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OFFICE WEST VIRGINIA
SECRETARY OF STATE

AGENCY: Office of Health Facility Licensure and Certification TITLE NUMBER: 64

CITE AUTHORITY: W. Va. Code 15-5B-8

AMENDMENT TO AN EXISTING RULE: YES X NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 12

TITLE OF RULE BEING AMENDED: Hospital Licensure Rule

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: _____

TITLE OF RULE BEING PROPOSED: _____

Martha Zagan Walker
Authorized Signature

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Grammatical errors corrected

TITLE 64
LEGISLATIVE RULE
WEST VIRGINIA DIVISION OF HEALTH **FILED**

SERIES 12
HOSPITAL LICENSURE

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OFFICE WEST VIRGINIA
SECRETARY OF STATE

64-12-1. General.

1.1. Scope -- This legislative rule establishes standards and procedures for the licensing of hospitals and extended care facilities operated in connection with a hospital.

1.2. Authority -- W. Va. Code 16-5B-8.

1.3. Filing Date --

1.4. Effective Date --

1.5. Repeal of former rule -- This legislative rule repeals and replaces West Virginia 64CSR12 Hospital Licensure, filed July 1, 1994 and effective July 1, 1994.

1.6. Applicability -- This rule applies to any person, partnership, association, corporation, state or local governmental unit, political subdivision, division, department, board or agency that establishes, maintains, or operates a hospital or an extended care unit in connection with a hospital as defined in this rule and W. Va. Code 16-5B-1, *et seq.*

1.7. Enforcement -- This rule is enforced by the Secretary of the Department of Health and Human Resources or his or her lawful designee.

1.8. Purpose -- The purpose of this rule is to ensure all West Virginia hospitals conform to a common set of standards and procedures. All standards and procedures are minimum requirements whereby hospitals may be surveyed and evaluated to ensure the health and safety of all patients treated in West Virginia hospitals.

64-12-2. Definitions.

2.1. Abuse -- The infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish.

2.2. Applicant -- The person who submits an application for a license or renewal of a license to operate a hospital or extended/skilled care facility operated in connection with a hospital.

2.3. Bed Capacity -- The maximum number of beds a hospital is licensed to offer for inpatient care including all specialty beds.

2.4. Board of Directors or Board -- The voting members of the governing authority of a hospital.

2.5. Consumer Representative -- A member of the Board of Directors of a hospital as defined in subsection 2.32 of this rule who is not a member of management of the hospital or one of its related organizations, and who has been designated by the board as a person representing one of the following four consumer categories, either small business, organized labor, elderly persons, or persons whose income is less than the national median income.

2.6. Coronary Care Unit -- A specialized area of a hospital containing a grouping of single bedrooms or single bed enclosures where constant, intensive visual observation, and immediate emergency and prescribed non-emergency coronary care, and treatment are provided.

2.7. Critical Access Hospital -- A hospital is a critical access hospital if it:

2.7.a. Is a not-for-profit, for-profit or public hospital and is located in a county in a rural area as defined in 42 U.S.C.A. 1395.i.4(e);

2.7.b. Is located more than a thirty-five (35) mile drive from a hospital or another health care facility or is located more than a fifteen (15) mile drive from a hospital or another health care facility in the case of mountainous terrain or in areas where only secondary roads are available;

2.7.c. Is designated by the state as being a necessary provider of health care services to residents in the area;

2.7.d. Makes available twenty-four (24) hour emergency care services: Provided, That the State shall determine necessary criteria for ensuring access to emergency care in each area served by the hospital;

2.7.e. Provides not more than twenty-five (25) beds for providing inpatient care for a period not to exceed ninety-six (96) hours for each hospitalization to be averaged annually, unless a longer period is required because transfer to a hospital is precluded because of inclement weather or other emergency conditions: Provided, That swing bed patients are not limited to the ninety-six (96) hour requirement;

2.7.f. Has nursing services available on a twenty-four (24) hour basis;

2.7.g. Provides basic services as required under Critical Access Regulations 42 C.F.R. 485.635; and

2.7.h. Meets the requirements of 42 U.S.C.A. 1395, *et seq.*, Emergency Medical Treatment and Active Labor Act (EMTALA).

2.8. Department -- West Virginia Department of Health and Human Resources.

2.9. Director -- The official designated by the Secretary of the Department of Health and Human Resources as his or her designee. Unless otherwise specifically noted, that individual is the Director of the Office of Health Facility Licensure and Certification.

2.10. Elderly Persons -- Individuals who are sixty-five (65) years of age or older.

2.11. Extended Care Unit -- A unit that provides skilled nursing and related services for long term care patients who require medical, nursing and other professional health care services.

2.12. Family -- A group of two (2) or more persons related by blood, marriage, significant relationship, or adoption.

2.13. Hospital -- Any institution, place, building, or agency in which an accommodation of five (5) or more beds, including beds that may be a part of a specialty unit, is maintained, furnished, or offered for patient care and treatment.

2.14. Hospitalization -- The in-house accommodation and care of any person for a continuous period of time, generally longer than twenty-four (24) hours, for the purpose of providing medical, surgical, nursing and other professional health care services.

2.15. Intensive Care Unit -- A specialized area of a hospital containing a grouping of single-bed rooms or enclosures where close and frequent, if not constant, nursing observation can occur for critically and seriously ill patients requiring highly skilled nursing care.

2.16. License -- The document issued by the Secretary that constitutes the hospital's authority to receive patients and perform services included within the scope of this rule.

2.17. Licensed or Registered -- When applied to a person, means that the person licensed or registered to follow a profession by the proper authority within the State of West Virginia and when applied to a hospital means that the hospital is licensed by the Department. A licensed physician is licensed by the West Virginia Board Of Medicine or the West Virginia Board of Osteopathy.

2.18. Long Term Acute Care Hospital (LTACH) -- A hospital where patients receive care who have been in intensive care or in a short-term

acute care setting and require an extended length of stay greater than twenty-five (25) days. LTACHs are referred to as a hospital within a hospital.

2.19. Medical Staff -- The group of physicians and other licensed health care professionals who practice in the hospital in accordance with Section 11 of this rule.

2.20. Member of Management -- Any individual representing the hospital who oversees the day to day business of the hospital.

2.21. Midlevel practitioner -- Physician assistants, clinical nurse specialists, or nurse practitioners.

2.22. Neglect -- Failure to provide goods and services necessary to prevent physical harm and/or mental anguish.

2.23. Nurse Aide Registry -- A list of nurse aides whose names appear on a registry as referenced by 42 C.F.R. 483.156 maintained by the department who have:

2.23.a. Successfully completed a State approved or other recognized nurse aide training and competency evaluation program;

2.23.b. Been determined as meeting these requirements; and

2.23.c. Have had the requirements in the Department of Health and Human Resources Rule, Nurse Aide Abuse Registry, 69CSR6 waived by the secretary.

2.24. Organized Labor Members -- Members of organized labor unions covered by the National Labor Relations Act, the Railroad Labor Act or other Federal labor acts.

2.25. Patient Care/Nursing Unit -- A designated area of the hospital that provides a bedroom or a grouping of bedrooms with supporting facilities and services to provide nursing care and clinical management of inpatients and that is planned, organized, operated, and maintained to

function as a separate distinct unit.

2.26. Person -- An individual and every form of organization, whether incorporated or unincorporated, including any partnership, corporation, trust, association, or political subdivision of the state.

2.27. Persons Whose Income is Less than the National Median Income Individuals -- persons whose gross family income, or gross individual income in the case of individuals not residing with a family member, is less than the national median family income. The Director shall establish and periodically revise the national median family income figure after consideration of Bureau of Census Current Population Reports, Consumer Income, Series P 60.

2.28. Principal Stockholder -- Any person who beneficially owns, holds or has the power to vote ten percent (10%) or more of any class of securities issued by a corporation.

2.29. Restraint -- Any device that limits movement by the patient and cannot be removed easily by the patient, or any chemical or drug used to limit movement by a patient, or to limit the mental capacity of a patient beyond the requirements of therapeutic treatment.

2.30. Rural Health Network -- For the purpose of this rule, a rural health network is an organization that contains at least one (1) hospital that the State has designated as a critical access hospital and at least one (1) hospital that furnishes acute care services. The members of the organization must enter into agreements regarding:

2.30.a. Patient referral and transfer;

2.30.b. The development and use of a communications system that may include telemetry and the electronic sharing of patient data; and

2.30.c. The provision of emergency and non-emergency transportation of patients among the members.

2.31. Seclusion -- The involuntary confinement of a person in a room or an area where the person is physically prevented from leaving.

2.32. Secretary -- The Secretary of the Department of Health and Human Resources.

2.33. Section 6a Hospital -- A not-for-profit hospital, as identified in W. Va. Code 16-5B-6a, whether governed by an in state or out of state Board of Directors, or a hospital owned by a county, city, or other political subdivision of the State of West Virginia, except for existing nonprofit hospitals that are owned or operated by a corporation which was incorporated in another state prior to March 9, 1983: Provided, That this definition does not include the corporation defined in W. Va. Code 18-11C-1d.

2.34. Small Business Representatives -- Persons classified as owning or operating a small business by the United States Small Business Administration pursuant to the 15 U.S.C. 631 *et seq.*, and applicable provisions of the Code of Federal Regulations, currently 13 C.F.R. 121.201 *et seq.*

2.35. Specialty Care/Critical Care Unit -- Specialized areas of the hospital which contain a grouping of single bed rooms or enclosures for critically and seriously ill patients requiring highly skilled nursing care, with frequent if not constant, nursing observation and interventions.

2.36. Swing Bed -- A bed that is approved for dual use and reimbursement under the Federal Medicare program for both acute and extended care.

2.37. The Act -- The Social Security Act Titles XVIII and XIX.

2.38. Unit Dose -- The ordered amount of a drug dispensed by a pharmacist in a dosage form ready for administration to a particular person by the prescribed route at the prescribed time.

2.39. Violation -- Failure to comply with W. Va. Code 16-5B-1 *et seq.* or any provisions of this rule. A violation constitutes a misdemeanor as set

forth in W. Va. Code 16-5B-11.

64-12-3. State Administrative Procedures.

3.1. General Licensure Provisions.

3.1.a. A person may not establish, conduct, or maintain in West Virginia any hospital or extended care unit operated in conjunction with a hospital without first obtaining a license. Only one (1) license is required for any person that operates any hospital or extended care unit operated in conjunction with a hospital at the same site.

3.1.b. A license is not transferable or assignable.

3.1.c. If the ownership of a hospital with a valid unexpired license changes, the new owner shall immediately apply for a new license. The new owner's application for a license has the effect of a valid license for three (3) months from the date the application is received by the Director.

3.1.d. Any change in location of the hospital, the total and types of beds or other major changes in the operation of the hospital requires the issuance of a new license.

3.1.e. The hospital or extended care unit operated in conjunction with a hospital shall:

3.1.e.1. Notify the Director in writing of any proposed change in the location of the hospital, the total and types of beds or operation of the hospital or extended care unit operated in conjunction with a hospital; and,

3.1.e.2. Request an application form for a new license.

3.2. Application For License.

3.2.a. An applicant for license shall complete and submit an application to the department on forms provided by the Director and shall pay the annual fee as required by W. Va. Code 16-5B-4. The name used on the application forms shall be the legal name of the hospital or extended

care unit operated in conjunction with a hospital.

3.2.b. A Section 6a hospital shall include in its application a list of the voting members of the Board of Directors who have been designated as consumer representatives as designated in subdivisions 4.2.a and 4.2.h of this rule.

3.3. Issuance of License.

3.3.a. The Director shall issue a license if:

3.3.a.1. The hospital or extended care unit operated in conjunction with a hospital is in compliance with this rule and applicable sections of W. Va. Code 16-5B-1 *et seq.*;

3.3.a.2. The hospital or extended care unit operated in conjunction with a hospital is in compliance with the rules of the State Fire Commission;

3.3.a.3. The hospital or extended care unit operated in conjunction with a hospital has submitted a complete application with all required documentation;

3.3.a.4. In the case of a project that is subject to review under W. Va. Code 16-2D-1 *et seq.*, the West Virginia Health Care Authority has issued a finding, after a final conformance review, that the completed project conforms to the terms of the certificate of need decision issued for the project; and

3.3.a.5. In the case of a Section 6a hospital, the composition of the hospital's Board of Directors is in conformance with subsection 4.2 of this rule or a plan of correction has been accepted: Provided, That the Director shall not withhold a license for noncompliance with subsection 4.2 of this rule in the case of the corporation defined in W. Va. Code 18-11C-1d.

3.3.b. The Director shall issue a separate license for each separate and distinct

location of the hospital or extended care unit operated in conjunction with a hospital.

3.3.c. The license shall include:

3.3.c.1. The legal name of the hospital or extended care unit operated in conjunction with a hospital to which it applies;

3.3.c.2. The location of the hospital or extended care unit operated in conjunction with a hospital;

3.3.c.3. The maximum number of beds classified by type for which it is granted; and

3.3.c.4. The date the license is issued and the date the license expires.

3.4. Expiration and Renewal of License.

3.4.a. All licenses expire on the thirtieth day of June following the date of their issuance unless continued pursuant to the provisions of W. Va. Code 16-5B-4.

3.4.b. Licensed hospitals and extended care units shall annually complete and return to the Director applications for licensure renewal with the required license fee on or before the thirtieth day of April. The Director shall provide licensure renewal forms to each licensed hospital and extended care unit by mail or other means he or she may consider proper.

3.4.c. The application for license shall specify the hospital's and extended care unit's proposed total bed capacity and the numbers of beds categorized by service provided, excluding bassinets.

3.4.d. A Section 6a hospital shall include a list of the voting members of its Board of Directors who have been designated as consumer representatives and specify in its application for license renewal which of the consumer members are women, members of racial minorities, or handicapped persons.

3.4.e. The Director shall renew a license if:

3.4.e.1. The hospital or extended care unit operated in conjunction with a hospital is in compliance with subsection 3.3 of this rule;

3.4.e.2. The hospital has received approval for all renovations or new building projects from the state agency;

3.4.e.3. The hospital or extended care unit operated in conjunction with a hospital has submitted the appropriate fee according to the provisions of WV Code 16-5B-4; and

3.4.e.4. The hospital has a paternity program as defined in W. Va. Code 16-5B-13.

3.5. Inspections.

3.5.a. The Director or his or her designee may enter the premises of any hospital or extended care unit operated in conjunction with a hospital to conduct inspections necessary to determine compliance with this rule.

3.5.b. The Director or his or her designee shall notify a hospital or extended care unit operated in conjunction with a hospital of any violations of this rule.

3.5.c. A periodic licensure inspection is not required by the Department for any hospital that is exempted by the provisions of W. Va. Code 16-5B-5a.

3.5.d. The Department shall grant an exemption from a periodic licensure inspection in the licensing year following accreditation when a hospital applies for this exemption by submitting with the yearly licensure application a complete copy of the accreditation report from the Joint Commission on Accreditation of Health Care Organizations or the American Osteopathic Association.

3.5.e. No exemption granted diminishes the right of the State Department of Health and Human Resources to conduct complaint investigations or relieves a hospital from compliance with W. Va. Code 16-5B-6a.

3.5.f. If the accreditation of a hospital is for a period longer than one (1) year, the Department may conduct at least one (1) licensure inspection of the hospital after the first year of accreditation and before the accreditation has expired and may conduct additional licensure inspections as considered necessary.

3.5.g. A hospital receiving a three (3) year accreditation shall conduct annual self-evaluations using the current year Accreditation Manual for Hospitals by the thirty-first day of March of each year that an inspection has not occurred.

3.5.h. A hospital shall incorporate the results of the self-evaluation in its quality improvement program and make a copy of the self-evaluation available to the State Department of Health and Human Resources upon request.

3.5.i. A hospital is not required to conduct self-evaluations for any licensing year when they are inspected by the Department.

3.5.j. Accreditation reports filed with the Department shall be treated as confidential in accordance with W. Va. Code 16-5B-10.

3.6. Penalties.

3.6.a. After notice of an opportunity for a hearing, pursuant to the provisions of W. Va. Code 29A-5-1, the Director may revoke the license of any hospital or extended care unit operated in conjunction with a hospital found in violation of this rule.

3.6.b. The licensee shall return a revoked license to the Director immediately upon receiving notice of its revocation. If a hospital or extended care unit operated in conjunction with a hospital voluntarily ceases operation, it shall return

its license to the Director.

3.6.c. If the Director revokes a license, the Director shall consider a new application for a license when evidence has been furnished that the conditions upon which the revocation was based have been corrected.

3.7. Miscellaneous Requirements.

3.7.a. A hospital may not change its name without submitting a new licensure application identifying the hospital by the new name. The Director shall issue a new license with the hospital identified by the new name.

3.7.b. All hospitals and extended care units operated in conjunction with a hospital shall comply with applicable rules of the State Fire Commission, the State Air Pollution Control Commission, and the Department of Environmental Protection Solid or Hazardous Waste Unit.

3.7.c. The hospital or extended care unit shall post its license in a conspicuous place on the licensed premises.

3.7.d. A hospital shall not admit more patients than the number of beds for which it is licensed except in the case of public catastrophe or emergency and then only as a temporary measure.

64-12-4. Administration of the Hospital.

4.1. Governing Authority.

4.1.a. The governing authority or owner is the highest authority responsible for the management and control of the hospital including employment of a hospital administrator, a licensed nursing home administrator when applicable and appointment of medical staff. The administrator is responsible for the direction and control of the hospital operation in accordance with policies established by the governing authority. The medical staff is responsible for the quality of medical care provided and for submitting reports on the quality of this care to the governing body of the hospital at defined intervals.

4.1.b. The governing authority is legally responsible for the management and control of the hospital. In the discharge of its duties, the governing authority exercises its responsibility for the care of patients through the medical staff. The governing authority is responsible for the establishment of policies and compliance with the requirements of this rule.

4.1.c. The governing authority shall adopt bylaws, subject to amendment, which require it to:

4.1.c.1. Appoint members to the medical staff;

4.1.c.2. Approve the bylaws and regulations of the medical staff;

4.1.c.3. Define the committees of the governing authority and their functions and responsibilities;

4.1.c.4. Develop and maintain a formal liaison with the medical staff;

4.1.c.5. Appoint a full time administrator and delegate to him or her executive authority and responsibility;

4.1.c.6. Maintain an up-to-date file of all medical and ancillary staff licensed, registered, or certified by the appropriate agency of the State;

4.1.c.7. Provide for the proper control of all assets and funds, including requiring annual audits;

4.1.c.8. Provide for an assessment of all hospital clinical departments and functions provided directly or under contract through review and approval of the hospital's quality improvement reports at intervals defined by the governing body, but at least yearly;

4.1.c.9. Determine the scope of services to be offered by the hospital; and,

4.1.c.10. Ensure the hospital is meeting all State requirements, inclusive of certificate of need, for the addition or termination of services, and notification of the Department of Health and Human Resources, Office of Health Facility Licensure and Certification of the additions or termination of services.

4.1.d. The governing authority shall record, sign, and retain in the hospital as a permanent record minutes of all of its meetings and the meetings of all of its committees, including a record of attendance for a minimum of five (5) years.

4.1.e. The governing authority shall ensure for the provision of a safe physical plant, equipped, and staffed to maintain adequate facilities and services for hospital patients.

4.1.f. The governing authority shall ensure there is a system in place to prevent, control, investigate, and resolve, through appropriate actions, infections and communicable diseases within the hospital.

4.1.g. The governing authority is responsible for the effective operation of the patient grievance process.

4.2. Consumer Representation on Board of Directors for Section 6a Hospitals.

4.2.a. The Boards of Directors of a Section 6a hospital shall designate at least forty percent (40%) of its voting members as consumer representatives with an equal number of the representatives in each of the following four (4) consumer categories: small business representatives; organized labor members; elderly persons or persons whose income is less than the national median income. If the product of four-tenths (4/10) multiplied by the number of the voting members, when rounded to the next higher whole number, is not a multiple of four (4), then the number of representatives in the consumer categories may be unequal. The number of representatives in any consumer category shall not exceed the number of consumers in any other

category by more than one (1).

4.2.b. A member of the Board of Directors of a Section 6a hospital may not be designated by the hospital in more than one (1) consumer representative category.

4.2.c. A Section 6a hospital may change the designation of its consumer representatives from one (1) category to another by notifying the Director in writing within thirty (30) days of the change.

4.2.d. If a person designated as a consumer representative on a Section 6a hospital's Board of Directors ceases to meet the definition of a consumer representative, then the person may retain his or her designation until the end of his or her term or until the next license application is submitted for the applicable hospital, whichever occurs first.

4.2.e. Each Section 6a hospital shall maintain a file containing affidavits by its consumer representatives as to their consumer category. The affidavits shall be in a form approved by the Director.

4.2.f. If a hospital's designation of a consumer representative is selected for verification or is the subject of a complaint received by the Director, upon request from the Director, the consumer representative shall provide the Director with whichever of the following documentation is applicable to his or her consumer designation:

4.2.f.1. For small business representatives, a copy of the financial statement of the business, workers' compensation filing or other evidence of business size acceptable to the Director;

4.2.f.2. For organized labor members, written verification of membership from the union;

4.2.f.3. For elderly persons, a birth certificate, a copy of his or her driver's license, or an evidence of age acceptable to the Director; or

4.2.f.4. For persons whose income is less than the national median income, written verification by the Internal Revenue Service, as authorized by the board member, that the incomes of the persons are less than the established national median income, or copies of the signature pages of federal income tax returns, or an affidavit that the filing of the returns with the federal government was not required.

4.2.g. If the consumer representative designation of a board member of a Section 6a hospital is selected for verification or if the consumer representative designation of a board member of a Section 6a hospital is the subject of a complaint and if, upon request by the Director, the consumer representative does not provide adequate documentation to justify the designation, and if, after written notice to the hospital, the board member has not been replaced before that current license for the hospital is no longer in effect, the Director shall consider the hospital to be out of compliance with subsection 4.2 of this rule.

4.2.h. The Board of Directors of each Section 6a hospital shall develop a procedure to ensure the consideration of women, racial minorities and the handicapped in the selection of consumer representative board members and document that the procedure has been followed.

4.2.i. In no event shall a Board of Directors of a Section 6a hospital be required to be composed of more consumer representatives than are necessary to achieve forty percent of the voting members of the board, regardless of the number of hospitals for which the board is the governing authority.

4.3. Hospital Administrator.

4.3.a. The governing authority shall appoint a hospital administrator qualified by education and experience, who is responsible for:

4.3.a.1. Directing, coordinating and supervising the administration of the hospital;

4.3.a.2. Carrying out the policies of the governing authority; and

4.3.a.3. Ensuring compliance with the rules of the medical staff as established in subsection 11.2 of this rule.

4.3.b. The administrator shall serve as liaison to the governing body, medical staff and other professional and supervisory staff.

4.4. Patient Rights.

4.4.a. The administrator shall ensure that the hospital informs each patient, family members or interested persons of:

4.4.a.1. The patient's rights in advance of furnishing care; and

4.4.a.2. The process for submission of a patient grievance. This process should include informing the interested parties of the name of the hospital contact person and the address and telephone number of the Office of Health Facility Licensure and Certification.

4.4.b. The hospital shall develop and implement a written policy and procedure designating how each patient shall be informed of his or her rights in accordance with the hospital's specific manner of operation.

4.4.c. Patient rights include but are not limited to the following:

4.4.c.1. The right to be informed of his or her rights, to participate in the development and implementation of his or her plan of care and to make decisions regarding that care;

4.4.c.2. The facilitation and the communication of information to the patient, family, and/or other legally responsible party regarding understanding and participating in the plan of care;

4.4.c.3. The right to formulate advance directives and to have those

directives followed;

4.4.c.4. The right to privacy and to receive care in a safe setting;

4.4.c.5. The right to be free from all forms of abuse or harassment;

4.4.c.6. The right to be free from the use of seclusion and restraints of any form that are not medically necessary or are used as a means of coercion, discipline, convenience or retaliation by staff;

4.4.c.7. The right to confidentiality of his or her medical records as defined in subsection 7.2 of this rule; and,

4.4.c.8. The right to access information contained in his or her clinical records within a reasonable time, as defined by hospital policy.

4.4.d. The corporation shall provide, in a timely manner, skilled interpreters and personnel skilled in communicating with vision and hearing impaired individuals either by direct employment with the corporation or by employment under a contract with the corporation.

4.4.e. The hospital shall establish a process for prompt resolution of patient grievances and shall inform each patient of the person to contact to file a grievance.

4.4.e.1. The grievance process shall specify time frames for review of the grievance and the provision of a response.

4.4.e.2. In its resolution of the grievance, the hospital shall provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion of the investigation.

4.4.f. A licensed hospital shall permit patient visitation privileges for non-relatives

unless otherwise requested by the patient or legal designee. For the purposes of this section, the term "legal designee" means and includes those persons eighteen years of age or older, appointed by the patient to make health care decisions for the patient.

64-12-5. Physical Facilities, Equipment, and Related Items.

5.1. General Requirements.

5.1.a. The provisions of this Section shall apply to all hospitals. If the Director determines that changes necessary for compliance with this rule would create undue hardship for hospitals in existence at the time this rule becomes effective, the hospital may be governed by rules that were in effect at the time the hospital or an addition or renovation was completed.

5.1.b. The following documents are adopted as construction, equipment, physical facility, and related procedural standards for all existing hospitals, all new construction and any additions, alterations, renovations, or conversions of existing buildings:

5.1.b.1. The relevant sections of the 2001 edition of The Guidelines for Design and Construction of Hospitals and Health Care Facilities as recognized by the American Institute of Architects Academy of Architecture for Health with assistance from the United States Department of Health and Human Resources shall be used as planning standards;

5.1.b.2. The National Fire Protection Association codes and standards relevant to Health Care Facilities including the National Electric Code and the 2002 Edition of NFPA 99 Standard for Health Care Facilities; and

5.1.b.3. Applicable rules of the State Fire Commission including the State Building Code. When standards of this rule exceed requirements of the State Fire Commission including the State Building Code, this rule takes precedence.

5.1.c. The hospital shall comply with the guidelines set forth in the Americans With Disabilities Act 42 U.S.C. 12101, *et seq.*

5.1.d. Door widths of all patient rooms, delivery rooms and any room where entrance of an assembled bed may be required shall be at least three (3) feet, eight (8) inches.

5.1.e. No door shall open into the corridor except those on rooms used for janitorial purposes or toilet room doors. Bathroom doors shall open outward into patient rooms.

5.1.f. Corridors, stairways, and elevators shall be of a width and design that shall easily accommodate the removal of patients in a bed, including beds with traction equipment, and shall be constructed and maintained in compliance with all safety regulations and requirements. Use of these areas for purposes other than for which they were originally designed shall not be permitted at any time.

5.1.g. Handrails shall be installed in all corridors and adjacent to ramps, inclines and passageways used by patients in an extended care unit operated in conjunction with a hospital or in any hospital or hospital unit specializing in chronic or convalescent care.

5.1.h. Screens shall be provided for all exterior openings that are left open for extended periods. Where provided, screen doors shall open outward and shall be self closing.

5.1.i. Operable windows shall have screens and safety design features.

5.1.j. The hospital shall have a system in place to ensure routine biomedical equipment checks and maintenance for all applicable medical equipment.

5.2. Site Selection.

5.2.a. The site of any hospital shall, except in circumstances approved by the Director, be located in relation to the center of population,

close to where patients live, where competent medical and surgical consultation is readily available and where employees can be recruited and retained. There shall be good drainage, electricity, telephone, public transportation and other necessary facilities available on or near the site.

5.2.b. Local building codes and zoning restrictions shall be observed. Information as to zoning restrictions is available from local authorities. Where local codes or regulations permit lower standards than required by this rule, the standards contained in this rule take precedence.

5.2.c. Site conditions shall comply with the relevant sections of the 2001 edition of The Guidelines for Design and Construction of Hospitals and Health Care Facilities as recognized by the American Institute of Architects Academy of Architecture for Health.

5.2.d. The hospital shall request, in writing, an inspection of a proposed hospital site and obtain approval for construction from the Director before beginning construction.

5.3. New Construction.

5.3.a. Hospitals constructed subsequent to the effective date of this rule shall comply with the General and Psychiatric Hospital sections, as applicable, of the latest edition of Guidelines for Construction and Equipment of Hospital and Medical Facilities.

5.3.b. The hospital shall submit to the Director for review, complete construction drawings and specifications for any hospital construction project which alters a floor plan, impacts life safety or requires approval under W. Va. Code §16-2D-1 *et seq.* prior to beginning work on the project. An architect and/or engineer registered to practice in West Virginia, shall prepare and sign the drawings and specifications including architectural, life safety, structural, mechanical and electrical drawings and specifications.

5.4. Additions and Renovations.

5.4.a. Additions and renovations or alterations of any hospital which are begun after the effective date of this rule shall comply with the General and Psychiatric Hospital sections, as applicable, of the latest edition of Guidelines for Design and Construction of Hospitals and Health Care Facilities.

5.4.b. Prior to starting any renovations the facility shall complete an infection control and safety risk assessment and shall develop a plan to control exposure of patients, employees and the public. This plan shall be implemented during construction phases.

5.4.c. Minor renovations that do not alter floor plans or impact life safety or require approval under W. Va. Code 16-20-1 *et seq.*, may not require approval from the Office of Health Facility Licensure and Certification or the services of an architect.

5.4.d. The hospital shall submit to the Director for review, complete construction drawings and specifications for any hospital construction project which alters a floor plan, impacts life safety or requires approval under W. Va. Code §16-2D-1 *et seq.* prior to beginning work on the project. An architect and/or engineer registered to practice in West Virginia, shall prepare and sign the drawings and specifications including architectural, life safety, structural, mechanical and electrical drawings and specifications. Minor renovations which alter floor plans may not require the services of an architect and a full set of drawings. However, an actual as built drawing is required for the specific area to be renovated. The approval of minor renovations shall be determined by the Secretary.

5.4.e. Any existing building, or portions of that building converted for use as a hospital shall comply with Section 5 of this rule whether or not in use as a hospital, as of the effective date of this rule.

64-12-6. Operational Services.

6.1. Safety, Sanitation, Housekeeping

and Maintenance.

6.1.a. The hospital's water supply shall comply with the Department's Administrative Rules, Public Water Systems, 64CSR3, and Cross Connection and Backflow Prevention, 64CSR15.

6.1.b. Sewage disposal shall comply with the Department's Administrative Rules, Sewage System Rules, 64CSR9.

6.1.c. The overall condition of the physical plant shall be maintained to assure and promote safe, clean, and sanitary conditions.

6.1.d. Accumulated waste material shall be removed daily or more frequently as necessary.

6.1.e. The grounds shall be kept in a sanitary, safe, and presentable condition.

6.1.f. The premises shall be kept free from rodent and insect infestation.

6.1.g. There shall be sufficient supplies and equipment, properly stored and conveniently located, to permit frequent cleaning of floors, walls, woodwork, windows and screens, and to facilitate all necessary building and ground maintenance.

6.1.h. Stairwells and corridors shall be kept free from obstruction at all times.

6.1.i. All garbage shall be stored and disposed of in a manner that shall not permit the transmission of disease, create a nuisance, or provide a breeding place for insects and rodents.

6.1.j. All garbage containers shall be watertight, nonabsorbent, rodent proof, and have tight-fitting covers.

6.1.k. Garbage containers shall be emptied at frequent intervals and those containers that do not use an auxiliary liner shall be thoroughly washed and sanitized each time they are emptied.

6.1.1. The hospital shall comply with the Department's Administrative Rules, Infectious Medical Waste, 64CSR56.

6.2. Lighting

6.2.a. All rooms and areas in the hospital shall be provided with sufficient artificial illumination to enable personnel to properly carry out procedures normally performed.

6.2.b. Emergency lighting shall be provided for exits, stairs, corridors, nurseries, emergency rooms, delivery rooms, operating rooms, soiled utility rooms, medication preparation areas, and other areas necessary for safe effective patient care.

6.2.c. Emergency lighting shall be supplied by an automatic emergency generator or the equivalent and each shall be tested routinely.

6.2.d. The dates on which the testing is conducted shall be recorded in a permanent log for a minimum of five years.

6.3 Medical Gas Systems and Indoor Air Quality

6.3.a. All hospitals shall provide medical gas systems in accordance with the 2002 Edition of N.F.P.A. 99 and Section 5 of this rule.

6.3.b. Medical gas systems shall be inspected and tested routinely as defined by hospital policy.

6.3.c. All hospitals shall provide air systems that are virtually free of dust, dirt, odor, chemical, and radioactive pollutants. Standards as set forth in the Guidelines for Design and Construction of Hospitals and Healthcare Facilities and/or A.A.S.H.R.A.E., American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. shall be used.

6.3.d. Facilities shall have in place a management plan for all indoor air systems which shall provide information about filters, supply air

including outdoor air, return air including exhaust air, pressure relationships between critical areas, space temperatures, and relative humidity levels in critical areas

6.4. Laundry Services.

6.4.a. The provision of laundry services shall comply with Section 5 of this rule.

6.4.b. The hospital shall make provisions for the proper cleaning of linens with special provisions for handling and decontamination of contaminated linens

6.4.c. Hospitals maintaining and operating a laundry within the hospital building shall provide ventilation for the elimination of steam and odors and proper insulation to prevent the transmission of noise to patient areas.

6.4.d. The laundry shall have:

6.4.d.1. Separation of clean and soiled linen, receiving, storing and sorting areas with facilities to wash hands;

6.4.d.2. Soiled linen processing areas separate from patient care, food preparation, clean supply, and equipment storage areas;

6.4.d.3. Washing, extracting, drying, and ironing areas equipped with all necessary safety appliances and meeting all sanitary requirements; and,

6.4.d.4. A storage area for laundry supplies.

6.4.e. When an off-site commercial laundry service is used, there shall be:

6.4.e.1. A soiled linen collection and storage area separate from patient care areas, food preparation, clean supply, and equipment areas; and,

6.4.e.2. A central clean linen

storage area.

6.4.f. Contaminated newborn nursery linen shall be separately stored and washed as shall linen contaminated with radioactive material.

6.4.g. A supply of clean linen shall be provided sufficient for the hospital's capacity.

6.4.h. Soiled linen shall be bagged for collection at the site of use in bags that prevent leakage.

6.4.i. All personnel involved in the collection, transportation, sorting and washing of soiled linens shall:

6.4.i.1. Receive periodic job related training, as defined by hospital policy;

6.4.i.2. Have access to hand washing facilities; and

6.4.i.3. Use appropriate personal protective equipment.

6.5. Central Sterilization and Supply

6.5.a. The hospital shall provide for the decontamination and sterilization of reusable equipment and supplies for all areas of the hospital.

6.5.b. If the hospital practices in-house sterilization, it shall have a central sterilizing and supply room to prepare, sterilize, store, and dispense sufficient sterile supplies and equipment to all units of the hospital.

6.5.c. The hospital shall have policies and procedures, using acceptable clinical standards, for the decontamination and reprocessing of supplies.

6.5.d. A cabinet or other suitable enclosed space shall be provided for storing sterile equipment and supplies in a convenient and orderly manner.

6.6. General Storage

6.6.a. All clean and sterile storage shall be concentrated in one area on each unit to the extent possible. Mechanical maintenance items may be in a separate area.

6.6.b. All soiled storage shall be concentrated in one area on each unit separate from clean storage.

6.6.c. Hand washing facilities shall be in or convenient to work areas.

6.6.d. Separate storage areas shall be provided in each applicable hospital unit for flammable materials such as oxygen gases.

64-12-7. Paramedical Services.

7.1. Pharmaceutical Service

7.1.a. A licensed pharmacist shall be responsible for developing, supervising, and coordinating all pharmacy services, including the distribution of samples, provided at the hospital.

7.1.b. The pharmacist may be employed on a full-time, part-time, or consulting basis.

7.1.c. All compounding, packaging, and dispensing of drugs and biologicals shall be under the supervision of a pharmacist and performed consistent with Federal and State laws.

7.1.d. All drugs, including drugs stored outside the pharmacy, shall be stored in locked cabinets, medication rooms, or medication carts approved by the Director of Pharmacy. This shall ensure the integrity of the medications and safety for the patients and the general population. It shall further ensure medications are only accessible to authorized personnel according to hospital policy.

7.1.e. When a pharmacist is not available, drugs and biologicals may be removed from the pharmacy or storage area only by

personnel authorized in accordance with Federal and State law and hospital and medical staff policies.

7.1.f. Drugs and biologicals not specifically prescribed as to a time or number of doses shall be stopped after a reasonable period of time which is pre-determined by medical staff policy.

7.1.g. All medication storage areas shall have a designated area or compartment for the separate storage of external medications.

7.1.h. The medication preparation area shall be clean, well illuminated and have adequate space for the storing and preparation of medications.

7.1.i. Narcotics and controlled drugs which are required to conform to Federal or State regulations or rules shall be kept within a secure storage area accessible only to authorized personnel.

7.1.j. Surplus narcotics or narcotics with an expired date shall be disposed of according to applicable Federal and State regulations.

7.1.k. A record shall be maintained or a system developed to track the receipt and distribution of controlled drugs.

7.1.l. Outdated, mislabeled, or otherwise unusable drugs and biologicals shall not be accessible for patient use.

7.1.m. Except for medication packaged for unit doses, all unused medications shall be discarded when orders have been discontinued or the patient has been discharged from the hospital.

7.1.n. Drug administration errors, adverse drug reactions, and incompatibilities shall be immediately reported to the attending practitioner and Director of Pharmacy and investigated using current and readily accessible drug and patient information. This information

shall be evaluated as part of the hospital quality improvement program.

7.1.o. The medical staff shall establish a formulary system and review it as necessary.

7.1.p. The Director of Pharmacy shall provide a system for the recognition and treatment of any drug/drug or food/drug interactions and incompatibilities.

7.1.q. Drugs and biologicals shall be prepared and administered in accordance with:

7.1.q.1. Federal and State law;

7.1.q.2. The orders of the practitioner or practitioners responsible for the patient's care; and

7.1.q.3. Accepted standards of practice.

7.2. Medical Records Department and Information System.

7.2.a. The hospital shall maintain a medical records department and information system sufficient to support the maintenance of patient records, including computer generated medical records, and quality improvement activities. The medical records department shall be under the supervision of a person qualified by training and experience as defined by hospital policy.

7.2.b. The hospital shall ensure that a coding and indexing system is used that allows for retrieval of medical records by diagnosis and procedures.

7.2.c. The hospital shall employ adequate personnel to ensure prompt completion, filing, and retrieval of records.

7.2.d. The hospital shall maintain a medical record for every individual evaluated or treated in the hospital on an inpatient and an outpatient basis.

7.2.e. The hospital shall use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.

7.2.f. The hospital shall preserve medical records, including records of patients treated in the emergency room or outpatient department, for a minimum of five (5) years in their original form or in a legally reproduced form.

7.2.g. The hospital shall have procedures in place for ensuring the confidentiality of patient records and for ensuring that only authorized individuals can gain access to or alter patient records.

7.2.h. The hospital shall only release originals or copies of medical records in accordance with Federal and State laws or upon receipt of an order from a court of competent jurisdiction.

7.2.i. The hospital shall provide copies of medical records and any other pertinent data within forty-eight (48) hours of a written request by the Office of Health Facility Licensure and Certification.

7.2.j. The inpatient medical record shall include at a minimum the following:

- 7.2.j.1. Documentation to justify admission and support the diagnosis;
- 7.2.j.2. Patient identification;
- 7.2.j.3. The date of admission and discharge;
- 7.2.j.4. Advance directives information;
- 7.2.j.5. A history of the present illness;
- 7.2.j.6. A personal and family history;

7.2.j.7. A physical examination completed within thirty (30) days prior to admission or within forty-eight (48) hours after admission. If the history and physical was performed within the thirty (30) days prior to admission there shall be an updated note addressing the patient's current status and/or any changes in the patient's status. This note shall be on or attached to the history and physical. A history and physical performed within seven (7) days prior to admission does not require an updated note;

- 7.2.j.8. Practitioner's orders;
- 7.2.j.9. Examinations and consultations;
- 7.2.j.10. Clinical laboratory and imaging results;
- 7.2.j.11. Provisional or working diagnosis;
- 7.2.j.12. Treatments and medications provided;
- 7.2.j.13. Surgical reports including operative and anesthesia records;
- 7.2.j.14. Gross and microscopic pathological findings;
- 7.2.j.15. Progress and nurses' notes;
- 7.2.j.16. Any assessments implemented;
- 7.2.j.17. Final diagnosis and condition on discharge;
- 7.2.j.18. Multi-disciplinary discharge planning and the physician's discharge summary;
- 7.2.j.19. Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law, if applicable, to require written

patient consent;

7.2.j.20. Death
certificate when the hospital considers it necessary;
and

7.2.j.21. Autopsy
findings, if an autopsy is performed.

7.2.k. The hospital shall maintain a
medical record for each newborn infant, including
stillborn infants, separate from the mother's record.

7.2.l. A short form medical record
may be used for patients who are in the hospital less
than forty-eight (48) hours except in the case of
maternity and newborn infants. The short form
shall contain a minimum of the following:

7.2.l.1. Documentation of a
history and physical;

7.2.l.2. Diagnosis; and

7.2.l.3. Any treatment and
services provided.

7.2.m. All entries shall be legible
and shall be authenticated and dated promptly by
the person, identified by name and discipline, who
is responsible for ordering, providing or evaluating
the service furnished.

7.2.n. Authentication may include
signatures which may be electronic.

7.2.o. All clinical information
pertaining to each patient shall be filed in the
patient's medical record.

7.2.p. All orders for medication or
treatment shall be recorded in writing or validated
by a secure electronic system and filed in the
patient's medical record or appropriately filed in the
patient's electronic record. The use of signature
stamps or electronic identification is acceptable
when a mechanism is in place to ensure the stamp
or identifier is limited to use by the identified
person only.

7.2.q. The hospital shall ensure that
verbal and telephone orders shall be given to
registered professional nurses and other licensed or
registered health care professionals, in their area of
training and professional expertise, when authorized
by the medical staff policies: Provided, That any
verbal or telephone order received by a licensed or
registered health care professional shall also be
communicated to the registered professional nurse
responsible for the overall care of that patient.

7.2.r. Physicians shall countersign
and date all verbal and telephone orders at the next
hospital visit in which a patient visit occurs and an
entry is written in the chart.

7.2.s. A plan of care shall be
developed and maintained for each patient through
the coordinated efforts of the registered professional
nurses and other health care professionals involved
in the care of the patient. The plan of care shall be
maintained as part of the patient's medical record.

7.2.t. Only abbreviations approved
by the medical staff shall be used in medical
records.

7.2.u. Medical records shall be
completed, authenticated, and signed by the
physician or dentist within thirty (30) days
following the discharge of the patient.

7.2.v. The hospital shall report a
complete list of all births, deaths, and fetal deaths
occurring within each month in licensed hospitals
by the tenth of the following month on forms
approved by the Director or on a comparable
computer printout approved by the Director to the
state registrar of vital statistics.

7.2.w. The hospital shall send all
completed birth certificates to the state registrar of
vital statistics within ten (10) days following the
birth.

7.2.x. Licensed hospitals shall
comply with the Department's Administrative
Rules, Reportable Diseases, 64CSR7, AIDS Related
Medical Testing and Confidentiality, 64CSR64, and

any other applicable rules regarding the reporting of diseases, infections, or laboratory test results to the State.

7.2.y. The hospital shall have a procedure to provide information to the cancer registry as defined in W. Va. Code 16-5A-2a.

7.2.z. In the event of closure, a hospital shall make arrangements for medical record retention and retrieval. The hospital shall provide written documentation of this arrangement to the Director.

7.2.aa. The hospital shall have a mechanism in place to supply to any patient who has received services from the hospital, whether on an inpatient or outpatient basis, upon request, one (1) itemized statement which describes with specificity the exact service or medication for which a charge is assessed to the patient at the institution, at no additional cost to the patient. In the event of the death of the patient, an authorized individual to be determined on a case by case basis may make the request and shall receive the statement at no additional cost.

7.3. Dietetic Service.

7.3.a. The hospital dietetic service shall comply with the Department's Administrative Rules, Food Service Sanitation Rules, 64CSR17.

7.3.b. There shall be an organized dietetic service, planned, equipped, and staffed to meet the nutritional needs of the patient population.

7.3.c. The hospital shall have a full-time employee who:

7.3.c.1. Serves as supervisor of the dietetic services;

7.3.c.2. Is responsible for daily management of the dietetic services; and

7.3.c.3. Is qualified by experience or training.

7.3.d. Provisions shall be made for continued in-service training of the designated dietetic service supervisor.

7.3.e. The food services department shall be under the direction of a full-time dietician or a person with training and experience in food service administration. Only a qualified dietician or other person with suitable training may direct the food services department.

7.3.f. Responsibilities of the Director of the Dietetic Services shall include:

7.3.f.1. Approval of menus;

7.3.f.2. Establishment of policies and procedures;

7.3.f.3. Patient and family counseling; and

7.3.f.4. Maintenance of liaison with other services.

7.3.g. There shall be a qualified dietician available on a full-time, part-time, or a consultant basis. A qualified dietician shall be registered or eligible for registration with the Commission on Dietetic Registration of the American Dietetic Association and be licensed in the State of West Virginia by the Board of Licensed Dietitians.

7.3.h. The dietetic service department shall maintain records which include the following:

7.3.h.1. A staffing schedule for all persons employed full-time or part-time in the food service department indicating the number of hours each employee works weekly; and

7.3.h.2. A job description for each type of food service department position with verification that each employee has been familiarized with his or her duties and responsibilities.

7.3.i. The dietetic service department shall post written and dated menus planned at least fourteen (14) days in advance for both therapeutic and general diets in appropriate places in the food preparation area and be available to administrative personnel.

7.3.j. Menus, as served, with all substitutions noted, shall be filed in the dietetic service department for at least four (4) weeks.

7.3.k. All therapeutic diets, including between meal nourishments, shall be prepared and served as prescribed by the attending practitioner.

7.3.l. A current therapeutic diet manual approved by the dietitian and medical staff shall be readily available to the medical, nursing and dietetic service personnel.

7.3.m. The hospital shall employ adequate personnel to perform the functions of the dietetic service department.

7.3.n. The hospital shall provide procedures to prevent the contamination of meals and other items prepared or served by the dietetic service department employees.

7.3.o. The hospital shall provide an in-service training program designed to meet the needs of dietetic service employees, including training in proper food sanitation practices and personal hygiene.

7.3.p. The hospital may contract with an outside company for the dietetic service if the outside company has a qualified dietitian who serves the hospital on a full-time or part-time consulting basis, and if the company complies with the Department's Administrative Rules and Food Service Sanitation Rules, 64CSR17.

7.3.q. Dry or staple food items shall be stored at least six (6) inches off the floor in well-ventilated rooms which are not subject to contamination by sewage, water backflow, contaminated water, leakage, rodents, or vermin.

7.3.r. Potentially perishable foods shall be maintained at a temperature of forty-five (45) degrees Fahrenheit or below. Refrigerators and storerooms used for perishable foods shall be equipped with reliable thermometers.

7.3.s. All ice used in contact with food or drink shall comply with the Department's Administrative Rules, Public Water Systems, 64CSR3.

7.3.t. The dietetic service department shall retain a sample of potentially hazardous foods from the menu of each meal under adequate refrigeration for a period of at least twenty-four (24) hours after serving. By this method, proper samples of food are available for laboratory examination in the event of a food borne disease outbreak.

7.3.u. Poisonous and toxic materials shall bear warning labels, be stored separately from food or equipment used on preparing and serving food and shall be used only in ways that shall neither contaminate food nor be hazardous to employees.

7.3.v. Food being served or transported shall be protected from contamination and held at the proper temperature in clean containers, cabinets or serving carts.

7.3.w. Garbage and refuse shall be placed in impervious containers equipped with tightly fitting covers.

7.3.x. Garbage containers shall be stored in a safe area or refrigerated space pending removal and shall be removed from the premises and sanitized daily.

7.4. Infection Control

7.4.a. The hospital shall provide a sanitary environment to avoid sources and transmission of infections and communicable diseases.

7.4.b. The hospital shall have an

active surveillance and education program for the prevention, early detection, control, and investigation of infections and communicable diseases.

7.4.c. The program shall include implementation of a nationally recognized system of infection control guidelines.

7.4.d. The program shall be both hospital-wide and program-specific and enforced by the individual designated by the medical staff.

7.4.e. The hospital shall designate a person or persons as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases for patients and personnel.

7.4.f. The infection control professional or designee shall maintain a log of incidents related to infections and communicable diseases.

7.4.g. The hospital administrator, medical staff, and the Director of Nursing shall ensure that the quality improvement program and training programs address problems identified by the infection control officer or officers and be responsible for the implementation of successful corrective action plans in affected problem areas.

64-12-8. Patient Care Units or Departments.

8.1. General Requirements.

8.1.a. The hospital shall develop and maintain all patient care units or departments in accordance with Section 5 of this rule.

8.1.b. All patient care areas and units shall be segregated from areas used by the public or occupied by the hospital ancillary facilities, including adjunct diagnostic and treatment areas.

8.1.c. All areas in which patient care is rendered shall maintain or have easy access to an

emergency cart for use in the event of patient respiratory or cardiac arrest. The contents of this cart, such as medications and supplies shall be determined by hospital policy. The frequency of monitoring of the contents of the emergency carts shall be determined by nursing service policies and procedures.

8.1.d. The hospital shall develop protocols for implementation of respiratory and cardiac arrest care on a twenty-four (24) hour basis using all necessary staff throughout the hospital including any available physicians for immediate emergency response.

8.1.e. Each nursing unit and patient service department shall maintain a current policy and procedure manual governing the specific care provided by that unit or department. The manual shall be reviewed and revised at least every three (3) years.

8.2. Patient Care and Nursing Unit

8.2.a. The hospital shall provide private rooms to meet the needs of patients and programs of the hospital. There shall be no more than four (4) beds in each patient room in existing construction. In construction after the approval date of this rule, there may be no more than two (2) patient beds in each room.

8.2.b. No sleeping area may be located below ground level.

8.2.c. Each one (1) bedroom shall contain a minimum floor area in existing construction of one hundred (100) square feet or one hundred twenty (120) square feet in new construction. Each multiple bedroom shall contain a minimum floor area of eighty (80) square feet for each bed.

8.2.d. Each patient room shall have direct entry from a corridor.

8.2.e. Artificial light shall be provided and include general illumination and other sources of illumination sufficient for reading,

observations, examinations, and treatments.

8.2.f. All new or renovated facilities shall have a night light control switch located at the point of entry into patient rooms.

8.2.g. Patient rooms shall have movable furnishings. The director may make exceptions as needed regarding all furnishings for psychiatric hospitals. Patient rooms shall be equipped with the following:

8.2.g.1. An adjustable bed with side rails;

8.2.g.2. A cabinet or bedside table;

8.2.g.3. An over-bed table;

8.2.g.4. A wastepaper receptacle with impervious disposable liner or a disposable waste receptacle; and

8.2.g.5. Personal care items such as water pitcher, cups, emesis basin and oral and personal hygiene products as necessary.

8.3. Obstetric Service

8.3.a. Obstetric facilities, including accommodations for mothers and infants, and the delivery suites, shall be a self contained unit and shall be segregated from all other parts of the hospital.

8.3.b. The supervision of the obstetric service shall be under the direction of a professional registered nurse licensed in West Virginia with experience in obstetric care.

8.3.c. The hospital shall establish specific policies for the training and competency of nursing personnel from other areas of the hospital working in the obstetric and neonatal care areas, or nursing personnel from the obstetric and neonatal care areas working on other units of the hospital.

8.3.d. Nursing personnel shall not move between perinatal and non-perinatal units without training and orientation to these areas.

8.3.e. The obstetric/delivery unit, the obstetric nursing unit, and the nursery shall be designed so that prenatal, natal, and postnatal processes are a continuous, safe, and satisfying experience for mother and infant.

8.3.f. Caesarean deliveries shall be performed in a caesarean delivery room suite or in the hospital's operating room.

8.3.g. The Caesarean delivery room shall be properly furnished, stocked, and maintained at all times to perform Caesarean delivery procedures.

8.3.h. As determined by medical staff, there shall be equipment for general anesthesia and a supply of drugs and anesthetics ordinarily needed for spinal, epidural, and/or pudendal anesthesia available at all times.

8.3.i. A heated bassinet or isolette shall be ready for the reception and care of the newborn infant in all delivery suites.

8.3.j. There shall be supplies and equipment for resuscitation of mother and newborn.

8.3.k. Staff shall maintain current certification in neonatal resuscitation.

8.3.l. The hospital shall establish and make available in all delivery suites a means of identification for each infant, approved by the medical staff, which shall be applied at the time of delivery in the delivery suite.

8.3.m. The medical staff or designee shall instill in the eyes of the newborn baby medications approved by the medical staff for the prevention of inflammation, according to current standards of practice.

8.3.n. Birthing rooms and/or labor/delivery/recovery rooms are considered as

delivery rooms for the purposes of this rule.

8.3.o. The hospital shall include the beds that are used for postnatal care in the count of the hospital's licensed beds.

8.3.p. Noninfectious patients may be admitted to the obstetrics unit according to policies and procedures for all services approved by the medical staff. If a patient develops an elevated temperature, she shall be moved to another location within the hospital.

8.4. Nursery

8.4.a. A separate nursery shall be available for the care of newborn infants. The nursery shall not be used for any other purpose and shall be conveniently located in reference to the rooms of the mothers. The hospital shall provide postnatal provisions for the safety and security of the infant.

8.4.b. Nurseries shall provide twenty-four (24) square feet of floor space per bassinet with at least twelve (12) inches between bassinets.

8.4.c. A separate bassinet for each infant shall be provided, except in the case of multiple births in accordance with hospital policy.

8.4.d. In the case of each viable delivery, infants shall be weighed on accurate infant scales provided for each nursery.

8.4.e. There shall be other equipment and supplies essential for the care of newborns, including, but not limited to, isolettes and oxygen.

8.4.f. Commercially prepared formula shall be handled and prepared in a manner consistent with the requirements of the Department's Administrative Rules, Food Service Sanitation Rules, 64CSR17.

8.4.g. The hospital shall provide immediate segregation and isolation of any infant with a communicable infection.

8.4.h. All equipment shall be maintained separately for each infant.

8.4.i. The hospital shall furnish infant clothing and diapers.

8.4.j. The hospital shall include in the discharge planning process, instructions to the infant's care givers for feeding and care of the infant.

8.4.k. Air conditioning, heating and ventilation systems shall have supply delivered from ceiling outlets and return air shall be from the floor level.

8.5. Surgical Department

8.5.a. The surgical department shall be under the direction of a physician licensed in West Virginia by the West Virginia Board of Medicine or West Virginia Board of Osteopathy and experienced in the practice of surgery. The surgeon or his or her designee shall be available to the hospital staff at all times.

8.5.b. The surgical suites shall be self contained units under the supervision of a qualified registered professional nurse or physician experienced in the practice of surgery and licensed in West Virginia.

8.5.c. Access to the surgical area shall be limited to authorized personnel only.

8.5.d. There shall be no through traffic to any other part of the hospital.

8.5.e. The surgical suites shall be separated physically from the delivery unit and emergency unit.

8.5.f. The hospital shall maintain a current list of surgical privileges for all practitioners conducting surgical procedures both in the surgery suite and the area where the scheduling of surgical procedures is completed. The list shall be updated periodically and at least every two (2) years with additions and/or deletions of surgical privileges.

8.5.g. The hospital shall maintain a log for daily documentation of each surgical procedure and shall include the following information:

8.5.g.1. The patient's name;

8.5.g.2. The patient's hospital identification number;

8.5.g.3. The date of the procedure;

8.5.g.4. Total time of the procedure;

8.5.g.5. Names of the surgeon or practitioner and any assistants;

8.5.g.6. Names of nursing personnel in attendance;

8.5.g.7. Type of anesthesia and name of person administering it; and

8.5.g.8. The procedure performed.

8.5.h. There shall be a complete patient history and physical work up in the chart of every patient prior to surgery, except in emergencies. If the history and physical has been done but is not yet recorded in the patient's chart there shall be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient.

8.5.i. A completed and signed informed consent form for the intended surgical procedure shall be in the patient's chart before surgery, except in emergencies.

8.5.j. The hospital shall ensure completion and authentication by the practitioner, of the operative report describing techniques, findings, and tissues removed or altered immediately following surgery. The content and format of the operative report shall be determined by hospital

policy.

8.5.k. Operating rooms shall be provided with adequate standard equipment and supplies to ensure safe surgical care.

8.5.l. Adequate provisions shall be made for the storage of sterile surgical supplies and instruments.

8.5.m. Separate scrub facilities with non-manual controls readily accessible to each operating room shall be provided.

8.5.n. The hospital shall have written policies concerning the use of flammable anesthetics in the event flammable anesthetics are used.

8.5.o. Staff clothing change areas shall be provided within the surgical suite.

8.6. Post-Anesthesia Care Unit

8.6.a. There shall be adequate provisions for immediate post-anesthesia care in a room or area separate from the surgical suite.

8.6.b. For each bed, sufficient area shall be allowed to permit space for bulky equipment and to afford access of personnel on all sides of the bed, including the head.

8.6.c. Beds shall be arranged so that all patients can be observed simultaneously.

8.6.d. Necessary equipment and adequate supplies shall be provided including space for proper storage.

8.6.e. Access to the post-anesthesia unit shall be limited to authorized personnel only.

8.6.f. The post-anesthesia unit shall be under the direction of a registered professional nurse licensed in West Virginia and experienced in the care and management of post-anesthesia patients.

8.6.g. At least one (1) registered professional nurse and when necessary, one (1) assisting person shall be in the post-anesthesia unit when a patient or patients are present.

8.6.h. The hospital shall record all pertinent information related to care provided while the patient is in the post-anesthesia unit in the patient's medical record. This includes physician orders, patient respirations, pulse and blood pressure, treatments and medications given. The patient's condition on admission to the unit and transfer from the unit shall also be recorded in the patient's record.

8.6.i. If patients are not transferred to the recovery room, provisions shall be made for direct observation by a registered professional nurse until they have regained consciousness and are transferred to the intensive care unit.

8.7. Anesthesia Department

8.7.a. The hospital shall have an organized anesthesia department under the medical direction of a qualified physician member of the medical staff licensed by the West Virginia Board of Medicine or West Virginia Board of Osteopathy in West Virginia who will be responsible for all anesthesia administered in the hospital.

8.7.b. Anesthesia may be administered only by a licensed practitioner permitted by State law to administer anesthesia, a certified registered nurse anesthetist as permitted by state law or other professionals as permitted by the medical staff and state law.

8.7.c. A practitioner qualified for the administration of anesthesia shall perform a pre-anesthesia evaluation no more than forty eight (48) hours prior to surgery.

8.7.d. The hospital shall ensure completion of an intra operative anesthesia record for all surgical patients.

8.7.e. A practitioner qualified for the administration of anesthesia shall perform a post

anesthesia evaluation within forty eight (48) hours of surgery for all inpatients.

8.7.f. The hospital's policy shall determine the content and format of the pre-anesthesia evaluation, intra operative anesthesia record, and the post anesthesia evaluation.

8.7.g. The hospital shall establish written policies for safeguards in the use of various types of anesthetics in accordance with the National Fire Protection Association.

8.7.h. The hospital shall store all equipment and medications used in administration of anesthesia in a secure, safe, and readily accessible location according to current professional standards. Qualified technicians shall service and maintain all equipment.

8.8 Pediatric Service

8.8.a. Hospitals providing pediatric care shall have separate rooms designated for pediatric use.

8.8.b. Adult and pediatric patients shall not be placed in the same room at the same time. Designated pediatric rooms may be used for providing adult care when the rooms are not needed for pediatric patients.

8.8.c. The hospital shall have proper facilities and procedures for the isolation of children with infectious or communicable diseases.

8.8.d. The hospital shall have pediatric emergency supplies, medications, and equipment organized and readily available on any patient care unit that provides pediatric services.

8.9. Specialty Care and Critical Care Unit

8.9.a. The hospital shall provide specialty care units, such as coronary care units and intensive care units, organized under the direction of a physician who is licensed in West Virginia and has experience in the specialty care provided.

8.9.b. The authority in determining criteria for admission, length of stay, and discharge and the resolution of operational problems shall be clearly delineated through policies developed cooperatively by the medical staff, nursing service, and administration and approved by the governing body.

8.9.c. A qualified physician shall be readily available to each unit at all times. The physician shall be available within thirty (30) minutes for a response or an in-person meeting according to hospital policy. One (1) physician may be available to more than one (1) specialty unit at one (1) time if the care provided is within his or her scope of practice.

8.9.d. The critical care unit organization and staffing shall be appropriate for the scope of services offered to ensure the health and safety of the patients.

8.9.e. The hospital shall provide nursing care under the supervision of a registered professional nurse licensed in West Virginia with experience in the specialty care provided.

8.9.f. Nursing personnel providing care in a specialty care unit shall have documented training and competence in the specific care provided.

8.9.g. An adequate number of staff shall be provided to ensure the health and safety of the patients.

8.9.h. A minimum of one (1) registered professional nurse shall be on duty at all times and available to provide direct patient care.

8.9.i. Beds in a specialty care unit shall be arranged or provided with visual surveillance equipment to enable the nursing personnel to observe all patients closely and frequently from the nurse's station.

8.9.j. Equipment in a specialty care unit shall include at a minimum:

8.9.j.1. Variable height, adjustable beds, and adequate storage space for equipment and personal effects;

8.9.j.2. Bedside emergency call systems;

8.9.j.3. Bedside suctioning equipment;

8.9.j.4. Bedside cardiac monitoring equipment with an alarm system that can be monitored from the bedside or a centralized location;

8.9.j.5. An external defibrillator;

8.9.j.6. Adequate respiratory care supplies and equipment for resuscitation; and

8.9.j.7. Sufficient supplies and equipment appropriate for the scope of services provided.

8.10. Outpatient Department

8.10.a. Outpatient services shall be provided under the supervision of a registered professional nurse licensed in West Virginia or other health care professional as appropriate for the service being offered.

8.10.b. Outpatient departments shall be easily accessible for all patients receiving treatment.

8.10.c. Outpatient departments shall be conveniently located to other hospital departments, such as the laboratory and the radiology department.

8.10.d. The outpatient department shall have accommodations and facilities to provide for the care, comfort and privacy of patients.

8.10.e. The outpatient department staffing patterns shall be based upon patient needs and services provided.

8.10.f. The outpatient department medical staff shall meet the same requirements and qualifications that apply to the attending medical staff of the hospital including credentialing and privilege determination by the hospital governing body.

8.10.g. The outpatient department shall maintain accurate and complete medical records for all outpatients, according to hospital policy.

8.11. Emergency Department.

8.11.a. All general acute care hospitals shall provide emergency services, unless it would result in an unnecessary duplication of services.

8.11.b. The emergency department shall be under the direction of a physician experienced in emergency medicine who is licensed in West Virginia and who is a member of the hospital medical staff.

8.11.c. Emergency department non-physician staff shall be under the supervision of a registered professional nurse licensed in West Virginia.

8.11.d. All emergency department staff shall be currently certified in, at least, basic life support measures.

8.11.e. At least one (1) registered professional nurse, certified in advanced cardiac life support, and other patient care personnel as needed, experienced in emergency care, shall be available for all hours that emergency services are provided.

8.11.f. All physicians employed to provide services in the emergency department shall maintain certification in advanced cardiac life support.

8.11.g. A physician or midlevel practitioner shall be on duty at the hospital to provide care whenever emergency services are provided.

8.11.h. If the hospital provides emergency services, the emergency department shall be located so as to permit easy access from automobiles and ambulances.

8.11.i. The emergency department shall keep records on all patients treated in the emergency department. The content and format of these records shall be determined by hospital policy.

8.11.j. Emergency services shall be integrated with other departments of the hospital.

8.11.k. The hospital shall take all measures necessary to ensure compliance with the requirements of Section 1867 of the Emergency Medical Treatment and Active Labor Act, even when emergency services are not available.

64-12-9. Extended Care Unit and Nursing Facility.

9.1. General Requirement - The extended care unit shall be located in a segregated, physically separated area of the hospital and shall include the usual complement of ancillary services required in the conventional care unit and meet the general rules and regulations for hospitals.

9.2. Special Requirements - Adequate space shall be provided for dining and recreation areas, special equipment storage, training toilets, showers and bath facilities. Handrails, drinking fountains, lavatories, thresholds and telephone alcoves shall be designed to meet the requirements of patients using crutches, walkers and wheelchairs.

9.3. Organization and Staffing

9.3.a. The extended care unit shall be organized under the direction of a committee of the medical staff. Written policies shall be developed by professional personnel including at least one (1) registered professional nurse.

9.3.b. The Nursing service shall be under the direction of a registered

professional nurse.

9.3.c. A registered professional nurse shall be in charge of the extended care unit on each tour of duty with sufficient other personnel to assure adequate patient care.

9.3.d. For all units with more than sixty (60) resident beds, the hospital governing body shall appoint a qualified administrator who holds a current valid license or emergency permit issued by the West Virginia Nursing Home Administrators Licensing Board.

9.3.e. The hospital shall appoint a physician licensed by the West Virginia Board of Medicine or the West Virginia Board of Osteopathy to serve as Medical Director for a unit with more than sixty (60) resident beds. The hospital physician Medical Director may fulfill these responsibilities for any unit or facility with sixty (60) or less resident beds.

9.3.f. The hospital shall assign a registered professional nurse as the Director of Nursing, different from the hospital Director of Nursing, who shall be responsible for care provided in an extended care unit with more than sixty (60) resident beds and shall ensure a sufficient number of personnel are available to provide adequate patient care.

9.3.g. The unit may use the hospital pharmacy services to fulfill the pharmacy services requirements as defined in the Code of Federal Regulations, 42 CFR 483.60. No written agreement is required if the pharmacist is an employee of the hospital.

9.3.h. The unit may use social workers employed by the hospital to provide services to unit patients: Provided, that at least one (1) social worker shall be assigned responsibility only for social work services for any unit with more than sixty (60) resident beds. The social worker shall have a license to practice social work in the state of West Virginia.

9.4. Financial Rights and

Responsibilities

9.4.a. An extended care resident or his or her representative lawfully authorized to manage fiscal matters on behalf of the resident have the right to manage his or her own personal financial affairs.

9.4.b. A hospital which manages or holds personal funds for extended care patients shall do so only upon written prior authorization of the patient or his or her representative lawfully authorized to manage fiscal matters on behalf of the patient, and shall hold the funds separately and in trust. Patient funds shall not be commingled with hospital operating or other funds.

9.4.c. The hospital shall administer the funds on behalf of the resident in the manner directed by the depositor.

9.4.d. The hospital shall render a true and complete account upon request to the depositor and at least quarterly to the resident on forms designated by the director.

9.4.e. Upon termination of the deposit, the hospital shall account to the depositor for all funds received, expended and held on hand on forms specified by the director.

9.4.f. If the hospital manages or holds personal funds for extended care patients, it shall make provision for the protection, in the form of insurance or other means providing equivalent protection, of the funds from theft or other forms of loss in an amount equal to the hospital's average daily balance of patient funds handled within the hospital's preceding fiscal year. Hospitals which have not handled patient funds in the preceding year may use an estimated daily balance, but shall update their estimate every three months based on actual experience until they have a full year on which to base an average.

9.4.g. If emergency services are not included in the extended care per diem rate, the hospital shall inform the patient in writing at the

time of admission or at the time this exclusion is adopted by the hospital.

64-12-10. Adjunct Diagnostic Services and Treatment Departments.

10.1. General Requirements.

10.1.a. The hospital shall develop and maintain all ancillary diagnostic and treatment departments in accordance with Section 5 of this rule.

10.1.b. The hospital shall locate ancillary patient departments conveniently to provide services to all patient populations.

10.1.c. A waiting area for patients shall provide for patient comfort and confidentiality.

10.1.d. The hospital shall provide toilets for ambulatory patients and the public.

10.1.e. The hospital shall ensure that all ancillary diagnostic services and treatment departments shall maintain current policy and procedure manuals approved by the medical staff. These manuals shall be reviewed and revised, as necessary, but at least, every three (3) years.

10.1.f. All outpatient specialty services such as outpatient surgery and cardiac catheterization laboratory shall be equipped and maintained according to current professional standards.

10.2. Laboratory Department.

10.2.a. The hospital shall maintain, either directly or through contractual agreement with a certified laboratory, adequate laboratory services to meet the needs of the patients.

10.2.b. The hospital shall ensure that all laboratory services provided to patients are performed in a facility certified in accordance with 42 C.F.R. 493, and the 1988 Clinical Laboratory Improvement Amendments (CLIA).

10.2.c. Emergency laboratory services shall be available twenty-four (24) hours a day.

10.2.d. Laboratory personnel shall be in sufficient numbers for the scope and complexity of services provided.

10.2.e. The hospital shall provide laboratory personnel with in-service training appropriate to the type and complexity of the services offered on a regularly scheduled basis as defined by hospital policy.

10.2.f. The hospital shall provide space for administrative services and clean-up and decontamination of equipment.

10.2.g. A written description of services provided shall be readily available to the medical staff.

10.3. Blood and Blood Products.

10.3.a. The hospital shall maintain a process for procurement, safekeeping, and transfusion of blood and provide that blood products are provided or readily available.

10.3.b. Blood shall be obtained, processed, stored, and administered under the supervision of a pathologist or designated physician.

10.3.c. The hospital shall make arrangements for procurement, transfer, and availability of blood types not ordinarily kept at the hospital.

10.3.d. Blood storage facilities in the hospital shall have an adequate temperature alarm system that is regularly inspected according to hospital policy.

10.3.e. The hospital shall evaluate blood use through the hospital quality improvement program. A pathologist and/or designated physician shall be included in this evaluation.

10.3.f. The hospital shall ensure

that all transfusion-related fatalities are investigated and reported as required by the provisions of 21 C.F.R. 606.170.

10.3.g. The hospital shall ensure that the laboratory is properly registered, if appropriate, as required by the Federal Food, Drug and Cosmetic Act, 42 C.F.R. 417.124(2)(i)(ii)(iii)(iv).

10.3.h. The hospital shall have a process to take action if it has received or administered HIV blood or blood products in accordance with 42 C.F.R. 482.27.

10.4. Radiology and Imaging Service.

10.4.a. The hospital shall maintain, or have available, diagnostic radiology services to meet the needs of the patients.

10.4.b. If therapeutic and diagnostic services are provided they shall be administered according to professionally approved standards for safety and personnel qualifications.

10.4.c. Radiology services shall only be provided according to a practitioner's orders consistent with State law, as authorized by the medical staff and the governing body.

10.4.d. Radiology services shall be under the medical direction of a qualified full-time, part-time, or consulting radiologist. A qualified radiologist is a Doctor of Medicine or Osteopathy who is qualified by education and experience in radiology and is licensed by the West Virginia Board of Medicine or West Virginia Board of Osteopathy. A radiologist's responsibilities shall include:

10.4.d.1.
Ensuring that radiology reports are signed by the practitioner who interpreted them;

10.4.d.2.
Enforcing safety and infection control standards;

10.4.d.3.

Assigning duties to radiology personnel based on their training, experience, and licensure when applicable;

10.4.d.4.
Ensuring files, scans, and other image records are secure, retrievable, and maintained for a minimum of five (5) years; and

10.4.d.5.
Providing in-services and training to radiology personnel including management of radiation hazards and equipment safety, etc.

10.4.e. A radiologist shall interpret all imaging tests, except in cases where the medical staff has determined through its credentialing process that a test can be interpreted by another physician who has equal training and expertise in performing and interpreting certain designated tests.

10.4.f. Proper safety precautions shall be maintained against radiation hazards in compliance with the Department's Administrative Rules, Radiologic Health Regulations, 64CSR23 including:

10.4.f.1.
Adequate shielding for patients, personnel, and facilities; and

10.4.f.2.
Appropriate storage, use, and disposal of radioactive materials.

10.4.g. The hospital shall make periodic inspections of equipment according to hospital policy and any identified hazards shall be corrected promptly.

10.4.h. The hospital shall periodically check radiology service personnel, and other appropriate personnel, by the use of exposure meters or badge tests, according to hospital policy, to determine the amount of radiation exposure to which they may have been exposed.

10.4.i. Only radiology technologists or other individuals licensed in West

Virginia or other individuals approved by hospital policy may operate radiology equipment and administer procedures according to W. Va. Code 30-23-1-et.seq.

10.4.j. The radiology service area shall have at least:

10.4.j.1. One

(1) radiographic room with adequate radiology equipment;

10.4.j.2. A

darkroom unless a one hundred percent (100%) filmless environment negates the need for a darkroom;

10.4.j.3. An

office, viewing facilities, and film filing cabinets for both active and inactive records. This may be in one room in a small radiology department;

10.4.j.4.

Dressing booths with an adjoining toilet and lavatory for patients;

10.4.j.5.

Waiting space under the supervision of qualified personnel for patients using stretchers or wheelchairs;

10.4.j.6. A

utility area with a sink and counter space; and

10.4.j.7. Supply

and equipment storage space.

10.4.k. Therapeutic radiology and radiological isotopes, if provided, shall be provided according to current national professional standards.

10.5. Rehabilitation Service.

10.5.a. The hospital, if it provides rehabilitation, physical therapy, occupational therapy, audiology, sports medicine, or speech pathology services, shall organize those services and make staff available to ensure the health and safety of patients.

10.5.b. If any or all of the services referenced in subdivision 10.5.a are provided, they shall be provided by a sufficient number of staff who meets the qualifications specified by the medical staff, consistent with State law. The number of qualified staff is based upon the type of patients treated and the frequency, duration and complexity of treatment required.

10.5.c. Each service, whether provided through a single discipline department or within a multi-discipline department, shall function with established lines of authority and responsibility that ensure accountability in patient care and administrative matters regarding the provision of the service.

10.5.d. Each service shall be accountable to an individual who directs the overall operation of the service.

10.5.e. The director of the services shall have the necessary knowledge, experience and capabilities to properly supervise and administer the services. An individual may serve as director of more than one (1) service either as the director of a multi-service department or as the director of single service departments. The director may serve on either a full-time or part-time basis.

10.5.f. A qualified professional defined by medical staff policy, consistent with State law, shall:

10.5.f.1.

Evaluate each patient;

10.5.f.2. Initiate

the plan of treatment; and

10.5.f.3.

Instruct and supervise supportive personnel.

10.5.g. The space and equipment required shall depend upon the services provided.

10.5.h. The hospital shall provide services in accordance with a written plan of treatment and in accordance with written orders of

practitioners authorized by the medical staff.

10.5.i. The hospital shall ensure that the plan of treatment includes treatment goals and type, amount, frequency, and duration of services and shall be revised when appropriate.

10.6. Respiratory Care Service.

10.6.a. If the hospital provides respiratory care services, the scope of the diagnostic and therapeutic services offered shall be defined in writing and meet the needs of the patients.

10.6.b. Respiratory care services shall be under the medical direction of a physician licensed by the West Virginia Board of Medicine or West Virginia Board of Osteopathy with the knowledge and experience to supervise and administer the services. The Director may serve on either a full-time or part-time basis.

10.6.c. The hospital shall employ adequate numbers of respiratory therapists, respiratory therapy technicians and other personnel who meet the qualifications specified by the medical staff, consistent with State law.

10.6.d. The hospital shall deliver services in accordance with medical staff directives.

10.6.e. The hospital shall provide services only in accordance with the written orders of practitioners authorized by the medical staff.

10.6.f. The hospital shall designate in writing the personnel qualified to perform specific procedures and the amount of supervision required for these individuals.

10.6.g. The hospital shall designate in writing the personnel who are qualified to provide direct supervision.

10.6.h. If blood gases or other clinical laboratory tests are performed in the respiratory care unit, the unit shall meet the requirements for clinical laboratories with respect to management, adequacy of facilities, proficiency

testing, and quality control, according to 42 C.F.R. 482.27(a),(b),(c) and (f).

10.7. Additional Services.

10.7.a. If the hospital does not have morgue and autopsy facilities available at the hospital, the hospital shall maintain written agreements with an area mortuary, when available, or another hospital for these services to be provided.

10.8. Organ Procurement Responsibilities.

10.8.a. The hospital shall have and implement written protocols that ensure compliance with Condition of Participation: Organ, tissue, and eye procurement, 42 C.F.R. 482.45.

64-12-11. Medical Staff.

11.1. Each hospital shall have an organized medical staff that is composed of one (1) or more licensed physicians and may include other practitioners, in accordance with State law, that operates under by-laws approved by the governing authority. The medical staff is accountable to the governing body for the quality of medical care provided to the patients.

11.2. The governing authority of the hospital shall appoint the medical staff in accordance with its by-laws, rules and regulations.

11.3. The medical staff shall periodically conduct appraisals of its members as defined by hospital policy.

11.4. The medical staff shall examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of candidates.

11.5. Medical staff recommendations to the governing authority for new members shall be specific to the type of appointment and extent of clinical privileges.

11.6. The governing authority shall

delineate clinical privileges of each medical staff member in writing.

11.7. The governing authority shall approve the manner of organization of the medical staff.

11.8. If the medical staff has an executive committee, a majority of the members shall be physicians licensed in the state of West Virginia.

11.9. The medical staff shall adopt and enforce by-laws, rules and regulations consistent with standard medical staff practices. These shall be reviewed and revised as appropriate, but no less than every two (2) years.

11.10. The by-laws shall:

11.10.a. Be approved by the governing body;

11.10.b. Include a statement of the duties and privileges of each category of medical staff;

11.10.c. Describe the organization of the medical staff; and

11.10.d. Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.

11.11. All medical staff members shall sign a document that specifies they have read the by-laws, rules, and regulations. These rules, regulations and policies shall specifically provide for:

11.11.a. Requiring departmentalized medical staffs to meet every other month if the executive committee meets monthly. The full medical staff shall meet annually. In the event the executive committee does not meet monthly, then the departmental meeting of the medical staff shall be monthly. Non-departmentalized medical staffs shall have monthly

meetings of the executive committee and the full medical staff shall meet every other month. In the event there is no executive committee, the full medical staff shall meet monthly;

11.11.b. Staff review and analysis of clinical experiences in the various departments of the hospital such as medicine, surgery, obstetrics, and other specialties. The clinical records of patients shall be the basis of the review and analysis;

11.11.c. The performance of committee functions in at least the following areas: credentials, medical records, case and utilization review, quality assurance/improvement, infection control mortality, pharmacy and therapeutic practices, and any other committees the hospital considers necessary; and

11.11.d. A chief of staff with direct responsibility for the organization and administration of the medical staff in accordance with the terms of the medical by-laws, rules, and regulations.

11.11.d.1. The chief of staff shall be responsible for the functioning of the clinical organization of the hospital and maintaining careful supervision over the clinical work in all departments of the hospital.

64-12-12. Nursing Service.

12.1. The hospital shall organize the nursing services to provide comprehensive, effective nursing care to each patient under the direction of a registered professional nurse currently licensed in West Virginia and with the education and experience to demonstrate his or her ability to properly execute his or her functions and responsibilities.

12.2. The Director of Nursing shall ensure that there are policy and procedure manuals developed for each different type of patient care unit and that the specific manuals are available on each specific unit.

12.3. The hospital shall maintain a written nursing service plan of administrative authority with delineation of responsibilities and duties of each category of nursing personnel, which shall include at least:

12.3.a. A statement of the policy, mission, and objectives of the nursing service; and

12.3.b. Current job descriptions, qualifications, and specifications for each category of nursing personnel of which there is documented annual review.

12.4. The following records shall be available at the hospital:

12.4.a. Documentation that lists and verifies that all licensed nursing personnel, including private duty and per diem nurses, are currently licensed to practice nursing in West Virginia and that those licenses are in good standing; and

12.4.b. A confidential personnel record for each employee containing information to support the employee's assignment.

12.5. The record shall contain at least the following information:

12.5.a. A dated application for employment verified by references which includes the applicant's training and experience;

12.5.b. Current licensure, registration, or certification status;

12.5.c. Evaluations of work performance signed by the employee and his or her supervisor;

12.5.d. Subsequent change of status forms including change of address, salary adjustments, merit increases, and promotions; and

12.5.e. A record of each employee's participation in continuing education.

12.6. The hospital shall maintain a job description for each job category, including the following:

12.6.a. The job title and qualifications, including educational and skill requirements;

12.6.b. A general description of the employee's duties and responsibilities including limitations, if applicable; and

12.6.c. Supervision to be given and received.

12.7. The hospital shall make available to all nursing employees and provide explanation of the written personnel policies, procedures, and organizational charts.

12.8. The following records shall be available in the nursing department:

12.8.a. Current nursing care policy and procedure manuals;

12.8.b. Minutes and records of attendance at all meetings;

12.8.c. A list of nursing service committees and other committees on which nursing is represented; and

12.8.d. A master staffing plan for the current year.

12.9. The hospital shall provide an adequate number of registered professional nurses and other nursing personnel to meet the following minimum staff requirements:

12.9.a. To provide administrative assistance and supervision during the absence of the Director of Nursing;

12.9.b. To provide supervisory personnel qualified by experience, education, and ability for each specialty area of the nursing department;

12.9.c. To provide a registered professional nurse on duty and immediately available for bedside care of any patient when needed on each shift, twenty-four (24) hours per day, seven (7) days a week; and

12.9.d. To provide the availability of licensed practical nurses and/or other health care personnel to supplement registered professional nurses according to patient acuity.

12.10. If it is hospital policy to use nursing assistants interchangeably between acute patient care units and an extended care unit, the hospital shall maintain documented evidence of nurse assistant training certification for personnel used in this manner.

12.11. The hospital shall provide additional personnel, as needed, to provide clerical procedures.

12.12. The registered professional nurse shall plan, supervise, and evaluate the nursing care for each patient, according to the needs of the patient.

12.13. The hospital shall establish and maintain a current individualized patient care plan for each patient.

12.14. The hospital shall maintain documented nursing notes for each patient.

12.15. Nursing representatives shall be members of committees concerned with interdepartmental policies affecting nursing services and nursing care.

12.16. Planned meetings shall be held by the nursing department according to hospital policy to discuss patient care, nursing service problems and administrative policies and to analyze the quality of nursing care rendered to patients.

12.17. The hospital shall provide documented, continuing education activities for all nursing personnel. These activities shall include, but not be limited to, on the job training and development programs. Records of these program

activities shall be maintained, including methods used and an evaluation of their effectiveness.

64-12-13. Patient Care Services.

13.1. Patient Care

13.1.a. Every patient shall be under the care of a practitioner who is:

13.1.a.1. A Doctor of Medicine or Osteopathy who possesses a valid license issued by the West Virginia Board of Medicine or the West Virginia Board of Osteopathy, respectively, or who is otherwise lawfully practicing in the State: Provided, that this paragraph is not to be construed to limit the authority of a Doctor of Medicine or Osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or rules;

13.1.a.2. A Doctor of Podiatric Medicine who possesses a valid license issued by the West Virginia Board of Medicine or who is otherwise lawfully practicing in the State, but only with respect to functions that he or she is legally authorized by the State to perform;

13.1.a.3. A Doctor of Dental Surgery or Dental Medicine who possesses a valid license issued by the West Virginia Board of Dental Examiners or who is otherwise lawfully practicing in the State, but only with respect to functions that he or she is legally authorized by the State to perform;

13.1.a.4. A Doctor of Optometry who possesses a valid license issued by the West Virginia Board of Optometry or who is otherwise lawfully practicing in the State, but only with respect to services related to the condition of aphakia;

13.1.a.5. A chiropractor who possesses a valid license issued by the West Virginia Board of Chiropractic Examiners or who is otherwise lawfully practicing in the State,

but only with respect to treatment by means of manipulation of the spine to correct a subluxation demonstrated to exist by x-ray or other medically accepted imaging media;

13.1.a.6. A psychologist who possesses a valid license issued by the West Virginia Board of Examiners of Psychologists or who is otherwise lawfully practicing in the State, but only with respect to functions that he or she is legally authorized by the State to perform; or

13.1.a.7. A midlevel practitioner who possesses a valid license issued by the appropriate licensing board who is lawfully practicing in the State.

13.1.b. A Doctor of Medicine or Osteopathy shall be on duty or on call at all times.

13.1.c. A Doctor of Medicine or Osteopathy shall be responsible for the care of each patient with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization.

13.2. Patient Care Delivery.

13.2.a. Delivery of patient care and treatment interventions shall be based on the needs identified in the plan of care.

13.2.b. The hospital shall ensure completion of a nursing assessment within twenty-four (24) hours of admission as an inpatient. This assessment shall include information necessary to develop an effective plan of care.

13.2.c. Each patient's clinical response to the plan of care shall be evaluated by the physician and registered nurse with other responsible practitioners, as appropriate, to determine that the patient care goals are being met.

13.2.d. The hospital shall ensure completion of a reassessment of each patient and implementation of a revised plan of care, as often as necessary, to meet the patient's needs.

13.2.e. The hospital shall ensure that documentation of each patient's plan of care shall be written legibly or entered electronically to convey in an understandable manner the diagnostic, therapeutic or rehabilitative service, sentinel events, reassessments and revisions, physician's orders whether written or verbal, implementation of the orders, and patient compliance and responses.

13.3. Patient Admission, Assessment, and Plans of Care.

13.3.a. Patients shall be admitted to the hospital only upon orders of a practitioner licensed in West Virginia with admitting privileges at the hospital.

13.3.b. The hospital shall ensure completion of a comprehensive assessment, including any information necessary to develop an effective, interdisciplinary plan of care, in the time frame identified by hospital policy and placed in the medical record.

13.3.c. The comprehensive assessment shall include, at minimum, the patient's health history including any pertinent psycho-social factors and the results of the physical examination performed upon admission.

13.3.d. Patient assessment activities shall encompass the full scope of the patient's care needs, which may include services provided by other licensed or registered health care professionals as authorized by medical staff policies.

13.3.e. Each patient shall have an effective plan of care based upon the specific needs identified by all assessment activities.

13.3.f. Identified, accepted clinical outcomes should be attained as a result of implementation of a patient specific plan of care.

13.3.g. The hospital shall ensure that each patient be reassessed as determined by patient diagnosis, expected clinical outcomes, changes in the patient's condition and evaluation of

the patient's response to treatment and therapies.

13.3.h. Each licensed or registered health care professional involved in a patient's care may perform reassessments of the patient within his or her area of training and professional expertise as determined by hospital policy and the scope of practice of the practitioner.

64-12-14. Discharge Planning.

14.1. The hospital shall have in effect a discharge planning process for post-hospital services, including hospice, which includes early assessment of the needs of each patient, particularly those with potential risk for adverse consequences upon discharge. The assessment shall be based upon the patient's functional abilities and probable environment to which the patient shall return. The hospital's policies and procedures shall be specified in writing.

14.2. A discharge needs assessment, evaluating the factors that affect the patient's need for post-hospital care, shall be performed or supervised by a registered nurse, social worker or other appropriately qualified person, as identified by hospital policy, and be completed in enough time for appropriate arrangements to be made prior to discharge. The assessment shall address the biopsychosocial needs of the patient, the level of understanding of those needs and an identification of post hospital care resources.

14.3. The hospital shall provide counseling as needed, to the patient and family members or interested persons, to prepare them for post-hospital care, including hospice services.

14.4. The hospital shall arrange for the initial implementation of the patient's discharge plan, including obtaining post-hospital services as necessary.

14.5. The hospital shall ensure that the discharge plan be reassessed, as needed, and entered into the patient's record.

14.6. The hospital shall transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies or outpatient services, as needed, for follow-up or ancillary care.

14.7. The discharge planning process shall be an integral part of the quality assessment and performance improvement program, as detailed in Section 15 of this rule.

64-12-15. Quality Assessments and Performance Improvement.

15.1. The governing body, medical staff, and hospital administration are responsible for and shall review at least annually the development, implementation, and maintenance and effective evaluation of quality assessments for performance improvement. This process systematically collects, measures, analyzes, and tracks objective indicators of the care and hospital operations. This evaluation plan should reflect the complexity of the hospital's organization and services.

15.2. The focus of performance evaluation shall be in areas over which the hospital exercises authority and responsibility, including services furnished by contract.

15.3. Priorities for performance improvement projects shall be based upon the prevalence and severity of problems which most affect clinical outcomes identified through the data collected.

15.4. Performance measures may be designed and implemented under contract by the hospital staff through research or consensus groups within the facility or through the use of credible consultants.

15.5. Performance measures shall be commensurate with the size and resources available to each hospital.

15.6. Performance measures should use not only hospital-specific data, but peer review organizations and any other available relevant data

for comparative purposes as an integral part of the assessment plan.

15.7. The hospital shall make available to the Department the results of peer review and quality assessments and performance improvement information, upon the Department's request.

15.8. Quality improvement activities should be demonstrably linked to the findings of performance evaluations and cover the full range of the hospital's services to patients.

15.9. The hospital shall conduct an assessment of the impact of quality improvement activities and corrections or reevaluation of the performance indicators, no longer than six (6) months after any change is instituted, unless another time period for assessment can be justified based upon analytic factors, such as adequate sample size, or circumstances outside the control of the hospital.

15.10. Areas of measurement.

15.10.a. At a minimum the measure shall include, but not be limited to:

15.10.a.1. Nosocomial infections and other infection control issues;

15.10.a.2. Staff, administrative, and practitioner performance;

15.10.a.3. Complaints, grievances, or risk management findings;

15.10.a.4. Evaluation of diagnostic and therapeutic services provided;

15.10.a.5. Medication errors and other incidents or occurrences;

15.10.a.6. Drug therapy and adverse drug reactions; and

15.10.a.7. Evaluation of all services provided to patients by staff

accountable to the hospital through employment or contract.

64-12-16. Critical Access Hospital.

16.1. Critical Access Hospital Designation.

16.1.a. A critical access hospital is designated as such by the Office of Community and Rural Health and approved by the Centers for Medicare and Medicaid Services.

16.1.b. Upon designation as a Critical Access Hospital, the hospital shall remain subject to the provisions of Critical Access Hospital rules and public health law and rules applicable to general hospitals, including those parts pertaining to certificates of need and other operating certificates. This shall also apply to the proposed revocation, suspension, limitation, or decertification of a Critical Access Hospital designation.

16.2. Scope of Services.

16.2.a. Critical Access Hospitals shall provide initial diagnostic services, a limited range of therapeutic services, resuscitation and stabilization services, and shall have the ability to arrange transport to other more appropriate facilities for patients in need of services not offered at the Critical Access Hospitals.

16.2.b. A Critical Access Hospital shall provide a minimum set of core services to meet patient needs including:

16.2.b.1. Emergency services provided by a licensed West Virginia physician or an experienced and trained midlevel practitioner who can handle urgent and emergent care services, within his or her scope of practice, and in compliance with 42 C.F.R. 485.618. In the event services are provided by a clinician other than a Doctor of Medicine or a Doctor of Osteopathy, this clinician must be supervised by a Doctor of Medicine or Osteopathy who is available by telephone or radio contact twenty-four (24) hours a day and be available on site within thirty (30)

minutes from initial contact;

16.2.b.2.

Inpatient acute care and ambulatory services;

16.2.b.3.

Laboratory services;

16.2.b.4.

Imaging services; and

16.2.b.5.

Pharmacy services.

16.2.c. When a Critical Access Hospital does not require a physician to be on site, it must ensure that patients in need of emergency care arriving at the facility are provided with emergency medical treatment within the capabilities of the facility.

16.3. Licensure.

16.3.a. A Critical Access Hospital shall meet all hospital licensure standards for the State of West Virginia, cited in subsections 12.1 through 14 of this rule in addition to the following requirements:

16.3.a.1. A licensed professional registered nurse, nurse practitioner, physician's assistant, or physician shall provide twenty-four (24) hour on-site care when the Critical Access Hospital renders inpatient services;

16.4.a.2.

Authorized admissions to a Critical Access Hospital may include only patients that, by the judgment of the admitting practitioner, are determined to have medical needs that can be managed and resolved within the ninety-six (96) hour period estimated for inpatient services pursuant to 42 C.F.R. 485.620. The Critical Access Hospital shall transfer patients presenting with conditions that are beyond the clinical capabilities of the Critical Access Hospital to a hospital that has available appropriate services.

16.4. Quality Improvement.

16.4.a. The governing authority shall require the establishment and maintenance of a written quality assurance program which integrates the review activities of all Critical Access Hospital services to enhance the quality of patient care. In meeting the general hospital quality assessment under subsection 12.15 of this rule, this program shall be designed to focus on the continuum of care that concentrates on improving the outcomes of care to patients from all services provided at the facility.

16.4.b. At a minimum the quality improvement program shall include, but not be limited to, the following:

16.4.b.1. Access and availability of care;

16.4.b.2. Variations from generally accepted standards of care;

16.4.b.3. Unanticipated transfers to a more intensive facility;

16.4.b.4. Cases that exceed the ninety-six (96) hour length of stay for the Critical Access Hospital;

16.4.b.5. Nosocomial infections and other infection control issues;

16.4.b.6. Complaints, grievances, or risk management findings;

16.4.b.7. Evaluation of diagnostic and therapeutic services provided;

16.4.b.8. Medication errors and other incidents or occurrences; and

16.4.b.9.

Adverse drug reactions.

16.5. Medical Staff.

16.5.a. The medical staff shall develop a system in which network medical and professional staff participates and collaborates to provide consultation, assistance with medical emergencies, and patient referrals.

16.5.b. The Critical Access Hospital shall ensure that physicians are present for sufficient periods of time, as defined by the hospital's governing body, to provide the necessary and appropriate medical direction, medical care services, consultation and supervision of hospital health care staff in accordance with patient needs.

16.5.c. When the Critical Access Hospital does not require a physician to be on site, the medical staff shall ensure that at least one (1) Doctor of Medicine or Osteopathy is available by radio or telephone on a twenty-four (24) hour a day basis, and is available on-site within thirty (30) minutes of patient need twenty-four (24) hours a day.

64-12-17. Specialized Hospitals.

17.1. Long Term Acute Care Hospital.

17.1.a. To be licensed as a Long Term Acute Care Hospital, a hospital shall:

17.1.a.1. Be devoted exclusively to the care of patients requiring hospitalization because of prolonged illness or who are not acutely ill and not in need of general acute hospital care but who do require continuing medical care, skilled nursing care and related medical services; and

17.1.a.2. Have a professional staff qualified in the diagnosis and treatment of chronic diseases.

17.1.b. The hospital shall

surrender the license of any acute care beds used in the development of the Long Term Acute Care Hospital.

17.1.c. If the Long Term Acute Care Hospital ceases to exist, terminates its services, or fails to offer its services for a period of twelve (12) months, any beds whose license was surrendered by the hospital to establish the Long Term Acute Care Hospital shall revert back to the hospital's licensed bed capacity.

17.2. Psychiatric Hospital.

17.2.a. To be licensed as a psychiatric hospital, a hospital shall:

17.2.a.1. Be devoted exclusively to the care of psychiatric patients;

17.2.a.2. Have professional personnel especially qualified in the diagnosis and treatment of psychiatric disorders;

17.2.a.3. Have adequate facilities for the protection of the patients and staff;

17.2.a.4. Meet the requirements for a general hospital; and

17.2.a.5. Be in compliance with requirements at 42 C.F.R. 482.61 and 482.62.

17.3. Rehabilitation Hospital.

17.3.a. To be licensed as a rehabilitation hospital a hospital shall:

17.3.a.1. Be devoted exclusively to the care of patients requiring rehabilitation services and therapies; and

17.3.a.2. Have professional personnel especially qualified in the diagnosis and treatment of conditions requiring these services and therapies.

64-12-18. Administrative Due Process.

18.1. Administrative due process and remedies for actions taken pursuant to this rule or W. Va. Code 16-5B-1 et seq. are as provided by this rule, by applicable statutes, and in the West Virginia Division of Health Procedural Rules, Rules of Procedure for Contested Case Hearings and Declaratory Rulings, 64CSR1.