

**WEST VIRGINIA
SECRETARY OF STATE
BETTY IRELAND
ADMINISTRATIVE LAW DIVISION**

Form #3

Do Not Mark In This Box

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2005 JUL 19 P 1:35

OFFICE WEST VIRGINIA
SECRETARY OF STATE

**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE
AND
FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE**

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

CITE AUTHORITY: WV Code 16-5B-8

AMENDMENT TO AN EXISTING RULE: YES _____ NO X

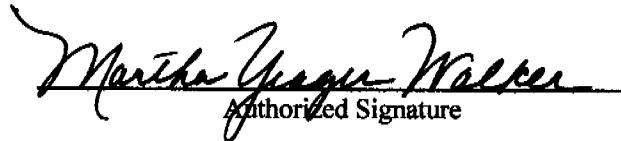
IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 12

TITLE OF RULE BEING PROPOSED: Hospital Licensure Rule

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.


Authorized Signature

Summary of rule

This rule repeals and replaces the hospital licensure rule with the effective date July 1, 1994. It sets forth the requirements for hospitals to be licensed in the state of West Virginia.

Statement of Circumstances which require the proposed rule

The hospital licensure rule has not been updated since July 1, 1994. The proposed rule brings the licensing requirements for hospitals in line with current practice and current Centers for Medicare and Medicaid Services regulations.

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Hospital Licensure Rule

Type of Rule: x Legislative Interpretive Procedural

Agency: HEALTH AND HUMAN RESOURCES

Address: Office of Health Facility Licensure and Certification
1 Davis Square, Suite 101
Charleston, WV 25301

Phone Number: (304) 558-0050 Email: anltabarnhouse@wvdhhr.org

Fiscal Note Summary

Summarize in a clear and concise manner what effect this measure will have on costs and revenues of state government.

There will be no effect on costs and revenues of state government.

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

Effect of Proposal	Fiscal Year		
	2005 Increase/Decrease (use "-")	2006 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services			
Current Expenses			
Repairs and Alterations			
Equipment			
Other			
2. Estimated Total Revenues	0	0	0

3. Explanation of above estimates (including long-range effect):

Please include any increase or decrease in fees in your estimated total revenues.

Not applicable.

Memorandum

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

There are no increased requirements on the state agency or the hospitals as a result of the proposed rule, therefore there will be no fiscal impact.

Date

May 24, 2005

Agency

Department of Health and Human Resources

Authorized Representative

Martha Walker

Martha Walker
Secretary

TITLE 64
LEGISLATIVE RULE
WEST VIRGINIA DIVISION OF HEALTH

FILED

SERIES 12
HOSPITAL LICENSURE RULE

2005 JUL 19 P 1:35

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 64CSR12, §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 will 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 Nurse Aide Rule 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 -- 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 will 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. No person may 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 will 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 will:

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. Applicants for license will complete and submit an application to the department on forms provided by the Director and will pay the annual fee as required by W. Va. Code §16-5B-4. The name used on the application forms will be the legal name of the hospital or extended care unit operated in conjunction with a hospital.

3.2.b. A Section §6a hospital will 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 Sections §§4.2.a and 4.2.h of this rule.

3.3. Issuance of License.

3.3.a. The Director will 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.

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 Section §4.2 of this rule or a plan of correction has been accepted. Provided, That the Director will not withhold a license for noncompliance

with Section §4.2 of this rule in the case of the corporation defined in W. Va. Code §18-11C-1d.

3.3.b. The Director will 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 will 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 provisions of W. Va. Code §16-5B-4.

3.4.b. Licensed hospitals and extended care units will 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 will provide licensure renewal forms to each licensed hospital and extended care unit by mail or other means he or she may deem proper.

3.4.c. The application for license will 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 will 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 will renew a license if:

3.4.e.1. The hospital or extended care unit operated in conjunction with a hospital is in compliance with Section §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.

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 will 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 will not be required by the State Department of Health and Human Resources for any hospital that is exempted by the provisions of W. Va. Code §16-5B-5a.

3.5.d. The Department of Health and Human Resources will 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 State Department of Health and Human Resources 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 for cause needed.

3.5.g. Hospitals receiving a three (3) year accreditation will 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. Hospitals will incorporate the results of the self-evaluation in their 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. Hospitals are not required to conduct self-evaluations for any licensing year when they are inspected by the State Department of Health and Human Resources.

3.5.j. Accreditation reports filed with the State Department of Health and Human Resources will 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 will 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 will return its license to the Director.

3.6.c. If the Director revokes a license, the Director will 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. A new license will be issued with the hospital identified by the new name.

3.7.b. All hospitals and extended care units operated in conjunction with a hospital will 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 will post its license in a conspicuous place on the licensed premises.

3.7.d. No hospital will 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 body 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 will be 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 will 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 such additions or termination of services.

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

4.1.e. The governing authority will 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 will 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 will be responsible for the effective operation of the patient grievance process.

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

4.2.a. The Boards of Directors of Section §6a hospitals will 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 will not exceed the number of consumers in any other category by more than one (1).

4.2.b. No member of the Board of Directors of a Section §6a hospital will 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 will maintain a file containing affidavits by its consumer representatives as to their consumer category. The affidavits will 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 will 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; and

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 will consider the hospital to be out of compliance with Section §4.2 of this rule.

4.2.h. The Board of Directors of each Section §6a hospital will 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 will 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 will 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.

4.3.a.3. Ensuring compliance with the rules and regulations of the medical staff as established in 64CSR12, §11.2.

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

4.4. Patient Rights.

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

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

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

4.4.c. Patient rights will include but not be 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 Section §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. Skilled interpreters and personnel skilled in communicating with vision and hearing impaired individuals either directly employed by the corporation or employed under a contract will be provided by the facility in a timely manner.

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

4.4.e.1. The grievance process must 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 must 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 will 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 of this rule will 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 will 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 has precedence.

5.1.c. The hospital will 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 will be at least three (3) feet, eight (8) inches.

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

5.1.f. Corridors, stairways, and elevators will be of a width and design that will easily accommodate the removal of patients in a bed, including beds with traction equipment, and will 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 will not be permitted at any time.

5.1.g. Handrails will 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 will be provided for all exterior openings that are left open for extended periods. Where provided, screen doors will open outward and will be self closing.

5.1.i. Operable windows must have screens and safety design

features.

5.1.j. The hospital will 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 will, 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 will 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 will 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 will have precedence.

5.2.c. Site conditions will 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. An inspection of the site for a proposed hospital will be requested in writing and approval for construction will be obtained from the Director before construction is started.

5.3. New Construction.

5.3.a. Hospitals constructed subsequent to the effective date of this rule will 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. 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., will be submitted to the Director for review prior to beginning work on the project. The drawings and specifications will include architectural, life safety, structural, mechanical and electrical drawings and specifications and will be prepared and signed by an architect and/or engineer registered to practice in West Virginia.

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 will 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 must

complete an infection control and safety risk assessment and will develop a plan to control exposure of patients, employees and the public. This plan must 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 this office or the services of an architect.

5.4.d. Complete construction drawings and specifications for any hospital addition or renovation project which alters a floor plan, impacts life safety, or requires approval under W. Va. Code §16-2D-1 et seq., will be submitted to the Director for review, prior to work beginning on the project. The drawings and specifications will include architectural, life safety, structural, mechanical, and electrical drawings, and specifications and will be prepared and signed by an architect registered to practice in West Virginia. 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 such minor renovations will be determined by the Secretary.

5.4.e. Any existing building, or portions of that building converted for use as a hospital will 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 will comply with West Virginia Department of Health and Human Resources Administrative Rules, Public Water Systems, 64CSR3, and Cross Connection and Backflow Prevention, 64CSR15.

6.1.b. Sewage disposal will comply with West Virginia Department of Health and Human Resources Administrative Rules, Sewage System Rules, 64CSR9.

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

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

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

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

6.1.g. There will 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 will be kept free from

obstruction at all times.

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

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

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

6.1.l. The hospital will comply with West Virginia Department of Health and Human Resources Administrative Rules, Infectious Medical Waste, 64CSR56.

6.2. Lighting

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

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

6.2.d. The dates on which the testing is conducted will 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 will be inspected and tested routinely as defined by hospital policy.

6.3.c. All hospitals will 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. will be used.

6.3.d. Facilities will have in place a management plan for all indoor air systems which will 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 provisions of laundry services will comply with Section §5 of this rule.

6.4.b. The hospital will 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 will 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 will have:

6.4.d.1. Separation of clean and soiled linen, receiving, storing and sorting areas with facilities to wash your 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 will 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 will be separately stored and washed as will linen contaminated with radioactive material.

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

6.4.h. Soiled linen will 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 will:

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 will 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 will 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 will 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 will 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 will 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 will be concentrated in one area on each unit separate from clean storage.

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

6.6.d. Separate storage areas will 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 will 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 will 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, will be stored in locked cabinets, medication rooms, or medication carts approved by the Director of Pharmacy. This will ensure the integrity of the medications and safety for the patients and the general population. It will 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 will 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 will be stopped after a reasonable period of time which is pre-determined by medical staff policy.

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

7.1.h. The medication preparation area will 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 will be kept within a secure storage area accessible only to authorized personnel.

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

7.1.k. A record will 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 will not be accessible for patient use.

7.1.m. Except for medication packaged for unit doses, all unused medications will 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 will be immediately reported to the attending practitioner and Director of Pharmacy and investigated utilizing current and readily accessible drug and patient information. This information will be evaluated as part of the hospital quality improvement program.

7.1.o. A formulary system will be established by the medical staff and reviewed as necessary.

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

7.1.q. Drugs and biologicals will 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 will 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 will be under the supervision of a person qualified by training and experience as defined by hospital policy.

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

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

7.2.d. A medical record will be maintained for every individual evaluated or treated in the hospital on an inpatient and an outpatient basis.

7.2.e. The hospital will 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. Medical records, including records of patients treated in the emergency room or outpatient department, will be preserved for a minimum of five (5) years in their original form or in a legally reproduced form.

7.2.g. The hospital will 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. Originals or copies of medical records will only be released by the hospital in accordance with Federal and State laws or upon receipt of an order from a court of competent jurisdiction.

7.2.i. Copies of medical records and any other pertinent data will be provided 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 will 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 must be an updated note addressing the patient's current status and/or any changes in the patient's status. This note must 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 physicians 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 deems necessary; and

7.2.j.21. Autopsy findings if performed.

7.2.k. A medical record will be maintained 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 will 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 will be legible and will 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 will include signatures which may be electronic.

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

7.2.p. All orders for medication or treatment will 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. Verbal and telephone orders will 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 will also be communicated to the registered professional nurse responsible for the overall care of that patient.

7.2.r. Physicians will 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 will 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 will be maintained as part of the patient's medical record.

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

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

7.2.v. A complete list of all births, deaths, and fetal deaths occurring within the month in licensed hospitals will be reported by the tenth of the following month on forms provided by or approved by the Director or on a comparable computer printout approved by the Director to the state registrar of vital statistics.

7.2.w. All completed birth certificates will be sent to the state registrar of vital statistics within ten (10) days following the birth.

7.2.x. Licensed hospitals will comply with West Virginia Department of Health and Human Resources 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 will 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 will make arrangements for medical record retention and retrieval. Written documentation of this arrangement will be provided to the Director.

7.2.aa. The hospital will 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 any such patient, an authorized individual to be determined on a case by case basis may make such request and will receive such statement at no additional cost.

7.3. Dietetic Service.

7.3.a. The hospital dietetic service will comply with West Virginia Department of Health and Human Resources Administrative Rules, Food Service Sanitation Rules, 64CSR17.

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

7.3.c. The hospital will 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 will be made for continued in-service training of the designated dietetic service supervisor.

7.3.e. The food services department will 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 can direct the food services department.

7.3.f. Responsibilities of the Director of the Dietetic Services will 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 will be a qualified dietician available on a

full-time, part-time, or a consultant basis. A qualified dietitian will 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 will 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/her duties and responsibilities.

7.3.i. Written and dated menus planned at least fourteen (14) days in advance for both therapeutic and general diets will be posted in appropriate places in the food preparation area and be available to administrative personnel.

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

7.3.k. All therapeutic diets, including between meal nourishments, will 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 will be readily available to the medical, nursing and dietetic service personnel.

7.3.m. Adequate personnel will be employed to perform the functions of the dietetic service department.

7.3.n. There will be procedures to prevent the contamination of meals and other items prepared or served by the dietetic service department employees.

7.3.o. There will be 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 West Virginia Department of Health and Human Resources Administrative Rules and Food Service Sanitation Rules, 64CSR17.

7.3.q. Dry or staple food items will 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 will be maintained at a temperature of forty-five (45) degrees Fahrenheit or below. Refrigerators

and storerooms used for perishable foods will be equipped with reliable thermometers.

7.3.s. All ice used in contact with food or drink will comply with West Virginia Department of Health and Human Resources Administrative Rules, Public Water Systems, 64CSR3.

7.3.t. A sample of potentially hazardous foods from the menu of each meal will be retained 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 will bear warning labels, be stored separately from food or equipment used on preparing and serving food and will be used only in ways that will neither contaminate food nor be hazardous to employees.

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

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

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

7.4. Infection Control

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

7.4.b. There will be an active surveillance and education program for the prevention, early detection, control, and investigation of infections and communicable diseases.

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

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

7.4.e. A person or persons will be designated 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. A log of incidents related to infections and communicable diseases will be maintained by the infection control professional or designee.

7.4.g. The hospital administrator, medical staff, and the Director of Nursing will 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. All patient care units or departments will be developed and maintained in accordance with Section §5 of this rule.

8.1.b. All patient care areas and units will 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 will maintain or have easy access to an emergency cart for use in the event of patient respiratory or cardiac arrest. Contents of this cart such as medications and supplies will be determined by hospital policy. The frequency of monitoring of the contents of the emergency carts will be determined by nursing service policies and procedures.

8.1.d. Protocols will be developed for implementation of respiratory and cardiac arrest care on a twenty-four (24) hour basis utilizing all necessary staff throughout the hospital including any available physicians for immediate emergency response.

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

8.2. Patient Care/Nursing Unit

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

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

8.2.c. Each one (1) bedroom will 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 will contain a minimum floor area of eighty (80) square feet for each bed.

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

8.2.e. Artificial light will 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 will have a night light control switch located at the point of entry into patient rooms.

8.2.g. Patient rooms will have movable furnishings. The

director will make exceptions as needed regarding all furnishings for psychiatric hospitals. Patient rooms will 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, will be a self contained unit and will be segregated from all other parts of the hospital.

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

8.3.c. Specific policies will be established 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 will not be moved 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 will 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 will be performed in a caesarean delivery room suite or in the hospital's operating room.

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

8.3.h. As determined by medical staff, there will 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 will be ready for the reception and care of the newborn infant in all delivery suites.

8.3.j. There will be supplies and equipment for resuscitation of

mother and newborn.

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

8.3.l. A means of identification for each infant, approved by the medical staff, will be established and available in all delivery suites and will be applied at the time of delivery in the delivery suite.

8.3.m. Medications approved by the medical staff for the prevention of inflammation of eyes of the newborn will be instilled in the eyes of the newborn baby, 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. A bed that is utilized for postnatal care will be included in 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 will be moved to another location within the hospital.

8.4. Nursery

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

8.4.b. Nurseries will 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 will 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 will be weighed on accurate infant scales provided for each nursery.

8.4.e. There will 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 will be handled and prepared in a manner consistent with the requirements of West Virginia Department of Health and Human Resources Administrative Rules, Food Service Sanitation Rules, 64CSR17.

8.4.g. Immediate segregation and isolation of any infant with a communicable infection will be provided.

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

8.4.i. Infant clothing and diapers will be furnished by the hospital.

8.4.j. Instructions for feeding and care of the infant will be included in the discharge planning process for the infant's care givers.

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

8.5. Surgical Department

8.5.a. The surgical department will 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 will be available to the hospital staff at all times.

8.5.b. The surgical suites will 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 will be limited to authorized personnel only.

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

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

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

8.5.g. A log will be maintained for daily documentation of each surgical procedure and will 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 will 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 must 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 will be in the patient's chart before surgery, except in emergencies.

8.5.j. An operative report describing techniques, findings, and tissues removed or altered will be completed immediately following surgery and authenticated by the practitioner. The content and format of the operative report will be determined by hospital policy.

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

8.5.l. Adequate provisions will 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 will be provided.

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

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

8.6. Post-Anesthesia Care Unit

8.6.a. There will 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 will 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 will be arranged so that all patients can be observed simultaneously.

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

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

8.6.f. The post-anesthesia unit will 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 will be in the post-anesthesia unit when a patient or patients are present.

8.6.h. All pertinent information related to care provided while the patient is in the post-anesthesia unit will be recorded 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 will also be recorded in the patient's record.

8.6.i. If patients are not transferred to the recovery room, provisions will 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. There will be 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 to administer anesthesia by State law, a certified nurse anesthetist who is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed, or a trainee in an approved educational program in anesthetic techniques who is under the direct supervision of an anesthesiologist who is physically present. Anesthesia may also be administered by a licensed anesthesia assistant who has completed a six (6) year program for anesthesiology assistants. This anesthesia assistant will be under the direct supervision of an anesthesiologist who is physically present.

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

8.7.d. An intra-operative anesthesia record will be completed for all surgical patients.

8.7.e. A post-anesthesia evaluation will be performed within forty-eight (48) hours of surgery for all inpatients by the individual who administered the anesthesia.

8.7.f. Content and format of the pre-anesthesia evaluation, intra-operative anesthesia record, and the post-anesthesia evaluation will be determined by hospital policy.

8.7.g. Safeguards in the use of various types of anesthetics will be established by written policies in accordance with the National Fire Protection Association.

8.7.h. All equipment and medications utilized in administration of anesthesia will be stored in a secure, safe, and readily accessible location according to current professional standards. All equipment will be

serviced and maintained by qualified technicians.

8.8 Pediatric Service

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

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

8.8.c. There will be proper facilities and procedures for the isolation of children with infectious or communicable diseases.

8.8.d. There will be pediatric emergency supplies, medications, and equipment organized and readily available on any patient care unit that provides pediatric services.

8.9. Specialty Care/Critical Care Unit

8.9.a. Specialty care units, such as coronary care units and intensive care units, will be 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 will 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 will be readily available to each unit at all times. The physician will 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 must be appropriate for the scope of services offered to ensure the health and safety of the patients.

8.9.e. Nursing care will be 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 will have documented training and competence in the specific care provided.

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

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

8.9.i. Beds in a specialty care unit will 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 will 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 will 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 will be easily accessible for all patients receiving treatment.

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

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

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

8.10.f. The outpatient department medical staff will 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. Accurate and complete medical records will be maintained for all outpatients, according to hospital policy.

8.11. Emergency Department.

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

8.11.b. The emergency department will 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 will be under the supervision of a registered professional nurse licensed in West Virginia.

8.11.d. All emergency department staff will 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, will be available for all hours that emergency services are provided.

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

8.11.g. A physician or midlevel practitioner will 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 will be located so as to permit easy access from automobiles and ambulances.

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

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

8.11.k. All measures necessary to ensure compliance with the requirements of Section §1867 of the Emergency Medical Treatment and Active Labor Act, will be taken even when emergency services are not available.

§64-12-9. Extended Care Unit/Nursing Facility.

9.1. General Requirement - The extended care unit will be located in a segregated, physically separated area of the hospital and will 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 will be provided for dining and recreation areas, special equipment storage, training toilets, showers and bath facilities. Handrails, drinking fountains, lavatories, thresholds and telephone alcoves will 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 will be organized under the direction of a committee of the medical staff. Written policies will be developed by professional personnel including at least one (1) registered

professional nurse.

9.3.b. The Nursing service will be under the direction of a registered professional nurse.

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

9.4. Financial Rights and Responsibilities

9.4.a. Extended care residents or their representatives lawfully authorized to manage fiscal matters on behalf of the resident have the right to manage their own personal financial affairs.

9.4.b. A hospital which manages or holds personal funds for extended care patients will 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 will hold the funds separately and in trust. Patient funds will not be commingled with hospital operating or other funds.

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

9.4.d. The hospital will 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 will 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 will 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 will 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 will inform the patient in writing at the time of admission or at the time this exclusion is adopted by the hospital.

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

9.6. The hospital will 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.

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

9.8. The unit may utilize 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 will be required if the pharmacist is an employee of the hospital.

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

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

10.1. General Requirements.

10.1.a. All ancillary diagnostic and treatment departments will be developed and maintained in accordance with Section §5 of this rule.

10.1.b. Ancillary patient departments should be conveniently located to provide services to all patient populations.

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

10.1.d. Toilets for ambulatory patients and the public will be provided.

10.1.e. All ancillary diagnostic services and treatment departments will maintain current policy and procedure manuals approved by the medical staff. These manuals will 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 will be equipped and maintained according to current professional standards.

10.2. Laboratory Department.

10.2.a. The hospital will 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 will 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 will be available twenty-four (24) hours a day.

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

10.2.e. Laboratory personnel will receive 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. Space will be provided for administrative services and clean-up and decontamination of equipment.

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

10.3. Blood and Blood Products.

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

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

10.3.c. Arrangements will be made for procurement, transfer, and availability of blood types not ordinarily kept at the hospital

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

10.3.e. Blood utilization will be evaluated through the hospital quality improvement program. A pathologist and/or designated physician will be included in this evaluation.

10.3.f. The hospital will 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 will 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 will 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/Imaging Service.

10.4.a. The hospital will 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 will be administered according to professionally approved standards

for safety and personnel qualifications.

10.4.c. Radiology services will 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 will 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. Their responsibilities will 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. All imaging tests will be interpreted by a radiologist 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 will be maintained against radiation hazards in compliance with West Virginia Department of Health and Human Resources 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. Periodic inspections of equipment will be made according to hospital policy and any identified hazards will be corrected promptly.

10.4.h. Radiology service personnel, and other appropriate personnel, will be checked periodically 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 will operate radiology equipment and administer procedures according to W. Va. Code §30-23-1-et.seq.

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

10.4.j.1. One (1) radiographic room with adequate radiology equipment;

10.4.j.2. A darkroom unless 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 utilizing 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, will be provided according to current national professional standards.

10.5. Rehabilitation Service.

10.5.a. If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, sports medicine, or speech pathology services, the services will be organized and staff will be available to ensure the health and safety of patients.

10.5.b. If any or all of the services referenced in Section §10.5.a are provided, they will be provided by a sufficient number of staff who meet 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, will 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 will be accountable to an individual who directs the overall operation of the service.

10.5.e. The director of the services will 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, will be responsible to:

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 will depend upon the services provided.

10.5.h. Services will be furnished 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 plan of treatment will include treatment goals and type, amount, frequency, and duration of services and will 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 will be defined in writing and meet the needs of the patients.

10.6.b. Respiratory care services will 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. There will be 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. Services will be delivered in accordance with medical staff directives.

10.6.e. Services will be provided only in accordance with the written orders of practitioners authorized by the medical staff.

10.6.f. Personnel qualified to perform specific procedures and the amount of supervision required for these individuals will be designated in writing.

10.6.g. Personnel who are qualified to provide direct supervision will be designated in writing.

10.6.h. If blood gases or other clinical laboratory tests are performed in the respiratory care unit, the unit must 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 a morgue and autopsy facilities are not available at the hospital, written agreements will be maintained 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 must 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 will 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 body. The medical staff will be accountable to the governing body for the quality of medical care provided to the patients.

11.2. The medical staff will be appointed by the governing body of the hospital in accordance with its by-laws, rules and regulations.

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

11.4. The medical staff will 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 body for new members will be specific to the type of appointment and extent of clinical privileges.

11.6. Clinical privileges of each medical staff member will be delineated in writing.

11.7. The medical staff will be organized in a manner approved by the governing body.

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

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

11.10. The by-laws will:

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 will sign a document that specifies they have read the by-laws, rules, and regulations. These rules, regulations and policies will specifically provide for:

11.11.a. Requiring departmentalized medical staffs to meet every other month provided the executive committee meets monthly. The full medical staff will meet annually. In the event the executive committee does not meet monthly then the departmental meeting of the medical staff will be monthly. Non-departmentalized medical staffs will have monthly meetings of the executive committee and the full medical staff will meet every other month. In the event there is no executive committee, the full medical staff will 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 will 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 other such committees as the hospital may consider necessary.

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 will 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 nursing services will be organized 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 will ensure 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. A written nursing service plan of administrative authority with delineation of responsibilities and duties of each category of nursing personnel will be maintained and 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 will 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 will 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 employee and 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 facility will 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 will make available to all nursing employees and provide explanation of the written personnel policies, procedures, and organizational charts.

12.8. The following records will 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. There will be 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 utilize nursing assistants interchangeably between acute patient care units and an extended care unit, documented evidence of nurse assistant training certification will be maintained for personnel utilized in this manner.

12.11. Additional personnel, as needed, to provide clerical procedures.

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

12.13. A current individualized patient care plan will be established and maintained for each patient.

12.14. Documented nursing notes will be maintained for each patient.

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

12.16. Planned meetings will 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. Documented, continuing education activities will be provided for all nursing personnel. These activities will include, but not be limited to, on the job training and development programs. Records of these program activities will 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 will 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 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 regulations;

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 will be on duty or on call at all times.

13.1.c. A Doctor of Medicine or Osteopathy will 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 will be based on the needs identified in the plan of care.

13.2.b. A nursing assessment will be completed within twenty-four (24) hours of admission as an inpatient. This assessment will include information necessary to develop an effective plan of care.

13.2.c. Each patient's clinical response to the plan of care will 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. Each patient will be reassessed and a revised plan of care implemented as often as necessary to meet the patient's needs.

13.2.e. Documentation of each patient's plan of care will 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 will be admitted to the hospital only upon orders of a practitioner licensed in West Virginia with admitting privileges at the hospital.

13.3.b. A comprehensive assessment, including any information necessary to develop an effective, interdisciplinary plan of care will be completed in the time frame identified by hospital policy and placed in the medical record.

13.3.c. The comprehensive assessment will 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 will 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 will 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. Each patient will 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 will 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 will be based upon the patient's functional abilities and probable environment to which the patient will return. The hospital's policies and procedures will be specified in writing.

14.2. A discharge needs assessment, evaluating the factors that affect the patient's need for post-hospital care, will 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 will address the biopsychosocial needs of the patient, the level of understanding of those needs and an identification of post hospital care resources.

14.3. As needed, the patient and family members or interested persons must be counseled to prepare them for post-hospital care including hospice services.

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

14.5. The discharge plan will be reassessed as needed and entered into the patient's record.

14.6. The hospital will 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 will 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 will be responsible for and 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 will be in areas over which the hospital exercises authority and responsibility including services furnished by contract.

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

15.4. 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 will 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 results of peer review and quality assessments and performance improvement information will be made available to the West Virginia Department of Health and Human Resources upon 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. An assessment of the impact of quality improvement activities and corrections or reevaluation of the performance indicators will be conducted 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 will include, but not be limited to:

- control issues; 15.10.a.1. Nosocomial infections and other infection
- performance; 15.10.a.2. Staff, administrative, and practitioner
- findings; 15.10.a.3. Complaints, grievances, or risk management
- services provided; 15.10.a.4. Evaluation of diagnostic and therapeutic
- incidents/occurrences; 15.10.a.5. Medication errors and other

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 will remain subject to the provisions of Critical Access Hospital regulations and public health law and rules applicable to general hospitals, including those parts pertaining to certificates of need and other operating certificates. This will 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 Assess Hospitals will provide initial diagnostic services, a limited range of therapeutic services, resuscitation and stabilization services, and will 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 will 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 will be 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 will meet all hospital licensure standards for the State of West Virginia, cited in Sections §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 will 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 will 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. Patients presenting with conditions that are beyond the clinical capabilities of the Critical Access Hospital will be transferred to a hospital that has available appropriate services.

16.4. Quality Improvement.

16.4.a. The governing body will 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 Section §12.15 of this rule, this program will 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 will 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/occurrences; and

16.4.b.9. Adverse drug reactions.

16.5. Medical Staff.

16.5.a. The medical staff will develop a system in which network medical/professional staff participate and collaborate to provide consultation, assistance with medical emergencies, and patient referrals.

16.5.b. The Critical Access Hospital will 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 will 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, an institution will:

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 host hospital must 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 host hospital to establish the Long Term Acute Care Hospital will revert back to the host hospital's licensed bed capacity.

17.2. Psychiatric Hospital.

17.2.a. To be licensed as a psychiatric hospital, an institution will:

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

17.2.a.2. Have professional personnel especially

TITLE 64
LEGISLATIVE RULE
WEST VIRGINIA DIVISION OF HEALTH

FILED

SERIES 12
HOSPITAL LICENSURE RULE

2005 JUL 19 P 1:35

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 64CSR12, §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 will 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 Nurse Aide Rule 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 -- 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 will 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. No person may 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 will 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 will:

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. Applicants for license will complete and submit an application to the department on forms provided by the Director and will pay the annual fee as required by W. Va. Code §16-5B-4. The name used on the application forms will be the legal name of the hospital or extended care unit operated in conjunction with a hospital.

3.2.b. A Section §6a hospital will 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 Sections §§4.2.a and 4.2.h of this rule.

3.3. Issuance of License.

3.3.a. The Director will 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.

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 Section §4.2 of this rule or a plan of correction has been accepted. Provided, That the Director will not withhold a license for noncompliance

with Section §4.2 of this rule in the case of the corporation defined in W. Va. Code §18-11C-1d.

3.3.b. The Director will 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 will 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 provisions of W. Va. Code §16-5B-4.

3.4.b. Licensed hospitals and extended care units will 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 will provide licensure renewal forms to each licensed hospital and extended care unit by mail or other means he or she may deem proper.

3.4.c. The application for license will 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 will 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 will renew a license if:

3.4.e.1. The hospital or extended care unit operated in conjunction with a hospital is in compliance with Section §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.

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 will 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 will not be required by the State Department of Health and Human Resources for any hospital that is exempted by the provisions of W. Va. Code §16-5B-5a.

3.5.d. The Department of Health and Human Resources will 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 State Department of Health and Human Resources 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 for cause needed.

3.5.g. Hospitals receiving a three (3) year accreditation will 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. Hospitals will incorporate the results of the self-evaluation in their 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. Hospitals are not required to conduct self-evaluations for any licensing year when they are inspected by the State Department of Health and Human Resources.

3.5.j. Accreditation reports filed with the State Department of Health and Human Resources will 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 will 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 will return its license to the Director.

3.6.c. If the Director revokes a license, the Director will 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. A new license will be issued with the hospital identified by the new name.

3.7.b. All hospitals and extended care units operated in conjunction with a hospital will 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 will post its license in a conspicuous place on the licensed premises.

3.7.d. No hospital will 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 body 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 will be 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 will 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 such additions or termination of services.

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

4.1.e. The governing authority will 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 will 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 will be responsible for the effective operation of the patient grievance process.

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

4.2.a. The Boards of Directors of Section §6a hospitals will 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 will not exceed the number of consumers in any other category by more than one (1).

4.2.b. No member of the Board of Directors of a Section §6a hospital will 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 will maintain a file containing affidavits by its consumer representatives as to their consumer category. The affidavits will 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 will 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; and

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 will consider the hospital to be out of compliance with Section §4.2 of this rule.

4.2.h. The Board of Directors of each Section §6a hospital will 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 will 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 will 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.

4.3.a.3. Ensuring compliance with the rules and regulations of the medical staff as established in 64CSR12, §11.2.

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

4.4. Patient Rights.

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

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

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

4.4.c. Patient rights will include but not be 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 Section §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. Skilled interpreters and personnel skilled in communicating with vision and hearing impaired individuals either directly employed by the corporation or employed under a contract will be provided by the facility in a timely manner.

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

4.4.e.1. The grievance process must 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 must 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 will 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 of this rule will 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 will 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 has precedence.

5.1.c. The hospital will 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 will be at least three (3) feet, eight (8) inches.

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

5.1.f. Corridors, stairways, and elevators will be of a width and design that will easily accommodate the removal of patients in a bed, including beds with traction equipment, and will 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 will not be permitted at any time.

5.1.g. Handrails will 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 will be provided for all exterior openings that are left open for extended periods. Where provided, screen doors will open outward and will be self closing.

5.1.i. Operable windows must have screens and safety design

features.

5.1.j. The hospital will 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 will, 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 will 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 will 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 will have precedence.

5.2.c. Site conditions will 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. An inspection of the site for a proposed hospital will be requested in writing and approval for construction will be obtained from the Director before construction is started.

5.3. New Construction.

5.3.a. Hospitals constructed subsequent to the effective date of this rule will 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. 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., will be submitted to the Director for review prior to beginning work on the project. The drawings and specifications will include architectural, life safety, structural, mechanical and electrical drawings and specifications and will be prepared and signed by an architect and/or engineer registered to practice in West Virginia.

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 will 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 must

complete an infection control and safety risk assessment and will develop a plan to control exposure of patients, employees and the public. This plan must 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 this office or the services of an architect.

5.4.d. Complete construction drawings and specifications for any hospital addition or renovation project which alters a floor plan, impacts life safety, or requires approval under W. Va. Code §16-2D-1 et seq., will be submitted to the Director for review, prior to work beginning on the project. The drawings and specifications will include architectural, life safety, structural, mechanical, and electrical drawings, and specifications and will be prepared and signed by an architect registered to practice in West Virginia. 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 such minor renovations will be determined by the Secretary.

5.4.e. Any existing building, or portions of that building converted for use as a hospital will 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 will comply with West Virginia Department of Health and Human Resources Administrative Rules, Public Water Systems, 64CSR3, and Cross Connection and Backflow Prevention, 64CSR15.

6.1.b. Sewage disposal will comply with West Virginia Department of Health and Human Resources Administrative Rules, Sewage System Rules, 64CSR9.

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

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

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

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

6.1.g. There will 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 will be kept free from

obstruction at all times.

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

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

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

6.1.l. The hospital will comply with West Virginia Department of Health and Human Resources Administrative Rules, Infectious Medical Waste, 64CSR56.

6.2. Lighting

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

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

6.2.d. The dates on which the testing is conducted will 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 will be inspected and tested routinely as defined by hospital policy.

6.3.c. All hospitals will 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. will be used.

6.3.d. Facilities will have in place a management plan for all indoor air systems which will 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 provisions of laundry services will comply with Section §5 of this rule.

6.4.b. The hospital will 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 will 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 will have:

6.4.d.1. Separation of clean and soiled linen, receiving, storing and sorting areas with facilities to wash your 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 will 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 will be separately stored and washed as will linen contaminated with radioactive material.

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

6.4.h. Soiled linen will 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 will:

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 will 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 will 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 will 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 will 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 will 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 will be concentrated in one area on each unit separate from clean storage.

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

6.6.d. Separate storage areas will 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 will 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 will 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, will be stored in locked cabinets, medication rooms, or medication carts approved by the Director of Pharmacy. This will ensure the integrity of the medications and safety for the patients and the general population. It will 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 will 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 will be stopped after a reasonable period of time which is pre-determined by medical staff policy.

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

7.1.h. The medication preparation area will 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 will be kept within a secure storage area accessible only to authorized personnel.

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

7.1.k. A record will 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 will not be accessible for patient use.

7.1.m. Except for medication packaged for unit doses, all unused medications will 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 will be immediately reported to the attending practitioner and Director of Pharmacy and investigated utilizing current and readily accessible drug and patient information. This information will be evaluated as part of the hospital quality improvement program.

7.1.o. A formulary system will be established by the medical staff and reviewed as necessary.

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

7.1.q. Drugs and biologicals will 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 will 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 will be under the supervision of a person qualified by training and experience as defined by hospital policy.

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

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

7.2.d. A medical record will be maintained for every individual evaluated or treated in the hospital on an inpatient and an outpatient basis.

7.2.e. The hospital will 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. Medical records, including records of patients treated in the emergency room or outpatient department, will be preserved for a minimum of five (5) years in their original form or in a legally reproduced form.

7.2.g. The hospital will 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. Originals or copies of medical records will only be released by the hospital in accordance with Federal and State laws or upon receipt of an order from a court of competent jurisdiction.

7.2.i. Copies of medical records and any other pertinent data will be provided 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 will 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 must be an updated note addressing the patient's current status and/or any changes in the patient's status. This note must 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 physicians 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 deems necessary; and

7.2.j.21. Autopsy findings if performed.

7.2.k. A medical record will be maintained 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 will 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 will be legible and will 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 will include signatures which may be electronic.

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

7.2.p. All orders for medication or treatment will 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. Verbal and telephone orders will 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 will also be communicated to the registered professional nurse responsible for the overall care of that patient.

7.2.r. Physicians will 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 will 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 will be maintained as part of the patient's medical record.

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

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

7.2.v. A complete list of all births, deaths, and fetal deaths occurring within the month in licensed hospitals will be reported by the tenth of the following month on forms provided by or approved by the Director or on a comparable computer printout approved by the Director to the state registrar of vital statistics.

7.2.w. All completed birth certificates will be sent to the state registrar of vital statistics within ten (10) days following the birth.

7.2.x. Licensed hospitals will comply with West Virginia Department of Health and Human Resources 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 will 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 will make arrangements for medical record retention and retrieval. Written documentation of this arrangement will be provided to the Director.

7.2.aa. The hospital will 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 any such patient, an authorized individual to be determined on a case by case basis may make such request and will receive such statement at no additional cost.

7.3. Dietetic Service.

7.3.a. The hospital dietetic service will comply with West Virginia Department of Health and Human Resources Administrative Rules, Food Service Sanitation Rules, 64CSR17.

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

7.3.c. The hospital will 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 will be made for continued in-service training of the designated dietetic service supervisor.

7.3.e. The food services department will 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 can direct the food services department.

7.3.f. Responsibilities of the Director of the Dietetic Services will 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 will be a qualified dietician available on a

full-time, part-time, or a consultant basis. A qualified dietitian will 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 will 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/her duties and responsibilities.

7.3.i. Written and dated menus planned at least fourteen (14) days in advance for both therapeutic and general diets will be posted in appropriate places in the food preparation area and be available to administrative personnel.

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

7.3.k. All therapeutic diets, including between meal nourishments, will 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 will be readily available to the medical, nursing and dietetic service personnel.

7.3.m. Adequate personnel will be employed to perform the functions of the dietetic service department.

7.3.n. There will be procedures to prevent the contamination of meals and other items prepared or served by the dietetic service department employees.

7.3.o. There will be 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 West Virginia Department of Health and Human Resources Administrative Rules and Food Service Sanitation Rules, 64CSR17.

7.3.q. Dry or staple food items will 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 will be maintained at a temperature of forty-five (45) degrees Fahrenheit or below. Refrigerators

and storerooms used for perishable foods will be equipped with reliable thermometers.

7.3.s. All ice used in contact with food or drink will comply with West Virginia Department of Health and Human Resources Administrative Rules, Public Water Systems, 64CSR3.

7.3.t. A sample of potentially hazardous foods from the menu of each meal will be retained 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 will bear warning labels, be stored separately from food or equipment used on preparing and serving food and will be used only in ways that will neither contaminate food nor be hazardous to employees.

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

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

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

7.4. Infection Control

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

7.4.b. There will be an active surveillance and education program for the prevention, early detection, control, and investigation of infections and communicable diseases.

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

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

7.4.e. A person or persons will be designated 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. A log of incidents related to infections and communicable diseases will be maintained by the infection control professional or designee.

7.4.g. The hospital administrator, medical staff, and the Director of Nursing will 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. All patient care units or departments will be developed and maintained in accordance with Section §5 of this rule.

8.1.b. All patient care areas and units will 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 will maintain or have easy access to an emergency cart for use in the event of patient respiratory or cardiac arrest. Contents of this cart such as medications and supplies will be determined by hospital policy. The frequency of monitoring of the contents of the emergency carts will be determined by nursing service policies and procedures.

8.1.d. Protocols will be developed for implementation of respiratory and cardiac arrest care on a twenty-four (24) hour basis utilizing all necessary staff throughout the hospital including any available physicians for immediate emergency response.

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

8.2. Patient Care/Nursing Unit

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

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

8.2.c. Each one (1) bedroom will 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 will contain a minimum floor area of eighty (80) square feet for each bed.

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

8.2.e. Artificial light will 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 will have a night light control switch located at the point of entry into patient rooms.

8.2.g. Patient rooms will have movable furnishings. The

director will make exceptions as needed regarding all furnishings for psychiatric hospitals. Patient rooms will 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, will be a self contained unit and will be segregated from all other parts of the hospital.

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

8.3.c. Specific policies will be established 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 will not be moved 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 will 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 will be performed in a caesarean delivery room suite or in the hospital's operating room.

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

8.3.h. As determined by medical staff, there will 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 will be ready for the reception and care of the newborn infant in all delivery suites.

8.3.j. There will be supplies and equipment for resuscitation of

mother and newborn.

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

8.3.l. A means of identification for each infant, approved by the medical staff, will be established and available in all delivery suites and will be applied at the time of delivery in the delivery suite.

8.3.m. Medications approved by the medical staff for the prevention of inflammation of eyes of the newborn will be instilled in the eyes of the newborn baby, 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. A bed that is utilized for postnatal care will be included in 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 will be moved to another location within the hospital.

8.4. Nursery

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

8.4.b. Nurseries will 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 will 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 will be weighed on accurate infant scales provided for each nursery.

8.4.e. There will 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 will be handled and prepared in a manner consistent with the requirements of West Virginia Department of Health and Human Resources Administrative Rules, Food Service Sanitation Rules, 64CSR17.

8.4.g. Immediate segregation and isolation of any infant with a communicable infection will be provided.

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

8.4.i. Infant clothing and diapers will be furnished by the hospital.

8.4.j. Instructions for feeding and care of the infant will be included in the discharge planning process for the infant's care givers.

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

8.5. Surgical Department

8.5.a. The surgical department will 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 will be available to the hospital staff at all times.

8.5.b. The surgical suites will 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 will be limited to authorized personnel only.

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

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

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

8.5.g. A log will be maintained for daily documentation of each surgical procedure and will 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 will 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 must 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 will be in the patient's chart before surgery, except in emergencies.

8.5.j. An operative report describing techniques, findings, and tissues removed or altered will be completed immediately following surgery and authenticated by the practitioner. The content and format of the operative report will be determined by hospital policy.

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

8.5.l. Adequate provisions will 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 will be provided.

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

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

8.6. Post-Anesthesia Care Unit

8.6.a. There will 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 will 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 will be arranged so that all patients can be observed simultaneously.

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

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

8.6.f. The post-anesthesia unit will 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 will be in the post-anesthesia unit when a patient or patients are present.

8.6.h. All pertinent information related to care provided while the patient is in the post-anesthesia unit will be recorded 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 will also be recorded in the patient's record.

8.6.i. If patients are not transferred to the recovery room, provisions will 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. There will be 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 to administer anesthesia by State law, a certified nurse anesthetist who is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed, or a trainee in an approved educational program in anesthetic techniques who is under the direct supervision of an anesthesiologist who is physically present. Anesthesia may also be administered by a licensed anesthesia assistant who has completed a six (6) year program for anesthesiology assistants. This anesthesia assistant will be under the direct supervision of an anesthesiologist who is physically present.

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

8.7.d. An intra-operative anesthesia record will be completed for all surgical patients.

8.7.e. A post-anesthesia evaluation will be performed within forty-eight (48) hours of surgery for all inpatients by the individual who administered the anesthesia.

8.7.f. Content and format of the pre-anesthesia evaluation, intra-operative anesthesia record, and the post-anesthesia evaluation will be determined by hospital policy.

8.7.g. Safeguards in the use of various types of anesthetics will be established by written policies in accordance with the National Fire Protection Association.

8.7.h. All equipment and medications utilized in administration of anesthesia will be stored in a secure, safe, and readily accessible location according to current professional standards. All equipment will be

serviced and maintained by qualified technicians.

8.8 Pediatric Service

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

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

8.8.c. There will be proper facilities and procedures for the isolation of children with infectious or communicable diseases.

8.8.d. There will be pediatric emergency supplies, medications, and equipment organized and readily available on any patient care unit that provides pediatric services.

8.9. Specialty Care/Critical Care Unit

8.9.a. Specialty care units, such as coronary care units and intensive care units, will be 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 will 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 will be readily available to each unit at all times. The physician will 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 must be appropriate for the scope of services offered to ensure the health and safety of the patients.

8.9.e. Nursing care will be 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 will have documented training and competence in the specific care provided.

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

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

8.9.i. Beds in a specialty care unit will 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 will 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 will 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 will be easily accessible for all patients receiving treatment.

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

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

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

8.10.f. The outpatient department medical staff will 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. Accurate and complete medical records will be maintained for all outpatients, according to hospital policy.

8.11. Emergency Department.

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

8.11.b. The emergency department will 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 will be under the supervision of a registered professional nurse licensed in West Virginia.

8.11.d. All emergency department staff will 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, will be available for all hours that emergency services are provided.

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

8.11.g. A physician or midlevel practitioner will 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 will be located so as to permit easy access from automobiles and ambulances.

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

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

8.11.k. All measures necessary to ensure compliance with the requirements of Section §1867 of the Emergency Medical Treatment and Active Labor Act, will be taken even when emergency services are not available.

§64-12-9. Extended Care Unit/Nursing Facility.

9.1. General Requirement - The extended care unit will be located in a segregated, physically separated area of the hospital and will 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 will be provided for dining and recreation areas, special equipment storage, training toilets, showers and bath facilities. Handrails, drinking fountains, lavatories, thresholds and telephone alcoves will 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 will be organized under the direction of a committee of the medical staff. Written policies will be developed by professional personnel including at least one (1) registered

professional nurse.

9.3.b. The Nursing service will be under the direction of a registered professional nurse.

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

9.4. Financial Rights and Responsibilities

9.4.a. Extended care residents or their representatives lawfully authorized to manage fiscal matters on behalf of the resident have the right to manage their own personal financial affairs.

9.4.b. A hospital which manages or holds personal funds for extended care patients will 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 will hold the funds separately and in trust. Patient funds will not be commingled with hospital operating or other funds.

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

9.4.d. The hospital will 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 will 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 will 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 will 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 will inform the patient in writing at the time of admission or at the time this exclusion is adopted by the hospital.

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

9.6. The hospital will 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.

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

9.8. The unit may utilize 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 will be required if the pharmacist is an employee of the hospital.

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

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

10.1. General Requirements.

10.1.a. All ancillary diagnostic and treatment departments will be developed and maintained in accordance with Section §5 of this rule.

10.1.b. Ancillary patient departments should be conveniently located to provide services to all patient populations.

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

10.1.d. Toilets for ambulatory patients and the public will be provided.

10.1.e. All ancillary diagnostic services and treatment departments will maintain current policy and procedure manuals approved by the medical staff. These manuals will 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 will be equipped and maintained according to current professional standards.

10.2. Laboratory Department.

10.2.a. The hospital will 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 will 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 will be available twenty-four (24) hours a day.

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

10.2.e. Laboratory personnel will receive 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. Space will be provided for administrative services and clean-up and decontamination of equipment.

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

10.3. Blood and Blood Products.

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

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

10.3.c. Arrangements will be made for procurement, transfer, and availability of blood types not ordinarily kept at the hospital

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

10.3.e. Blood utilization will be evaluated through the hospital quality improvement program. A pathologist and/or designated physician will be included in this evaluation.

10.3.f. The hospital will 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 will 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 will 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/Imaging Service.

10.4.a. The hospital will 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 will be administered according to professionally approved standards

for safety and personnel qualifications.

10.4.c. Radiology services will 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 will 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. Their responsibilities will 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. All imaging tests will be interpreted by a radiologist 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 will be maintained against radiation hazards in compliance with West Virginia Department of Health and Human Resources 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. Periodic inspections of equipment will be made according to hospital policy and any identified hazards will be corrected promptly.

10.4.h. Radiology service personnel, and other appropriate personnel, will be checked periodically 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 will operate radiology equipment and administer procedures according to W. Va. Code §30-23-1-et.seq.

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

10.4.j.1. One (1) radiographic room with adequate radiology equipment;

10.4.j.2. A darkroom unless 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 utilizing 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, will be provided according to current national professional standards.

10.5. Rehabilitation Service.

10.5.a. If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, sports medicine, or speech pathology services, the services will be organized and staff will be available to ensure the health and safety of patients.

10.5.b. If any or all of the services referenced in Section §10.5.a are provided, they will be provided by a sufficient number of staff who meet 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, will 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 will be accountable to an individual who directs the overall operation of the service.

10.5.e. The director of the services will 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, will be responsible to:

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 will depend upon the services provided.

10.5.h. Services will be furnished 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 plan of treatment will include treatment goals and type, amount, frequency, and duration of services and will 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 will be defined in writing and meet the needs of the patients.

10.6.b. Respiratory care services will 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. There will be 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. Services will be delivered in accordance with medical staff directives.

10.6.e. Services will be provided only in accordance with the written orders of practitioners authorized by the medical staff.

10.6.f. Personnel qualified to perform specific procedures and the amount of supervision required for these individuals will be designated in writing.

10.6.g. Personnel who are qualified to provide direct supervision will be designated in writing.

10.6.h. If blood gases or other clinical laboratory tests are performed in the respiratory care unit, the unit must 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 a morgue and autopsy facilities are not available at the hospital, written agreements will be maintained 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 must 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 will 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 body. The medical staff will be accountable to the governing body for the quality of medical care provided to the patients.

11.2. The medical staff will be appointed by the governing body of the hospital in accordance with its by-laws, rules and regulations.

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

11.4. The medical staff will 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 body for new members will be specific to the type of appointment and extent of clinical privileges.

11.6. Clinical privileges of each medical staff member will be delineated in writing.

11.7. The medical staff will be organized in a manner approved by the governing body.

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

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

11.10. The by-laws will:

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 will sign a document that specifies they have read the by-laws, rules, and regulations. These rules, regulations and policies will specifically provide for:

11.11.a. Requiring departmentalized medical staffs to meet every other month provided the executive committee meets monthly. The full medical staff will meet annually. In the event the executive committee does not meet monthly then the departmental meeting of the medical staff will be monthly. Non-departmentalized medical staffs will have monthly meetings of the executive committee and the full medical staff will meet every other month. In the event there is no executive committee, the full medical staff will 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 will 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 other such committees as the hospital may consider necessary.

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 will 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 nursing services will be organized 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 will ensure 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. A written nursing service plan of administrative authority with delineation of responsibilities and duties of each category of nursing personnel will be maintained and 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 will 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 will 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 employee and 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 facility will 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 will make available to all nursing employees and provide explanation of the written personnel policies, procedures, and organizational charts.

12.8. The following records will 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. There will be 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 utilize nursing assistants interchangeably between acute patient care units and an extended care unit, documented evidence of nurse assistant training certification will be maintained for personnel utilized in this manner.

12.11. Additional personnel, as needed, to provide clerical procedures.

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

12.13. A current individualized patient care plan will be established and maintained for each patient.

12.14. Documented nursing notes will be maintained for each patient.

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

12.16. Planned meetings will 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. Documented, continuing education activities will be provided for all nursing personnel. These activities will include, but not be limited to, on the job training and development programs. Records of these program activities will 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 will 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 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 regulations;

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 will be on duty or on call at all times.

13.1.c. A Doctor of Medicine or Osteopathy will 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 will be based on the needs identified in the plan of care.

13.2.b. A nursing assessment will be completed within twenty-four (24) hours of admission as an inpatient. This assessment will include information necessary to develop an effective plan of care.

13.2.c. Each patient's clinical response to the plan of care will 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. Each patient will be reassessed and a revised plan of care implemented as often as necessary to meet the patient's needs.

13.2.e. Documentation of each patient's plan of care will 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 will be admitted to the hospital only upon orders of a practitioner licensed in West Virginia with admitting privileges at the hospital.

13.3.b. A comprehensive assessment, including any information necessary to develop an effective, interdisciplinary plan of care will be completed in the time frame identified by hospital policy and placed in the medical record.

13.3.c. The comprehensive assessment will 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 will 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 will 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. Each patient will 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 will 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 will be based upon the patient's functional abilities and probable environment to which the patient will return. The hospital's policies and procedures will be specified in writing.

14.2. A discharge needs assessment, evaluating the factors that affect the patient's need for post-hospital care, will 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 will address the biopsychosocial needs of the patient, the level of understanding of those needs and an identification of post hospital care resources.

14.3. As needed, the patient and family members or interested persons must be counseled to prepare them for post-hospital care including hospice services.

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

14.5. The discharge plan will be reassessed as needed and entered into the patient's record.

14.6. The hospital will 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 will 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 will be responsible for and 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 will be in areas over which the hospital exercises authority and responsibility including services furnished by contract.

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

15.4. 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 will 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 results of peer review and quality assessments and performance improvement information will be made available to the West Virginia Department of Health and Human Resources upon 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. An assessment of the impact of quality improvement activities and corrections or reevaluation of the performance indicators will be conducted 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 will include, but not be limited to:

- control issues; 15.10.a.1. Nosocomial infections and other infection
- performance; 15.10.a.2. Staff, administrative, and practitioner
- findings; 15.10.a.3. Complaints, grievances, or risk management
- services provided; 15.10.a.4. Evaluation of diagnostic and therapeutic
- incidents/occurrences; 15.10.a.5. Medication errors and other

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 will remain subject to the provisions of Critical Access Hospital regulations and public health law and rules applicable to general hospitals, including those parts pertaining to certificates of need and other operating certificates. This will 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 Assess Hospitals will provide initial diagnostic services, a limited range of therapeutic services, resuscitation and stabilization services, and will 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 will 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 will be 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 will meet all hospital licensure standards for the State of West Virginia, cited in Sections §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 will 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 will 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. Patients presenting with conditions that are beyond the clinical capabilities of the Critical Access Hospital will be transferred to a hospital that has available appropriate services.

16.4. Quality Improvement.

16.4.a. The governing body will 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 Section §12.15 of this rule, this program will 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 will 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/occurrences; and

16.4.b.9. Adverse drug reactions.

16.5. Medical Staff.

16.5.a. The medical staff will develop a system in which network medical/professional staff participate and collaborate to provide consultation, assistance with medical emergencies, and patient referrals.

16.5.b. The Critical Access Hospital will 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 will 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, an institution will:

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 host hospital must 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 host hospital to establish the Long Term Acute Care Hospital will revert back to the host hospital's licensed bed capacity.

17.2. Psychiatric Hospital.

17.2.a. To be licensed as a psychiatric hospital, an institution will:

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 an institution will:

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. Severability.

18.1. The provisions of this rule are severable. If any provisions of this rule are held invalid, the remaining provisions remain in effect.

§64-12-19. Administrative Due Process.

19.1. 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.

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: 7/15/05

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency Name, Address & Phone No.) Office of Health Facility Licensure and Certification

1 Davis Square, Suite 101

Charleston, WV 25301 (304) 558-0050

LEGISLATIVE RULE TITLE: Hospital Licensure Rule

1. Authorizing statute(s) citation WV Code 16-5B-8

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

May 25, 2005

b. What other notice, including advertising, did you give of the hearing?

Sent copy to all hospitals in West Virginia

c. Date of Public Hearing(s) *or* Public Comment Period ended:

June 23, 2005

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached x

No comments received

- e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

7/15/05

- f. Name, title, address and phone/fax/e-mail numbers of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

Anita Barnhouse D.O., Program Manager II

1 Davis Square, Suite 101

Charleston, WV 25301

phone - (304) 558-1500, fax (304)558-2515, anitabarnhouse@wvdhhr.org

- g. **IF DIFFERENT FROM ITEM 'f',** please give Name, title, address and phone number(s) of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

Same

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

- a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

b. Date of hearing or comment period:

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

d. Attach findings and determinations and reasons:

Attached _____



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05 JUN 23 PM 12: 33

June 23, 2005

Anita Barnhouse, D.O., Program Director
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1 Davis Square, Suite 101
Charleston, WV 25301

Re: Title Number 64, Series 12, proposed revisions to Hospital Licensure

Dear Dr. Barnhouse:

The purpose of this letter is to provide comment on the proposed revisions to legislative rule 64CSR12, which was filed in the West Virginia Secretary of States Office on May 25, 2005.

On behalf of the 73 member hospitals and health systems in West Virginia, the West Virginia Hospital Association would like to thank the agency and its staff for all the hard work in revising licensure rules which are in dire need of updating. We also would like to thank the agency for involving the hospitals during the rewriting stages. Because of this involvement, most of our concerns were addressed at an early stage in the process.

At this time, the Association desires to make specific comments and suggestions with respect to the following proposed rules.

§64-12-2 Definitions

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

Suggested: Neglect – Is willful failure to provide goods and services necessary to prevent physical harm and/or mental anguish.

Comment: Every other definition of neglect in WV Code specifies that the neglect needs to be “willful”. The current Nursing Home Rules do not even have a definition for neglect, so if we are going to have one, it needs to be consistent.

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

Comment: In sections 5.3.b, 5.4.c, 5.4.d and 3.4.e.2, all require that "complete construction drawings and specifications for any hospital construction project which alters a floor plan" be submitted to the Director for review. This requirement is excessive. Moving a door or opening a wall in non-patient care areas should not require blue prints, architects and approval just because the floor plan has a minor change. Major construction and renovations of patient care areas is understandable. While it is nice that a hospital could submit minor plans for review, it should not be required.

7.1 Pharmaceutical Services

7.4.f
71.5 All drug administrative errors, adverse drug reactions, and incompatibilities will be immediately reported to the attending practitioner and Director of Pharmacy and investigated utilizing current and readily accessible drug and patient information. This information will be evaluated as part of the hospital quality improvement program.

Suggested: Drug administrative errors, adverse drug reactions, and incompatibilities will be immediately reported to the attending practitioner and Director of Pharmacy and investigated utilizing current and readily accessible drug and patient information. This information will be evaluated as part of the hospital quality improvement program.

Comment: Since a "drug administration error" is not defined, as written, this says that everything for example administering the drug later than scheduled would require to be investigated. Events such as this are captured on safety reports, but to try and investigate every such incident would be impossible. We are suggesting to just remove the word "All".

7.2 Medical Records Department and Information System

7.2.r Physicians shall countersign and date all verbal and telephone orders at the next hospital visit.

Suggested: Physicians shall counter sign and date all verbal and telephone orders as soon as possible as designated in federal regulations.

Comment: By using the phrase "as soon as possible" the rule would remain consistent with the CMS Conditions of Participation. Most hospitals further define this in

hospital policy to read within a certain number of hours. The phrase “at the next hospital visit” could not be validated by either the hospital or OHFLAC without an audit of each individual physician’s personal calendar.

7.4 Infection Control

7.4.f A log of incidents related to infections and communicable diseases will be maintained by the infection control nurse or designee.

Suggested: A log of incidents related to infections and communicable diseases, as specified by state and federal regulations, will be maintained by the infection control professional or designee.

Comment: As written, this says that ALL infections and communicable diseases need to be logged. Since this is simply not possible and we believe that it is not the intent of the rule, we suggest that we reference the two sources that specify what needs to be logged and reported (CDC and State Epidemiology). Also, the term “infection control nurse” is no longer a national standard. They are more commonly known as “Infection Control Professionals”, many of which are not nurses. There is a certification program for an ICP and being an RN is not a requirement.

8.3 Obstetric Service

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

8.3.f There will be a Caesarean delivery room/suite provided in accordance with Section §5 of this rule.

Suggested: Delete 8.3f since it is already a part of the 2001 edition of The Guidelines for Design and Construction of Hospitals and Health Care Facilities which are a part of Section §5.

Comment: There are hospitals that, based on their physical plant layout, utilize a surgical suite rather than a caesarean suite within the obstetrics unit. Rather than reference this standard twice in the same rules, striking 8.3f still maintains its intent in Section §5, but provides some leeway as deemed appropriate by the Director.

8.4 Nursery

8.4.b There will be at least four (4) feet between bassinets

Comment: This is a new requirement that none of the nurseries in the hospitals could currently meet, including the states largest hospital. This needs left as currently written. The financial impact on hospitals for this single change would be substantial.

8.7 Anesthesia Department

8.7.a There shall be an organized anesthesia department under the supervision of a physician specializing in anesthesiology licensed in West Virginia who shall be responsible for all anesthesia administered in the hospital.

Suggested: There shall be an organized anesthesia department under the medical direction of a qualified physician member of the medical staff licensed in West Virginia who shall be responsible for all anesthesia administered in the hospital.

Comment: By changing this rule to only allow an anesthesiologist to supervise the anesthesia department we would prevent some small/rural and critical access hospitals from providing surgical services to their communities. Additionally, only a few states in the country have the anesthesiologist requirement and those states have no small/rural or critical access hospitals.

10.4 Radiology/Imaging Service

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

10.4.j.1 One (1) radiographic room with adequate radiology and fluoroscopic equipment;

Suggested: One (1) radiographic room with adequate radiology equipment;

Comment: In today's small/rural hospital setting it is not always necessary or possible for a radiology department to have a fluoroscopic unit. For some, having a mobile CT or MRI scanner has greater medical value than having a fluoroscopic unit. In this case, the listing of this type equipment as a requirement is outdated.

10.6 Respiratory Care Services

- 10.6.b The Director of Respiratory Care Services will be 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.

Suggested: Respiratory Care Services will be under the medical direction of a physician licensed by the West Virginia Board of Medicine or the West Virginia Board of Osteopathy with the knowledge and experience to supervise and administer the services. The medical director may serve on either a full-time or part-time basis.

Comment: The director of a clinical department is normally a licensed professional in that specialty area. In this case we are not referring to that person but rather the "medical" director. This should be the same as 10.4.d for Radiology services.

64-12-9 Extended Care Unit/Nursing Facility

- 9.3.a The extended care unit will be in compliance with the current Nursing Home Licensure, 64CSR13, which was effective July 1, 2001.

Comment: We believe this proposed change is both inconsistent and unnecessary. Hospital based nursing facilities already follow all hospital licensure requirements, many of which either exceed or are duplicates of similar requirements in Nursing Home Licensure. If there are some pertinent crossover requirements, then those should be listed within this section of the Hospital Licensure Rules. Additionally, there are requirements within the Nursing Home rules which are not applicable.

The following Regulations from Nursing Home Licensure are examples of requirements that are not applicable to Hospital Based Skilled Nursing Facilities:

Definitions:

64-13-2 Definitions

- 2.1 Administrator. -- A person licensed in the State of West Virginia as a nursing home administrator who is responsible for the day to day operation of the nursing home.

Comment: Hospital Based SNF's are under the administrative oversight of the hospital President/CEO. Requiring each of these CEO's to become licensed nursing home administrators is not only impractical but it brings with it no greater quality of care to the residents. Additionally, 64-12-9.3a already addresses this issue for units with more than sixty (60) beds.

2.24 License – The document issued by the secretary that is the license authority to receive residents and perform services include within the scope of this rule.

Comment: Hospitals are not licensed under this rule.

2.25 Licensed or Registered

2.25.b. Nursing Home – a nursing home licensed by the department.

Comment: The department does not license hospital based units. They are licensed under the hospital license.

4.9 Right to Choose a Personal Physician:

4.9.b. Upon admission the nursing home will provide the resident with the names of physicians who have attending privileges at the nursing home.

Comment: In general most physicians attend their patient at the HB SNF and patients arrive with their own physicians. Most of the medical staff would attend.

4.10 Personnel Funds

Comment: HB SNF do not hold personal funds for patients due to their short length of stay. HB SNF should develop a policy to meet the intent of this requirement.

4.1 Admissions and Payment

4.15.c.2 Medicaid residents and their legal representatives shall be informed that if they desire a private room they may privately supplement the Medicaid payment by directly paying the facility the difference between the semi-private room rate and the private room rate.

Comment: Does not apply

4.15.e.1 A nursing home may charge a resident who is eligible for Medicaid for items and services the resident has requested and received, and that are not specified in the State Medicaid Plan as included in the term “nursing home services” if the nursing home gives proper notice of the availability and cost of these services to residents and does not condition the resident’s admission or continued stay on the request for or receipt of such additional services.

Comment: Does not apply

4.16.c. Abuse

A nursing home will not employ persons who have

4.16.c.3.b Had a finding entered into the Certified Nurse Assistant Registry or the WV Adult Abuse Registry concerning abuse, neglect, exploitation or mistreatment of residents or misappropriation of their property.

Comments: Proposed Hospital Licensure Changes

Comment: Most hospitals now perform a Criminal Background Check on all new hires. We also feel it is appropriate to check employees with the Aide Abuse Registry. The question on this is does a hospital have to check every single employee on campus with the WV Adult Abuse Registry or just those that work in the SNF? This would cause quite a problem if every employee at the hospital had to have this performed.

8.15.a Dietary Staffing

8.15.a.2 A dietary manager shall be employed if a dietician is not employed full time and shall be one of the following...

Comment: Not applicable to HB SNF because the hospital already has such person employed as per Section 7.3.e of Hospital Licensure rules.

8.19.i Storage of drugs and biological

8.19.j A nursing home shall establish a policy to assure that resident's request for prescription medication from sources other than the contracted pharmacy is honored.

Comment: The hospital pharmacy provides the medications for all Part A patients.

9.8 Solid Waste and Biohazard Waste Disposal

9.8a.1.Chain of custody receipts and forms shall be maintained by the nursing home for one year.

Comment: The hospitals keep these records not the SNF.

11.6 Personnel Records

11.6.d Results of annual physical.

Comment: Many hospitals do not require an annual physical. Most only require an annual TB test (PPD) and blood work.

11.7 Medical Director

11.7.a.3 Assisting in the evaluation of credentialing and re-credentialing of licenses independent practitioners, PA and nurse practitioners to determine whether they will be authorized to practice within the organization by recommendation.

Comment: This is performed by the medical staff services department at each hospital and would not be a separate function for a HB SNF.

13.1 Records maintenance and Retention.

13.1.d A nursing home shall ensure that each clinical record contains a photograph of the resident unless the resident objects.

Comment: Hospitals do not take pictures of their patients.

R. Terrance Rodgers
Chairman of the Board



David M. McWatters, III
President & CEO


05 JUN 23 PM 1:01

FLAC

June 23, 2005

Office of Health Facility Licensor and Certification
1 Davis Square, Suite 101
Charleston, WV 25301

RE: HOSPITAL LICENSOR RULE 12 COMMENTS




Please accept these comments relevant to Hospital Licensor Rule 12. The comments are provided in the context of a free standing psychiatric hospital which does not provide the scope of services found in an acute care medical facility. As Psychiatric patients can be more volatile and are often a danger to themselves or others, certain requirements under the Proposed Rule could actually be harmful to the patients, staff and hospital. Our concerns are self-explanatory and are itemized below;

- 7.3.1 This proposed rule will result in additional liability exposure for Hospitals unless "hazardous foods" are identified in the rule. With a growing population of patients with food allergies, most any food can be hazardous to someone. The rule needs to be more focused if there are particular foods of concern.
- 8.1.c. Emergency carts are needed and appropriate for use on a Hospital medical floor. They may not be appropriate for Psychiatric Hospitals. Psychiatric Hospitals do not have physicians or other cardiac certified staff on duty 24/7 and the use of items found on an emergency cart could be detrimental to the patients well being if used inappropriately. We would request that this rule be limited to Hospitals other than free standing Psychiatric.
- 8.2.8 Moveable furnishings within a Psychiatric facility put both patients and staff at risk. It is not uncommon for psychiatric patients to barricade themselves in their room when furniture is moveable and can be used to block the door. More common is the use of moveable objects as missiles or weapons against staff or other patients in instances when patients are paranoid or fearful. Moveable furnishings should under no condition be required in psychiatric facilities.
- 8.2.4.1. Both adjustable beds and siderails offer patients the accommodation for a suicide attempt by hanging. Neither should be required for psychiatric patients who are not being treated for a medical condition.
- 8.2.2 Cabinets and bed side tables have been used as weapons against staff in our Hospital. If these are to be required they should 1. Not be moveable 2. Not have removeable drawers

3. Not have easily removeable parts such as legs, trim, brackets, or screws which could be removed and used to injure self or others 4. Not have doors and 5. Not have sufficient space for patients to crawl into eliminating the ability of staff to closely monitor..

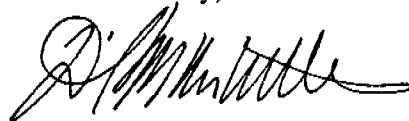
8.2.g.3 Over bed tables are an ideal weapon and provide an ideal hanging facility for seriously impaired psychiatric patients. They should not be required on psychiatric units or in Psychiatric hospitals.

 8.2.g.4 This rule should be expanded to say that the trash receptacles are to be made of plastic or other lightweight materials and should not be lined with removeable liners which could be used for self suffocation.

10.8 Psychiatric Hospitals should be excluded from being required to have protocols for organ, tissue, and eye procurement.

11.11.a This rule is overly burdensome on physician time and forced compliance will result in physicians withdrawing their hospital privileges. It is suggested that this rule be modified to allow for quarterly medical staff meetings and to be applicable to only those Hospitals having 15 or more attending physicians on their active medical staffs. Private Physicians often see inpatient care as a burden and their withdraw of privileges could be catastrophic to small facilities who could not attract sufficient staff to replace those leaving inpatient work.

Sincerely,



David M. McWatters
President and Chief Executive Officer

June 22, 2005

05 JUN 23 PM 1:02

Office of Health Facility Licensure and Certification
1 Davis Square, Suite 101
Charleston, WV 25301

AC

RE: Comments on proposed revisions to Hospital Licensure Rule

Dear Sir or Madam:

On behalf of various affected departments at Cabell Huntington Hospital, I am writing to comment on the proposed revisions to the Hospital Licensure Rule that were filed on May 25, 2005, in the Office of the West Virginia Secretary of State.

- 7.2.a. The prior rule, at 10.3.1 required that the department be under the supervision of a "medical records registered record administrator". Currently, the designation of an appropriately credentialed health information management profession would be either a "Registered Health Information Administrator (RHIA)" or a "Registered Health Information Technician (RHIT)". Those designations should be included in this revision to ensure appropriately qualified supervision.
- 7.2.h. It is recommended that the following language be added to the end of this sentence: "or upon receipt of an order from a court of competent jurisdiction."
- 7.2.i This requires information to be provided within 48 hours of a written request. What happens if that written request is received on a Friday? It is recommended that the time requirement be changed to: "within two (2) business days".
- 7.2.r. As proposed, this requires physicians to "countersign and date all verbal and telephone orders at the next hospital visit." It is recommended that the language found in the current 10.3.8 be retained: "Physicians shall countersign all verbal and telephone orders as determined by the medical staff bylaws."
- 8.9.c. As proposed, this sets a thirty (30) minute response time. It is recommended that both the time and nature of the response be set by hospital policy.

Thank you for the opportunity to comment on the Hospital Licensure Rule. If you have any questions, I can be reached at (304) 526-2057.

Sincerely,



Paul English Smith
Vice President and General Counsel

June 20, 2005

Anita Barnhouse, D.O., Program Director
Office of Health Facility Licensure and Certification
1 Davis Square, Suite 101
Charleston WV 25301

05 JUN 22 PM 3:13

Re: Title Number 64, Series 12, Proposed revisions to the Hospital Licensure Rule

Dear Dr. Barnhouse:

After careful consideration of the proposed revisions to the Hospital Licensure Rule, we are requesting that the following issues be reviewed and taken into consideration during completion of the rulemaking process.

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

5.3 New Construction

5.3.b. 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., will be submitted to the Director for review, prior to beginning work on the project. The drawings and specifications will include architectural, life safety, structural, mechanical, and electrical drawings, and specifications and will be prepared and signed by an architect and / or engineer registered to practice in West Virginia.

Comment: Requiring complete, stamped construction drawings and specifications for minor projects that simply alter a floor plan is excessive. The OHFLAC Architect should have discretion over when they are required.

5.4 Additions and Renovations

5.4.d. Complete construction drawings and specifications for any hospital addition or renovation project which alters a floor plan, impacts life safety or requires approval under W. Va. Code §16-2D-1 et seq., will be submitted to the Director for review, prior to beginning work on the project. The drawings and specifications will include architectural, life safety, structural, mechanical, and electrical drawings, and specifications and will be prepared and signed by an architect registered to practice in West Virginia.

Comment: Requiring complete, stamped construction drawings and specifications for minor projects that simply alter a floor plan is excessive. We recommend that the OHFLAC Architect should have discretion over when they are required.

§64-12-6 Operational Services

6.1 Safety, Sanitation, Housekeeping and Maintenance

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

Comment: This requirement as stated would encompass both clinical and non-clinical areas. It would be very costly to replace all garbage containers throughout the hospital in order to obtain ones with tight-fitting covers.

UHC has received the 2005 Distinguished Hospital Award for Clinical Excellence

F:\Admin\Regulatory\Proposed Revision to Hosp Licensure 2005.doc
Now ranked among Top 5% in the nation for clinical excellence



§64-12-7 Paramedical Services

7.2 Medical Records Department and Information System

7.2.j.20. The inpatient medical record will include at a minimum the following: Death certificate when appropriate; and

Comment: Death certificates are filed in the medical record when received. However, a requirement to assure that this always occurs would be burdensome, in that it would require a considerable amount of staff time in tracking (i.e., calling Funeral Home Directors or the State Registrar to obtain those that are not automatically returned to us).

7.2 Medical Records Department and Information System

7.2.r. Physicians will countersign and date all verbal and telephone orders at the next hospital visit.

Comment: Our Medical Staff Bylaws state that verbal orders should be signed at the physician's next visit. However, a requirement to assure that this always occurs would be very difficult to comply with. It would require a considerable amount of time enforcing a system of manual interventions to alert physicians to each of their own verbal orders. This is especially difficult when there are multiple physicians who are writing orders on the same medical record.

§64-12-8 Patient Care Units or Departments

8.2 Patient Care/Nursing Unit

8.2.g.2. Patient rooms will have movable furniture and be equipped with the following for each patient: A cabinet or bedside table;

Comment: With today's furniture configurations, this is not necessary. We recommend removing this requirement.

8.3 Obstetric Service

8.3.f. There will be a Caesarean delivery room/suite provided in accordance with Section §5 of this rule.

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

8.3.h. As determined by medical staff, there will 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.

Comments: These requirements need clarification. To require a Caesarean delivery room/suite to be located on the Obstetrics Unit is not feasible for our hospital at this time, for many reasons. These include having a staff anesthesiologist available on the unit, a recovery area and staff trained in recovery procedures, a storage area for the OR carts and a sterilizing area. As these services are currently being provided in the OR Suite, this requirement would cause duplication of services.

8.4 Nursery

8.4.b. There will be at least four (4) feet between bassinets.

Comment: The existing language calls for "twenty-four (24) square feet of floor space per bassinet with at least twelve inches (12") between bassinets." To change this space requirement to four (4) feet between bassinets would have a serious impact on our Nursery. This would require our hospital to renovate that unit.

8.11 Emergency Department

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

Comment: If the physician is residency trained and board certified in Emergency Medicine, they do not have to have the certification in advanced cardiac life support.

§64-12-11 Medical Staff

11.11.a. Requiring the full medical staff to meet at least once each month unless medical staff department meetings are held monthly. In the latter case, the full medical staff is then required to meet at least once annually.

Comment: Requiring medical staff department meetings on a monthly basis is excessive. It places a burden on physicians to meet more frequently than needed, rather than spending more time on patient care. We recommend this requirement be revised to require medical staff departments to meet at least quarterly.

§64-12-12 Nursing Service

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

Comment: This requirement needs clarification. It sounds as if we need to require a resume from applicants, in addition to the application form itself, which includes sections for training and work experience. This presents a problem in that many candidates (i.e., support services personnel) would probably have problems writing a resume on their own.

§64-12-9 Extended Care Unit/ Nursing Facility

9.3. The extended care unit will be in compliance with the current Nursing Home Licensure, 64CSR13, which was effective July 1, 2001.

Comments: As a Hospital-Based Skilled Nursing Facility (HB SNF), we have not been previously required to comply with the full Nursing Home Licensure Rule. Our analysis of the current Nursing Home (NH) Licensure Rule highlights the regulations that are not currently applicable to HB SNF, and are as follows:

§64-13-2 Definitions

2.24 License. The document issued by the secretary that is the license authority to receive residents and perform services include within the scope of this rule.

Comment: We will not be licensed under this rule.

2.25 Licensed or Registered.

2.25.b. Nursing Home. A nursing home licensed by the Department.

Comment: The Department will not license us; we will be under the Hospital's License.

§64-13-4 Resident's Rights.

4.9 Right to Choose a Personal Physician.

4.9.b. Upon admission, the nursing home shall provide the resident with the names of physicians who have attending privileges at the nursing home.

Comment: In general, most physicians attend their patients at the HB SNF and patients arrive with their own physicians. Most of the medical staff would attend.

4.10 Management of Residents' Personal Funds.

Comment: HB SNF do not hold personal funds for patients due to their short length of stay. HB SNF should develop a policy to meet the intent of this requirement.

4.15 Admissions and Payment Policy.

4.15.c.2. Medicaid residents and their legal representatives shall be informed that if they desire a private room they may privately supplement the Medicaid payment by directly paying the facility the difference between the semi-private room rate and the private room rate.

Comment: Delete; this does not apply, as we are a Medicare only Skilled Nursing Facility.

4.15.e.1. A nursing home may charge a resident who is eligible for Medicaid for items and services the resident has requested and received, and that are not specified in the State Medicaid Plan as included in the term "nursing home services" if the nursing home gives proper notice of the availability and cost of these services to residents and does not condition the resident's admission or continued stay on the request for or receipt of such additional services.

Comment: Delete; this does not apply, as we are a Medicare only Skilled Nursing Facility.

4.16 Freedom from Restraints and Abuse

4.16.c. Abuse

4.16.c.3 A nursing home will not employ persons who have:

4.16.c.3.B Had a finding entered into the Certified Nurse Assistant Registry or the WV Adult Abuse Registry concerning abuse, neglect, exploitation or mistreatment of residents or misappropriation of their property.

Comment: We feel it is appropriate to check every employee with the Aide Abuse Registry and we have begun to do this for every new employee at the hospital. All new employees are screened with a Criminal Background Check. We do not feel we should also have to screen new employees at the WV Adult Abuse Registry (Central Abuse Registry).

4.16.c.4. A nursing home shall report any knowledge it has of actions by a court of law against an employee that would indicate unfitness for service as a nurse aide or other nursing home staff to the WV Certified Nursing Assistant Registry or the appropriate licensing authority and the director.

4.16.c.4.A. Actions by a court of law, which indicates unfitness for service include a substantiated charge of abuse, neglect or exploitation against an employee, or conviction of an offense for actions related to bodily injury, theft, or misuse of funds or property or other crimes related to public welfare, in any jurisdiction within or outside of the State of West Virginia.

Comment: There could be instances where this would seem excessive. For example, if an individual has been accused of a petty theft at the age of 19 but has had no offenses since, then we could never employ them?

Just a Note:

7.4.b.2.B. referring to discharge planning. This regulation refers to Subdivision 6.2.b
I could not find 6.2.b.

§64-13-8 Quality of Care

8.15.a Dietary Staffing.

8.15.a.2. A dietary manager shall be employed if a dietician is not employed full time and shall be one of the following:

Comment: Not applicable to HB SNF.

8.19. Pharmacy Services

8.19.j. A nursing home shall establish a policy to assure that resident's request for prescription medication from sources other than the contracted pharmacy is honored.

Comment: The hospital pharmacy provides the medications for Medicare Part A patients.

§64-13-9 Physical Facilities, Equipment, and Site Information

9.8 Solid Waste and Biohazard Waste Disposal.

9.8a.1. Chain of custody receipts and forms shall be maintained by the nursing home for one year.

Comment: The hospital keeps these records, not the SNF.

§64-13-11 Human Resources.

11.6 Personnel Records. A nursing home shall maintain a confidential personnel record for each employee containing the following information:

11.6.d. Results of annual physical;

Comment: Some hospital do not required annual physicals. Some only require PPD and blood work.

11.7 Medical Director. A nursing home shall designate in writing, a physician accountable to the governing body to serve, as medical director to ensure that medical care provided to residents is adequate and appropriate.

11.7.a. The medical director is responsible for:

11.7.a.3. Assisting in the evaluation of credentialing and re-credentialing of licensed independent practitioners, physician assistants and nurse practitioners to determine whether they will be authorized to practice within the organization by recommendation.

Comment: These are done by the medical staff at each hospital.

§64-13-13 Clinical Records.

13.1. Records Maintenance and Retention.

13.1.d A nursing home shall ensure that each clinical record contains a photograph of the resident, unless the resident objects.

Comment: We do not take pictures of our patients.

§64-13-15 Inspections and Investigations.

15.1 Regular Inspections.

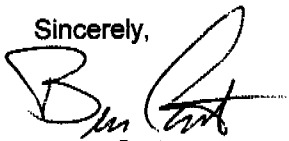
15.1.b. All licensed nursing homes shall be inspected annually, or in accordance with Section 17 of this rule to determine the nursing homes compliance with applicable statutes and rules.

Comment: Hospitals do not have annual inspection surveys. This would apply to freestanding facilities, and it is my understanding that the HB SNF would be surveyed when and if its hospital is surveyed.

From this section to the end of the rules 15.2 through 17.2.c.

Includes complaints investigation, civil money penalties, and temporary management for poor performers. These do not apply to HB SNF. They would properly fall under the hospital rules or our certification rules from CMS.

Sincerely,

A handwritten signature in black ink, appearing to read 'Bruce Carter', with a stylized flourish at the end.

Bruce Carter
President

cc: Aleta Stout, Compliance Officer
James A. Kranz, WV Hospital Association



Pleasant Valley Hospital

June 20, 2005

05 JUN 22 PM 3:16

PLAC

Martha Yeager Walker
Office of Health Facility Licensure
And Certification
1 Davis Square, Suite 101
Charleston, West Virginia 25301

RE: Comments on Hospital Licensure Proposed Rule

Dear Honorable Secretary Martha Walker:

We appreciate the opportunity to comment. My comments are:

1. **Under 4.3- Hospital Administration:**

The title more generally used is Chief Executive Officer and/or President.

2. **Under 8.7-a- Anesthesia Department:**

8.7 a – says the organized anesthesia department under the supervision of a physician specializing in anesthesiology. Some small and mid-size facilities do not have an anesthesiologist on staff, but generally under the direction of the Chief of Surgery or the operating practitioner. It appears this is allowed under 8.7 b –allowing the supervision to be the operating practitioner. We recommend saying: the Anesthesia Department is under the supervision of a physician approved by the Medical Staff.

We appreciate you addressing this in the final rule. Thank you.

Sincerely,


Alvin R. Lawson, JD, FACHE
Chief Executive Officer

ARL/sjf

2520 Valley Drive
Point Pleasant, WV 25550
Main Number: 304-675-4340
Dept. of Administration Fax: 304-675-5243

1. Comment: The West Virginia Hospital Association requests clarification of the definition of neglect. They request this "so it would be consistent with every other definition of neglect in West Virginia code". They state that all other definitions of neglect contain the word "willful".

Response: Upon review of all of the rules promulgated by the Office of Health Facility Licensure and Certification, none of the definitions of neglect contain the word "willful". We believe that neglect does not always occur as a willful act, but can occur as the result of ignorance, understaffing, and forgetfulness, just to name a few. Therefore, we believe the definition should remain as written.

2. Comment: The West Virginia Hospital Association requests that the word "all" be removed from section 7.1.n. in regards to drug administration errors, adverse drug reactions and incompatibilities. They contend, as an example, that investigating the administration of a drug given later than scheduled would require it to be fully investigated. They contend that events such as this are usually captured on safety reports. To try and investigate every such incident would be impossible.

Response: Upon consideration, we agree that the investigation of drug issues as above may require different degrees of investigation and by removing the word "all", this would allow for reasonable flexibility in the investigation process.

3. Comment: The West Virginia Hospital Association requested a change at 7.2.r. as to when physicians will countersign and date all verbal and telephone orders. They recommend we change the phrase "at the next hospital visit" to read "as soon as possible" because the phrase "at the next hospital visit" could be interpreted "at any time the physician is in the hospital", such as stopping by for breakfast.

Response: Upon consideration, we recommend a clarification of the phrase "at the next hospital visit" to read "at the next hospital visit in which a patient visit occurs and an entry is written in the chart".

4. Comment: The West Virginia Hospital Association requests to change the wording at 7.4.f. by adding "as specified by state and federal regulations" and also changing "infection control nurse" to "infection control professional".

Response: Upon consideration, this requirement is found in the federal certification regulations, therefore, we do not believe that the state requirement should be less stringent than the federal requirement. We do agree, however, to change "infection control nurse" to "infection control professional".

5. Comment: The West Virginia Hospital Association requests that 8.4.b. be unchanged from the current hospital licensure rule which states "nurseries shall provide twenty-four square feet of floor space per bassinet with at least twelve inches between bassinets". They state that no hospital in the state would be able to comply with the language in the

proposed rule because of the substantial financial impact on hospitals for this single change.

Response: Upon consideration, we will change the language to read “nurseries will provide twenty four (24)square feet of floor space per bassinet with at least twelve (12) inches between bassinets”.

6. Comment: The West Virginia Hospital Association requests that the requirement in 8.7.a. be changed from a physician specializing in anesthesiology to “an organized anesthesia department under the medical direction of a qualified physician member of the medical staff licensed in West Virginia”. They contend that the requirement for an anesthesiologist would prevent small rural hospitals and critical access hospitals from providing surgical services to the community.

Response: Upon consideration, we agree that the requirement for an anesthesiologist may impose undue hardship on small rural hospitals and critical access hospitals. The federal certification requirements allow for a qualified physician to be responsible for anesthesia services. Therefore, the change will be made as requested.

7. Comment: The West Virginia Hospital Association requests that the reference to fluoroscopic equipment in 10.4.j.1 be excluded because in today’s small rural hospital setting it is not always necessary or possible for a radiology department to have a fluoroscopic unit. For some, having a mobile CT or MRI scanner has greater medical value than having a fluoroscopic unit. In this case, the listing of this type of equipment as a requirement is outdated.

Response: Upon consideration, we agree that the requirement for fluoroscopic equipment is not practical for every hospital. Since CT and MRI scanners have become more mobile, their availability has now included hospitals in rural settings. These units, in most cases, provide greater diagnostic service. Therefore, 11.4.j.1 will read “one (1) radiographic room with adequate radiology equipment”.

8. Comment: The West Virginia Hospital Association requests clarification of the language in 10.6.b. The proposed rule speaks of a “director of respiratory care services” to be a physician. Is this the intent of the proposed rule?

Response: In an effort to clarify 10.6.b., we suggest that the respiratory service will be under the medical direction of a physician licensed by the West Virginia Board of Medicine or the West Virginia Board of Osteopathy. In practice, the director of a clinical department is normally a licensed professional in that specialty area, but not necessarily a physician. Therefore, we will change the wording to “Respiratory care services will be under the medical direction of a physician licensed by the West Virginia Board of Medicine or the 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.”

9. Comment: The West Virginia Hospital Association requests deletion of 9.3.a. because they believe this proposed change from the previous hospital licensure rule is both inconsistent and unnecessary. Hospital based extended care units already follow all hospital licensure requirements, many of which either exceed or are duplicate of similar requirements in nursing home licensure. Also there are requirements in the nursing home licensure rule which are not applicable to extended care units.

Response: Upon consideration and because we agree that the extended care units have somewhat different requirements than free-standing nursing homes, and because the extended units are required to comply with the federal certification requirements for long-term care facilities, we will delete the extended care unit/nursing facility section and replace it with the following:

§64-12-9. Extended Care Unit/ Nursing Facility

9.1. General Requirement - The extended care unit will be located in a segregated physically separated area of the hospital and will 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 will be provided for dining and recreation areas, special equipment storage, training toilets, showers and bath facilities. Handrails, drinking fountains, lavatories, thresholds and telephone alcoves will 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 will be organized under the direction of a committee of the medical staff. Written policies will be developed by professional personnel including at least one (1) registered professional nurse.

9.3.b. The Nursing service will be under the direction of a registered professional nurse.

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

9.4. Financial Rights and Responsibilities

9.4.a. Extended care residents or their representatives lawfully authorized to manage fiscal matters on behalf of the resident have the right to manage their own personal financial affairs.

9.4.b. A hospital which manages or holds personal funds for extended care patients will 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 will hold the funds separately and in trust. Patient funds will not be commingled with hospital operating or other funds.

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

9.4.d. The hospital will 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 will 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 patient, it will 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 will 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 will inform the patient in writing at the time of admission or at the time this exclusion is adopted by the hospital.

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

9.6. The hospital will 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.

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

9.8. The unit may utilize 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 will be required if the pharmacist is an employee of the hospital.

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

10. Comment: The West Virginia Hospital Association requests that the requirement in 5.3.b. and 5.4.d. be changed so as to allow minor renovations (that alter floor plans) be allowed without the services of an architect and a full set of drawings. The Office of Health Facility Licensure and Certification's architect would have discretion over such renovations.

Response: Upon consideration, we are adding the following language at 5.4.d. "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 such minor renovations will be determined by the Secretary".

11. Comment: United Hospital Center requests reconsideration/clarification of the requirement at 6.1.j. which states "all garbage containers will be watertight, nonabsorbent, rodent proof, and have tight-fitting covers". They contend it would be very costly to replace all garbage containers throughout the hospital to obtain containers with tight-fitting lids.

Response: This rule does not apply to waste baskets, it applies to garbage containers only. All garbage containers must be leak-proof and covered in order to prevent spills and contamination.

12. Comment: The West Virginia Hospital Association requests clarification of 8.3.f., 8.3.g. and 8.3.h. Hospitals perform caesarean deliveries in operating room suites instead of having one room specifically designated for caesarean deliveries.

Response: Upon consideration, the language at 8.3.f. will be revised to read "Caesarean deliveries will be performed in a caesarean delivery room suite or in the hospital's operating room."

13. Comment: United Hospital Center requests removing 8.2.g.2. which requires patient rooms to have moveable furniture and be equipped with a cabinet or bedside table since "today's furniture configurations made this requirement outdated."

Response: This requirement may not apply to certain larger hospitals, but it does apply to many smaller hospitals in our rural state and needs to remain as part of the Rule. Certain smaller hospitals do not have the new furniture configurations.

14. Comment: United Hospital Center requests consideration as to the need for 7.2.j.20. They say the death certificates are filed in the medical record when received. However, a requirement to assure that this will always occur would be burdensome in that it would require a considerable amount of staff time in tracking death certificates that are not received.

Response: Upon consideration, we will change the language in 7.2.j.20. to read "death certificate when the hospital deems necessary."

15. Comment: United Hospital Center requests that 8.11.f. be deleted because if the physician is residency trained and board certified in emergency medicine, they do not have to have a certificate in advanced life support.

Response: Upon consideration, all emergency room physicians in West Virginia hospitals are not residency trained and board certified. We believe that periodic training in advance life support is necessary for all physicians working in the emergency departments in order to keep their skills current. Therefore the requirement will remain as written.

16. Comment: United Hospital Center and Highland Hospital request the meeting requirements of the medical staff be changed from requiring the departments to meet monthly to meeting quarterly.

Response: Upon consideration, we feel that quarterly meetings of the departments are not sufficient. We do agree the monthly meeting requirement may be excessive. Therefore we are changing 11.11.a. to read "requiring departmentalized medical staffs to meet every other month provided the executive committee meets monthly. The full medical staff will meet annually. In the event the executive committee does not meet monthly then the departmental meeting of the medical staff will be monthly. Non - departmentalized medical staffs will have monthly meetings of the executive committee and the full medical staff will meet every other month. In the event there is no executive committee, the full medical staff will meet monthly.

17. Comment: United Hospital Center requests clarification of 12.5.a. They state that requiring a resume from some new hires, i.e. support services personnel, would be problematic. Writing a resume in this instance would not be practical.

Response: We would like to clarify 12.5.a. to read as "a dated application for employment verified by references which includes the applicant's training and experience.

18. Comment: Cabell Huntington Hospital requests that in 7.2.a., the "person qualified by training and experience" be changed to either a "registered health information administrator or a registered health information tech." to ensure appropriately qualified supervision.

Response: In an effort to give all hospitals flexibility in complying with 7.2.a. we believe the language should remain as written.

19. Comment: Cabell Huntington Hospital requests that the following language be added to the end of the sentence at 7.2.h. "or upon receipt of an order from a court of competent jurisdiction".

Response: Upon consideration of the recommendation, we will add this language as requested.

20. Comment: Cabell Huntington Hospital requests a change in 7.2.i. by using "within two (2) business days" in place of "within 48 hours".

Response: After reviewing this request, we believe because hospitals are open for business during the weekend including admissions, discharges, surgical services and patient care the language at 7.2.i. will remain as written.

21. Comment: Cabell Huntington Hospital requests that the response time of thirty (30) minutes at 8.9.c. be changed so that both the time and nature of the response be set by hospital policy.

Response: After reviewing this request, we believe a thirty (30) minute response time is a state-wide standard of practice that has been established for years. Thirty (30) minutes is a responsible approximate time in which to respond to a call from a Specialty Care or Critical Care unit. Therefore, this will remain as written.

22. Comment: Highland Hospital is requesting we be "more focused" at 7.3.t. regarding certain foods that may be considered "hazardous foods" since with a growing population of patients with food allergies, most any food can be hazardous to someone. They contend this proposed rule will result in additional liability for hospitals.

Response: This is not a new section of the licensure rule. It has been in the current rule since 1994 (see page 14, section 10.4.20.). It would be impractical for 7.3.t. to list all the foods that are potentially hazardous. The dietitian of each hospital must determine those foods that are potentially hazardous, i.e. meats, mayonnaise, etc. 7.3.t will remain as written.

23. Comment: Highland Hospital is requesting to limit 8.1.c. to hospitals other than free standing psychiatric hospitals. They state emergency carts are appropriate for use on a hospital medical floor, but may not be appropriate for psychiatric hospitals. They continue by saying psychiatric hospitals do not have physicians or other cardiac certified

staff on duty 24/7. The items found on an emergency cart could be detrimental to the patients if used inappropriately.

Response: The hospital licensure rule and the federal certification regulations for hospitals apply to both psychiatric and acute care hospitals. Psychiatric hospitals are responsible to provide care in the event of patient respiratory or cardiac arrest. Key members of the staff must be trained in cardiac resuscitation in order to ensure patient care is provided as needed. 8.1.c. states the content of an emergency cart can be determined by hospital policy. Therefore, this requirement will remain as written.

24. Comment: Highland Hospital states movable furnishings including adjustable beds with side rails, cabinets and bedside tables, over bed tables and waste baskets with disposable liners within a psychiatric facility put both patients and staff at risk. Often patients will misuse movable furnishings as missiles or weapons against staff or other patients. Movable furnishings should not be a requirement for psychiatric facilities.

Response: Upon consideration, 8.2.g. will read "Patient rooms will have movable furnishings. The director will make exceptions as needed regarding all furnishings for psychiatric hospitals. Patient rooms will be equipped with the following:"

25. Comment: Highland Hospital proposes that the requirement at 10.8. regarding protocols for organ, tissue and eye procurement be excluded for psychiatric hospitals.

Response: Upon consideration, this requirement will remain as written because it is included in the federal Conditions of Participation for psychiatric hospitals located at 482.60 (b). We do not believe the state requirement should be less stringent than the federal requirement.

26. Comment: Pleasant Valley Hospital requests that 4.3. be changed from "hospital administrator" to "chief executive officer and/or president".

Response: We agree the terms "chief executive officer and/or president" are commonly used today in reference to hospital administration. The proposed rule however, uses the term "administrator" throughout the text. Changing the language from "administrator" to "chief executive officer and/or president" would result in unnecessary inconsistencies in the rule. Most everyone recognizes and understands the term "administrator", thus the language in 4.3. will remain as written.

27. Comment: The West Virginia Hospital Association feels the Critical Access Hospital section §64-12-16 is excessive in length and redundant with respect to the federal Conditions of Participation.

Response: Upon consideration, §64-12-16 will be revised to eliminate redundancy. §64-12-16 will read as follows:

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 will remain subject to the provisions of Critical Access Hospital regulations and public health law and rules applicable to general hospitals, including those parts pertaining to certificates of need and other operating certificates. This will 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 Assess Hospitals will provide initial diagnostic services, a limited range of therapeutic services, resuscitation and stabilization services, and will 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 will 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 will be 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 will meet all hospital licensure standards for the State of West Virginia, cited in Sections §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 will provide twenty-four (24) hour on-site care when the Critical Access Hospital renders inpatient services; and

16.3.a.2. Authorized admissions to a Critical Access Hospital will 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. Patients presenting with conditions that are beyond the clinical capabilities of the Critical Access Hospital will be transferred to a hospital that has available appropriate services

16.4. Quality Improvement.

16.4.a. The governing body will 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 Section §12.15 of this rule, this program will 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 will 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;

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

16.4.b.9. Adverse drug reactions.

16.5. Medical Staff.

16.5.a. The medical staff will develop a system in which network medical/professional staff participate and collaborate to provide consultation, assistance with medical emergencies, and patient referrals.

16.5.b. The Critical Access Hospital will 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 will 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.

28. Comment: An anonymous comment was received regarding House Bill 2381 and visitation privileges for non relatives.

Response: We will add in the Patient Rights section 4.4.f. " A licensed hospital will 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".

29. Comment: An anonymous comment was received regarding a typographical error on the last page. It states §64-1-18 and should state §64-12-18.

Response: We will replace §64-1-18 with §64-12-18.