have an infection control committee to perform at least the following functions:

1. Establish a hospital-wide infection surveillance program and designate an infection control officer to conduct all infection surveillance activities and to maintain appropriate records to include infection rates by body site and clinical service and all hospital acquired blood stream pathogens.

2. Establish written policies governing the admission and isolation, including protective isolation, of patients with known or suspected infectious diseases.

3. Develop, periodically evaluate, and revise as needed, infection control policies, procedures and techniques for all appropriate phases of hospital operation and service in order to protect patients, employees, and visitors. These policies shall include, but are not limited to, appropriate employee health screening and immunization and acceptable techniques and practices for high risk procedures such as parenteral hyperalimentation, urinary tract catheterization, dialysis, and intravenous therapy.

B. An educational program on infection control for all appropriate personnel shall be conducted.

C. The hospital shall report promptly to its local health department diseases designated as "reportable" according to 12VAC5-90-80 when such cases are admitted to or are diagnosed in the hospital and shall report any outbreak of infectious disease, including nosocomial infections, as required by 12VAC5-90. An outbreak is defined as an increase in incidence of any infectious disease above the usual incidence at the hospital.

In addition, two or more epidemiologically related infections, including, but not limited to, staphylococcus aureus, group A beta hemolytic streptococcus, and salmonella species occurring in the obstetrical or nursery units shall be reported through the local health department.

D. Accumulated waste, including all contaminated sharps, dressings, or similar infectious waste, shall be disposed of in a manner compliant with the OSHA Bloodborne Pathogens standard (29 CFR 1910.1030).

12 VAC 5-410-500. Laundry service. (revised 1/25/2006)

A. Hospitals providing laundry service shall have adequate facilities and equipment for the safe and effective operation of such service. Those areas used for storage and handling of soiled linens shall be negatively pressurized or vented to the outside.

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B. Special procedures shall be established for the handling and processing of contaminated linens.

C. All soiled linen shall be placed in closed containers prior to transportation.

D. To safeguard clean linens from cross-contamination, they shall be:

1. Transported in containers used exclusively for clean linens unless such containers are routinely and regularly sanitized before use as a clean linen transport container and shall be kept covered at all times while in transit; and

2. Stored in areas designated exclusively for this purpose.

Article 5.

Physical Plant Requirements for Existing Buildings.

12 VAC 5-410-510 to 12VAC5-410-640. [Repealed]

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PART III.

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

Article 1.

Standards and Design Criteria.

12 VAC 5-410-650. General building and physical plant information. (revised 8/2010)

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 2.2-8 of Part 2 of the 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.

12 VAC 5-410-655. Additional building regulations and standards. (added 1/25/2006)

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

B. Water shall be obtained from an approved water supply system. Hospitals shall be connected to sewage systems approved by the Department of Health or the Department of Environmental Quality.

C. Each hospital shall establish a monitoring program for the internal enforcement of all applicable fire and safety laws and regulations.

D. 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 12 VAC 5-480.

E. A hospital's food services operation shall comply with 12 VAC 5-421.

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F. Hospital pharmacy services shall comply with Chapter 33 (§54.1-3300 et seq.) of Title 54.1 of the Code of Virginia and 18VAC110-20.

12 VAC 5-410-660 to 12VAC5-410-710. [Repealed]

12 VAC 5-410-720. Drawings and specifications. (revised 1/25/2006)

A. Architectural drawings and specifications for all new construction or for additions, alterations or renovations to any existing building shall be dated, stamped with licensure seal and signed by the architect. The architect shall certify that the drawings and specifications were prepared to conform to building code requirements. The certification shall be forwarded to the OLC.

B. Additional approval may include a Certificate of Public Need.

C. Upon completion of the construction, the hospital shall maintain a complete set of legible "as built" drawings showing all construction, fixed equipment, and mechanical and electrical systems, as installed or built.

12 VAC 5-410-730 to 12VAC5-410-750. [Repealed]

12 VAC 5-410-760. Long-term care nursing units. (revised 3/1/2007)

Construction and renovation of long-term care nursing units, including intermediate and skilled nursing care nursing units shall conform to section 2.1-3.9 of Part 2 of the 2006 Guidelines for Design and Construction of Health Care Facilities of the American Institute of Architects.

12 VAC 5-410-770 to 12VAC5-410-1140. [Repealed]

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PART IV.

**Outpatient Surgical Hospitals: Organization, Operation and Design Standards
for Existing and New Facilities.**

Article 1.

Organization and Management.

12 VAC 5-410-1150. Governing authority.

A. Each outpatient surgical hospital shall have a governing body or other legal authority responsible for the management and control of the operation of the facilities.

B. There shall be disclosure of hospital ownership. Ownership interest shall be made known to the OLC and in the case of corporations, all individuals or entities holding 5.0% or more of total ownership shall be identified by name and address. The OLC shall be notified of any changes in ownership.

C. The governing body shall provide facilities, personnel, and other resources necessary to meet patient and program needs.

D. The governing body shall have a formal organizational plan with written bylaws, rules and regulations or their equivalent. These shall clearly set forth organization, duties, responsibilities, accountability, and relationships of professional staff and other personnel. The person or organizational body responsible for formulating policies shall be identified.

E. The bylaws, rules and regulations, or their equivalent, shall include at least the following:

1. A statement of purpose;
2. Description of the functions and duties of the governing body, or other legal authority;
3. A statement of authority and responsibility delegated to the chief administrative officer and to the medical staff;
4. Provision for selection and appointment of medical staff and granting of clinical privileges;
5. Provision of guidelines for relationships among the governing body, the chief administrative officer, and the medical staff.

F. The responsibility for administration and management of the outpatient surgical hospital shall be vested in an individual whose qualifications, authority and duties shall be defined in a written statement adopted by the governing body.

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**Article 2.
Policies and Procedures.**

12 VAC 5-410-1160. General statement.

Policies and procedures may vary depending on scope and type of service, personnel, equipment and location of the facility. It is recognized that no two facilities will be identical because of variations in the scope and objective of the outpatient service. Even though each facility may be different, certain standards and procedures shall be applicable to all in assuring the delivery of a high quality of care.

12 VAC 5-410-1170. Policy and procedures manual. (revised 11/2011)

A. Each outpatient surgical hospital shall develop a policy and procedures manual that shall include provisions covering the following items:

1. The types of emergency and elective procedures that may be performed in the facility.
2. Types of anesthesia that may be used.
3. Admissions and discharges, including criteria for evaluating the patient before admission and before discharge.
4. Written informed consent of patient prior to the initiation of any procedures.
5. Procedures for housekeeping and infection control.

B. A copy of approved policies and procedures and revisions thereto shall be made available to the OLC upon request.

C. Each outpatient surgical hospital shall establish a protocol relating to the rights and responsibilities of patients based on Joint Commission on Accreditation of Healthcare Organizations' Standards for Ambulatory Care (2000 Hospital Accreditation Standards, January 2000). The protocol shall include a process reasonably designed to inform patients of their rights and responsibilities. Patients shall be given a copy of their rights and responsibilities upon admission.

D. Each outpatient surgical hospital shall obtain a criminal history record check pursuant to §32.1-126.02 of the Code of Virginia on any compensated employee not licensed by the Board of Pharmacy whose job duties provide access to controlled substances within the outpatient surgical hospital pharmacy.

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**Article 3.
Staffing.**

12 VAC 5-410-1180. Medical staff.

A. The size and organizational structure of the medical staff will vary depending on the scope of service.

1. Professional and clinical services shall be supervised by a physician licensed to practice medicine or surgery in Virginia.

2. Surgical procedures shall be performed by a physician licensed to perform such procedures in Virginia.

3. Clinical privileges of physician and nonphysician practitioners shall be clearly defined.

4. Credentials including education and experience shall be reviewed and privileges identified, established, and approved for each person allowed to diagnose, treat patients or perform surgical procedures in accordance with guidelines, policies or bylaws adopted by the governing body and approved by the medical staff.

B. No medication or treatment shall be given except on the signed order of a person lawfully authorized by state statute.

1. Outpatient surgical hospital personnel, as designated in medical staff bylaws, rules and regulations, or policies and procedures, may accept emergency telephone and other verbal orders for medication or treatment for outpatient surgical hospital patients from physicians and other persons lawfully authorized by state statute to give patient orders.

2. As specified in the hospital's medical staff bylaws, rules and regulations, or hospital policies and procedures, emergency telephone and other verbal orders shall be signed within a reasonable period of time not to exceed 72 hours by the person giving the order, or, when such person is not available, cosigned by another physician or other person authorized to give the order.

12 VAC 5-410-1190. Nursing staff.

The total number of nursing personnel will vary depending upon the number and types of patients to be admitted and the types of operative procedures to be performed or the services programmed.

1. A registered nurse qualified on the basis of education, experience, and clinical ability shall be responsible for the direction of nursing care provided the patients.

2. The number and type of nursing personnel, including registered nurses, licensed practical nurses, and supplementary staff, shall be based upon the needs of the patients and the types of services performed.

3. At least one registered nurse shall be on duty at all times while the facility is in use.

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4. Job descriptions shall be developed for each level of nursing personnel and include functions, responsibilities, and qualifications.

5. Evidence of current Virginia registration required by state statute shall be on file in the facility.

**Article 4.
Patient Care Services.**

12 VAC 5-410-1200. Anesthesia service.

A. The anesthesia service shall be directed by and under the supervision of a physician licensed to practice medicine or surgery in Virginia.

B. The physician responsible for the anesthesia service shall be present for the administration of anesthetics and recovery of patients when any general or major regional anesthetic is used.

C. There shall be written procedures to assure safety in storage and use of inhalation anesthetics and medical gases.

D. Unless the hospital program and official written action by the governing body prohibit use of flammable anesthetics, the requirements of 12VAC5-410-240 of this chapter must be met.

12 VAC 5-410-1210. Sterile supply services.

A. Adequate provisions shall be maintained for the processing, sterilizing, storing, and dispensing of clean and sterile supplies and equipment.

B. Written procedures shall be established for the appropriate disposal of pathological and other potentially infectious waste and contaminated supplies.

12 VAC 5-410-1220. Dietary service.

If the program calls for the dietary service, serving of snacks or other foods, adequate space, equipment, and supplies shall be provided. Applicable state and local codes pertaining to receiving, storage, refrigeration, preparation, and serving of food shall be followed.

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12 VAC 5-410-1230. Evacuation plan.

A. Each outpatient surgical hospital shall develop a written evacuation plan to assure reasonable precautions are taken to protect patients, employees, and visitors from hazards of fire and other disaster. The evacuation plan shall provide:

B. A program to acquaint all personnel with evacuation procedures shall be maintained.

C. A copy of the plan and procedures shall be made available to the Office upon request.

12 VAC 5-410-1240. Emergency services.

A. Each outpatient surgical hospital shall provide emergency service and maintain on the premises adequate monitoring equipment, suction apparatus, oxygen, and related items necessary for resuscitation and control of hemorrhage and other complications.

B. A written agreement which ensures emergency transportation to a licensed general hospital shall be executed with an ambulance service.

C. A written agreement shall be executed with a general hospital to ensure that any patient of the outpatient surgical hospital shall receive needed emergency treatment. The agreement shall be within a licensed general hospital capable of providing full surgical, anesthesia, clinical laboratory, and diagnostic radiology service on 30 minutes notice and which has a physician in the hospital and available for emergency service at all times.

12 VAC 5-410-1250. Laboratory and pathology services. (revised 1/25/2006)

A. Laboratory and pathology services each patient admitted to the outpatient surgical hospital shall receive appropriate laboratory testing according to 42 CFR Part 493.

B. All tissue removed shall be submitted for histological examination by a pathologist and a written report of his examination provided to the attending physician. The report of findings shall be filed in the patient's clinical record.

12 VAC 5-410-1260. Medical records. (revised 1/25/2006)

A. Medical records. An accurate and complete clinical record or chart shall be maintained on each patient. The record or chart shall contain sufficient information to satisfy the diagnosis or need for the medical or surgical service. It shall include, when applicable, but not be limited to the following:

1. Patient identification;
2. Admitting information, including patient history and physical examination;

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3. Signed consent;
4. Confirmation of pregnancy, if applicable;
5. Physician orders;
6. Laboratory tests, pathologist's report of tissue, and radiologist's report of x-rays;
7. Anesthesia record;
8. Operative record;
9. Surgical medication and medical treatments;
10. Recovery room notes;
11. Physician and nurses' progress notes,
12. Condition at time of discharge,
13. Patient instructions, preoperative and postoperative;
14. Names of referral physicians or agencies.

B. Provisions shall be made for the safe storage of medical records or accurate and legible reproductions thereof according to §32.1-127.1:03 of the Code of Virginia and the Health Insurance Portability and Accountability Act, or HIPPA (42 USC §1320d et seq.).

C. All medical records, either original or accurate reproductions, shall be preserved for a minimum of five years following discharge of the patient.

1. Records of minors shall be kept for at least five years after such minor has reached the age of 18 years.

2. Birth and death information shall be retained for 10 years in accordance with §32.1-274 of the Code of Virginia.

3. Record of abortions and proper information for the issuance of a fetal death certificate shall be furnished the Division of Vital Records, Virginia Department of Health, within 10 days after the abortion.

12 VAC 5-410-1270. Preoperative admission.

A. Prior to the initiation of any procedure, a medical history and physical examination shall be completed for each patient.

B. Where medical evaluation, examination, and referrals are made from a private physician's office, another hospital, clinic, or medical service pertinent available records thereof shall be made and included as a part of the patient's medical record at the time the patient is admitted to the outpatient surgical hospital.

C. Sufficient time shall be allowed between initial examination and initiation of any procedure to permit the reporting and review of laboratory tests by the responsible physician.

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D. In outpatient surgical hospitals which provide abortion services, the diagnosis of pregnancy shall be the responsibility of the physician performing the abortion procedure.

E. Outpatient surgical hospitals which provide abortion services shall offer each patient appropriate counseling and instruction in the abortion procedure and in birth control methods.

12 VAC 5-410-1280. Post-operative recovery.

A. Each patient shall be observed for post-operative complications under the direct supervision of a registered professional nurse. Recovery room nurses shall have specialized training in resuscitation techniques and other emergency procedures consistent with policies and procedures of the institution for designated special units.

B. A physician licensed in Virginia shall be present on the premises at all times during the operative and post-operative period until discharge of the patient.

C. Patients shall be discharged from the recovery only on written order of the attending physician.

12 VAC 5-410-1290. Environment and maintenance. (revised 1/25/2006)

A. All parts of the outpatient surgical hospital and its premises shall be kept clean, neat, and free of litter and rubbish.

B. Hazardous cleaning solutions, compounds, and substances shall be labeled, stored in a safe place, and kept in an enclosed section separate from other materials.

C. Accumulated waste, including all contaminated sharps, dressings, or similar infectious waste, shall be disposed of in a manner compliant with the OSHA Bloodborne Pathogens standard (29 CFR 1910.1030).

12 VAC 5-410-1300. Laundry services.

A. Each outpatient surgical hospital shall make provisions for the cleaning of all linens.

B. There shall be distinct areas for the separate storage and handling of clean and soiled linens.

C. All soiled linen shall be placed in closed containers prior to transportation.

12 VAC 5-410-1310. [Repealed]

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PART V.

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

Article 1.

General Considerations.

12 VAC 5-410-1320 to 12VAC5-410-1340. [Repealed]

12 VAC 5-410-1350. Codes; fire safety; zoning; construction standards. (revised 3/1/2007)

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 3.1-8 and 3.7 of Part 3 of the 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.

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.

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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.

12 VAC 5-410-1360. [Repealed]

**Article 2.
Architectural Plan Review.**

12 VAC 5-410-1370. [Repealed]

12 VAC 5-410-1380. Drawings and specifications. (revised 1/25/2006)

A. All new construction or for additions, alterations or renovations to any existing building shall be dated, stamped with licensure seal and signed by the architect. The architect shall certify that the drawings and specifications were prepared to conform to building code requirements. The certification shall be forwarded to the OLC.

B. Additional approval may include a Certificate of Public Need.

C. Upon completion of the construction, the outpatient surgery center shall maintain a complete set of legible "as is" drawings showing all construction, fixed equipment, and mechanical and electrical systems, as installed or built.

**Article 3.
Design Requirements.**

12 VAC 5-410-1390 to 12VAC5-410-1420. [Repealed]

APPENDIX A to C. [REPEALED]

DOCUMENTS INCORPORATED BY REFERENCE (revised 3/1/2007)

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