

Office of Licensure and Certification

Draft Regulations for the Licensure of Inpatient Hospitals in Virginia

July 2009

Project 1172 - none**DEPARTMENT OF HEALTH
Licensure of Inpatient Hospitals****CHAPTER 411
LICENSURE OF INPATIENT HOSPITALS
Part I
Definitions and General Information****12VAC5-411-10. Definitions.**

The following words and terms, when used in this chapter, shall have the following meaning unless the context clearly indicates otherwise:

"Administrator" means the individual appointed by the governing body to act in its behalf in the overall management of the hospital. Job titles may include chief executive officer, superintendent, director, executive director, president, vice-president, and executive vice-president.

"Basic neonatal service" or "Level I newborn nursery" means a hospital newborn unit organized with the personnel and equipment to perform neonatal resuscitation, evaluate and provide postnatal care of healthy newborn infants, stabilize and provide care for infants born at 35 to 37 weeks' gestation who remain physiologically stable, and stabilize newborn infants born at less than 35 week's gestational age or ill newborns until transfer to a hospital that can provide the appropriate higher level of neonatal care.

"Bed capacity" means the total number of adult and pediatric beds that are used by patients, excluding beds intended for ancillary usage such as emergency department beds or stretchers, observation beds, labor room beds, recovery room beds, and newborn nursery infant care stations.

"Charity care" means free or discounted health services provided to persons who meet the hospital's criteria for financial assistance and are thereby deemed unable to pay for all or a portion of the care. Charity care does not include (i) bad debt or uncollectible charges that the hospital recorded as revenue but wrote off due to failure to pay by patients, or the cost of providing such care to patients; (ii) the difference between the cost of care provided under Medicaid or other means-tested government programs or under Medicare and the revenue derived therefrom; (iii) contractual adjustments with any third party payors.

"Clinical privileges" means the permission granted by a hospital to practitioners to render medical care based on the practitioner's professional license and related experience, competence, ability and judgment.

"Commissioner" means the State Health Commissioner.

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"Conscious sedation" means a level of reduced consciousness as defined in 18VAC60-20-10.

"Critical access hospital" means any hospital as defined in § 32.1-125.3 of the Code of Virginia and §1820 (c) (2) (B) of the Social Security Act.

"Diversion management" means a coordinated program with other area hospitals to handle emergency department overflow when a hospital finds it is temporarily unable to deliver emergency services.

"Emergency department" means that component of a hospital, regardless of whether such department is freestanding or located on the hospital's campus, that is understood by the public (by name, posted signs, advertising, or other means) as a place that provides at least one third (1/3) of all its outpatient visits for the treatment of emergency conditions on an urgent basis without requiring a previously scheduled appointment. A freestanding emergency department may not be co-located on the grounds of another hospital within the same hospital system.

"Emergency medical condition" means a medical condition manifesting itself by acute symptoms or sufficient severity (including severe pain, psychiatric disturbances or symptoms of substance abuse) such that the absence of immediate medical attention could reasonably be expected to result in:

1. Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;
2. Serious impairments to bodily functions;
3. Serious dysfunction of a bodily organ or part; or
4. With respect to a pregnant woman who is having contractions
 - a. That there is inadequate time to effect a safe transfer to another hospital before delivery; or
 - b. That transfer may pose a threat to the health or safety of the woman or the unborn child.

"EMTALA" means the federal Emergency Medical Treatment and Active Labor Act, section 42 USC 1395dd of the U.S. Code.

"Freestanding patient care" means a component of the hospital's services located on premises other than those of the hospital's main campus. Outpatient surgery centers are not considered freestanding entities for the purpose of this definition.

"Governing authority" means the group that has ultimate authority and responsibility of the hospital, maintains quality of care, and provides for organization management and planning. Other names for this group include the board, board of trustees, board of governors, and board of commissioners.

"Hospital" means any facility as defined in §32.1-123 of the Code of Virginia.

"Inpatient services" means the provision of health or health-related services, with continuous support services such as food, laundry, and housekeeping, to patients who generally remain in the facility 24 hours or longer.

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"Joint Commission" means the Joint Commission on Accreditation of Healthcare Organizations."

"Long term acute care hospital" or "LTACH" means an inpatient hospital that provides care to patients with an average length of stay greater than 25 days and is certified by the Centers for Medicare and Medicaid Services as a long term acute care hospital pursuant to 42 CFR Part 412.22 (e). An LTACH requires a certificate of public need and may be located within an existing or host hospital or a freestanding facility.

"Medical staff" means a formal organization of practitioners with the responsibility to achieve and maintain proper standards of medical care and to plan the continued improvement of that care.

"Network hospital" means an inpatient hospital that has an agreement with a critical access hospital to provide ongoing acute care services and other services for patients transferred or referred from the critical access hospital.

"NICU" means a neonatal intensive care unit that provides a comprehensive range of specialty and subspecialty newborn services to severely ill newborns, including infants who have an elevated risk of mortality as a consequence of very low birth weight, surgical conditions, or other forms of severe illness in full-term newborns.

"Nursing services" means the performance of any nursing act defined as "professional nursing" pursuant to § 54.1-3000 of the Code of Virginia.

"Observation bed" means a bed used for periodic monitoring by a nurse or other clinical staff necessary to evaluate a patient's conditions on an outpatient basis or to determine the need for a possible admission to the hospital as an inpatient. Such beds may not be used for the convenience of the hospital, physician, patient or family, or while awaiting placement in another facility.

"Obstetrical services" means a distinct organized program, equipment and care related to pregnancy and the delivery of newborns.

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

"Operating room" means a room used solely or principally for the provision of surgical procedures especially those involving the administration of anesthesia, multiple personnel, recovery room access, and a fully controlled environment.

"Outbreak" means an increased incidence or occurrence of disease as defined in 12VAC5-90-10.

"Outpatient services" means the provision of health or health-related services to individuals who are not expected to require hospitalization for longer than 24 hours but who require treatment in a medical care facility exceeding the normal capability found in a physician's office.

"Person" means any individual, partnership, association, trust, corporation, municipality, county, local government agency or any other legal or commercial entity that operates a hospital.

"Physical plant" means the buildings, equipment, and supplies necessary for implementation of medical care and related services.

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"Qualified" means meeting current legal requirements of applicable licensure, registration or certification in Virginia and having appropriate training and experience commensurate with assigned responsibilities. When referring to a professional, it means possessing an appropriate degree or having documented equivalent education, training or experience.

"Special care unit" means appropriately equipped areas of the hospital where there is a concentration of physicians, nurses, and others who have special skills and experience to provide medical care for patients assigned to the unit. Such units include, but are not limited to, intensive care, cardiac care, trauma and burn units.

"Specialty neonatal service" or "Level II neonatal nursery" means a hospital newborn unit organized with the personnel and equipment to provide care to infants born at more than 32 weeks gestation and weighing more than 1500 grams who have physiologic immaturity such as apnea of prematurity, inability to maintain body temperature, or inability to take oral feedings. This level also cares for infants who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis and infants convalescing from intensive care. This level of nursery may provide mechanical ventilation for not more than 24 hours or continuous positive airway pressure.

"Subspecialty neonatal service" or "Level III neonatal nursery" means a hospital NICU organized with personnel and equipment to provide continuous life support and comprehensive care for extremely low birth weight infants (1000 grams or less and 28 weeks' gestation or less) or those with complex and critical illnesses. This level provides advanced respiratory care such as high-frequency ventilation and inhaled nitric oxide; prompt and on-site access to a full range of pediatric medical subspecialties and advanced imaging with interpretation on an urgent basis including computed tomography, magnetic resonance imaging, and echocardiography and has pediatric surgical specialists and pediatric anesthesiologists on site or at a closely related institution to perform major surgery such as surgical repair of serious congenital cardiac malformations that require cardiopulmonary bypass.

"VDH" means the Virginia Department of Health.

12VAC5-411-20. License.

A. The commissioner shall issue or renew a license to operate a hospital if the hospital is in compliance with applicable laws and this chapter. Licenses shall be renewed annually upon filing an application and payment of the applicable service charge.

B. Every hospital shall be designated by a permanent and appropriate name.

C. Licenses shall not be transferred or assigned.

D. A separate license shall be required for hospitals maintained on separate premises even though operated under the same management or health system. Hospitals that provide services of a classification covered by provisions of other state statutes or regulations shall have an additional license, as applicable, for that type of classification of services, e.g., nursing facility, home care, outpatient surgery, or psychiatric services.

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However, a separate license is not required for free-standing patient care service locations provided no more than 2 related services are offered, e.g., an emergency department with a CT scanner and clinical laboratory services. The addition of inpatient beds or operating rooms shall require a certificate of public need and licensure as a hospital.

E. Licensure applications shall be obtained from the OLC. The OLC shall consider an application complete when all requested information and the appropriate fee as stated in 12 VAC 5-411-60 is submitted.

If the application is determined to be incomplete, the applicant will be notified in writing.

F. At the time of each license renewal, a hospital shall disclose its compliance with any agreements made as a condition of Certificate of Public Need approval to:

1. Provide a level of care at a reduced rate to indigents or accept patients requiring specialized care; or
2. Facilitate the development and operation of primary medical care services in designated medically underserved areas of the hospital's service area or health planning region.

The license of any hospital that made such agreement shall not be renewed without demonstrating prior to or at the time of applying for license renewal that it is in compliance with its agreement.

G. In addition, 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.

H. There shall be full disclosure of hospital ownership at the time of an initial application and when requested thereafter. In the case of corporations and partnerships, the names of all corporate officers and all others owning 5% or more of corporate stock shall be identified.

When the owner delegates the operation of the hospital to an individual, corporation or other legal entity by management contract or lease agreement, disclosure of entities holding 5% or more of the total ownership shall be identified by name and address.

I. A completed application for initial licensure must be submitted at least 60 days prior to a new hospital's planned opening date to allow time to process the application.

J. Completed renewal applications shall be returned at least 60 days prior to the expiration date of the current license.

K. It is the hospital's responsibility to complete and return a renewal application to assure timely processing. Should a current license expire before a new license is issued, the current license shall remain in effect providing a complete and accurate application was filed on time.

12VAC5-411-30. Exemptions from licensure.

A. This chapter is not applicable to those entities listed in §32.1-124 of the Code of Virginia.-

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B. In addition, this chapter is not applicable to hospitals established or operated for the practice of religious tenets pursuant to §32.1-128 of the Code of Virginia. However, such hospitals shall comply with the statutes and regulations on environmental protection and life safety.

C. Exempted hospitals are subject to complaint investigations in keeping with state law.

12VAC5-411-40. Compliance with Certificate of Public Need; license application; initial and renewal.

A. No hospital shall be licensed without first obtaining a Certificate of Public Need (COPN) pursuant to Article 1.1 (§32.1-102.1 et seq.) of Chapter 4 of Title 32.1 of the Code of Virginia.

B. In addition, certain specified services defined in §32.1-102.1 of the Code of Virginia will also require a COPN prior to initiating patient care, whether on the hospital's campus or at the hospital's freestanding patient care location.

12VAC5-411-50. Changes that require the re-issuance of a license.

A. It is the responsibility of the hospital's administrator to maintain a current and accurate license at all times.

B. A hospital shall give written notification 30 working days in advance of any of the proposed changes listed in 12VAC5-411-130E affecting the licensure status of the hospital. Notices shall be sent to the attention of the Director of the Office of Licensure and Certification.

C. The OLC will determine if any planned changes affect the terms of the license or the continuing eligibility for a license. A licensing representative may inspect the hospital during the process of evaluating a proposed change.

D. The hospital will be notified in writing whether a license can be re-issued or a new application is needed.

12VAC5-411-60. Service charges or fees.

Pursuant to §32.1-130 of the Code of Virginia, a service charge or fee for each initial and renewal license shall be collected. The fee shall accompany the license application and is not refundable.

12VAC5-411-70. On-site inspections.

A. An OLC representative shall make periodic on-site inspections of each hospital as necessary, but not less often than biennially, to determine if the hospital is in compliance with

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the provisions of this chapter, applicable state law and regulation, and the hospital's own policies, procedures and by-laws. The hospital shall be responsible for correcting any deficiencies found during any on-site inspection. Compliance with all standards will be determined by the OLC.

B. The hospital shall make available to the OLC's representative any necessary records and shall allow access to interview the agents, employees, contractors, and any person under the hospital's control, direction or supervision.

C. After the on-site inspection, the OLC's representative shall discuss the findings of the inspection with the administrator or his designee.

D. The administrator shall submit, within 10 working days of receipt of the inspection report, a plan for correcting any deficiencies found. The plan of correction shall contain:

1. A description of the corrective action or actions to be taken and the personnel to implement the corrective action;
2. The expected correction date;
3. A description of the measures implemented to prevent a recurrence of the deficiency; and
4. The signature of the person responsible for the validity of the report.

E. The administrator will be notified whenever any item in the plan of correction is determined to be unacceptable.

F. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.

12VAC5-411-80. OLC complaint investigations.

A. The OLC has the responsibility to investigate any complaints regarding alleged violations of this chapter and applicable law. When the investigation is complete, the licensee and the complainant, if known, will be notified of the findings of the investigation.

B. As applicable, the administrator shall submit a plan of correction for any deficiencies found during a complaint investigation.

C. The administrator will be notified in writing whenever any item in the plan of correction is determined to be unacceptable.

D. The administrator shall be responsible for assuring the plan of correction is implemented and monitored so that compliance is maintained.

12VAC5-411-90. Bed capacity.

A. A hospital shall not put into use more beds than the total bed capacity for which the hospital has been authorized by a certificate of public need. Changes in the use or location of such authorized beds within the hospital may occur at any time without prior OLC approval. A

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hospital shall not locate more patients in a room than the capacity for which the room was approved.

B. A hospital shall not increase its authorized bed capacity without first obtaining a Certificate of Public Need pursuant to Article 1.1 (§32.1-102.1 et seq.) of Title 32.1 of the Code of Virginia.

The OLC will not accept any requests for a variance to this standard.

C. No hospital shall receive for care, treatment or services patients in excess of the facility's authorized bed capacity, except in cases of seasonal fluctuations such as flu season, local epidemics, multiple casualty emergencies, during a state of emergency as declared by the Governor, or quarantine as declared by the commissioner. In those cases, the hospital may exceed the authorized capacity for the duration of the emergency only, provided the health, safety, and well being of all patients is not compromised and the OLC is notified.

D. The following categories of beds are not chargeable to the hospital's authorized bed capacity:

1. Labor and delivery rooms;
2. Neonatal nursery infant care stations;
3. Recovery room;
4. Emergency department;
5. Classroom.

E. Beds shall not be placed in corridors, solaria or other locations not designated as patient room areas except in cases of emergency as described subsection C.

12VAC5-411-100. Allowable variances.

A. The OLC can authorize variances only to its own licensing regulations, not to regulations of another agency or to any requirements in federal, state, or local laws.

B. A hospital may request a variance to a particular regulation or requirement contained in this chapter when the standard or requirement poses a special hardship and when a variance to it would not endanger the safety or well being of patients. The request for a variance must describe how compliance with the current regulation is economically burdensome and constitutes a special hardship to the hospital and to the patients it serves. When applicable, the request should include proposed alternatives to meet the purpose of the requirements that will ensure the protection and well being of patients. At no time shall a specific variance be extended to general applicability. The hospital may at any time withdraw a request for a variance.

C. The OLC shall have the authority to waive, either temporarily or permanently, the enforcement of one or more of these regulations provided safety, patient care and services are not adversely affected.

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D. The OLC may rescind or modify a variance if: (i) conditions change; (ii) additional information becomes known which alters the basis for the original decision; (iii) the hospital fails to meet any conditions attached to the variance; or (iv) results of the variance jeopardize the safety, comfort, or well-being of patients.

E. Consideration of a variance is initiated when a written request is submitted to the Director, Office of Licensure and Certification. The OLC shall notify the hospital in writing of the receipt of the request for a variance. The OLC may attach conditions to a variance to protect the safety and well being of patients.

F. The licensee shall be notified in writing if the requested variance is denied.

G. If a variance is denied, expires, or is rescinded, routine enforcement of the regulation or portion of the regulation shall be resumed.

H. The hospital shall develop procedures for monitoring the implementation of any approved variances to assure the ongoing collection of any data relevant to the variance and the presentation of any later report concerning the variance as requested by the OLC.

12VAC5-411-110. Revocation of a license.

A. The commissioner may revoke or suspend any license if the hospital fails to comply with the provisions of Article 1 (§32.1-123 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia, the regulations of the Board, applicable law or regulation.

B. If a license is revoked, the commissioner may issue a new license when the conditions upon which revocation was based have been corrected and compliance with all provisions of the law and this chapter has been achieved.

C. When a license is revoked or suspended, the hospital shall cease operations. If the hospital continues to operate after its license has been revoked or suspended, the commissioner may request the Office of the Attorney General to petition the circuit court of the jurisdiction in which the hospital is located for an injunction to cause such hospital to cease operations.

D. Suspension of a license shall in all cases be for an indefinite time. The suspension may be lifted and rights under the license fully or partially restored at such time as the commissioner determines that the rights of the licensee appear to so require and the interests of the public will not be jeopardized by resumption of operation.

12VAC5-411-120. Closure of a hospital.

If the hospital is no longer operational, or the license has been suspended or revoked, the license shall be returned to the OLC within five working days. The hospital shall notify its patients and the OLC where all medical records will be located.

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Part II
Administrative Services

12VAC5-411-130. Management and administration.

A. No person shall establish, conduct, maintain, or operate a hospital as defined and included within the 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.

B. The hospital must comply with:

1. This chapter (12VAC5-411);
2. Other applicable federal, state or local laws and regulations; and
3. The hospital's own policies, procedures and bylaws.

C. The hospital shall submit, or make available, reports and information necessary to establish compliance with this chapter and applicable law.

D. The hospital shall permit representatives from the OLC to conduct inspections to:

1. Verify application information;
2. Determine compliance with this chapter;
3. Review necessary records and documents; and
4. Investigate complaints.

E. A hospital shall notify the OLC when the following changes occur:

1. Ownership;
2. Operator;
3. Hospital name;
4. Location or address;
5. Administrator; or
6. Implementing any proposed addition, deletion, or change in hospital services, including, but not limited to bed capacity, newborn service level, freestanding emergency or patient care department, or trauma service.

The hospital shall notify the OLC, in writing, 30 days prior to discontinuing any services.

F. All organized services providing patient care shall be under the supervision of a qualified practitioner. Each department and service shall maintain:

1. Clearly written definitions of its organization, authority, responsibility, and relationships; and
2. Written policies and procedures addressing patient care where applicable.

G. The current license from the department shall be posted for public inspection.

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H. Service providers or community affiliates under contract with the hospital must comply with the hospital's policies and this chapter, where applicable.

I. The hospital shall not use any advertising that contains untrue, deceptive or misleading statements or claims or untrue, deceptive or misleading disclosures of fees and payment for services.

12VAC5-411-140. Governing authority.

A. The governing board or the person or persons designated by the owner as the governing authority shall be the ultimate authority responsible for the hospital's organization and administration that is consistent with appropriate national standards of patient care, environmental safety and institutional management.

B. At a minimum, the governing authority shall:

1. Ensure adequate physical resources and personnel for appropriate patient care;
2. Participate in planning to define and help meet the health needs of the community;
3. Formulate short-term and long-term plans for the development of the hospital;
4. Review the annual audit of the financial operations of the hospital;
5. Appoint the members of and maintain effective communication with the medical staff;
6. Require the medical staff to establish controls that are designed to achieve and maintain appropriate standards of ethical professional practice based on national standards of practice;
7. Establish a structure to effectively fulfill the governing authority's responsibilities and to evaluate the implementation of programs and policies;
8. Maintain a written record of governing body proceedings; and
9. Implement and maintain a quality management program.

C. The governing authority shall formulate a written set of bylaws for the operation of the hospital and shall provide for committees as determine by the needs and services, such as, but not limited to:

1. Safety;
2. Infection control;
3. Pharmacy; and
4. Tissue.

D. If a hospital does not provide an organized emergency department, the governing authority shall ensure that the hospital has documented policies and procedures for the assessment of emergencies, initial treatment or stabilization, and the referral, as appropriate, of patients needing emergency care.

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12VAC5-411-150. Hospital management and operation.

A. The governing authority shall select a chief administrative officer who shall be responsible for the management, operation and fiscal affairs of the hospital in all its branches and departments.

B. The administrator shall ensure that:

1. There is effective communication between the governing authority, the medical staff, the nursing staff and departments within the hospital;
2. Patients receive the same quality of care throughout the hospital;
3. The appropriate licensing board is informed of any member of the medical staff whose privileges have been denied, restricted, or revoked, or who has resigned from practice at the hospital pursuant to §54.1-2400.6 of the Code of Virginia; and
4. Families of patients who are potential donors are informed of organ, tissue, and eye donation options.

C. A qualified individual shall be designated to act as the alternate administrator in the absence of the administrator.

12VAC5-411-160. Medical staff accountability.

A. Each hospital shall have an organized medical executive committee that is directly responsible to the governing authority.

B. The medical staff shall adopt and enforce bylaws and protocols that govern staff activities and provide accountability for the quality of care provided to all patients. The bylaws and protocols shall be approved by the governing authority and address at a minimum:

1. The medical staff organizational structure;
2. The qualifications for staff membership;
3. The procedures for admission, retention, assignment, and reduction or withdrawal of privileges;
4. The verification of professional credentials, including evidence of inquiry through relevant practitioner databases, such as databases maintained by licensing boards, the National Practitioner Data Bank, the Medicare/Medicaid Sanction-Reimbursement Report (HCFA Pub. 69), and specialty certification boards.
5. Procedures for fair hearing and appellate review mechanisms for denial of staff appointments, reappointments, suspension, or revocation of clinical privileges;
6. The composition, functions and attendance of standing committees;
7. Policies for completion of medical records and procedures for disciplinary actions;
8. The formal liaison between the medical staff and the governing authority;

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9. Methods to formally verify staff member agreement with current medical staff bylaws and facility policies and procedures;
 10. Referral consultations provided to patients when a patient's physical or mental condition exceeds the clinical expertise of the attending member of the medical staff
Procedures for members of medical staff;
 11. Choice and control of all drugs in the hospital, including the prudent use of certain drug classifications such as antibiotics and anticoagulants;
 12. Completion of medical records, including requirements for the patient's medical history and physical examination performed within 24 hours after admission or within 30 days prior to admission and updated upon admission;
 13. Verbal/telephone orders to include the personnel who may receive such orders according to Virginia law and an acceptable timeline for authentication of orders not to exceed 72 hours;
 14. Temporary or emergency staff privileges when needed; and
 15. Review and update of the bylaws and protocols as necessary, but at least once every three years.

C. All individuals granted clinical privileges shall comply with generally accepted standards of practice. Every member of the medical staff shall provide appropriate medical care for their patients until the patient is stable for discharge or until care of the patient has been transferred to another member of the medical staff or to another facility.

D. Measures shall be implemented to monitor the on-going performance of the delivery of patient care by those granted clinical privileges, including monitoring of compliance with the medical staff bylaws, hospital policies and procedures and applicable laws and regulations.

12VAC5-411-170. Policies and procedures.

A. The hospital shall implement written policies and procedures that are reviewed at least once every three years, revised more frequently as needed. These policies and procedures shall include, but are not limited to:

1. Admission, transfer to another facility, and discharge of patients;
2. Patient communication, including but not limited to:
 - a. Informed consent;
 - b. Patient rights and grievances;
 - c. Advance directives; and
 - d. Decision making for patients who are incapable of making informed decisions and who are without advance directives.
3. Pain assessment and management;
4. Patient care including:

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- a. Medical direction and physician services;
 - b. Nursing direction and nursing services;
 - c. Patient safety, including but not limited to protocols and systems to recognize and mitigate full capacity and overcrowding situations.
5. Medical supplies and appliances, including drugs and biologicals, disposal or re-dispensing of controlled drugs when no longer needed, and handling of medications;
 6. Quality management and critical incident reporting;
 7. Maternal and newborn services, including, but not limited to:
 - a. Transport agreements;
 - b. Identification of high-risk neonatal patients;
 - c. Care of infants after delivery, including required assessments within 1 hour after delivery;
 - d. Newborn screenings as required by 12VAC5-70 and 12VAC5-80;
 - e. Circumstances when an infant is not allowed to remain with its mother; and
 - f. Completion of the birth certificate;
 8. Infection control including:
 - a. Communicable and reportable diseases, including reporting as required by 12VAC5-90; and
 - b. The admission and isolation, including protective isolation, of patients with known or suspected infectious diseases;
 9. Postmortem activities;
 10. Mandated reporting of abuse, neglect, and exploitation pursuant to §§54.1-2400.6 and 63.2-1606 of the Code of Virginia;
 11. Dietary and food services;
 12. Restraints;
 13. Contractual services;
 14. Medical records, including confidentiality and record retention;
 15. Patient and environmental safety and disaster preparedness; and
 16. Professional and clinical ethics.
- B. Financial policies and procedures shall include, but are not limited to:
1. Admission agreements, including assessment of financial need;
 2. Data collection and verification of services delivered;
 3. Methods of billing for services by the hospital and contractors;
 4. Patient notification of hospital sponsored financial assistance programs and changes in fees and charges;
 5. Refund policy and correction of billing errors; and

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6. Collection of delinquent patient accounts.
- C. Admission and discharge policies and procedures shall include, but are not limited to:
1. Criteria for accepting patients;
 2. The process for assessing a patient, regardless of ability to pay, and maintaining a treatment plan;
 3. Criteria for determining discharge and referral to other entities or community services; and
 4. The process for notifying patients of intent to discharge or refer.
- D Policies and procedures shall be readily available for staff use at all times.

12VAC5-411-180. Personnel and employment practices.

- A. The hospital shall select and organize sufficient qualified and competent personnel to meet patient needs in a manner appropriate to the scope and complexity of the services offered.
- B. The hospital shall establish and implement personnel policies and procedures to include at least:
1. Written job descriptions specifying responsibility, qualifications and authority for each job classification;
 2. Processes for obtaining a criminal background check as required by law for non-licensed or certified staff;
 3. Processes for annually evaluating employee performance and competency. Individual staff development needs and plans shall be a part of the performance evaluation;
 4. Compliance with applicable state and federal laws and regulations;
 5. A mechanism for advising employees of changes in their job responsibilities;
 6. A mechanism for initial and targeted health screenings of personnel who are employed, under contract, or providing patient care services within the hospital setting. The screening shall be sufficient in scope to identify conditions that may place patients or other personnel at risk of infection, injury or improper care. The health screening program shall be developed in consultation with hospital administration, medical staff, occupational health, and infection control/risk management staff; and
 7. Processes for reporting licensed and certified medical personnel for violations of their licensing or certification to the appropriate Board within the Department of Health Professions, as required by law.
- C. Each department within the hospital shall implement a staffing plan that reflects the types of services offered and that provides qualified staff in sufficient numbers to meet the treatment needs of all patients in the department.
- D. Any person who assumes the responsibilities of any position or positions in the hospital shall meet the minimum qualifications for that position or positions. Professional staff may be assigned multiple job responsibilities provided they are appropriately qualified.

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- E. Employees shall have access to their current position description.
- F. Personnel records shall be maintained for each employee and shall contain at least:
1. The employment application or resume;
 2. Dates of hire and position changes since hiring;
 3. The job or position description for the employee;
 4. All evaluations of performance or competencies for the employee since the date of hire or at least 5 years;
 5. Credible evidence of current registration, licensure, or certification as required for the position by state law;
 6. Evidence of completion of in-service training;
 7. Evidence of completion of any requirements of the employee health programs at the hospital;
 8. A record of disciplinary action taken by the hospital, if any;
 9. A record of adverse actions taken by any licensing bodies and the hospital, if any; and
 10. A criminal record history, as applicable.
- G. There shall be a planned program of training for all personnel that includes at least:
1. Hospital policies and procedures;
 2. Patient safety, hazardous materials handling and disposal, and disaster preparedness;
 3. Maintenance of patient medical records;
 4. Infection control;
 5. Confidentiality practices;
 6. Patient rights;
 7. Mandated reporting of abuse, neglect and exploitation;
 8. Applicable personnel policies; and
 9. Applicable laws, regulations, and other policies and procedures that apply to specific positions, duties, and responsibilities.
- H. The hospital shall provide opportunities for, and record participation in, staff development activities designed to enable staff to perform the responsibilities of their positions.
- I. All hospital staff shall be readily identifiable by employee nametag or badge.
- J. The hospital shall maintain an organized system to safeguard personnel files and records against loss and unauthorized use.
- K. Each employee personnel record shall be maintained in its entirety for a minimum of three years after termination of employment.
- L. Employee health-related information shall be maintained separately within the hospital personnel files, but may be maintained in a separate secure section for confidentiality.

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M. Non-employee staff working in the hospital or on the hospital grounds, including but not limited to volunteers, per diem staff and contractors, shall adhere to applicable policies and procedures of the hospital. The hospital shall provide orientation, supervision and evaluation of non-employee staff activities.

12VAC5-411-190. Indemnity coverage.

The hospital and its contractors shall have appropriate indemnity coverage to compensate patients for injuries and losses resulting from services provided.

12VAC5-411-200. Contract services.

A. If the hospital contracts for patient care services, there shall be a written agreement for the provision of those services. The agreement shall include at least:

1. The services to be furnished by each party to the contract;
2. Compliance with generally accepted standards of practice;
3. The manner in which the services will be controlled, coordinated, and evaluated by the hospital;
4. The process for payment of services furnished under the contract; and
5. Adequate indemnity coverage.

B. The hospital shall have a mechanism for verifying that any contractor conforms to applicable hospital policies and procedures as specified in the contract.

12VAC5-411-210. Hospital to patient communications.

A. Each hospital shall establish, implement and enforce a protocol, based on Joint Commission standards, relating to the rights and responsibilities of patients. In addition, the protocol shall include processes designed to:

1. Provide patients, or a patient's legal representative, an opportunity to give informed consent with documentation of the provision of the opportunity in the patient's medical record;
2. Provide written information to patients of the hospital's charity care policies, including free and discounted care.
3. Afford patients the opportunity to issue advance directives and to have those advance directives honored according to the law;
4. Provide patients or patient's representatives with copies of the hospital's complaint procedures prior to furnishing or discontinuing patient care;
5. Assure prompt resolution of patient grievances that includes, but is not limited to:

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- a. A clearly explained procedure for submission of a written or verbal grievance to the hospital;
 - b. The name of the person to contact to file a grievance;
 - c. A mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate utilization and quality control organization;
 - d. Time frames for review of the grievance and the provision for a response;
 - e. Written notice of its decision that includes the:
 - (1) Name of the hospital contact person;
 - (2) Steps taken on behalf of the patient to investigate the grievance;
 - (3) Results of the process;
 - (4) Date of completion;
 - (5) Name, address and telephone number for the OLC; and
 - (6) A description of the appeals process if the complainant is not satisfied with the resolution of the grievance.
 6. Provide, upon request, a written summary of hospital charge rates per service sufficient and timely enough to allow the patient to compare charges and make cost-effective decisions in the purchase of hospital services; and
 7. Provide an itemized statement of all charges for which the patient or third-party payer is being billed.
- B. Pursuant to Title VI of the Civil Rights Acts of 1964, the hospital shall communicate with its patients using a language and method that is effective for the recipient, whether the recipient is the patient or the patient's representative pursuant to subsection C. If the hospital cannot provide such communication, attempts to provide such shall be documented in the patient's medical record.
- C. If an appropriate bilingual clinician is not available to translate, the hospital shall provide a qualified interpreter, at no additional charge to the patient, to assist non-English speaking patients seeking care and treatment and not accompanied or represented by an interpreter or a sign language interpreter. Electronic translation services are acceptable for meeting the intent of this regulation.
- D. The hospital shall maintain documentation of all complaints received and the status of each complaint from the date of receipt through its final resolution. Records shall be maintained from the date of the last licensure inspection and for no less than three years.
- E. Upon a patient's written request for an itemized statement of any medical services received, the hospital shall provide such itemized statement within 30 days.
- F. The hospital shall post its charity care policies in public areas of the hospital as required by §32.1-137.01 of the Code of Virginia.
- G. Hospitals shall not discourage persons who cannot afford to pay from seeking essential medical services nor shall hospitals encourage persons who cannot afford to pay to seek essential medical services from other hospitals or providers.

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Part III
Quality Management, Infection Control and Critical Incident Reporting

12VAC5-411-220. Quality management.

A. The governing body shall establish and approve a plan for a hospital-wide quality management program to measure, evaluate, and improve the provision of patient care.

B. The scope and organization of the quality management program shall include, but is not limited to:

1. All patient services and clinical support services, and
2. Patient care services provided by the medical staff and contract services.

C. The quality management program shall be designed to systematically collect and assess performance data, prioritize data, and take appropriate action on important processes or outcomes related to patient care, including but not limited to:

1. Operative procedures and other invasive and non-invasive procedures that place patients at risk;
2. Hospital acquired infection rates;
3. Maternal and newborn services as described in 12VAC5-411-480 M;
4. Patient mortality;
5. Medication use;
6. Patient injuries, such as, but not limited to, those related to falls and restraint usage; and
7. Investigation of serious reportable events as described in 12VAC5-411-240.

D. The quality management program shall utilize a defined methodology for implementation, including at least mechanisms and methodologies for:

1. Performance measures, including scope of services;
2. Monitoring, evaluating, and assessing accountability;
3. Setting priorities;
4. Root cause analysis, as appropriate, of problems identified;
5. Process improvement;
6. Identification of expected outcomes;
7. Reporting mechanisms; and
8. Authority for problem resolution.

E. The results or findings from quality management activities shall be disseminated to the governing body, the medical staff, and any services impacted by the results.

F. The hospital shall take and document actions to address opportunities for improvement identified through the quality management program.

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G. There shall be an on-going evaluation of the quality management program to determine its effectiveness, which shall be presented for review and appropriate action by the medical staff and governing body at least annually.

H. The hospital shall implement a program whereby employees and health care providers can report clinical care concerns to the risk manager, chief of staff, or administrator.

I. The hospital shall actively participate in at least one of the nationally recognized quality hospital measures programs.

12VAC5-411-230. Infection control generally.

A. There shall be a hospital-wide infection control program coordinated by qualified infection control staff.

B. To reduce the risks of hospital acquired infections in patients, health care workers, volunteers and visitors, the infection control program shall encompass the entire physical plant, all campuses, all departments and services of the hospital. Participants in the program shall include staff from hospital administration, the medical and nursing staff, and other non-medical services.

C. The design of the program's surveillance plan shall;

1. Be based on accepted epidemiological principles;
2. Be tailored to meet the needs of the hospital; and
3. Include outcomes and process surveillance methodologies.

D. The surveillance plan shall require collection of sufficient baseline data on the incidence of hospital acquired infections in order to identify outbreaks.

E. Infection control methodologies shall include at least:

1. The availability of microbiology laboratory capacity to detect and investigate outbreaks;
2. A system for obtaining appropriate clinical specimens for culture;
3. Access to necessary information to investigate infectious outbreaks; and
4. Administration, physician, and nursing support to direct hospital changes to achieve immediate control of outbreaks and for implementation of corrective actions.

F. The program shall specify policies and procedures for infection control that apply to all areas of the hospital, including but not limited to:

1. Handling, storing, processing and transporting of hazardous waste products to prevent the spread of infection;
2. Standards for approved cleaning, disinfection and sterilization for all areas of the hospital;
3. Standards for hand washing and hand antisepsis;
4. An effective pest control program; and

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5. A communicable disease health screening plan, developed in consultation with hospital administration, medical and safety staff, that includes required communicable disease activities, immunizations, exposure evaluations, tuberculosis surveillance, and work restrictions.

G. There shall be an organized and ongoing education plan for hospital staff and volunteers that includes at least:

1. Orientation to basic infection control practices such as hand washing, isolation techniques, and employee health issues;
2. Training on isolation precautions, aseptic practices, and prevention of blood and body fluid exposure;
3. Acceptable techniques and practices for high risk procedures such as parenteral hyperalimentation, urinary tract catheterization, dialysis, and intravenous therapy; and
4. Provision for targeted training programs resulting from outcome and process surveillance data.

H. The hospital shall designate which departments are responsible for reporting to the OLC and the local health department cases of reportable diseases as specified in 12VAC5-90.

I. Accumulated waste, including all contaminated sharps, dressing, or similar infectious waste, shall be disposed of consistent with the OSHA bloodborne pathogens standards (29 CFR 1910.1030) and applicable state regulation.

J. The program shall be evaluated at least annually to determine the effectiveness of the program at lowering the risks and improving the trends of hospital-acquired infections in patients, staff and volunteers with necessary changes made to the program.

12VAC5-411-240. Serious reportable events.

A. The hospital shall report the following serious events to the OLC:

1. An unanticipated death or premature loss of a major function, not related to the natural course of a patient's illness or underlying condition, including but not limited to:
 - a. Brain injury;
 - b. Any permanent paralysis;
 - c. Loss of limb or organ;
 - d. Birth injury;
 - e. Impairment of sight or hearing;
2. A patient death or serious disability or injury associated with:
 - a. The use of contaminated drugs, devices, or biologics;
 - b. The use or function of a device in patient care in which the device is used or functions other than as expected;
 - c. Intravascular air embolism;

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- d. A fall;
 - e. An electric shock; or
 - f. The use of restraints or bedrails;
3. Surgery performed on the wrong patient or wrong body part or the wrong surgical procedure performed;
 4. Unintended retention of a foreign object in a patient after surgery or other procedure;
 5. Subjecting a patient to a procedure or treatment not ordered or intended by the patient's physician, excluding procedures not requiring a physician's order and collection of specimens for laboratory study obtained by non-invasive means or routine phlebotomy;
 6. Medication errors that result in injury, disability or death;
 7. A patient suicide while admitted to the hospital;
 8. An abduction of a patient of any age;
 9. A maternal death or serious disability associated with labor or delivery in a low-risk pregnancy;
 10. A death or serious disability associated with failure to identify and treat hyperbilirubinemia in neonates;
 11. An infant discharge to the wrong family;
 12. Artificial insemination with the wrong donor sperm or donor egg;
 13. A stage 3 or 4 pressure ulcer acquired after admission to the hospital;
 14. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances;
 15. Poisoning involving patients;
 16. Sexual assault or rape of a patient or staff member while in the hospital;
 17. A death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the hospital grounds;
 18. A hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities;
 19. Elopements from inpatient psychiatric units or elopements by minors who are inpatients; elopements of psychiatric patients from outpatient or emergency departments thought to be a danger to themselves or others;
 20. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare practitioner;
 21. A major malfunction of a facility system such as heating, ventilation, electrical, electronic information management, or water supply that affects patient care or services within the hospital, including any unanticipated interruption in power to a facility, as well as any event that triggers the use of the back-up generator for more than 6 hours;

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22. A fire or internal disaster that disrupts patient care services or causes harm to patients and staff;

23. Personnel actions that disrupts normal patient care and services; and

24. Any other incident reported to the malpractice insurance carrier or self-insurance program or in compliance with the federal Safe Medical Devices Act of 1990.

B. Written notification of the events listed in subsection A shall be required within two administrative business days of hospital senior management learning of the confirmed event. Each notice shall include the:

1. Hospital name;

2. Type and circumstances of event being reported;

3. Date of the occurrence; and

4. Actions taken by the hospital for patient and staff safety and to prevent recurrence.

C. Compliance with this section does not relieve the hospital from complying with any other applicable reporting or notification requirements, such as those relating to law enforcement or professional regulatory agencies.

D. Records that are confidential under federal or state law shall be maintained as confidential by the OLC and shall not be further disclosed except as permitted by law. However, there shall be no right of access to communications that are privileged pursuant to § 8.01-581.17 of the Code of Virginia.

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Part IV Patient Care Management

12VAC5-411-250. Patient services.

A. Each hospital shall provide the necessary care and treatment within the hospital's ability to meet the needs of patients. Care and treatment provided shall meet the prevailing professional standards and scope of practice requirements.

B. A plan of care shall be established, implemented and kept current to meet the identified needs for each patient. The plan of care shall be interdisciplinary when appropriate.

C. Hospitals shall:

1. Provide sufficient and appropriate personnel, space, equipment, reference materials and supplies for the care and treatment of patients;
2. Have registered nurses in the hospital at all times available for consultation; and
3. Provide for continuation of essential patient support services in the event of absence from work of any portion of the work force resulting from inclement weather or other causes.

D. Hospitals shall activate protocols and systems to mitigate overcrowding and full capacity situations.

E. No medication or treatment shall be given except on the signed order of an authorized practitioner.

1. Hospital personnel, as designated in medical staff bylaws or hospital policies and procedures, may accept emergency telephone and other verbal orders for medication or treatment from practitioners lawfully authorized to give patient orders.
2. As specified in the hospital's medical staff bylaws, or hospital protocols and 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.

F. Each hospital shall have a reliable method of identification for each patient, including newborn infants.

G. Hospitals may implement standing order programs authorizing licensed nurses and other licensed health care professionals to administer influenza and pneumococcal vaccines without a physician order according to medical staff by-laws pursuant to the Advisory Committee on Immunization Practices of the Centers for Disease Control.

H. Testing for all surgical patients and for all patients undergoing specific procedures requiring anesthesia shall be appropriate for the surgical services to be performed.

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I. Hospitals shall have an active program designed to prevent the occurrence of hospital acquired decubitus ulcers.

J. The phone number for the Poison Control Center shall be readily available.

12VAC5-411-260. Admission, discharge and referral.

A. The hospital shall have written admission, discharge and referral policies.

B. There shall be at least one employee in the hospital at all times authorized to receive patients and make arrangements for their care.

C. A patient shall be admitted only under the care of a member of the medical staff.

D. The hospital shall take appropriate precautions to protect the safety and legal rights of patients and employees.

E. The hospital shall maintain a complete and permanent record of all patients, including the date and time of admission and discharge. There shall be evidence of efforts to verify the full and true name, address, date of birth, nearest of kin, provisional diagnosis, condition on admission and discharge, referring physicians, attending physician or service.

F. Upon admission each patient shall be provided an identification bracelet, band or other suitable device for positive identification.

12VAC5-411-270. Discharge Planning.

A. There shall be an organized discharge planning process that includes an evaluation of the patient's capacity for self-care and the availability of post-hospital services to meet the needs of the patient.

B. A registered nurse or qualified social worker shall develop or supervise the development of the discharge plan if the patient's evaluation indicates a need for a discharge plan.

1. The hospital shall arrange for implementation of the discharge plan.

2. The hospital shall transfer or refer patients to appropriate facilities, agencies, or outpatient services, as needed, for follow-up care.

C. The hospital shall reassess its discharge planning process on an on-going basis. The reassessment shall include a review of discharge plans, as well as a review of patients who were discharged without plans, to ensure that the process is responsive to discharge needs.

12VAC5-411-280. Nursing service.

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

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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 be currently licensed by the Virginia Board of Nursing or hold a multistate licensure privilege to practice 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 and with a plan developed and implemented by the hospital.

D. Supervision of services shall be provided as often as necessary as determined by the patient's needs, assessment by the registered nurse and the hospital's written policies.

E. 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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Part V
Patient Services

12VAC5-411-290. Emergency services whether on campus or freestanding.

A. All hospitals shall provide care to persons needing emergency services pursuant to EMTALA.

B. Hospitals without an organized emergency department shall:

1. Have written policies governing the handling of emergencies;
2. Have sufficient qualified staff to provide for the assessment and initial treatment to any persons presenting with an emergency medical or psychiatric condition, within the capabilities of the hospital, and
3. Refer patients for further treatment where appropriate.

C. Hospitals with an organized emergency department, whether on campus or freestanding, shall have 24-hour medical and nursing staff coverage for each emergency department operated by the hospital. Such assignment need not be exclusive of other duties, but must have priority over all other assignments.

D. Each emergency department shall be under the supervision of a member of the hospital's medical staff who shall be responsible for the organization of the emergency department, including any freestanding emergency departments. Responsibilities include, but are not limited to:

1. A staffing plan that ensures availability of appropriate numbers of qualified staff for the emergency department and a process for accessing additional staff on an as-needed basis to meet unanticipated needs;
2. Ensuring staff training and experience appropriate to their assigned responsibilities.
3. Policies and procedures for processing patients presenting for emergency care, including at any freestanding emergency department, shall include:
 - a. Initial patient assessment;
 - b. Prioritization or triage for medical screening and treatment;
 - c. Patient reassessment and monitoring, including specific assessment of pediatric patients;
 - d. Appropriate admission to the hospital or transfer to other facilities;
 - e. A diversion management system in coordination with other area hospitals;
 - f. Management of mass casualty situations, such as a multi-car pile-up, that may require the coordination with other area hospitals, local emergency management agencies or local ambulance service providers; and
 - g. Admission of patients to the hospital regardless of the location of the emergency department; and

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4. Coordinating with the hospital's quality management program.

E. There shall be a central log of all patients presenting for emergency care that shall include:

1. The date and time the patient presents for treatment;
2. The presenting complaint; and
3. The level of acuity or triage.

Note: When a patient leaves prior to triage, documentation in the log that the patient left without being seen will satisfy the requirements of this standard.

F. An emergency medical record shall be maintained for each patient regardless of the location of the emergency department and shall include, but is not limited to:

1. Patient identifying information;
2. Presenting complaint;
3. All clinical observations;
4. Results of diagnostic assessments or tests;
5. A record of treatment administered and outcomes;
6. The names of treating or responsible practitioners;
7. Condition on discharge; and
8. Discharge destination and instructions.

G. A specialist physician shall be available for consultation on-site or by telecommunication to provide emergency services regardless of the location of the emergency department. When coverage is provided by telephone, the specialist physician must be able to arrive in the emergency department within the response time stated in minutes in the hospital's emergency department policies or medical staff bylaws of the determined need for such physician services.

H. All emergency departments shall have the equipment, drugs, supplies and ancillary services commensurate with the scope of anticipated needs to support emergency care for patients of all ages, including, but not limited to:

1. An emergency call system;
2. Oxygen, such supply may be centralized or on cylinder with a system for monitoring supply and quantity levels evident;
3. Manual breathing bags and masks, including bag and masks for children and infants;
4. Radiology and laboratory services;
5. Facilities for handling and administering blood and blood products;
6. Cardiac monitoring and defibrillator equipment ready for patient need;
7. Laryngoscopes and endotracheal tubes, including tubes for children;
8. Suction equipment, kept clean and ready for use; and
9. Emergency drugs and medications as specified by the medical staff.

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Emergency drugs and equipment shall remain accessible in all emergency departments at all times.

IK. The functions of the emergency department, whether on campus or freestanding, shall be integrated with other services provided by the hospital to ensure appropriate care and treatment including those patients awaiting admission to the host hospital or transfer to another facility.

J. A current roster of medical and nursing staff shall be posted in all emergency departments, regardless of location.

K. Hospital's operating emergency departments shall participate in area diversion management programs.

L. Hospitals operating free-standing emergency departments shall develop protocols with area hospitals not within its health system to expedite patients needing inpatient services.

M. Hospitals shall make training available, as required, for emergency department personnel including personnel assigned to any freestanding emergency department.

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

O. Documented protocols and standards of practice for emergency interventions shall be available in all emergency departments to guide non-physician staff.

P. Those hospitals that provide ambulance services shall comply with 12VAC5-31.

12VAC5-411-300. Outpatient services.

A. Hospitals offering outpatient services shall:

1. Implement procedures ensuring the outpatient care provided meets the needs of patients according to generally accepted standards of practice;
2. Have sufficient qualified medical personnel to promptly, safely, and effectively meet patient care needs; and
3. Designate responsibility for the periodic assessment of the quality and effectiveness of the services provided as part of the hospital's quality management program.

B. Each patient receiving outpatient services shall have a medical record that shall be maintained according to 12VAC5-411-610.

C. Outpatient surgical centers shall be licensed according to §32.1-125 of the Code of Virginia and 12VAC5-410.

12VAC5-411-310. Freestanding patient care services.

A. When establishing freestanding patient care services, hospitals shall submit a written plan to OLC describing:

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1. How the freestanding service meets the needs of the community in which the services will be provided;
 2. The location and hours of operation;
 3. The hospital's capabilities for rapid transport of patients to the main campus for further treatment;
 4. How the services of the free-standing service will be integrated into those on the main campus and how patients services at the free-standing location and who require further care will have access to all services of the main campus;
 5. How the hospital will maintain the same level of oversight and monitoring of its free-standing services as it does for its on campus services;
 6. The activities and responsibilities of the medical staff in the free-standing location; and
 7. How medical records from the free-standing location will be integrated into the hospital's medical record retrieval system.

The hospital shall notify the OLC within 15 days of any changes to the plan, including any services added.

B. Additional free-standing patient care service requirements include:

1. Appropriate medical and nurse staffing from the hospital's organized medical and nurse staff;
2. Access to necessary clinical testing and services from the hospital during the off site service operating hours;
3. Infection control practices; and
4. Operating under the same policies and procedures for medical care as its counterpart service on campus.

C. All free-standing patient care services shall be located within the hospital's identified primary and secondary health services areas.

D. All buildings used for free-standing patient services shall comply with the requirements specified in Part X (12VAC5-411-630 et seq.) of this chapter.

12VAC5-411-320. Pediatric services.

A. Hospitals providing pediatric services shall:

1. Define the scope of services to be provided;
2. Have space, facilities and appropriately sized equipment for providing those services apart from adult patients' rooms and newborn units; and
3. Provide space and equipment to allow for visitation of family members in the patient rooms and to allow for overnight stay of a parent or guardian when such presence will not interfere with the course of treatment.

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B. The director of pediatric services shall be a member of the medical staff with experience and training in pediatrics and shall be responsible for the supervision and organization of the pediatric services and for monitoring the quality and appropriateness of those services in coordination with the hospital's quality management program and for ensuring that identified opportunities for improvement are addressed.

C. Staff providing pediatric care shall have experience and training in serving the pediatric population and shall have documented in-service training at least annually on age-specific care issues for the pediatric populations served by the hospital.

D. Protocols for screening and assessment of pediatric patients shall be approved by the medical staff and shall be individualized for the age and presenting signs and symptoms of the patient.

E. There shall be policies and procedures to prohibit access to pediatric patients by unauthorized persons and to prevent kidnapping or elopement of pediatric patients.

F. Medical supplies and equipment including emergency equipment appropriate to the size and age of the pediatric patient shall be available in all areas providing services to pediatric patients.

G. There shall be regular and routine cleaning of play equipment according to protocols established for that purpose by the hospital's infection control program.

12VAC5-411-330. Nuclear medicine services.

A. If a hospital provides nuclear medicine services, those services shall be organized and provided in a manner consistent with 12VAC5-481 and generally accepted standards of practice.

B. Nuclear medicine services shall be under the direction of a board certified physician who shall be licensed by the U.S. Nuclear Regulatory Commission or the Division of Radiological Health of the Virginia Department of Health as a designated authorized user of isotopes. The director shall be a member of the medical staff and shall be responsible for the administration of nuclear medicine services including the evaluation of the effectiveness of services in coordination with the hospital's quality management program.

C. Nuclear medicine shall be administered only by authorized users pursuant to 12VAC5-481 who have been granted clinical privileges to administer nuclear medicine services or by radiologic technologists pursuant to §54.1-2900 of the Code of Virginia.

D. All hospitals providing nuclear medicine services shall participate in the Statewide Cancer Registry as required by Article 9 (§ 32.1-70 et seq.) of Chapter 2 of Title 32.1 of the Code of Virginia.

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

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12VAC5-411-340. Diagnostic imaging and therapeutic radiology services.

A. All hospitals shall provide or arrange for effective imaging services to meet the needs of patients. Radiological imaging services shall be organized and provided in a manner consistent with 12VAC5-481 and generally accepted standards of practice.

B. There shall be an organized plan for imaging services that:

1. Identifies the scope of services provided and the qualifications of the individuals necessary for the performance of various aspects of imaging services; and
2. That delineates the lines of authority and accountability.

C. Services shall be under the direct supervision of a qualified member of the medical staff who shall be responsible for the administration of services including the evaluation of the effectiveness of services in coordination with the hospital's quality management program.

D. Diagnostic imaging and radiological therapy services shall be staffed consistent with the types and volumes of services offered.

E. Interpretations of imaging test results or procedures shall be made only by those medical staff qualified to interpret those tests or procedures.

F. Basic radiology imaging services shall be available at all times, or there shall be a process to provide access to qualified x-ray personnel within one hour including weekends and holidays.

G. Radiation oncology services, if provided, shall be directed by a physician with appropriate training and experience. The services shall have a medical oncologist and hematologist available for consultation

H. There shall be documented protocols for managing:

1. Medical emergencies in the imaging and therapeutic radiology areas; and
2. Patients with infectious diseases and critical care patients in the imaging area or wherever imaging services are provided, and in the therapeutic radiology area.

I. There shall be a process for the timely notification of the patient's physician and responsible nursing staff of critical interpretations identified through imaging tests.

J. Films, scans, and other images shall be retained according to 12VAC5-411-610.

K. Hospitals providing radiation therapy services shall participate in the Statewide Cancer Registry as required by Article 9 (§32.1-70 et seq.) of Chapter 2 of Title 32.1 of the Code of Virginia.

L. All imaging and radiological interpretations, consultations and therapy shall be part of the patient's medical record.

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12VAC5-411-350. Rehabilitation or therapy services.

A. Hospitals shall define the scope of rehabilitation services provided. Services can be either limited, i.e., single or stand-alone therapy disciplines, or comprehensive and include the full range of services including rehabilitation, physical therapy, complementary therapy such as pet therapy, occupational therapy, audiology, speech-language pathology, music and art therapy, or other similar service.

B. Hospitals shall designate a member of the medical staff as responsible for:

1. The clinical aspects of the program;
2. The delivery of services offered; and
3. Monitoring the program quality and appropriateness and ensuring that identified problems are addressed through the hospital's quality management program.

C. Rehabilitation program staff shall have the qualifications necessary to provide the services offered, including such specialized care as cardiac rehabilitation or pediatric rehabilitation if offered as part of the rehabilitation program.

D. Treatment shall be provided according to a physician's order and developed with collaboration from the rehabilitation staff member, the patient's physician and the patient. The physician's order, treatment plan, goals, frequency and expected duration of services, and the patient's response to treatment shall be documented in the patient's medical record.

E. If a hospital contracts for rehabilitation services, the hospital shall implement a system for managing outpatient physician orders.

F. If a hospital utilizes pet therapy, household pets such as dogs, cats, birds, fish and hamsters are permitted under the following circumstances:

1. Pets must be clean and free of disease;
2. The immediate environs of the pets must be clean;
3. Small pets shall be kept in appropriate enclosures;
4. Pets that are not confined shall be kept under leash or voice control;
5. Pets that are kept at the hospital, or are frequent visitors, shall have current vaccinations as required by law, including rabies;
6. Procedures are implemented to protect patients, staff and visitors from psittacosis if birds are permitted in the hospital;
7. Procedures are implemented for the care, housing and feeding of pets and for the proper storage of pet food and supplies if pets are allowed to remain overnight;
8. Pets shall not be allowed in food preparation and storage areas, or where their presence creates a significant health or safety hazard or nuisance to staff and patients, and shall not be allowed near patients with pet allergies; and
9. Individuals caring for pets shall not be assigned patient care or food handling responsibilities.

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12VAC5-411-360. Respiratory/pulmonary services.

A. The hospital shall provide or arrange for effective services to meet the respiratory/pulmonary needs of patients.

B. There shall be an organized plan for respiratory/pulmonary services that clearly defines the:

1. Scope and complexity of services,
2. Necessary staff, equipment and supplies sufficient to support the scope of the services offered, and
3. Lines of authority and accountability.

C. The services shall be under the supervision of a member of the medical staff who shall be responsible for all clinical aspects of the services and delivery of clinical respiratory care including evaluation of the effectiveness of the services in coordination with the hospital's quality management program.

D. Protocols for respiratory/pulmonary care shall include, but are not limited to:

1. Routine inspection, cleaning and maintenance procedures for respiratory equipment, as well as procedures for their assembly and operation;
2. Handling adverse reactions;
3. Safety practices and interventions;
4. Staff participation in emergency situations at the hospital;
5. Infection control;
6. Handling, storage, and dispensing therapeutic gases;
7. Obtaining blood samples and analysis of samples as applicable;
8. Testing pulmonary function, as applicable;
9. Therapeutic percussion and vibration and bronchopulmonary drainage, as applicable;
10. Mechanical ventilation and oxygenation support and for administration of aerosol, humidification, and therapeutic gases, as applicable;
11. Administration of medications; and
12. A system for reissuing or discontinuing respiratory therapy orders.

E. There shall be a sufficient number of respiratory care practitioners licensed by the Board of Medicine pursuant to §54.1-2954 of the Code of Virginia and support personnel to meet the respiratory/pulmonary care needs of the patients. However, hospitals with obstetrical services shall have 24-hour staff coverage, including weekends and holidays, and shall be able to provide respiratory services when needed.

F. Respiratory services shall be provided only in response to medical orders that include the:

1. Modality to be used;
2. Type, frequency and duration of treatment; and

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3. Type and doses of medications, including dilution ratios.

G. All respiratory care services provided shall be documented in the patient's medical record, including the:

1. Type of therapy;
2. Date and time of administration;
3. Effects of therapy; and
4. Any adverse reactions.

H. If blood gases or other clinical laboratory tests are performed by respiratory care staff, the staff shall have demonstrated competency in the administration of tests as point-of-care technicians.

12VAC5-411-370. Renal dialysis services.

A. If the hospital provides dialysis services either directly or through contract arrangement, the scope and organization of those services shall be defined and provided according to 42 CFR Part 413 and accepted standards of care for persons requiring dialysis treatment.

B. There shall be an organized plan for dialysis services that clearly defines lines of authority, responsibility, accountability, and appropriate staffing. If the services are provided by contract, the plan shall specify how the coordination of patient care will be accomplished.

C. The director of dialysis services shall be a member of the medical staff qualified to provide oversight of the specialized care required for patients needing dialysis treatment. Problems identified during on-going monitoring shall be addressed through the hospital's quality management program.

D. A registered nurse with demonstrated clinical experience in providing dialysis services shall be available during all dialysis treatments. Nursing staff and dialysis care technicians shall have evidence of education, training, and demonstrated competencies in the provision of appropriate dialysis services and emergency care of patients receiving dialysis.

Note: If the hospital provides dialysis services by contract only, the qualified nurse may be available by telephone. However, staff at the hospital must be competent to assist in emergency situations related to dialysis.

E. Protocols for dialysis services shall include, but are not limited to:

1. Maintenance of dialysis equipment;
2. Water treatment system safety, including testing of chlorine/chloramines, water quality, and cultures, testing frequency and process, and disruptions in the water supply;
3. Infection control including screening for Hepatitis, water cultures and access infections;
4. Reuse of dialyzers and dialysis supplies; and
5. Care of dialysis patients experiencing common complications of dialysis treatments.

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F. If the hospital provides dialysis through contract, the contract shall specify:

1. What services will be provided;
2. Who is responsible for maintenance of the dialysis equipment, the water treatment safety system, infection control, reuse of dialyzers and supplies; and
3. The clinical supervision to be provided during the administration of dialysis treatments.

12VAC5-411-380. Pharmaceutical services.

A. Each hospital shall provide pharmaceutical services under the direction of a pharmacist licensed by the Virginia Board of Pharmacy. There shall be evidence of a current pharmacy license pursuant to Chapter 33 (§54.1-3300 et seq.) of the Code and 18VAC110-20.

B. 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 within the hospital pharmacy.

12VAC5-411-390. Laboratory services.

A. The hospital shall provide or arrange for clinical laboratory services to meet the needs of its patients. The administration, performance and functions performed by the hospital, as well as any laboratories used by the hospital, shall operate pursuant to 42 CFR Part 493.

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

C. There shall be an organized plan of laboratory service that:

1. Identifies the scope of services provided and the qualifications of the individuals necessary for performing the various aspects of clinical laboratory services;
2. That delineates the lines of authority and accountability.

D. The service shall be under the supervision of a member of the medical staff who shall be responsible for the administration of services, including the evaluation of the effectiveness of services in coordination with the hospital's quality management program.

E. If the supervising physician is not a pathologist, a pathologist shall be retained on a consultant basis. When the pathologist provides consultative services, services shall be provided as needed, but at least monthly with written evaluations or recommendations provided to the medical staff and administration.

F. The hospital shall have laboratory services available at all times. Such 24-hour availability may be arranged through callback systems. However, hospitals with obstetrical services shall have 24-hour laboratory staff coverage, including weekends and holidays, and shall be able to perform routine neonatal testing within one hour or less of the request.

G. A written description of all available laboratory services shall be available to the medical staff.

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H. There shall be an effective process for the timely notification of the patient's physician and responsible nursing staff of critical values from laboratory tests or unusual or abnormal pathology reports.

I. Reports of laboratory procedures and pathology reports and results shall be included in the patient's medical record.

J. When a laboratory isolates for clinical, pathological or environmental specimens, or any one of the special microorganisms in 12VAC5-90-80, it shall be reported as required by §§32.1-36 and 32.1-37 of the Code of Virginia and 12VAC5-70.

12VAC5-411-400. Blood banks and transfusion services.

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 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. Appropriate facilities and equipment for the storage and administration of whole blood and blood products shall be provided.

C. For emergency situations, the hospital shall:

1. Make arrangements for obtaining blood from community blood sources, or maintain an up-to-date list of available donors, as well as provide the equipment and personnel to obtain blood from the donor; or
2. Maintain a minimum supply of O negative blood, if the hospital provides obstetrical services.

D. Hospitals with obstetrical services shall have 24-hour blood bank and transfusion staff coverage, including weekends and holidays. In addition, the blood bank shall have group O Rh negative blood available at all times and be able to provide correctly matched blood within 45 minutes of a request.

12VAC5-411-410. Autopsy services.

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

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Part VI
Surgical and Anesthesia Services

12VAC5-411-420. Surgical services.

A. If the hospital provides surgical services, those services shall be provided in a manner that protects the health and safety of patients and follows current accepted standards of medical and surgical practice. Personnel, equipment, policies and procedures, and the number of operating rooms shall be appropriate for the scope of services offered.

B. Hospitals providing surgery and obstetric services shall maintain individually identified surgical and obstetric suites. Shared overflow may be considered provided one surgical suite remains available for operative delivery.

C. There shall be an organized plan defining the lines of authority, responsibility, and accountability within all operating room areas where surgical procedures are performed.

D. The director of surgical services shall be a member of the medical staff and shall be responsible for all clinical aspects of surgical services including evaluation of the effectiveness of the services in coordination with the hospital's quality management program.

E. A current roster of surgical privileges granted each medical staff member shall be available to nursing and scheduling staff in the surgical services areas.

F. Roles, responsibilities, and qualifications for any non-physician participating in surgery shall be defined by the hospital medical staff, including any limitations to their roles in patient care as defined by law and their professional scope of practice.

G. An operating room register shall be maintained which shall include at a minimum:

1. Patient's name and ID number;
2. Pre- and post-operative diagnoses;
3. Complications, if any;
4. Name of surgeon, first assistant, anesthesiologist or anesthetist, scrub nurse and circulating nurse;
5. Operation performed; and
6. Type of anesthesia.

H. Policies and procedures governing infection control and reporting techniques shall be established according to 12VAC5-411-440.

I. The patient's medical chart shall be available in the surgical suite at the time of surgery and shall contain no less than the following information:

1. A medical history, advance directive, and physical examination;
2. Evidence of appropriate informed consent; and
3. A pre-operative diagnosis.

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J. Within 24-hours prior to surgery either a history and physical examination or an update of a previous history and physical shall be completed for every surgical patient. When an update is used, the previous history and physical examination shall not have occurred more than 30 days prior to surgery.

K. A full operative report, completed within 24-hours after each surgery is performed, shall describe the:

1. Techniques, findings, complications, tissues removed or altered; and
2. General condition of the patient during and following surgery.

When a report is not available within 24-hours post surgery, an operative/progress note by the surgeon must be entered in the patient medical record immediately.

L. The recovery or post-operative care unit shall be located in proximity to the operating rooms to allow for rapid return to the operating room if necessary, or access to the emergency equipment listed in 12VAC5-411-450.

M. Policies and procedures for care of patients in the PACU shall include the criteria for patient transfer to and from the area.

N. If patients are not transferred to the PACU following surgery, provision shall be made for managing the patient until the patient is stable.

12VAC5-411-430. Surgical nurse manager.

A registered nurse, with training and experience in surgical nursing services, shall manage the surgical suites and shall be responsible for:

1. Ensuring a sufficient number of nursing personnel are on duty in the surgical suits to meet the needs and safety of the patients;
2. Ensuring surgical technicians perform scrub functions under the supervision of a licensed registered nurse who is immediately available to respond to emergencies;
3. Delineating the duties of scrub personnel and circulating registered nurses in the surgical suite;
4. Providing orientation and on-going education and training of surgical personnel including;
 - a. Equipment usage and inspections;
 - b. Infection control and safety in the surgical area;
 - c. Cardiopulmonary resuscitation;
 - d. Patient rights; and
 - e. Informed consent.
5. Ensuring that patients are monitored and provided nursing care from the time they enter the surgical suite to the time they exit the area;

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6. Developing criteria for the use of equipment and supplies brought into the surgical suite from other areas; and
 7. Ensuring that the operating room register is current and complete.

12VAC5-411-440. Infection control in the surgical suite.

Infection control procedures specific to the surgical suite and the population served shall address, but are not limited to:

1. Surgical attire;
2. Surgical scrub attire;
3. Housekeeping functions;
4. Cleaning, disinfecting and sanitizing areas;
5. Appropriate maintenance of HVAC systems for the area;
6. Packaging, sterilizing, and storage of equipment and supplies;
7. Waste disposal, including biomedical waste according to OSHA standards; and
8. Traffic control patterns, including who may enter the operating room areas and under what circumstances.

12VAC5-411-450. Minimum equipment for the surgical suite.

The following emergency equipment shall be available and in working order for the operating rooms and post-anesthesia area:

1. A call system;
2. Cardiac monitors;
3. Adult and child resuscitation equipment; such equipment may be a mechanical ventilator or a respirator;
4. A defibrillator;
5. Adult and child aspiration/suction equipment;
6. A tracheostomy kit;
7. A pulse oximeter; and
8. An end-tidal carbon dioxide monitor.

12VAC5-411-460. Anesthesia service.

A. A hospital providing surgical or obstetrical services shall have an organized anesthesia service responsible for all anesthesia delivered at the hospital. Surgical and obstetrical

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anesthesia shall be provided according to generally accepted standards of practice and in a manner that protects the health and safety of patients.

B. Anesthesia services shall be under the supervision of a member of the medical staff who shall be responsible for:

1. Organizing services;
2. Monitoring the quality and appropriateness of the service in coordination with the hospital's quality management program and for ensuring that identified opportunities for improvement are addressed; and
3. Establishing orientation and continuing education for anesthesia staff that includes, at a minimum, instruction in safety precautions, emergency patient management, equipment use and inspections, and infection control procedures in the surgical suite; and
4. Procedures for the administration of conscious sedation, if offered. Such procedures shall include at least the following:
 - a. Designation of the licensed personnel authorized to administer conscious sedation or monitor the patient during conscious sedation;
 - b. Drugs approved for use in administering conscious sedation;
 - c. Patient monitoring requirements; and
 - d. Criteria for discharge.

C. Anesthesia shall be administered only by qualified members of the medical staff or qualified individuals who have been granted clinical privileges to administer anesthesia as allowed by law and their professional scope of practice.

D. For hospitals with obstetrical services, anesthesia personnel with credentials to administer obstetric anesthesia shall be available on a 24 hours basis or be able to arrive within 20 minutes of being called, including weekends and holidays.

E. A pre-anesthesia patient evaluation shall be completed within a reasonable time prior to surgery for each patient. The evaluation shall include:

1. Heart and lung function;
2. Diagnostic data (laboratory, x-ray, etc., as applicable);
3. Medical and anesthesia history;
4. Notation of anesthesia risk;
5. Any potential anesthesia problems identified; and
6. Notation of patient's condition immediately prior to induction.

F. A check of all anesthesia equipment shall be performed and documented immediately prior to each anesthesia administration.

G. A staff person qualified and granted privileges to administer anesthesia shall be continuously present throughout the administration of all anesthesia.

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H. During the administration of anesthesia, patients shall be monitored as appropriate for the type of the anesthesia given. Such monitoring shall include, as appropriate:

1. Heart and breath sounds, using a pre-cordial or esophageal stethoscope;
2. Oxygenation levels;
3. Ventilation;
4. Circulatory function;
5. The qualitative content of expired gases, if the patient has an endotracheal tube; and
6. The patient's temperature.

I. The medical personnel shall remain immediately available until the patient has been determined to be stable and is ready for discharge or transfer from post-anesthesia care. For the purposes of this standard, "immediately available" means on the hospital grounds and able to be present within 10 minutes.

J. A post-anesthesia evaluation shall be completed for each patient receiving anesthesia and shall be included in the patient's medical record. The post-anesthesia evaluation shall include, at a minimum:

1. The presence or absence of anesthesia-related abnormalities and complications,
2. The patient's level of consciousness and cardiopulmonary status, and
3. Any follow-up care needed.

K. The intraoperative anesthesia record shall document all pertinent actions and events that occur during the induction, maintenance and emergence from anesthesia, including but not limited to:

1. Name, dosage, route, and time of administration of drugs and anesthesia agents;
2. IV fluids administered;
3. Estimated blood loss;
4. Any blood or blood products given;
5. Recordings of blood pressure;
6. Total intake and output;
7. Heart and respiration rate,
8. Any problems occurring during anesthesia and treatment given to address those problems; and
9. Patient response to treatment.

L. For outpatients, the post-anesthesia evaluation shall be performed prior to patient discharge to check for anesthesia recovery according to procedures and clinical protocols established by the hospital's medical staff.

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12VAC5-411-470. Anesthesia safety precautions.

Safety precautions related to administration of anesthesia, which shall be documented and enforced by hospital staff, shall include at a minimum:

1. Routine maintenance and inspection of anesthesia equipment recorded in a service record for each machine;
2. Care of patients under anesthesia any time during an event identified in 12VAC5-411-620;
3. Safety measures including:
 - a. Alarm systems for ventilators capable of detecting disconnection of any components;
 - b. Monitoring for scavenger gases; and
 - c. A system for internal reporting of equipment malfunctions and unavailability;
4. Infection control procedures sufficient to adequately sterilize or appropriately disinfect all equipment components; and
5. Patient safety procedures including:
 - a. Monitoring body alignment, positioning, and managing transfers;
 - b. Assessing patient's risk factors;
 - c. Anesthesia-reversal procedures; or
 - d. Detection and management of adverse drug reactions.

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Part VII
Perinatal Services

12VAC5-411-480. Maternal and newborn services generally.

A. Hospitals providing obstetric care to expectant mothers or newborns shall comply with the regulations in this section and shall offer at least basic obstetric and newborn services according to 12 VAC5-411-490 and 12VAC5-411-500.

B. The admission criteria for maternal and newborn services shall reflect the designated level of service offered by the hospital.

C. The hospital shall appoint a director of maternal and newborn services who shall be an employee of the hospital, responsible for the supervision and organization of perinatal services consistent with the hospital's designated level of such service and for monitoring the quality and appropriateness of those services in coordination with the hospital's quality management program.

D. Written protocols for perinatal services shall include, but are not limited to:

1. Patient care responsibilities antepartum, labor including pre-term labor, delivery, recovery and postpartum care;
2. A staffing plan that ensures availability of appropriate numbers of qualified staff for the Perinatal services offered according to generally accepted standards of practice;
3. The administration of oxygen including the proper apparatus for safe administration and concentration control such as flow meters, concentration monitoring devices and masks or equivalent;
4. The presence of partners, family members or other support persons, including other children, during and following labor and delivery ;
5. An infection control program for labor, delivery, and postpartum care and for the nursery that includes but is not limited to:
 - a. The cleaning, disinfection and sterilization of patient areas, equipment and suppliers;
 - b. The flow of staff and visitors between the obstetric and newborn units and other patient care areas; and
 - c. Specific procedures for patient isolation;
6. The method of matching newborn to mother prior to leaving the delivery area and throughout the newborn's hospital stay;
7. The drugs, devices, biologicals, equipment and supplies to be immediately available for provision of perinatal care as required by the mother or newborn;
8. A system to facilitate referral and follow-up for mothers and newborns at risk and those being discharged less than 24 hours post delivery;

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9. The care of infants born outside the hospital, for infants born to a mother who has had no prenatal care, or for infants suspected of harboring an infectious disease; and

10. Identified opportunities for improvement are addressed.

E. Provisions shall be made within the delivery area for the immediate care of emergencies with all necessary emergency equipment available, including but not limited to emergency medication, intravenous fluids, and related supplies and equipment, such as fetal heart rate monitors.

F. There shall be a system for communicating and consulting with board certified obstetricians or maternal-fetal medicine specialists and a board certified neonatologist for situations where transport of the high-risk patient prior to delivery is not feasible. Such communications shall be documented in the newborn's medical record.

G. There shall be methods for consulting with facilities providing higher neonatal service levels of care for those neonates who require such care. Such consultations shall ensure collaboration between the sending and receiving hospital prior to actual need for transfer and shall include mechanisms for communicating the outcome of each transfer. Such consultations shall be documented in the patient's medical record.

H. The hospital shall establish and implement effective security protocols for the perinatal service unit.

I. The hospital shall have a system for receiving prenatal records including the results of any routine laboratory tests.

J. The discharge plan shall include:

1. Documented needs of the mother and newborn;
2. Confirmed arrangements for appropriate home and community follow-up to address those risks; and
3. Educational information including, but not limited to:

- a. Domestic violence;

- d. Safe sleep environments; and

- c. Perinatal depression and shaken baby syndrome or traumatic brain injury as

require by §32.1-134.01 of the Code of Virginia.

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

K. Immediately upon identification of any substance-abusing postpartum woman, the hospital shall notify, pursuant to §54.1-2403.1 of the Code of Virginia and subject to federal law restrictions, the community services board of the jurisdiction in which the woman resides to appoint a discharge plan manager.

L. Written discharge planning for identified substance abusing, postpartum women and their infants shall include appropriate referral sources available in the community or locality for mother and infants such as:

1. Treatment services;

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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. ; and
 3. Family-oriented prevention services.
 4. The discharge planning process 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.

M. Regardless of the size or designated level of neonatal services provided, the hospital's quality management program shall include, but is not limited to:

1. A systematic review of the admissions and transfers for maternal and newborn services, with comparison to the established admission criteria;
2. A review of maternal and newborn mortality and morbidity conducted at least quarterly.

Prompt corrective action shall be taken when indicated.

12VAC5-411-490. Obstetric care.

A. A hospital providing obstetric care, regardless of how the perinatal service is organized, shall implement written policies and procedures that describe the process, and methods of providing risk appropriate care to the obstetric patient, including, but is not limited to:

1. The scope of the practice and services provided, including patient care responsibilities antepartum, labor including pre-term labor, delivery, recovery and post-partum care, including complications ;
2. Parental choice for specific care services except in emergency situations;
3. Admission criteria and documentation;
4. Circumstances requiring maternal transfer to another hospital;
5. Staff responsibilities during induction and augmentation of labor;
6. The use of oxytocic drugs and administration of anesthetics, sedatives, and analgesics;
7. Capability to perform emergency cesarean delivery within 30 minutes of the decision to do so;
8. Identification of high-risk mothers;
9. Proper detection and initial care of unanticipated maternal-fetal problems that occur during labor and delivery;
10. Immediate care of emergencies, including necessary emergency equipment;
11. The presence of partners, family members or other support persons during labor and delivery;

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12. Coordination of prenatal and postpartum referral and follow-up for mothers and newborns at risk and those being discharged less than 24 hours post delivery;

13. The alternative use of obstetric beds by nonmaternity patients; and

14. Care of postpartum conditions.

B. The obstetric unit shall be under the general supervision of a registered nurse with training and experience in obstetric nursing. Duties shall include, but are not limited to:

1. Accessing additional staff as needed to meet unanticipated needs;

2. Monitoring the flow of staff between the obstetric and newborn units and other patient care areas;

3. Accessing staff as needed, including additional staff to meet unanticipated needs;

4. Establishing orientation and continuing education for staff that includes, at a minimum:

a. Instruction in safety precautions;

b. Emergency patient management;

c. Equipment use and inspections, and infection control procedures.

C. Continuously available staff for basic obstetric services shall include, but is not limited to:

1. A physician with credentials in obstetric services;

2. A registered nurse responsible for the nursing care of the newborn;

3. An individual certified in neonatal resuscitation by the AAP Neonatal Resuscitation Program or a similar program;

4. A master's level medical social worker with experience in women and infants at high risk, ill neonates and their families; and

5. A registered dietitian or nutritionist with training in perinatal nutrition to plan diets that meet the needs of women and infants at high risk.

D. No less than the following supportive services shall be available on a 24-four hour basis:

1. Sonography, medical imaging, electronic monitoring, etc.

2. Blood and blood component transfusion services;

3. Clinical laboratory; and

4. Anesthesia services pursuant to 12VAC5-411-460 of this chapter.

E. There shall be sufficient space, facilities, equipment and supplies necessary for the delivery, management, and stabilization of women in active labor and for whom delivery is imminent, according to generally accepted standards of practice, regardless of the level of care anticipated for the newborn.

F. For cesarean deliveries, an additional physician or certified nurse midwife, a registered nurse, or surgical assistant qualified to assist with a cesarean section shall be available. To accommodate emergency C-sections, staff shall arrive within 30 minutes from the physician's decision to operate to the initial incision.

G. Obstetric patients needing a higher level of care than provided by the hospital shall be transferred as stated in the hospital's transfer protocol.

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H. Obstetric patients shall not be placed in rooms with non-obstetric patients.

I. The staffing plan for the obstetric unit shall ensure the availability of appropriate numbers of qualified staff according to each patient's need and generally accepted standards of practice.

J. The hospital shall have a system for receiving prenatal records for admission including the results of any routine laboratory tests.

Article 2.
Neonatal Services.

12VAC5-411-500. Basic newborn services.

A. Hospitals offering obstetric services shall provide, at a minimum, basic newborn service for infants that are full-term and preterm that are stable without complications. This may include small for gestational age or large for gestational age neonates.

B. In addition to the policies and procedures contained in 12VAC5-411-480 and 12VAC5-411-490, written protocols for basic newborn services shall include:

1. Identification of high-risk fetuses;
2. Circumstances under which the neonate is not allowed to remain with its mother; and
3. Completion of the birth certificate;

C. Services provided in the basic newborn services shall include, but are not limited to:

1. Surveillance and care of all neonates admitted, with an established triage system for identifying high risk neonates who should be transferred to a higher neonatal service level nursery;
2. Provisions for the immediate assessment and care of the newborn, including but not limited to:
 - a. Infant screenings according to 12VAC5-71 and 12VAC5-80;
 - b. Prophylaxis against gonococcal ophthalmia neonatorum to the eyes of all newborns, including those born by cesarean section; and
 - c. Assessment of the mother-child relationship including breast feeding;
3. Resuscitation and stabilization of all neonates in the hospital;
4. Evaluation and continuing care of healthy neonates in a nursery or with their mothers until discharge;
5. Adequate nursery facilities and support for stabilization of small or ill neonates before transfer to a higher neonatal service level nursery;
6. Stabilization of unexpectedly small or sick neonates before transfer; and
7. Arrangements for perinatal transfer when medically appropriate.

D. Continuously available staff for basic newborn services shall include, but is not limited to:

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1. A physician credentialed in pediatric services or family practice;
 2. A registered nurse responsible for the nursing care of the newborn; and
 3. An individual certified in neonatal resuscitation by the AAP Neonatal Resuscitation Program or a similar program.
- E. Staff available for consultation shall include:
1. A pediatrician; and
 2. A surgeon.
- F. Newborn services shall provide for newborn recovery, observation, and isolation, and for high-risk infants, access to care in a higher neonatal service level nursery when necessary.
- G. Equipment and supplies shall be immediately available and maintained for the newborn, including but not limited to:
1. Furnishings, including but not limited to:
 - a. An individual infant care station for each infant;
 - b. A covered soiled-diaper container with removable lining;
 - c. A linen hamper with removable bag for soiled linen other than diapers;
 - d. Accurate scales; and
 - e. Isolation area with separate hand washing facility;
 2. Mechanical and bulb suction;
 3. Resuscitation equipment;
 4. Equipment to monitor and maintain the optimum body temperature of the newborn;
 5. A clock capable of showing seconds;
 6. An adjustable examination light; and
 7. A newborn warming unit capable of administering oxygen and suctioning.
- H. The hospital shall manage a neonate with acute or potentially life-threatening problems while preparing for immediate transfer to a higher neonatal service level nursery. Such management shall include emergency resuscitation or stabilization for neonatal patients.
- I. A delivery room record keeping system shall be maintained to cross reference information with other departments.
- J. Hospitals providing basic newborn services shall not provide care or services that are designated only for higher neonatal service level nurseries.

12VAC5-411-510. Higher levels of neonatal care.

- A. A hospital providing a higher level of neonatal care shall clearly identify, in writing to the OLC, the scope of any such higher level of neonatal service provided according to the recommendations of the American Academy of Pediatrics as seen in the table:

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Level	Additional capabilities
Specialty - Level II Level IIA Level IIB	<p>Infants that are stable without complications but require special care and frequent feedings; infants of any weight who no longer require Level III neonatal services, but who still require more nursing hours than normal infants. This may include infants that require close observation.</p> <p>Stabilization of severely ill newborns before transfer Treatment of moderately ill, larger preterm and term newborns Can provide assisted ventilation on a limited basis until the infant can be transferred to a higher level nursery.</p> <p>Provides mechanical ventilation for up to 24 hours or continuous positive airway pressure</p>
Subspecialty - Level III NICU Level III A Level III B Level III C	<p>Provide comprehensive care for infants born at more than 28 weeks of gestation and weighing more than 1,000 grams Provides sustained mechanical ventilation but not more advanced life support Perform minor surgical procedures, such as placement of a central vein catheter or repair of an inguinal hernia</p> <p>Comprehensive care for infants born at 28 weeks of gestation or less and weighing 1,000 grams or less Advanced respiratory support, such as high-frequency ventilation and inhaled nitric oxide Advanced imaging, with interpretation on an urgent basis, including computed tomography (CT), magnetic resonance imaging(MRI), and echocardiography Prompt on-site access to a full range of pediatric medical subspecialists Pediatric surgical subspecialists and pediatric anesthesiologists on site or at a closely related institution to perform major surgery</p> <p>Provides extracorporeal life support Open-heart surgery for repair of complex, congenital cardiac malformations</p>

B. Any changes in neonatal care or service levels must be filed with the OLC and may require a COPN.

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12VAC5-411-520. Specialty neonatal services.

A. In addition to sections 12VAC5-411-480 and 12VAC5-411-500, hospitals providing specialty neonatal services shall provide basic newborn services and shall comply with the standards of this section according to the table in 12VAC5-411-510 as determined by the hospital.

B. This level of service shall have the following additional personnel continuously available:

1. A board certified pediatrician with subspecialty certification in neonatology medicine designated as physician-in-charge of neonatal services;
2. Pediatricians;
3. Respiratory therapists; and
4. Advanced practice nurses with formal education in acute care and training in the care of critically ill newborns.

C. This service shall provide the following for consultation:

1. A general or pediatric surgeon with a specialty neonatal surgery;
2. A clinical pathologist;
3. An occupational or physical therapist with neonatal expertise;
4. A speech-language pathologist with skills in evaluation and management of neonatal feeding and swallowing disorders; and
5. A respiratory therapist with expertise in assisted ventilation of neonates with cardiopulmonary disease.

D. In addition to the basic newborn services described in 12VAC5-411-500, specialty hospitals shall provide the following enhanced services;

1. Care of neonates at high risk;
2. Stabilization of severely ill newborns before transfer; and
3. Treatment of moderately ill, larger preterm and term neonates.

E. Neonates shall not require high frequency ventilation support and shall not need ventilation support for more than 24 cumulative hours.

F. Hospitals providing specialty newborn services shall not provide care or services that are designated only for higher neonatal service level nurseries.

12VAC5-411-530. Subspecialty neonatal services.

A. In addition to sections 12VAC5-411-480 through 12VAC5-411-500 and 12VAC5-411-520, hospitals providing subspecialty newborn care shall provide basic and specialty newborn care and shall maintain compliance with the standards in this section according to the table in 12VAC5-411-510 as determined by the hospital.

B. Subspecialty NICUs shall have the following additional personnel continuously available:

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1. A board certified pediatrician with subspecialty certification in neonatal medicine designated as physician-in-charge of subspecialty services;
 2. Neonatologists;
 3. A pediatric radiologist;
 4. An anesthesiologist with perinatal training or experience;
 5. Pathologists with special competence in placental, fetal, and neonatal disease; and
 6. Pediatric subspecialists in hematology, medical genetics, endocrinology, nephrology, gastroenterology, infectious diseases, pulmonology, immunology, and pharmacology;
 7. Pediatric surgical subspecialists to include: cardiovascular, neurosurgery, orthopedics, ophthalmology, urology and otolaryngology; and
 8. Advanced practice nurses with formal education in acute care and training in the care of critically ill newborns.

C. Hospitals providing subspecialty newborn services shall provide all aspects of perinatal care, including intensive care and shall have the staffing and technical capability to manage high-risk and complex neonatal patients, including neonates requiring prolonged ventilation support, surgical intervention, or 24 hour availability of multispecialty management.

D. Subspecialty hospitals shall coordinate a perinatal outreach education program to provide consultative and support services to all perinatal health professionals and lower-level neonatal nurseries within the hospital's planning region. As part of this program physician-to-physician consultation shall be available 24 hours a day.

E. Hospitals providing subspecialty newborn services shall provide a perinatal transport system that operates 24 hours a day, 7 days a week, and return transport neonates to lower level perinatal hospitals when the neonate's condition and care requirements are within the capability of those hospitals.

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Part VIII
Special Care Services

12VAC5-411-540. Organ/tissue donation and transplant services.

A. Hospitals providing organ and tissue donation shall establish a protocol for such donation in compliance with federal law and regulations, particularly 42 CFR §482.45 and the provisions of Virginia's Anatomical Gifts statutes ((Article 2 (§32.1-289 et seq.) of Chapter 8 of Title 32.1 of the Code of Virginia.

B. All hospitals with transplant services shall be a member of the federal Organ Procurement and Transplantation Network (OPTN). In addition, each hospital shall maintain membership in good standing with the United Network for Organ Sharing (UNOS). If patient or graft outcomes decline to a level mandating UNOS review, the hospital shall immediately notify the OLC and file a written plan of correction.

C. Hospital credentialing protocols shall identify those medical staff eligible to participate in the recovery and transplantation of organs and body parts.

D. There shall be a director of organ transplantation services who shall be a member of the medical staff qualified to provide oversight of transplantation services and shall be responsible for monitoring the quality and appropriateness of transplantation services in coordination with the hospital's quality management program.

E. If the hospital engages in harvesting tissue or transplanting organs and tissues from living donors, the hospital shall develop a living donor organ/transplants policy that addresses the issues related to such donations.

Note: For the purposes of this section, organ and tissue does not include donor sperm or eggs implanted via fertility procedures.

F. The protocols identified in subsection A shall be followed, without exception, unless the family of the relevant decedent or patient has expressed 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.

12VAC5-411-550. Psychiatric and substance abuse services.

If the hospital offers psychiatric or substance abuse services, whether as inpatient, outpatient or in combination, those services shall be provided according to 12VAC35-105 as applicable.

12VAC5-411-560. Other special care units.

A. Any special care unit not specifically addressed in this chapter shall have a defined organization, shall be equipped for its defined special function, and governed by documented policies specifically related to utilization of the service. Such special care units may include, but is not limited to: intensive care, burn care, coronary care, and pulmonary care.

B. Based on the scope and complexity of the services provided, appropriate medical staff shall be available.

C. The following supports, as applicable, shall be immediately available on a 24-hour basis:

1. Blood bank or supply;
2. Clinical laboratory; and
3. Radiology services.

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

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Part IX
Support Services
Article 1
Environmental and Maintenance Services

12VAC5-411-570. Housekeeping services.

A. Each hospital shall be equipped and maintained to provide a clean and safe environment for patients, employees, and visitors.

1. Written housekeeping procedures shall be established for the cleaning of all areas in the hospital.

2. All parts of the hospital and its premises shall be kept clean, neat, and free of litter, vermin and pests.

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

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

5. Cleaning shall be performed in a manner that minimizes the spread of airborne pathogens in the hospital.

B. The hospital shall implement a hospital-wide safety program that includes at least:

1. An incident monitoring system to identify, investigate and take corrective action regarding all incidences that involve injury to patients, employees, or visitors or that involve significant property damage;

2. A program to inspect, monitor, and maintain biomedical equipment, electrical equipment, and emergency power generators;

3. A program for monitoring and maintenance of electrical safety;

4. Security procedures for controlling access by patients, employees and visitors, to sensitive areas, as defined in hospital policy;

5. Procedures for the safe management of medical gases;

6. A system for patients and staff to summon assistance, when needed, from patient rooms, bathrooms, and treatment areas;

7. Policies regarding smoking; and

8. Procedures for storage and disposal of biohazardous medical waste consistent with OSHA bloodborne pathogens standards (29 CFR 1910.1030) and applicable state laws and regulation.

C. The hospital's sanitation program shall include at least:

1. Standardized daily, interim, and terminal cleaning routines for all areas;

2. Facilities for convenient and effective hand washing throughout the hospital;

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3. Systems for management of linens, including collection, sorting, transport, and washing of soiled linens and storage and distribution of clean linens.

D. The hospital shall provide adequate lighting, ventilation and control of temperatures and air humidity for optimal care and safety of patients and staff and shall monitor and maintain such systems.

E. The hospital shall provide sufficient space and equipment for the scope and complexity of services offered.

12VAC5-411-580. Sterile processing services.

A. There shall be a designated sterile processing services area for the decontamination, cleaning, and sterilizing of reusable equipment, instruments, and supplies.

B. With collaboration from the infection control program and the sterile processing services staff, standardized policies conforming to generally accepted standards of practice shall include, but are not limited to:

1. Decontamination and cleaning of instruments and other items and description of reprocessing protocols for contaminated patient equipment;
2. Disinfecting or sterilizing equipment and other items;
3. Monitoring systems used for sterilization;
4. Procedures for ensuring the sterility of packaged instruments and supplies;
5. Recall of items; and
6. Mechanisms for protection of workers from exposure to blood and other potentially infectious materials and environmental hazards.

C. The sterile processing service unit shall be staffed by personnel qualified by training or experience in processing sterile equipment and supplies.

12VAC5-411-590. Laundry services.

Each hospital shall make provisions for the safe and effective cleaning of all linens as follows:

1. Hospitals with in-house laundry service shall have adequate facilities and equipment for the safe and effective operation of such service;
2. There shall be distinct areas for the separate storage and handling of clean and soiled linens;
3. Special procedures shall be established for the handling and processing of soiled linens;
4. All soiled linen shall be placed in closed containers prior to transport;
5. To safeguard clean linens from cross-contamination they shall be:

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- a. Transported in containers used exclusively for clean linens unless such containers are routinely and regularly sanitized before use as a clean linen transport container;
 - b. Stored in areas designated exclusively for this purpose; and
 - c. Kept covered at all times while in transit.

12VAC5-411-600. Dietary services.

A. Each hospital shall maintain a dietary service directed by a full-time person, qualified by training and experience in organization and administration of food service.

B. Each hospital shall make arrangements with at least one dietitian, meeting the criteria of §54.1-2731 of the Code of Virginia, on a full-time, part-time or 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 12VAC5-421.

E. A diet manual 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 documented 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.

H. A hospital contracting for food service shall require, as part of the contract, that the contractor comply with the provisions of this section.

12VAC5-411-610. Medical records.

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.

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

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

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

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F. All orders, including verbal orders, must be dated, timed and authenticated promptly by the practitioner by written or electronic signature.

G. 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 HIPAA, (42 USC §1320d et seq.).

H. Films, scans, and other images shall be retained for at least five years after the date of the procedure unless the release of the original images is required for the care of the patient or otherwise specified in state or federal law. When original images are released, documentation of the disposition of the original images shall be retained for the applicable 5-year period. Storage of films, scans, and other images may be off-site so long as they remain retrievable within 48 hours.

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.

Article 3
Disaster and Mass Casualty Planning

12VAC5-411-620. All hazards response.

A. Each hospital shall develop, review, and maintain a written disaster preparedness and response plan that shall provide for manmade and natural disasters that disrupt the normal course of hospital operations; as well as disasters occurring within the local community.

B. The disaster plan shall be reviewed and revised annually, as appropriate including any related written agreements.

C. Hospitals may utilize non-traditional settings, as described in 12VAC5-411-90.E, to deal with surge capacity per their plan for the duration of an emergency.

D. In the event of a disaster, fire, emergency or any other condition that may jeopardize the health, safety and well being of patients, the hospital shall notify the OLC of the conditions and status of the patients and the hospital as soon as possible.

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Part X
Physical Plant

12VAC5-411-630. General building and physical plant information.

A. All construction of new buildings and additions, renovations, alterations or repairs of existing buildings for occupancy as a hospital shall conform to state and local codes, zoning and building ordinances, and the Uniform Statewide Building Code. In addition, hospitals shall be designed and constructed according to Part 1 and sections 2.1-1 through 2.1-10 of Part 2 of the 2006 Guidelines for Design and Construction of Health Care Facilities 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 demonstrated by a Certificate of Use and Occupancy indicating the building is classified for its proposed licensed purpose.

12VAC5-411-640. Additional building regulations and standards.

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 Division of Radiological Health of the Virginia Department of Health. Installation, calibration and testing of machines and storage facilities shall comply with 12VAC5-480.

E. A hospital's food operation shall comply with 12VAC5-421.

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

12VAC5-411-650. Drawings and specifications.

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.

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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.

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Part XI
Critical Access Hospitals

12VAC5-411-660. Requirements for a critical access hospital.

A. In order to apply for designation as a critical access hospital, a hospital shall meet all applicable criteria listed in §32.1-125.3 of the Code of Virginia and must meet the requirements to qualify for a written agreement with the Centers for Medicare and Medicaid Services or its successor to participate in Medicare as a critical access hospital as defined in 42 CFR 485.601 through 42 CFR 485.641.

B. A critical access hospital shall maintain not more than 45 beds according to the following break down:

1. Up to 25 acute care services beds that may be used interchangeably for swing-bed services;
2. 10 beds for excluded inpatient psychiatric services;
3. 10 beds for excluded inpatient rehabilitation services; and
4. No more than four permanently placed 24-hour observation beds.

C. The average length of stay shall not be more than 96 hours.

Exception: A patient's stay may be extended beyond 96 hours when transfer to a rural health referral network hospital or other hospital is precluded due to inclement weather or other emergency condition.

D. Emergency services shall be available 24 hours a day. Such services shall be provided by a practitioner with training or experience in emergency care and who is on call, immediately available, and on-site within 30 minutes of notification. A practitioner can be a physician or a nurse practitioner or physician assistant working as assigned by their supervising physician and within the parameters of professional licensing.

E. A critical access hospital may make available any services provided by staff under subsection G of this section on a part-time, off-site basis under arrangements as specified in 42 USC 1895x(e). However, no staff is required to be in the hospital when no patients are present.

F. A critical access hospital shall have a written agreement with one or more rural health network hospitals or other appropriate provider that addresses all of the following:

1. Referral and transfer of patients from the critical access hospital to the rural health referral network hospital or other appropriate provider;
2. Implementation of appropriate communication system;
3. Provision of emergency and nonemergency transportation and backup medical and emergency services; and
4. Credentialing of professional staff and quality assurance.

NOTE: For the purposes of this Part, 'rural health network' means an organization that meets the specifications as described in 42 CFR Part 485.603.

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- G. A critical access hospital shall comply with the following sections of this chapter:
1. Parts I through IV (12VAC5-411-10 through 12VAC5-411-270) of this chapter;
 2. Emergency services specified 12VAC5-411-280;
 3. Pharmacy services specified in 12VAC5-411-360;
 4. Laboratory services specified in 12VAC5-411-380; and
 5. Part IX and X (12VAC5-411-580 through 12VAC5-411-670) of this chapter;

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PART XII

Long Term Acute Care Hospitals (LTACH)

12VAC5-411-670. Requirements for an LTACH.

A. In order to apply for designation as a critical access hospital, a hospital shall meet all applicable criteria listed in §32.1-125.3 of the Code of Virginia and must meet the requirements to qualify for a written agreement with the Centers for Medicare and Medicaid Services or its successor to participate in Medicare as a critical access hospital as defined in 42 CFR 485.601 through 42 CFR 485.641.

B. A critical access hospital shall maintain not more than 45 beds according to the following break down:

1. Up to 25 acute care services beds that may be used interchangeably for swing-bed services;
2. 10 beds for excluded inpatient psychiatric services;
3. 10 beds for excluded inpatient rehabilitation services; and
4. No more than four permanently placed 24-hour observation beds.

C. The average length of stay shall not be more than 96 hours.

Note: A patient's stay may be extended beyond 96 hours only when transfer to a rural health referral network hospital or other hospital is precluded due to inclement weather or other emergency condition.

D. Emergency services shall be available 24 hours a day. Such services shall be provided by a practitioner with training or experience in emergency care and who is on call, immediately available, and on-site within 30 minutes of notification. A practitioner can be a physician or a nurse practitioner or physician assistant working as assigned by their supervising physician and within the parameters of professional licensing.

E. A critical access hospital may make available any services provided by staff under subsection G of this section on a part-time, off-site basis under arrangements as specified in 42 USC 1895x(e). However, no staff is required to be in the hospital when no patients are present.

F. A critical access hospital shall have a written agreement with one or more rural health network hospitals or other appropriate provider that addresses all of the following:

1. Referral and transfer of patients from the critical access hospital to the rural health referral network hospital or other appropriate provider;
2. Implementation of appropriate communication system;
3. Provision of emergency and nonemergency transportation and backup medical and emergency services; and
4. Credentialing of professional staff and quality assurance.

NOTE: For the purposes of this Part, 'rural health network' means an organization that meets the specifications as described in 42 CFR Part 485.603.

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- G. A critical access hospital shall comply with the following sections of this chapter:
1. Parts I through IV (12VAC5-411-10 through 12VAC5-411-270) of this chapter;
 2. Emergency services specified 12VAC5-411-280;
 3. Pharmacy services specified in 12VAC5-411-360;
 4. Laboratory services specified in 12VAC5-411-380; and
 5. Part IX and X (12VAC5-411-580 through 12VAC5-411-670) of this chapter;

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