

DEPARTMENT OF HEALTH, STATE BOARD OF HEALTH

SUBJECT: Rules for Critical Access Hospitals

DESCRIPTION:

Background

Pursuant to A.C.A. §§ 20-9-201 et seq., the Department has authority to promulgate Rules for Critical Access Hospitals. These rules establish a criterion for minimum standards for licensure, operation and maintenance of critical access hospitals in Arkansas that is consistent with current trends in patient care practices. These standards are not static and are subject to periodic revisions in the future as new knowledge and changes in patient care trends become apparent.

Key Points

The proposed rule:

- Adds requirement for pulse oximetry screening in newborns
- Makes changes to comply with Acts 226, 311, 449, 598, 949, and 1055 of 2021
- Updates the grievance process

Discussion

The Rules for Critical Access Hospitals in Arkansas are duly adopted and promulgated by the Arkansas State Board of Health pursuant to the authority expressly conferred by the laws of the State of Arkansas in Act 414 of 1961, as amended by Act 258 of 1971, Act 190 of 1975, Act 536 of 1977, Act 273 of 1983, Act 980 of 1985, and Act 516 of 1987, along with Acts 143 of 1987, 348 of 1987, and 399 of 1987 covered under these regulations. There were six legislative acts – Acts 226, 311, 449, 598, 949, and 1055 – which required modification to the Rules for Critical Access Hospitals in Arkansas.

The following changes are proposed:

Section 4: Licensure and Coding

4.L. – Granting of waiver during PHE. (Act 1055)

Section 7: General Administration

7.D.2-5. – Adds visitation requirements (Act 311)

7.P.4&5. – Updated QAPI requirements for grievance process

7.S. – Adds prohibition of abortions in hospitals (Act 949)

Section 14: Health Information Services

14.D.3. – Add consent for do-not-resuscitate for minors (Simon’s Law) (Act 226)

Section 29: Specialized Services: Anesthesia Services

29.C.3. – Removed under physician supervision for CRNA practice (Act 449)

Section 30: Specialized Services: Labor, Delivery, LRD, LDRP, Post-Partum, and Maternal-Child

30.C.8.a&b. – Requirement for Hepatitis C testing (Act 598)

30.D.2. – Add physician available for consult for CRNA practice (Act 449)

30.F.12. – Requirement for Hepatitis C counseling (Act 598)

Section 31: Specialized Services: Nursery Services

31.F. – Requirement for pulse oximetry screening in newborn (A.C.A. § 20-9-103)

31.G. – Requirement for genetic testing

31.H. – Requirement for hearing loss testing

PUBLIC COMMENT: No public hearing was held on these proposed rules. The public comment period expired on March 2, 2022. The agency provided the following summary of the single public comment it received and its response to that comment:

Commenter’s Name: Martha Hill

COMMENT: In particular, in Section 29 (C) (3), where you struck “under the supervision of a physician”, the proposed nursing regulations do not substitute that language with the new statutory requirement of “consultation”. In order for the nursing regulations to be consistent throughout the regulations, we would urge addition of the new statutory standard. **RESPONSE:** Recommended changes completed. See Critical Access Hospital Rules Section 29.

Lacey Johnson, an attorney with the Bureau of Legislative Research, asked the following questions and received the following responses:

1. Section 7.D.2 lists conditions that qualify a patient as disabled. The list includes deafness, but does not include “being hard of hearing, or other communication barriers” as listed in Act 311. Is there a reason these conditions were not included in § 7.D.2?

RESPONSE: Revision to CAH Section 7 attached with changes.

2. Per Act 226, parental consent for a do-not-resuscitate order or withdrawing treatment of a minor is not required if the minor is in DHS custody. Why was “in the custody of the Department of Human Services” excluded from § 14.D.3.b? **RESPONSE:** Revisions to CAH Section 14 attached with changes.

3. Act 226 also provides that the parental consent requirements do not apply “if a reasonably diligent effort of at least 72 hours without success has been made to contact and inform each known parent or guardian[.]” Why was this provision omitted from the proposed rules? **RESPONSE:** Revisions to CAH Section 14 attached with changes.

4. 31.F, 31.g, and 31.H all include citations to the Arkansas Code that do not appear to point to the correct sections. Could you confirm that the correct citations are as follows?

Section 31.F: A.C.A. § 20-9-103
Section 31.G: A.C.A § 20-15-302
Section 31.H: A.C.A. § 20-15-1504

RESPONSE: Revisions to CAH Section 31 attached with changes.

5. Is there a specific source for the updated grievance procedures? **RESPONSE:** The change was made to have the CAH rules mimic the hospital rules for this as CMS has this requirement. There is documentation which indicates this change was made to the hospital rules in 2004. The documentation indicates the same changes should have occurred to the CAH rules. The CAH Rules did not reflect this change. The documentation does not reference a state law for the change. The change does align the rules with CMS requirements.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: The agency indicated that this rule has no financial impact.

LEGAL AUTHORIZATION: The Arkansas Department of Health has the authority to inspect, regulate, and license hospitals and institutions. Ark. Code Ann. § 20-9-204(b)(3). The Department may promulgate rules as necessary to accomplish the purposes of Ark. Code Ann. §§ 20-9-201 to -223, which relate to health facilities services. Ark. Code Ann. § 20-9-205(b). This rule implements Acts 226, 311, 449, 598, 949, and 1055 of 2021.

Act 226, sponsored by Representative Jim Dotson, established Simon’s Law, clarified the requirement for parent or legal guardian consent for end-of-life medical procedures for minors, and prohibited healthcare facilities or healthcare professionals from instituting end-of-life medical procedures on a minor without consent of a parent or legal guardian.

Act 311, sponsored by Representative Julie Mayberry, created the No Patient Left Alone Act and concerned visitation rights of patients.

Act 449, sponsored by Representative Clint Penzo, amended the definition of “practice of certified registered nurse anesthesia” by removing supervision requirements.

Act 598, sponsored by Representative Justin Boyd, required Hepatitis C screening during pregnancy.

Act 949, sponsored by Senator Charles Beckham, modified laws concerning abortion clinics.

Act 1055, sponsored by Senator Missy Irvin, modified the authority of the Department of Health and deferred the authority of the Department of Health to the Centers for Medicare and Medicaid Services concerning the Hospitals Without Walls program.

ARKANSAS
STATE BOARD OF HEALTH

**RULES FOR CRITICAL ACCESS HOSPITALS
IN ARKANSAS**



Promulgated under the Authority of Ark. Code Ann. § 20-7-123, 20-9-201 et seq.

Revision effective date: **February 5, 2021**

ARKANSAS DEPARTMENT OF HEALTH
HEALTH FACILITY SERVICES

José Romero, MD
SECRETARY OF HEALTH

TABLE OF CONTENTS

<u>SECTION 1: AUTHORITY</u>	<u>1.1</u>
<u>SECTION 2: PURPOSE</u>	<u>2.1</u>
<u>SECTION 3: DEFINITIONS</u>	<u>3.1-3</u>
<u>SECTION 4: LICENSURE AND CODES</u>	<u>4.1-4</u>
<u>SECTION 5: GOVERNING BODY</u>	<u>5.1-2</u>
<u>SECTION 6: MEDICAL STAFF</u>	<u>6.1-5</u>
<u>SECTION 7: GENERAL ADMINISTRATION</u>	<u>7.1-5</u>
<u>SECTION 8: PERSONNEL ADMINISTRATION</u>	<u>8.1-2</u>
<u>SECTION 9: ADMINISTRATION REPORTS</u>	<u>9.1-2</u>
<u>SECTION 10: PATIENT IDENTIFICATION</u>	<u>10.1</u>
<u>SECTION 11: PATIENT CARE SERVICE</u>	<u>11.1-5</u>
<u>SECTION 12: MEDICATIONS</u>	<u>12.1-5</u>
<u>SECTION 13: RESTRAINTS</u>	<u>13.1</u>
<u>SECTION 14: HEALTH INFORMATION SERVICES</u>	<u>14.1-9</u>
<u>SECTION 15: MEDICAL RECORD REQUIREMENTS FOR OUTPATIENT SERVICES, EMERGENCY ROOM AND OBSERVATION SERVICES</u>	<u>15.1-5</u>
<u>SECTION 16: PHARMACY</u>	<u>16.1-13</u>
<u>SECTION 17: FOOD AND NUTRITION SERVICES</u>	<u>17.1-9</u>
<u>SECTION 18: INFECTION PREVENTION AND CONTROL</u>	<u>18.1-6</u>
<u>SECTION 19: LABORATORY</u>	<u>19.1-31</u>
<u>SECTION 20: RADIOLOGICAL SERVICES</u>	<u>20.1-7</u>
<u>SECTION 21: PHYSICAL THERAPY</u>	<u>21.1-3</u>
<u>SECTION 22: OCCUPATIONAL THERAPY</u>	<u>22.1-2</u>
<u>SECTION 23: SPEECH PATHOLOGY/AUDIOLOGY SERVICES</u>	<u>23.1-2</u>
<u>SECTION 24: RECREATIONAL THERAPY</u>	<u>24.1-2</u>
<u>SECTION 25: PET THERAPY PROGRAM</u>	<u>25.1-2</u>
<u>SECTION 26: SPECIALIZED SERVICES: SURGICAL SERVICES</u>	<u>26.1-4</u>
<u>SECTION 27: SPECIALIZED SERVICES: POSTANESTHESIA CARE UNIT</u>	<u>27.1</u>
<u>SECTION 28: SPECIALIZED SERVICES: AMBULATORY SURGERY SERVICES</u>	<u>28.1</u>
<u>SECTION 29: SPECIALIZED SERVICES: ANESTHESIA SERVICES</u>	<u>29.1-2</u>
<u>SECTION 30: SPECIALIZED SERVICES: LABOR, DELIVERY, LABOR DELIVERY RECOVERY (LDR), LABOR DELIVERY RECOVERY POST PARTUM (LDRP), POST PARTUM AND MATERNAL-CHILD EDUCATION</u>	<u>30.1-5</u>
<u>SECTION 31: NURSERY SERVICES</u>	<u>31.1-2</u>
<u>SECTION 32: SPECIALIZED SERVICES: CRITICAL CARE</u>	<u>32.1-2</u>
<u>SECTION 33: SPECIALIZED SERVICES: DENTAL SERVICES</u>	<u>33.1</u>
<u>SECTION 34: SPECIALIZED SERVICES: CENTRAL STERILIZATION AND SUPPLY</u>	<u>34.1-5</u>
<u>SECTION 35: SPECIALIZED SERVICES: RESPIRATORY CARE</u>	<u>35.1-3</u>
<u>SECTION 36: SPECIALIZED SERVICE: EMERGENCY SERVICES</u>	<u>36.1-5</u>
<u>SECTION 37: SPECIALIZED SERVICE: PSYCHIATRIC SERVICES</u>	<u>37.1-3</u>
<u>SECTION 38: SPECIALIZED SERVICE: CARE OF PATIENTS WITH PULMONARY DISEASE IN CRITICAL ACCESS HOSPITALS</u>	<u>38.1</u>
<u>SECTION 39: OUTPATIENT PSYCHIATRIC CENTERS</u>	<u>39.1-3</u>
<u>SECTION 40: REHABILITATION HOSPITALS AND UNITS</u>	<u>40.1-3</u>
<u>SECTION 41: RECUPERATION CENTERS</u>	<u>41.1-2</u>
<u>SECTION 42: PHYSICAL ENVIRONMENT</u>	<u>42.1-13</u>
<u>SECTION 43: PHYSICAL FACILITIES</u>	<u>43.1-19</u>
<u>SECTION 44: PHYSICAL FACILITIES, PATIENT ACCOMMODATIONS (ADULT MEDICAL, SURGICAL, COMMUNICABLE OR PULMONARY DISEASE)</u>	<u>44.1-7</u>
<u>SECTION 45: PHYSICAL FACILITIES, CRITICAL CARE UNIT</u>	<u>45.1-7</u>

RULES FOR CRITICAL ACCESS HOSPITALS 2021

<u>SECTION 46: PHYSICAL FACILITIES, NURSERY UNITS</u>	46.1-3
<u>SECTION 47: PHYSICAL FACILITIES, PEDIATRIC AND ADOLESCENT UNIT</u>	47.1-2
<u>SECTION 48: PHYSICAL FACILITIES, PSYCHIATRIC NURSING UNIT</u>	48.1-4
<u>SECTION 49: PHYSICAL FACILITIES, SURGICAL FACILITIES</u>	49.1-8
<u>SECTION 50: PHYSICAL FACILITIES, OBSTETRICAL FACILITIES</u>	50.1-8
<u>SECTION 51: PHYSICAL FACILITIES, EMERGENCY SUITE</u>	51.1-4
<u>SECTION 52: PHYSICAL FACILITIES, IMAGING SUITE</u>	52.1-6
<u>SECTION 53: PHYSICAL FACILITIES, NUCLEAR MEDICINE</u>	53.1-5
<u>SECTION 54: PHYSICAL FACILITIES, MOBILE, TRANSPORTABLE, AND RELOCATABLE UNITS</u>	54.1-5
<u>SECTION 55: PHYSICAL FACILITIES, LABORATORY SERVICES</u>	55.1
<u>SECTION 56: PHYSICAL FACILITIES, REHABILITATION THERAPY DEPARTMENT</u>	56.1-3
<u>SECTION 57: PHYSICAL FACILITIES, MORGUE AND NECROPSY</u>	57.1
<u>SECTION 58: PHYSICAL FACILITIES, PHARMACY</u>	58.1-2
<u>SECTION 59: PHYSICAL FACILITIES, DIETARY FACILITIES</u>	59.1-3
<u>SECTION 60: PHYSICAL FACILITIES, ADMINISTRATION AND PUBLIC AREAS</u>	60.1
<u>SECTION 61: PHYSICAL FACILITIES, HEALTH INFORMATION UNIT</u>	61.1
<u>SECTION 62: PHYSICAL FACILITIES, CENTRAL MEDICAL AND SURGICAL SUPPLY DEPARTMENT</u>	62.1
<u>SECTION 63: PHYSICAL FACILITIES, CENTRAL SUPPLY AND RECEIVING</u>	63.1
<u>SECTION 64: PHYSICAL FACILITIES, LINEN SERVICES</u>	64.1-2
<u>SECTION 65: PHYSICAL FACILITIES, CLEANING AND SANITIZING CARTS, EMPLOYEE FACILITIES AND ENVIRONMENTAL CLOSETS</u>	65.1
<u>SECTION 66: PHYSICAL FACILITIES, ENGINEERING SERVICE AND EQUIPMENT AREAS</u>	66.1-2
<u>SECTION 67: PHYSICAL FACILITIES, WASTE PROCESSING SERVICES</u>	67.1-2
<u>SECTION 68: PHYSICAL FACILITIES, DETAILS AND FINISHES</u>	68.1-6
<u>SECTION 69: PHYSICAL FACILITIES, CONSTRUCTION, INCLUDING FIRE RESISTIVE REQUIREMENTS</u>	69.1-3
<u>SECTION 70: PHYSICAL FACILITIES, MECHANICAL REQUIREMENTS</u>	70.1-8
<u>SECTION 71: PHYSICAL FACILITIES, PLUMBING AND OTHER PIPING SYSTEMS</u>	71.1-4
<u>SECTION 72: PHYSICAL ENVIRONMENT, ELECTRICAL STANDARDS</u>	72.1-6
<u>SECTION 73: HYPERBARIC SUITE</u>	73.1-2
<u>SECTION 74: PHYSICAL FACILITIES, HELICOPTER LANDING AREA</u>	74.1
<u>SECTION 75: PHYSICAL FACILITIES, OUTPATIENT CARE FACILITIES</u>	75.1-7
<u>SECTION 76: PHYSICAL FACILITIES, REHABILITATION FACILITIES</u>	76.1-6
<u>SECTION 77: SEVERABILITY</u>	77.1

APPENDIX

TABLE 1 Filter Efficiencies for Central Ventilation and Air Conditioning Systems in Health Care Facilities

TABLE 2 Sound Transmission Limitations in Health Care Facilities

TABLE 3 Temperature and Relative Humidity Requirements

TABLE 4 Ventilation, Medical Gas, and Air Flow Requirements in Health Care Facilities

TABLE 5 Final Occupancy Inspection Check List

TABLE 6 Dog Behavioral Screening Exam

TABLE 7 Dog History

TABLE 8 Record Retention Time Frames

TABLE 9 Required Temperatures

TABLE 10 Outlets for Oxygen, Vacuum (Suction), and Medical Air Systems

TABLE 11 Verbal Orders

TABLE 12 Third Party Reprocessing of Single Use Items

CERTIFICATION

RULES FOR CRITICAL ACCESS HOSPITALS 2021

SECTION 1: AUTHORITY.

The following Rules for Critical Access Hospitals in Arkansas are duly adopted and promulgated by the Arkansas State Board of Health pursuant to the authority expressly conferred by the laws of the State of Arkansas in Act 414 of 1961, as amended by Act 258 of 1971, Act 190 of 1975, Act 536 of 1977, Act 273 of 1983, Act 980 of 1985, and Act 516 of 1987, along with Acts 143 of 1987, 348 of 1987, and 399 of 1987 covered under these regulations.

SECTION 2: PURPOSE.

These rules have been prepared for the purpose of establishing a criterion for minimum standards for licensure, operation and maintenance of critical access hospitals in Arkansas that is consistent with current trends in patient care practices. By necessity they are of a regulatory nature but are considered to be practical minimum design and operational standards for these facilities. These standards are not static and are subject to periodic revisions in the future as new knowledge and changes in patient care trends become apparent. However, it is expected that facilities will exceed these minimum requirements and that they shall not be dependent upon future revisions in these standards as a necessary prerequisite for improved services. Critical Access Hospitals have a strong moral responsibility for providing optimum patient care and treatment for the populations they serve.

SECTION 3: DEFINITIONS.

For purposes of the rules, the following definitions apply.

- A. Administrator means the person responsible for the management of any facility requiring licensure under these rules.
- B. Alcohol/Drug Abuse Inpatient Treatment Center means a distinct unit within a hospital in which services are provided for the diagnosis, treatment and rehabilitation of alcohol and drug abuse.
- C. Basic hospital services means the services that all licensed hospitals must provide. Basic services consist of:
 - 1. Governing Body;
 - 2. Medical Staff;
 - 3. General Administration;
 - 4. Patient Care;
 - 5. Health Information;
 - 6. Pharmacy;
 - 7. Food and Nutrition;
 - 8. Infection Prevention and Control;
 - 9. Laboratory;
 - 10. Radiology;
 - 11. Respiratory Therapy;
 - 12. Emergency; and
 - 13. Physical facility maintenance
- D. Critical Access Hospital (CAH) means a hospital located in a rural area that is:
 - 1. Located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital, or;
 - 2. Provides 24-hour emergency care services as determined necessary for ensuring access to emergency care in each area served by a Critical Access Hospital;
 - 3. Provides staffing according to Rules and Regulations for Hospitals and Related Institutions in Arkansas;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

4. Meets Centers of Medicare and Medicaid Services (CMS) Conditions of Participation for Critical Access Hospitals; or
 5. Was operating as a licensed Critical Access Hospital in Arkansas as of April 2007.
- E. Department means the Arkansas Department of Health.
- F. Emergency Services Facility means a facility originally operated as a licensed hospital that has discontinued inpatient services but is licensed to continue to provide emergency services.
- G. General Hospital means any facility used for the purpose of providing short-term inpatient diagnostic care and treatment, including general medical care, surgical care, obstetrical care, and specialized services or specialized treatment.
- H. Infirmery means any facility used for the purpose of offering temporary medical care and/or treatment exclusively for persons residing on a designated premise, e.g., schools, reformatories, prisons, etc. and where the persons are kept for 24 hours or more.
- I. Institution means, for the purpose of these rules, a facility which requires a license. Institution does not include an establishment:
1. Operated by the federal government or by any of its agencies; or
 2. Licensed or certified by the Office of Alcohol and Drug Abuse Prevention of the Division of Behavioral Health of the Department of Human Services as an alcohol and drug abuse inpatient treatment center.
- J. Licensee means the person to whom a license is issued for the purpose of operating the institution described in the application for licensure, who shall be responsible for maintaining approved standards for the institution of any state, county, or local government unit and any division, board, or agency thereof.
- K. Observation is a designated patient status as opposed to a designated area. Patients in observation status are those patients requiring periodic monitoring and assessment necessary to evaluate the patient's condition or to determine the need for possible admissions to the hospital in an inpatient status. Usually observation status shall be for 48 hours or less.
- L. Off-campus Emergency Department means an emergency services department located off-site from the main hospital campus but functions as a fully integrated department of the parent hospital.
- M. Outpatient Psychiatric Center means a facility in which psychiatric services are offered for a period of 8 to 16 hours a day, and where, in the opinion of the attending

RULES FOR CRITICAL ACCESS HOSPITALS 2021

psychiatrist, hospitalization as defined in the present licensure law is not necessary. This definition shall not include Community Mental Health Clinics and Centers, as they now exist.

- N. 1. Outpatient Surgery Center (Ambulatory Surgery Center) means a facility in which surgical services are offered that require the use of general or intravenous anesthetics, and where, in the opinion of the attending physician, hospitalization is not necessary.
2. "Outpatient surgery Center" does not include:
- a. a medical office owned and operated by a physician or more than one (1) physician licensed by the Arkansas State Medical Board, if the medical office does not bill facility fees to a third party payor; or
 - b. a dental office that has a Facility Permit for Moderate Sedation or a Facility Permit for General/Deep Sedation issued by the Arkansas State Board of Dental Examiners.
- O. Psychiatric Hospital means any facility, or a distinct part of a facility, used for the purpose of providing inpatient diagnostic care and treatment for persons having mental disorders.
- P. Recuperation Center means any facility or distinct part of a facility, which includes inpatient beds with an organized Medical Staff, and with medical services that include physician services and continuous nursing services to provide treatment for patients who are not in an acute phase of illness but who currently require primarily convalescent or restorative services (usually post-acute hospital care of relatively short duration). A facility that furnishes primarily domiciliary care is not within this definition.
- Q. Rehabilitation Hospital or Facility means, for the purpose of these rules, an inpatient care facility, or a distinct part of a facility, which provides rehabilitation services for two or more disabled persons not related to the proprietor, for more than 24 hours through an integrated program of medical and other restorative services. A disabled person shall be considered to be an individual who has a physical or mental condition which, if not treated, will probably result in limiting the performance or activity of the person to the extent of constituting a substantial physical, mental, or vocational handicap.
- R. Shall means mandatory.
- S. State Health Officer means the Secretary of the State Board of Health.
- T. Surgery and General Medical Care Hospital means any facility limited to providing short-term inpatient surgical and general medical diagnostic care and treatment.

SECTION 4: LICENSURE AND CODES.

- A. License required. No general hospital or distinct part, critical access hospital or distinct part, recuperation center or distinct part, infirmary, rehabilitation facility or distinct part, outpatient surgery center, or alcohol/drug abuse inpatient treatment center, psychiatric hospital or distinct part, outpatient psychiatric center or emergency services facility may be established, conducted, or maintained in the State without first obtaining a license.
- B. Exceptions to license requirement. The following facilities do not require a license from the Department:
 - 1. A facility operated by the Federal Government; and
 - 2. A First Aid Station.
- C. Basic services required. Every licensed hospital must provide basic services.
- D. Application for License.
 - 1. An applicant shall file applications under oath with the Department upon forms provided by Health Facility Services and shall pay annual license fee as indicated by Act 574 of 1997.
 - 2. These fees shall be paid into the State Treasury or refunded to the applicant if a license is denied. The application shall be signed by the owner, if an individual or partnership, or in the case of a corporation, by two of its officers, or in the case of a governmental unit, by the head of the governmental department having jurisdiction over it. The application shall set forth the full name and address of the institution for which license is sought and such additional information as the Department may require, including affirmative evidence of ability to comply with such reasonable standards, rules, and regulations as may be lawfully prescribed hereunder. The application for annual license renewal shall be postmarked no later than January 2 of the year for which the license is issued. The license applicant for an existing institution postmarked after the date shall be subject to a penalty of one dollar per day for each day and every day after January 2.
 - 3. A license issued hereunder shall be effective on a calendar year basis and shall expire on December 31 of each calendar year. A license shall be issued only for the premises and persons in the application, and shall not be transferable. If the facility changes ownership the license shall expire. The license shall be posted in a conspicuous place on the licensed premises. A license issued under previous regulations shall be effective through the period for which it was issued. The adequacy of cooperative

agreements between hospitals in terms of service provided by each hospital and the type of licenses issued to each hospital shall be determined by the Arkansas Department of Health.

E. Facility Change of Ownership.

1. It shall be the responsibility of the licensed entity to notify Health Facility Services in writing at least 30 days prior to the effective date of change of ownership.
2. The following information shall be submitted to Health Facility Services for review and approval:
 - a. License application;
 - b. Request for Medicare Certification (where applicable);
 - c. Legal documents, ownership agreements, the license previously issued to the facility, and other information to support relicensure requirements; and
 - d. Licensure fee as indicated by Act 574 of 1997.
3. For the purpose of these rules the licensed entity is the party ultimately responsible for operating the facility. The same entity also bears the final responsibility in decisions made in the capacity of a Governing Body, and for the consequences of these decisions.

F. Facility Name Change and/or Address.

1. The facility shall notify Health Facility Services of any name and/or address change;
2. The previously issued license shall be returned to Health Facility Services; and
3. A fee, as indicated in Act 574 of 1997, shall be submitted to Health Facility Services for issuance of a new license.

G. Management Contract.

1. It shall be the responsibility of the licensed entity to notify Health Facility Services in writing at least 30 days prior to entering into a management contract or agreement with an organization or firm. A copy of the contract or agreement shall also be submitted to Health Facility Services for review to assure the arrangement does not materially affect the license status.

2. An organization or firm who contracts with the licensed entity to manage the health care facility, subject to Governing Body approval of operational decisions, is generally considered an agent rather than an owner. In such instances a licensure change is not required.
- H. **Separate License.** An individual license shall be required for an institution maintained on separate premises even though it is operated under the same management, except in cases where the hospital management of a general hospital operates a detached building which can be utilized in a limited way for general medical care. Separate licenses are not required for separate buildings on the same grounds.
- I. **Temporary Licenses.** This license shall be for less than one year and for a time specified on the temporary license by the Department.
- J. **Revocation of License.** The Department is empowered to deny, suspend, or revoke a license on any of the following grounds:
1. Violation of any of the provisions of Act 414 of 1961, as amended by Act 258 of 1971, or Act 190 of 1975, Act 536 of 1977, or Act 273 of 1983, Act 980 of 1985, or Act 516 of 1987; Act 143 of 1987, Act 399 of 1987, or Act 348 of 1987, or the Rules and Regulations lawfully promulgated hereunder; or
 2. Permitting, aiding, or abetting the commission of any unlawful act in connection with the operation of the institution. (Section 22, Act 414 of 1961, as amended).
 3. The right of appeal of any revocation shall be as specified in the appeal procedure of the Arkansas Department of Health.
- NOTE: If services are to be temporarily suspended, a functional program, with plans and specifications as applicable, shall be submitted to Health Facility Services for approval prior to such suspension.
- K. **Inspection.** Any authorized representative of the Department shall have the right to enter the premises of any institution at any time in order to make whatever inspection necessary in accordance with the minimum standards and rules prescribed herein.
- L. **CMS Waivers. When CMS declares a public health emergency (PHE) with the implementation of waivers which applies to Arkansas, ADH may consider implementing similar waivers. If implemented, the waiver request and authorization may vary based on the type of PHE and CMS requirements.**

M. Penalties.

1. Any person, partnership, association, or corporation which establishes, conducts, manages, or operates any institution within the meaning of Act 414 of 1961, as amended by Act 258 of 1971, Act 190 of 1975, Act 536 of 1977, Act 273 of 1983, Act 980 of 1985, And Act 516 of 1987; and Act 143 of 1987, Act 348 of 1987, and Act 399 of 1987, without first obtaining a license therefore as herein provided, or who violates any portion of this act or regulations lawfully promulgated hereunder, shall be guilty of a misdemeanor, and upon conviction thereof shall be liable to a fine of not less than \$25.00 nor more than \$100.00 for the first offense and not less than One Hundred Dollars 100.00), nor more than \$500.00 for each subsequent offense, and each day such institution operates after a first conviction shall be considered a subsequent offense. (Ark. Code Ann. §20-9-202.)
2. Any institution licensed by the authority of these rules that has received damage due to fire, tornado, earthquake, man-made or natural disaster shall notify the Department by telephone immediately and follow with a preliminary report within 48 hours, and a complete report when the incident has been thoroughly investigated. The submitted report shall include, but not be limited to, damage to the building, damage estimates, injuries to patients, staff and the public, etc. If the Department is not notified, the institution shall be assessed a fine in the amount of \$50.00 for each day, or portion thereof, the incident is not reported or \$500.00 maximum.

N. Codes. See Section 43, Physical Facilities, List of Referenced Publications.

SECTION 5: GOVERNING BODY.

An institution shall have an organized Governing Body which shall be legally responsible for maintaining quality patient care and establishing policies for the facility. The Governing Body shall be legally responsible for the conduct of the institution.

- A. Governing Body Bylaws. The Governing Body shall adopt written bylaws which shall be available to all members of the Governing Body. The bylaws shall ensure:
1. Maintenance of proper standards of professional work in the hospital;
 2. The Medical Staff functions in conformity with reasonable standards of competency;
 3. The method of selecting members and officers with terms and responsibilities delineated;
 4. The selection of an Administrator or Chief Executive Officer with responsibilities for operation and maintenance of the facility delineated. In the absence of the Administrator, an alternate with authority to act shall be designated;
 5. Methods for establishing Governing Body committees with the duties of each committee delineated;
 6. Coordination of activities and general policies of the departments and special committees;
 7. Liaison between the Governing Body and Medical Staff with quarterly documentation;
 8. Quarterly Governing Body meetings with maintenance of minutes signed by an officer;
 9. Provision for formal approval of the organization, bylaws, rules and regulations of the Medical Staff and their services;
 10. Admission of patients by a physician, patient choice of physician and/or dentist and emergency care by a physician. All institutions governed by these standards shall arrange for one or more persons duly licensed to practice medicine to be called in an emergency. All individuals, who are not hospital employees, who make entries into the medical record, shall be credentialed through the Medical Staff;
 11. A method of credentialing or appointing members to the Medical Staff and

RULES FOR CRITICAL ACCESS HOSPITALS 2021

other authorized staff;

12. Methods by which Quality Assurance/Performance Improvement (QA/PI) is established; and
13. Establishment of a quorum to be met in order to conduct business.

B. Governing Body Minutes. The Governing Body minutes shall include at least the following information:

1. Review, approval and revision of the Governing Body bylaws and the Medical Staff bylaws, Rules and Regulations;
2. Election of officers, as indicated in the bylaws;
3. Documentation that the liaison between the Governing Body and Medical Staff is maintained;
4. Appointment and reappointment of the Medical Staff and other authorized staff as indicated in the bylaws;
5. Review and approval of the hospital's annual operating budget and capital expenditure plan;
6. Review and approval of reports received from the Medical Staff and Administration; and
7. Review and approval of the Quality Assurance/Performance Improvement (QA/PI) plan of the facility, at least annually, also documentation of the quarterly Quality Assurance/Performance Improvement (QA/PI) summaries.

SECTION 6: MEDICAL STAFF.

All persons admitted and discharged to any institution governed by these standards shall be under the care of a person duly licensed to practice medicine in Arkansas (hereafter called physician or surgeon). In institutions where two or more physicians are allowed to practice there shall be an organized Medical Staff. Members of the staff shall be qualified legally and professionally for the positions to which they are appointed. Individuals who are not hospital employees, who work in the hospital shall be credentialed through the Medical Staff with approval from the Governing Body. (Refer to Section 36, Specialized Services: Emergency Services.)

Note: See Ark. Code Ann. § 17-95-107 regarding requirements for health care organizations that credential physicians/authorized staff to use the Arkansas State Medical Board's Centralized Credentials Verification Service (CCVS).

A. Credential Files of the Medical Staff and Other Authorized Staff. An individual file shall be maintained for each physician/other authorized staff practicing in the hospital and shall include at least the following:

1. Verification of age, year, and school of graduation and statement of postgraduate or special training and experience;
2. Specific delineation of privileges requested and granted;
3. A detailed application signed by the applicant, the Chairman of the Credentials Committee and an officer of the Governing Body;
4. Documentation of the applicant's agreement to abide by the Medical Staff Bylaws and hospital requirements;
5. Verification of current Arkansas license;
6. Verification of each applicable physician's Drug Enforcement Agency (DEA) registration;
7. Verification of at least three references;
8. Documentation of all actions taken by the Medical Staff and Governing Board indicating the type of privileges granted, approval of appointment/reappointment and other related data;
9. Evaluation of members' professional activities at the time of reappointment; and
10. Non-employee practitioners may be screened through the Human Resources Department or another hospital designee. The requested privileges and credentialing shall be approved by the Medical Staff.

NOTE: Hospitals shall report to the appropriate professional licensing board the names of individuals whose hospital privileges have been terminated or revoked for cause.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- B. Medical Staff Bylaws. The Medical Staff Bylaws shall include at least the following information:
1. A provision stating the Medical Staff shall be responsible to the Governing Body of the facility for the quality of medical care provided for patients in the hospital and for the ethical and professional practices of members;
 2. A provision stating the requirements for medical and other authorized staff membership, including allied health professionals;
 3. A provision stating the division of the Medical Staff and clinical departments;
 4. A provision stating the election of officers, responsibilities and terms;
 5. A provision establishing Medical Staff committees, functions, frequency of meetings and composition (quorum);
 6. A provision establishing frequency of general Medical Staff meetings, specifying attendance requirements;
 7. A provision establishing written minutes be maintained of all Medical Staff meetings and the minutes shall be signed by the physician chairman;
 8. A provision for an appeals process which delineates the procedures for a physician or other authorized staff to follow in challenging staff, that if ratified by the Governing Body, adversely affects his/her appointment or reappointment to the Medical Staff;
 9. A provision establishing the designation of a specific physician who shall direct each clinical/diagnostic service;
 10. A provision delineating requirements for maintaining accurate and complete medical records. (See Health Information Services, Section 14.);
 11. A provision for selection and approval of nationally recognized protocols for use in the Emergency Department;
 12. A provision for approval of the bylaws and amendments by the Medical Staff and the Governing Body; and
 13. Documentation of appointments, reappointments and approval of requested privileges to the medical and other authorized staff as specified in the bylaws, but at least every two years.
- C. Medical Staff Minutes. Medical Staff minutes shall include at least the following:
1. Documentation of review of committee reports including quarterly Quality Assurance/Performance Improvement (QA/PI);
 2. Review, approval and revision of the Medical Staff Bylaws and Rules and Regulations;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

3. Election of officers as specified by the Bylaws; and
 4. Documentation of physicians designated as chairmen of the committees to direct the services defined in the Medical Staff bylaws.
- D. Quality Assurance/Performance Improvement (QA/PI).
1. The organization shall develop, implement and maintain an ongoing program to assess and improve the quality of care and services provided. A multidisciplinary committee shall meet at least quarterly to provide oversight and direction for the program; the hospital shall maintain minutes of the meetings. A Quality Assurance/Performance Improvement Plan shall be developed and maintained to describe the manner in which QA/PI activities shall be conducted in the hospital. The QA/PI plan shall be reviewed and approved by the Chief Executive Officer, Medical Staff and Governing Body annually.
 - a. All hospital and Medical Staff programs, services, departments and functions, including contracted services related to patient care, shall participate in ongoing quality assurance/performance improvement activities.
 - b. The hospital shall collect and assess data on the functional activities identified as priorities in the QA/PI plan.
 - c. Data collected shall be benchmarked against past performance and/or national or local standards.
 - d. Improvement strategies shall be developed for programs, services, departments and functions identified with opportunities for improvement.
 - e. The effectiveness of improvement strategies and actions taken shall be monitored and evaluated, with documentation of conclusions regarding effectiveness.
 - f. Identify and reduce medical errors and adverse patient events.
 - g. Approved organizational abbreviation list.
 2. Scope of QA/PI Program. The QA/PI program shall include, but not be limited to, ongoing assessment and improvement activities regarding the following:
 - a. Access to care, processes of care, outcomes of care and hospital-specific clinical data, including applicable Peer Review Organization (PRO)/Quality Assurance/Performance Improvement Organization (QA/PIO) data;
 - b. Customer satisfaction (patients and families, physicians and employees);
 - c. Staff performance as it relates to the staff as a whole when reviewing aspects of care;
 - d. Complaint resolution;
 - e. Utilization and discharge planning data; and

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- f. Organizational performance.
3. Program Responsibilities. The Governing Body shall assume overall responsibility and accountability for the organization-wide QA/PI program. The Governing Body, Chief Executive Officer and Medical Staff shall ensure QA/PI activities, address identified priorities and be responsible for the development, implementation, monitoring and documentation of improvement activities.
 4. Reporting. QA/PI activities shall be reported to the Governing Body on at least a quarterly basis and shall be documented in the Governing Body meeting minutes.
 5. Policies and Procedures. Policies and procedures pertaining to the QA/PI program which are not contained within the QA/PI plan shall be maintained in a manual, reviewed and approved annually.
 6. Program Evaluation. An evaluation of the QA/PI program shall be conducted by the hospital and reported to the Governing Body annually. The evaluation shall be based upon objective data and shall include programs, services, departments and functions targeted by the hospital for improvement, as well as those conducting ongoing QA/PI activities. Changes in the QA/PI program and QA/PI plan shall be made in response to the evaluation.
- E. Discharge Planning. There shall be a discharge plan for each patient.
1. Discharge plans shall incorporate available community and hospital resources, such as social, psychological, nutritional, and educational services, to meet the medically-related needs of the patients and to facilitate the provision of follow-up care.
 2. There shall be policies and procedures developed for discharge planning which include:
 - a. initiation of discharge planning at the time of the patient's admission;
 - b. reassessment of patient's condition and needs prior to the patient's discharge;
 - c. patient and family education regarding the discharge plan which includes:
 1. follow-up care and treatment;
 2. available community and hospital resources; and
 - d. transfers and referral processes to appropriate facilities, agencies or outpatient services as needed for follow-up or ancillary care, including necessary medical information.
- F. Organ and Tissue Donation. The Governing Body of each Acute Care Hospital shall cause to be developed appropriate policies, procedures, and protocols for identifying and referring potential

RULES FOR CRITICAL ACCESS HOSPITALS 2021

organ and tissue donors. The written policies and procedures shall include but not be limited to the following subjects:

1. Determination and declaration of brain death;
2. Organ procurement procedures:
 - a. Identifying potential donors;
 - b. Referring potential donors; and
 - c. Obtaining consent.
3. Role of attending physician;
4. Role of the procurement coordinator (employee of procurement agencies);
5. Reimbursement for cost of donation;
6. Liabilities associated with donation;
7. Agreement with organ procurement agency designated by Center for Medicare and Medicaid Services (CMS);
8. A consent procedure which encourages reasonable discretion and sensitivity to the family circumstances in all decisions regarding organ and tissue donations;
9. Determination by the organ procurement agency personnel of the suitability of the organs and/or tissues for transplantation; and
10. Requirements for documentation in the patient's medical record that the family of a potential organ donor has been advised of their right to donate or decline to donate.

SECTION 7: GENERAL ADMINISTRATION.

- A. Each institution shall have an Administrator responsible for the management of the institution. In the absence of the Administrator, an alternate with authority to act shall be designated. The responsibilities of the Administrator shall include:
1. Keeping the Governing Body fully informed of the conduct of the hospital by submitting periodic written reports or by attending meetings of the Governing Body;
 2. Conducting interdepartmental meetings at regular intervals and maintaining minutes of the meetings;
 3. Preparing an annual operating budget of anticipated income and expected expenditures; and
 4. Preparing a capital expenditure plan for at least a three-year period.
- B. Policies and procedures shall be provided for the general administration of the institution and for each department, section or service in the facility. All policies and procedures for departments or services shall have evidence of ongoing review and/or revision. The first page of each manual shall have the annual review date signature of the department supervisor and/or person(s) conducting the review.
- C. An accurate daily patient census sheet as of midnight shall be available to the Department at all times.
- D. The facility shall have visitation policies determined by the Medical Staff, Governing Body and Administration which shall include:
- ~~1. Limitation when patient care is hindered or disrupted; and~~
 1. Development by the Governing Body with ~~advice~~ guidance from the Medical Staff and Infection Prevention and Control Committee regarding persons under the age of 12 who visit critical care areas of the hospital.
 2. Visitation and support for disabled patients
 - a. May include cognitive or mental health disabilities, need assistance with activities of daily living, blindness, deafness, behavioral health needs, or making decisions to consent or refuse treatment
 - b. Pt may designate 3 support people
 - c. At least 1 may be present at all times.
 3. Visitation and support for
 - a. A child may include parent, legal guardian, or loco parentis to be present while the child receives care
 - b. An adult may include a spouse, support person, or legal guardian to be present while receiving care.
 4. A clergy or spiritual lay person may be physically present with a patient.
 5. Visitor restriction may include:
 - a. When the presence of a visitor would be medically or therapeutically contraindicated.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

09102021

- b. If the person has signs or symptoms of a transmittable disease
 - 1. The hospital shall allow access through telephone, telecommunication, or other means when visitation is restricted for a. or b.
 - c. At the request of the patient, law enforcement, of court order.
 - d. If the presence of a visitor would interfere with the care of or rights of any patient.
 - e. If the person is determined to be a danger to staff, other patients, or visitor; non-complaint with healthcare facility policies; or engaging in disruptive, threatening, or violent behavior toward any staff member, patient, or other visitors.
- E. Provisions shall be made for safe storage of patients' valuables.
- F. Animals such as cats, dogs, birds and fish and aquatic animals shall not be permitted in health care facilities. Exceptions shall be made for service animals, animals that participate in pet therapy, fish and aquatic animals in approved aquariums. (See Section 25, Pet Therapy Program.) All exceptions shall be approved by Health Facility Services.
- 1. Service animals shall be permitted only under the following guidelines:
 - a. Only animals specifically trained as service animals shall be allowed into the facility.
 - b. Service animals shall not be allowed into the facility if they are unhealthy, feverish, or suffer from gastroenteritis, fleas or skin lesions.
 - c. Healthy, well-groomed animals shall be allowed to enter the facility into areas that are generally accessible to the public (i.e., lobbies, cafeteria, and nurses stations on unrestricted units). The owner of the animal shall be directed to inquire about the possibility of a visit before entering a patient's room. Authorization to visit shall be given by a unit supervisor.
 - d. Service animals shall be walked before entering the facility or shall be diapered in a manner to prevent contamination of the facility environment with excreta. Service animals shall not be fed within the facility.
 - e. Petting or playing with service animals by hospital personnel or patients shall be prohibited.
 - f. Owners of service animals shall be instructed to wash their hands before having patient contact.
 - g. Visiting with service animals shall be restricted in the following circumstances:
 - 1) The patient is in isolation for respiratory, enteric or infectious diseases or is in protective isolation;
 - 2) The patient, although not in protective isolation, is immunocompromised or has a roommate that is;
 - 3) The patient is in an intensive care unit, burn unit or restricted access unit of the hospital;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

09102021

- 4) The patient or roommate is allergic to animals or has a severe phobia; and
 - 5) The patient or roommate is psychotic, hallucinating or confused or has an altered perception of reality and is not amenable to rational explanation.
- h. Animals which become loud, aggressive or agitated shall be removed from the facility immediately.
2. Fish and aquatic animals shall not be permitted in health care facilities without prior written approval by Health Facility Services. Aquariums shall be approved by the Medical Staff and Infection Prevention and Control Committee. (Turtles will not be considered for approval.)
- a. Aquariums shall meet the following requirements:
- 1) Aquariums shall be self-contained, shock proof, break proof and quiet in operation.
 - 2) Aquariums shall be constructed or positioned in such a manner as to be leak-proof, spill proof and to preclude patients or staff from having direct contact with the animals or water in the aquarium.
 - 3) Aquariums and associated equipment shall be cleaned frequently by appropriately trained personnel who do not have direct contact with patients or patient care items.
 - 4) Aquariums shall be placed only in areas which are accessed by the general public. Aquariums shall not be placed in critical care areas (i.e., nursing stations, surgery, patient rooms, ICU, etc.)
 - 5) Aquariums shall be kept in a state of good repair at all times.
- b. There shall be written procedures for cleaning and caring for the aquarium.
- c. There shall be written procedures for dealing with clean up in the event there is a major accident concerning the aquarium.
- d. Fish or aquatic animals shall be of varieties that do not bite, sting and are considered non-toxic or non-poisonous.
- G. Each facility shall develop and maintain a risk-assessed all hazards written disaster plan. The plan shall:
1. be tailored to meet specific disaster risks present in the area, such as earthquakes, tornados, floods, nuclear reactor failures, etc;
 2. include widespread disasters as well as disasters occurring within the local community and hospital facility;
 3. provide for complete evacuation of the facility;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

09102021

4. provide for care of mass casualties and increased patient volume;
 5. provide for transfer of patients, including those with hospital equipment, to an alternate site;
 6. contain two rehearsals a year, preferably as part of a coordinated drill in which other community emergency agencies participate; and
 - a. one drill shall simulate a disaster of internal nature and the other external;
 - b. one drill shall be planned and one shall be "no notice;" and
 - c. written reports and evaluation of all drills shall be maintained;
 7. contain specific provisions to supply food, water, generator fuel and other essential items for 72 hours (applies to inpatient facilities only);
 8. develop, maintain and exercise redundant communication systems; and
 9. facilities with AWIN (Arkansas Wireless Information Network) issued equipment shall include regular maintenance and personnel training for its use.
- H. There shall be a posted list of names, telephone numbers and addresses available for emergency use. The list shall include the key hospital personnel and staff, the local police department, the fire department, ambulance service, Red Cross and other available emergency units. The list shall be reviewed and updated at least every six months.
- I. There shall be rules and regulations governing the routine methods of handling and storing flammable and explosive agents, particularly in operating rooms, delivery rooms, laundries and in areas where oxygen therapy is administered.
- J. All refrigerated areas, including freezers, shall be provided with thermometers and records maintained to document the temperatures checked on a daily or weekly basis, as required.
- K. The facility shall provide access to appropriate educational references to meet the professional and technical needs of hospital personnel.
- L. A safety committee shall develop written procedures for the reporting and prevention of safety hazards. The committee shall meet at least quarterly or more frequently if necessary to fulfill safety objectives. Minutes of the meeting shall be maintained.
- M. All Departments and/or Services shall receive annual education on safety, fire safety, back safety, infection prevention and control, universal/standard precautions, disaster preparedness and confidential information.
- N. Any hospital or related institution that closes shall meet the requirements for new construction in order to be eligible for re-licensure. Once a facility closes, it is no longer licensed. The license shall be immediately returned to Health Facility Services. To be eligible for licensure all the latest life safety and health regulations shall be met. Refer to Section 4, Licensure and Codes, item B., Application for License and item H., Revocation of Licenses.
- O. The facility Administrator shall assure the development of policies and procedures in

RULES FOR CRITICAL ACCESS HOSPITALS 2021

09102021

accordance with Ark. Code Ann. § 20-9-307 that, upon request of the patient, an itemized statement of all services shall be provided within 30 days after discharge or 30 days after request, whichever is later. The policy shall include a statement advising the patient in writing of his/her right to receive the itemized statement of all services.

- P. The facility shall establish a process for prompt resolution of patient grievances to include the following:
1. The facility shall inform each patient whom to contact to file a grievance.
 2. The Governing Body shall approve and be responsible for the effective operation of the grievance process unless delegated in writing to another responsible individual.
 3. The facility shall establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the facility.
 4. The grievance process shall specify timeframes for review of the grievance and the provisional response.
 5. The grievance process shall include a mechanism for timely referral of patient concerns regarding quality of care to the Quality Assurance/Performance Improvement Committee.
- Q. A physician shall pronounce the patient dead and document the date, time and cause of death.
- R. Patient care providers not employed by the hospital, who are involved in direct patient care, shall follow hospital policies and procedures.
- S. Pursuant to A.C.A § 20-9-302 hospitals shall not perform an abortion unless the abortion is to save the life of the pregnant woman in a medical emergency.

SECTION 8: PERSONNEL ADMINISTRATION.

- A. Medical Attendance. The name, address, and telephone number of the physician(s) attending each patient shall be recorded for ready reference.
- B. Qualified Personnel. The hospital shall maintain a sufficient number of qualified personnel to provide effective patient care and all other related services. There shall be personnel policies and procedures available. Provisions shall be made for orientation and continuing education.
- C. Minimum Age. Personnel who care for patients shall be a minimum of 16 years of age. For any exceptions, see Subpart C of Part 570 of Title 29 of the Code of Federal Regulations, Child Labor Regulations No. 3.
- D. Employee Health. It shall be the responsibility of Administration, with advice and guidance from the Medical Staff and/or Infection Control Committee, to establish and enforce policies concerning pre-employment physicals and employee health. The policies shall include but are not limited to:
 - 1. Requirements for an up-to-date health file for each employee;
 - 2. There shall be measures for prevention of communicable disease outbreaks, especially mycobacterium tuberculosis (TB). All plans for the prevention of transmission of TB shall conform to the most current CDC Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Healthcare Facilities.
 - 3. Work restrictions placed on hospital personnel who are known to be affected with any disease in a communicable stage or to be a carrier of such disease, to be afflicted with boils, jaundice, infected wounds, diarrhea or acute respiratory infections. Such individuals shall not work in any area in any capacity in which there is the likelihood of transmitting disease to patients, hospital personnel or other individuals within the hospital or a potential of contaminating food, food contact surfaces, supplies or any surface with pathogenic organisms.
- E. The licensure rules promulgated by the Arkansas Department of Health for hospitals and other related institutions shall be available to all personnel. All personnel shall be instructed in the requirements of the rules pertaining to their respective duties.
- F. Job descriptions shall be developed for each employee and shall include the responsibilities or actual work to be performed. The job descriptions shall include physical, educational and licensing or certification requirements for each job.
- G. Personnel records shall be maintained for each employee and shall include current and background information covering qualifications for employment, records of all required health examinations, evidence of current registration, certification, or

RULES FOR CRITICAL ACCESS HOSPITALS 2021

licensure of personnel subject to statutory regulation and an annual job specific performance evaluation.

SECTION 9: ADMINISTRATION REPORTS.

- A. All communicable diseases shall be immediately reported to the Arkansas Department of Health. The institution shall furnish pertinent required information related to the disease to the Arkansas Department of Health.
- B. Occurrences which threaten the welfare, safety or health of the public such as epidemic outbreaks, poisoning, etc., shall be reported either by phone or facsimile to the local or State Health Officer. The institution shall furnish other pertinent required information related to the occurrence to the Arkansas Department of Health.
- C. Immediate capacity for disaster admissions shall be reported daily to the Disaster Preparedness Section of the Arkansas Department of Health.
- D. The facility shall electronically submit to the Arkansas Department of Health, Division of Vital Statistics a report on each abortion complication diagnosed or treated by the Facility not later than the 30th day after the date on which the abortion complication was diagnosed or treated.
 - 1. The report must include:
 - a. The name of the Physician submitting the report and type of healthcare facility submitting the report
 - b. Not identify by any means the Physician performing the abortion or the patient on whom the abortion was performed
 - c. Include the most specific, accurate, and complete reporting for the highest level of specificity and include the following
 - 1) The date of the abortion that caused or may have caused the abortion complication;
 - 2) The type of abortion that caused or may have caused the abortion complication;
 - 3) The gestational age of the fetus at the time the abortion was performed;
 - 4) The name and type of healthcare facility in which the abortion was performed;
 - 5) The date the abortion complication was diagnosed or treated;
 - 6) The name and type of any healthcare facility other than the reporting healthcare facility in which the abortion

RULES FOR CRITICAL ACCESS HOSPITALS 2021

complication was diagnosed or treated;

7) A description of the abortion complication;

8) The patient's year of birth, race, marital status, state of residence, and county of residence;

9) The date of the first day of the patient's last menstrual period that occurred before the date of the abortion that caused or may have caused the abortion complication, if known;

10) The number of previous live births of the patient; and

11) The number of previous induced abortions of the patient

E. The Facility shall report to Arkansas Department of Health, Division of Vital Statistics transfers after midwife deliveries.

SECTION 10: PATIENT IDENTIFICATION.

Each patient admitted to the hospital shall have an identification bracelet applied during the admission process.

SECTION 11: PATIENT CARE SERVICE.

- A. Organization. Nursing Services shall be directed by a nurse executive who is a Registered Nurse qualified by advanced education and management experience. The nurse executive's education and experience shall be directly related to the facility's stated mission and to the nursing care needs of the patient population.
1. The nurse executive shall have overall authority for the development of organization-wide nursing standards and policies and procedures that describe how patient care needs are assessed, evaluated and met.
 2. Development and implementation of the organization's plans for providing nursing care to the patient shall be approved by the nurse executive.
 3. Policies, procedures and standards shall be defined, documented and accessible to the nursing staff in a written or electronic format. Each element shall be approved by the nurse executive or designee prior to implementation.
 4. The nurse executive and nursing staff shall collaborate with appropriate Governing Body, Medical Staff, management and other clinical leaders in developing, implementing, revising and monitoring patient care improvement activities.
 5. The nurse executive or designee shall be responsible for orienting and maintaining adequate numbers of qualified staff for patient care.
 6. Staff meetings shall be conducted at least monthly for the purpose of reviewing the quality of nursing care provided. Meeting minutes and attendance shall be maintained.
 7. If the organization provides clinical facilities for nursing students, there shall be a written agreement that defines:
 - a. The facility's responsibilities; and
 - b. Responsibilities of the educational institution, including supervision of students and responsibilities of the instructor.
 8. Clinically relevant in-service educational programs shall be conducted at regularly scheduled intervals not less than 12 times per year. There shall be evidence of program dates, attendees, and subject matter.
 9. There shall be a continuous QI program that is specific to the patient care administered. The program shall reflect nursing staff participation including reports to appropriate hospital committees.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

B. Qualifications.

1. A current, valid license to practice nursing in Arkansas shall be held by all nurses hired in the facility as well as private duty and contract/pool nurses. There shall be a procedure to assure all licenses are current.
2. Licensed nursing personnel shall practice under the Nurse Practice Act of the State of Arkansas and current Arkansas State Board of Nursing Rules and Regulations.
3. The qualifications required for each category of nursing staff shall be in written policy. Job descriptions shall be available for review.
4. There shall be documented evidence of appropriate training for all nonlicensed staff who are assigned patient care duties.
5. The nurse executive or designee(s) participates with administration in decisions relative to the selection and promotion of nursing personnel based on qualifications and capabilities and recommends the termination of employment when necessary.
6. All licensed nursing personnel shall be competent in life support measures.

C. Staffing.

There shall be an adequate number of Registered Nurses on duty at all times and available for bedside care of any patient when needed on a 24-hour basis. In addition, there shall be sufficient Registered Nurses to staff all patient care units. A Registered Nurse shall assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the preparation and competence of the nursing staff. There shall be written criteria to substantiate the assignments.

D. Evaluation and Review of Patient Care Services.

1. There shall be established working relationships with other services of the hospital, both administrative and professional. The factors explaining the standard are as follows:
 - a. Registered Nurses confer with the physicians relative to patient care;
 - b. Interdepartmental policies affecting patient care are made jointly with the nurse executive or designee(s); and

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- c. Procedures are established for scheduling laboratory and X-ray examinations, for ordering, securing, and maintaining supplies and equipment needed for patient care and for ordering diets, etc.
2. There shall be on-going review and evaluation of nursing care provided for patients.
 - a. A Registered Nurse plans, supervises, and evaluates the nursing care for each patient in all settings where nursing care is provided.
 - b. Each patient shall have a plan for provision of care. Each patient plan of care shall be current. Plans indicate patient care required, how it is to be accomplished, and the methods, approaches, goals, and modifications necessary to ensure best results for the patient. The patient's plan of care shall be initiated upon admission.
 - c. There shall be documentation of the nursing care provided. The following information shall be documented:
 - 1) The initial patient assessment;
 - 2) Date and time of treatments and/or dressing changes;
 - 3) Medication Administration Record (MAR) including the date, time, dosage and manner of administration and the initials of the nurse administering the medication. When personnel other than nursing administer medication and the MAR is not utilized, a record of that ancillary department shall comply with this requirement and be included in the medical record;
 - 4) Date, time, dosage and manner of administration of all PRN medications to include reason for administration and results;
 - 5) Bedtime and between meal snacks or feedings and the percentage of diets consumed;
 - 6) Change in patient's appearance and/or condition;
 - 7) Patient complaints; and
 - 8) Mode of discharge and to whom the patient was discharged. If a patient expires, the time the physician was called, time arrived, the time the patient was pronounced

RULES FOR CRITICAL ACCESS HOSPITALS 2021

dead and the fact that relatives were present shall be recorded. (If relatives were not present, a note shall be made regarding their notification and disposition of the patient's belongings).

- d. A Registered Nurse shall observe each patient at least once per shift and the observations shall be documented in the patient's medical record.

NOTE: Block charting and co signatures are not acceptable.

E. Patient Care Facilities and Equipment.

1. There shall be no more beds maintained in the building than the number of beds for which the hospital is licensed except in the case of a public disaster or national emergency and then only as a temporary measure.
2. No beds shall be in the hallway or on the floor except in case of emergency.
3. Children under the age of 16 years shall not be cared for in a room with an unrelated adult patient.
4. Provisions shall be made for safe storage of patients' valuables.
5. All facilities for cleaning and storage of patient care supplies and equipment shall be used only for the purpose for which they are designed.
6. Thermometers shall not come in contact with more than one patient without disinfection or proper covers.
7. All single-use equipment used by a patient shall either be sent home with the patient at the time of discharge or destroyed.
8. Only currently dated equipment and supplies shall be available for patient care. All equipment shall be kept clean and in good condition.
9. Observation is a designated patient status as opposed to a designated area. Patients in observation status are those patients requiring periodic monitoring and assessment necessary to evaluate the patient's condition or to determine the need for possible admission to the hospital in an inpatient status. Usually observation status shall be for 48 hours or less.

Patients in observation status may be accommodated within the facility:

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- a. In private, semi-private or multi-patient rooms. Furniture shall be arranged to provide adequate room for patient care procedures and to prevent the transmission of infection;
- b. Cubicle curtains, privacy screens, or an approved equivalent shall be provided for patient privacy in all multi-patient rooms. The utilization of such curtains or screens shall be such that each patient shall have complete privacy;
- c. Each room or cubicle shall be provided with oxygen, vacuum and a nurse call button;
- d. Hand hygiene facilities shall be available within the area;
- e. Hospital grade furniture shall be provided. Bed rails shall be provided on beds;
- f. For each area in which a patient bed is utilized, a reading light shall be provided for each bed. The location and design shall be such that the light is not annoying to other patients;
- g. Patient toilets shall be provided and accessible to all patients; and
- h. Adequate space shall be provided for medical supplies.

Patients that remain in observation status for a period of 24 hours or more shall have provided to them accommodations equivalent to the accommodations they would have if they were admitted as an inpatient.

SECTION 12: MEDICATIONS.

- A. All medical orders (medications and treatments) shall be in writing and signed by the prescriber. Telephone/verbal orders should be used infrequently. When used they shall be given only to licensed nurses and signed by the prescriber.
- B. No medication shall be dispensed or administered without a written order signed by a licensed prescriber. A pharmacist may receive telephone or verbal orders for medications from a prescriber and record them on the medical record.
- C. Medications shall be administered by licensed nursing personnel in accordance with the current Arkansas Nurse Practice Act. Other personnel may administer medications only in accordance with their current Practice Act (e.g., Respiratory, Physical Therapy).
- D. Blood transfusions and intravenous medications administered by licensed nursing personnel shall be in accordance with State law. If not administered by a Registered Nurse, only licensed nursing personnel who have documentation of training shall be permitted to administer blood transfusions and intravenous medications.
- E. There shall be an effective hospital procedure for reporting transfusion reactions and adverse medication reactions.
- F. All medications shall be properly labeled and stored in a specifically designated medication cabinet, cart or room. At nursing stations, medications shall only be accessible to licensed nursing personnel and pharmacists. In specialty units and treatment areas, medications shall only be accessible to licensed nursing personnel, pharmacists, and designated licensed personnel consistent with that unit (e.g., Respiratory, Physical Therapy).
- G. Refrigeration shall be provided for the proper storage of biologicals and other medications. Medications shall be stored in a separate compartment or area from food. Employee foods and/or medications shall be stored in a separate refrigeration area. An internal thermometer shall be provided and checked daily (or at least weekly when the unit is closed) with documentation to assure temperatures between 36°- 46° Fahrenheit (two to eight degrees Centigrade). Refrigerated controlled substances shall meet the requirement for double-lock security.
- H. Unused or damaged medications shall be returned to the pharmacy. All medications with incorrect or soiled labels shall be returned to the pharmacy for relabeling.
- I. In addition to patients' medical records, a record of the procurement and disposition of each controlled substance shall be maintained at each nursing and

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- specialty unit. Each entry on the disposition record shall reflect the actual dosage administered to the patient, the patient's name, the date, time, and signature of the licensed person administering the medication. (Licensed personnel who may legally administer controlled substances shall include only those personnel authorized by their current Practice Act. Any error of entry on the disposition record shall follow a policy for correction of errors and accurate accountability. If the licensed person who procures the medication from the double-lock security is not the licensed person who administers the medication, then both persons shall sign the disposition record.
- J. When breakage or wastage of a controlled substance occurs, the amount given and the amount wasted shall be recorded by the licensed person who wasted the medication and verified by the signature of a licensed person who witnessed the wastage. Documentation shall include or policy shall delineate how the medication was wasted. In addition to the above referenced licensed personnel (see I), licensed Pharmacists shall be allowed to witness wastage of controlled substances. When a licensed person is not available to witness wastage, the partial dose shall be sent to the Arkansas Department of Health, Pharmacy Services and Drug Control for destruction.
- K. There shall be an audit each shift change of all controlled substances stocked on the unit. At nursing stations such counts shall be recorded by the oncoming nurse and witnessed by the off-going nurse. At other units, audits shall be performed by two licensed personnel. In each case, both licensed personnel shall sign the record with notation made as to date and time of the audit. If discrepancies are noted, the Director of Nursing, the Department Director, as applicable, and the Director of Pharmacy shall be notified. As with the witnessing of wastage, licensed Pharmacists shall be allowed to witness controlled substance audits.
- L. If specialty units are not staffed on every shift, controlled substances shall be audited by two licensed personnel on each shift that is covered by licensed personnel.
- M. Controlled substances in areas that are covered only by on-call personnel shall be audited each shift the area is used and at least weekly; whichever time frame is less.
- N. Solutions and medications for "external use only" shall be kept separate from other medications.
- O. When a patient is discharged, the unused portion of the patient's medication may be sent home with the patient on direct written order of the attending physician; and only after the medication has been relabeled by the pharmacy. Documentation shall include the amount dispensed to the patient and quantities shall be consistent with the immediate needs of the patient.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- P. Policies and procedures shall be developed and implemented for the handling of medications brought into the facility by the patient.
- Q. All medication errors and adverse drug reactions shall be reported to the attending physician. A copy of all medications errors and adverse drug reactions shall be sent to the Director of Nursing or designee, QA/PI Committee and when appropriate, to the Director of Pharmacy.
- R. Records generated by Automatic Medication Distribution Devices shall comply with these rules. Policies and Procedures for the usage of Automatic Medication Distribution Devices shall be approved administratively by Health Facility Services prior to their usage.
- S. Drug Security.
 - 1. The pharmacist, with support from the Pharmacy and Therapeutics (P&T) Committee, is ultimately responsible for drug security throughout the facility; applicable licensed personnel at nursing and specialty units shall maintain the daily security of medications at their respective units.
 - 2. Access to medications shall be limited to designated licensed personnel at all times.
 - 3. Medications dispensed to nursing and specialty units shall be kept locked in accordance with all Federal and State regulations.
 - 4. Emergency-type medications (crash cart, crash kit), as approved by the P&T Committee, shall be secured with a breakaway seal under the following conditions:
 - a. The quantities of medication are limited;
 - b. A list of medications stocked with quantities listed is posted on the emergency cart or container;
 - c. The breakage of the seal clearly indicates that entry has occurred (and said broken seal cannot be repaired without obvious evidence);
 - d. Any remaining medications shall be secured and accessible only to licensed personnel whenever the seal has been broken and before a new seal is installed;
 - e. Applicable personnel shall check the cart for the integrity of the seal each shift. Documentation shall reflect that the seal is intact. The emergency cart shall be stored in an area observable by licensed

RULES FOR CRITICAL ACCESS HOSPITALS 2021

personnel;

- f. The quantities of a controlled substance stocked in a cart or container shall be limited to a maximum of two single doses of Schedule III, IV, or V drugs. No Schedule II drugs shall be included in this stock; and
 - g. Pharmacy Services shall check the condition of the carts or containers as part of the monthly inspections of nursing and specialty units.
5. Controlled substances maintained as floor stock at nursing and specialty units shall be stored separately from other medication under double-lock security.
 6. For patient safety, Schedule III, IV, and V controlled substances in unit dose packages and dispensed in quantities limited to a maximum of a two-day supply, may be stored with that patient's other medication.
 7. All medications shall be locked in the absence of immediate visual supervision by licensed personnel.
 8. When a hospital operates an outpatient pharmacy that stocks medications in various clinical areas, stock lists, records, and security measures shall be in compliance with the requirements for nursing and specialty units.
 9. Distribution of sample legend medications shall not be permitted by hospitals. Samples are defined as any prescription only medication which is not intended to be sold and is intended to promote the sale of the medication.
 10. Medication security as provided by Automatic Medication Distribution Devices shall comply with these rules. Policies and procedures for security provisions shall be approved administratively by Health Facility Services prior to usage of Automatic Medication Distribution Devices.

SECTION 13: RESTRAINTS.

- A. Restraint use should be implemented in the least restrictive manner possible, applied in accordance with safe and appropriate techniques and ended at the earliest possible time.
- B. Each order for the application of restraints shall be time limited and shall include the type of restraint to be used. Restraints orders shall not be written as a standing order or on an as needed basis (PRN).
- C. Restraints either physical or chemical shall be applied only after less restrictive measures have failed. Restraints shall not be used as a matter of convenience for the staff or as a tool for disciplining the patient. When the use of a restraint is clinically indicated, it shall be used only in accordance with the order of a physician or non-physician licensed medical professional who has been appropriately credentialed by the medical staff with approval by the governing body.
- D. Documentation of a comprehensive assessment and modification to the plan of care shall include the less restrictive measures attempted, justification for the continued need of restraint and that the patient and/or significant other has been informed of the reason for restraint use.
- E. Documentation in the patient's record regarding any type of restraint shall include the times the restraint was applied, released, and discontinued, as well as evidence of continual assessment, monitoring and re-evaluation of the patient's condition during the restraint incident.
- F. When restraint use is ordered by other than the attending physician, the attending physician shall be informed as soon as possible.
- G. Patients in leather or locked restraints shall be under constant observation.
- H. All staff that have direct patient contact shall have ongoing education and training in the proper and safe use of restraints.

SECTION 14: HEALTH INFORMATION SERVICES.

A. General Requirements.

1. A medical record shall be maintained for each patient admitted for care in the hospital.
2. The original or a copy of the original (when the original is not available) of all reports shall be filed in the medical record.
3. The record shall be permanent and shall be either typewritten or legibly written in blue or black ink.
4. All typewritten reports shall include the date of dictation and the date of transcription.
5. All dictated records shall be transcribed within 48 hours.
6. Errors shall be corrected by drawing a single line through the incorrect data, labeling it as "Error," initialing, and dating the entry.
7. Additional patient records room requirements are provided in Section 61, Physical Facilities, and Health Information Unit.
8. Disease, operation, and physicians' indices shall be maintained (manual, abstract, or computer). Records shall be indexed within one month following discharge. Indices maintained on computer shall be retrievable at any time for research or quality assurance/performance improvement monitoring.
9. Records of discharged patients shall be coded in accordance to accepted coding practices. Records shall be coded within one month of the patient's dictated discharge summary.
10. Relevant educational programs shall be conducted at regularly scheduled intervals with no less than 12 per year. There shall be written documentation with employee signatures, program title/subject, presenter, date, and outlines or narrative of presented program.
11. A Master Patient Index shall be maintained by the Health Information Services. Index information shall include at least the full name, address, birth date, and the medical record number of the patient. The index may be maintained manually or on computer and shall contain the dates of all patient visits to the facility. If the Index is maintained on computer, there shall be a policy and procedure on permanent maintenance.

12. Birth certificates shall be completed according to the current rules and regulations of Vital Records, Arkansas Department of Health.
13. A unit record system shall be maintained. A unit record is defined as all inpatient and outpatient visits for each patient being filed together in one unit.
14. A policy and procedure manual for the Health Information Management Department shall be developed. The manual shall have evidence of ongoing review and/or revision. The first page of each manual shall have the annual review date, signature of the department supervisor and/or person(s) conducting the review.
15. A qualified individual shall be employed to direct the hospital's Health Information Department. If a Registered Health Information Administrator (RHIA) or a Registered Health Information Technician (RHIT) is not employed as Director on a full-time basis by the hospital, a consultant shall make periodic visits to evaluate functions of the Department and train personnel.
16. All patient records, whether stored within the Health Information Management Department or other areas, either within the facility or away from the facility, shall be protected from destruction by fire, water, vermin, dust, etc.
17. Medical records shall be considered confidential. Only authorized personnel shall have access to the medical records. All medical records (including those filed outside the department) shall be secured at all times. If authorized personnel are not available, the department shall be locked. Records shall be available to authorized personnel from the Arkansas Department of Health.
18. Release of medical information shall be restricted by the facility's policies and procedures.
19. All medical records shall be retained in either the original, microfilm or other acceptable methods for 10 years after the last discharge. After 10 years a medical record may be destroyed provided the facility permanently maintains the information contained in the Master Patient Index. Complete medical records of minors shall be retained for a period of two years after the age of majority.
20. Procedures shall be developed for the retention and accessibility of the patients' medical records if the hospital or other facility closes. The medical records shall be stored for the required retention period and shall be accessible for patient use.

21. All entries into the medical record shall be legible. There shall be no erasures or obliterations of the original information contained in a medical record.
 22. Medical records shall be complete and contain all required signed documentation (including physician reports) no later than 30 days following the patient's discharge date.
 23. Patient records shall be destroyed by burning or shredding. Patient records shall not be disposed of in landfills or other refuse collection sites.
 24. A QA/PI program shall be continuous and specific to the services.
 25. In the event of a physician's death or permanent incapacitation, incomplete medical records shall be reviewed in a manner approved by the Medical Staff. Approval to file incomplete medical records shall be obtained in a manner approved by the Medical Staff and a statement explaining the circumstances be placed in each record.
- B. Authentication of Medical Record Entries.
1. Each entry into the medical record shall be authenticated by the individual who is the source of the information. Entries shall include all documents, observations, notes, and any other information included in the record.
 2. Signatures shall be at least, the first initial, last name and title. Computerized signatures may be either by code, number, initials, or the method developed by the facility.
 3. The hospital's Medical Staff and Governing Body shall adopt a policy regarding dictation that permits authentication by electronic or computer generated signature. The policy shall identify those categories of the staff within the hospital that are authorized to authenticate patient records using electronic or computer generated signatures.
 4. At a minimum, the policy shall include adequate safeguards to ensure confidentiality.
 - a. Each user shall be assigned a unique identifier which is generated through a confidential code.
 - b. The policy shall include penalties for inappropriate use of the identifier.
 - c. The user shall certify, in writing, that he or she is the only person authorized to use the signature code.
 - d. The hospital shall periodically monitor the use of identifiers; the

process by which the monitoring shall be conducted shall be described in the policy.

5. The system shall make an opportunity available to the user to verify that the document is accurate and the signature has been properly recorded.
 6. Each report generated by a user shall be separately authenticated.
 7. A user may terminate authorization for use of electronic or computer generated signature upon written notice to the Director of Health Information Services.
 8. Rubber stamp signatures shall be acceptable if a letter from the physician is on file explaining that the physician shall be the only person using the stamp and the stamp shall remain in his/her possession at all times. The signature stamp shall be the full legal name of the physician with his/her professional title.
 9. Transcribed reports dictated by other than the attending physician shall be signed by the credentialed individual dictating the report and the attending physician. Dictation of reports by other than the attending physician is limited to history, physical, discharge summary, operative reports and progress notes. Reports dictated by resident physicians for training purposes require only the signature of the attending physician.
- C. Electronic Health Information
1. Policies and procedures governing electronic health information within the organization and with external entities shall be adopted by the Governing Body.
 2. The policies and procedures shall provide for the use, exchange, security and privacy of electronic health information. The policies and procedures shall provide for standardized and authorized availability of electronic health information for patient care, administrative purposes and research. The policies and procedures will be in compliance with current guidelines and standards as established in federal and state status.
- D. Record Content.
1. Identification data shall include at least the following:
 - a. Patient's full name - maiden name if applicable;

- b. Patient's address, telephone number, and occupation;
 - c. Date of birth;
 - d. Age;
 - e. Sex;
 - f. Marital status (M.S.D.W.);
 - g. Dates and times of admission and discharge;
 - h. Full name of physician;
 - I. Name and address of nearest relative or person or agency responsible for patient and occupation of responsible party;
 - j. Name, address, and telephone number of person(s) to notify in case of emergency;
 - k. Medical record number; and
2. A general consent for medical treatment and care. This shall be signed by the patient or guardian. Written or verbal consent shall not release the hospital or its personnel from upholding the rights of its patients including but not limited to the right to privacy, dignity, security, confidentiality, and freedom from abuse or neglect.
3. A consent for a do-not-resuscitate order or otherwise withholding or withdrawing treatment of a minor.
- a. The consent shall:
 - Include the written or verbal consent of at least one parent or guardian of the minor;
 - Include the signature of two (2) witnesses attesting the consent was given by at least one parent or guardian when the consent was given verbally;
 - Be documented in the minor's medical record, specifying the parent or guardian who gave consent, the witnesses present, and the date and time the consent was obtained.
 - b. The consent does not apply if the minor is married, pregnant, emancipated, or incarcerated in the Division of Corrections, or the Division of Community Corrections.
 - c. The parent or guardian may revoke the consent verbally or in writing.
4. Clinical reports shall include the following and shall comply with listed requirements:

- a. A History and Physical Examination (HPE) shall be in the patient's medical record within 48 hours of the patient's admission to the facility. The HPE must be authenticated by the attending or treating physician and shall contain the following:
 - 1) Family (medical) history and review of systems - if noncontributory, the record shall reflect such;
 - 2) Past medical history;
 - 3) Chief complaint(s) - a brief statement of nature and duration of the symptoms that caused the patient to seek medical attention as stated in the patient's own words;
 - 4) Present illness with dates or approximate dates of onset;
 - 5) Physical examination;
 - 6) Provisional or admitting diagnosis(es); and
 - 7) History and physical examinations may be completed up to 30 days prior to admission if the examination is updated at the time of admission. The updated HPE must be authenticated by the attending or treating physician.
- b. Progress notes shall be recorded, dated and signed. The frequency of the physician's progress notes shall be determined by the patient's condition. Dictated progress notes are acceptable and shall be placed in the patient's medical record within 48 hours.
- c. Orders including verbal orders shall be authenticated with a legible and dated signature in a timely manner as defined by Medical Staff By-Laws.
- d. A discharge summary shall recapitulate the significant findings and events of the patient's hospitalization and his/her condition on discharge. The discharge summary must be authenticated by the attending or treating physician within 30 days of the patient's discharge. The final diagnosis shall be stated in the discharge summary.
- e. Autopsy findings shall be documented in complete protocol within 60 days and the provisional anatomical diagnosis shall be recorded within 72 hours. A signed authorization for autopsy shall be obtained from the next of kin and documented in the medical record before an autopsy is performed.

- f. Original, signed diagnostic reports (laboratory, X-rays, CATs, SCANS, EKGs, fetal monitoring, EEGs) shall be filed in the patient's medical record. Physicians' orders shall accompany all treatment procedures. Fetal monitor and EEG tracings may be filed separately from the medical record if accessible when needed.
 - g. Reports of ancillary services (Dietary, Physical Therapy, Respiratory Care, Social Services, etc.) shall be included in the patient's medical record.
 - h. Reports of Medical Consultation, if ordered by the attending physician, shall be included in the patient's medical record within time frames established by the Medical Staff.
- E. Records of Complementary Departments. In addition to the general record content requirements stated above, parts F., G. and H. are required, as applicable.
- F. Surgery Records.
- 1. A specific consent for surgery shall be documented prior to the surgery/procedure to be performed, except in cases of emergency, and shall include the date, time and signatures of the patient and witness. Consent shall be obtained by the surgeon and documented in the patient's medical record. (Abbreviations are not acceptable.)
 - 2. A History and Physical Examination (HPE) on admission containing medical history and physical findings shall be documented in the patient's medical record prior to surgery. In cases of emergency surgery, an abbreviated physical examination, and a brief description of why the surgery is necessary shall be included in the HPE. (See Section 14, Health Information Services, Record Content.) The HPE must be authenticated by the attending or treating physician or surgeon.
 - 3. An anesthesia report, including preoperative evaluation and postoperative assessment, shall be documented by the Anesthesiologist and/or Certified Registered Nurse Anesthetist (CRNA). The pre-evaluation and post assessment shall be dated and timed.
 - a. Preoperative anesthesia evaluation shall be completed prior to the patient's surgery.
 - b. Report of Anesthesia. A CRNA who has not been granted authority by a facility, as a DEA registrant, to order the administration of controlled substances shall give all orders as verbal orders from the supervising physician, dentist, or other person lawfully entitled to order an anesthetic.

- c. Post anesthesia assessment shall be documented in the medical record prior to the patient's discharge, not to exceed 48 hours after the patient's surgery. If the patient is in need of continued observation, the anesthetist shall be readily available. Discharge criteria shall be established and approved by the Medical Staff and Governing Body. If the patient meets the discharge criteria within a three-hour period postoperatively, a post anesthesia assessment is not required.
 4. An individualized operative report shall be written or dictated by the physician or surgeon immediately following surgery and shall be signed within 72 hours. The report shall describe (in detail) techniques, findings, pre and postoperative diagnosis, and tissues removed.
 5. A signed pathological report shall be maintained in the medical record of all tissue surgically removed. A specific list of tissues exempt from pathological examination shall be developed by the Medical Staff.
- G. Obstetrical Records.
 1. A pertinent prenatal record shall be updated upon admission, or history and physical examination signed by the physician shall be available upon the patient's admission and be maintained in the patient's medical record.
 2. A record of labor and delivery, authenticated by the physician, shall be maintained for every Obstetrical patient.
 3. Documentation of the patient's recovery from delivery shall be maintained.
 4. Nurses' postpartum record, graphics and nurses' notes shall be maintained.
- H. Newborn Records.
 1. A newborn history and physical examination shall be completed by the physician within 24 hours of birth. The following additional data shall be required:
 - a. History of the newborn delivery (sex, date of birth, type of delivery, and anesthesia given the mother during labor and delivery); and
 - b. Physical examination (weight, date, time of birth, and condition of infant after birth).
 2. There shall be a consent for circumcision (if applicable).

3. A procedure note for circumcision shall be documented by the physician.
4. A discharge note or summary describing the condition of the newborn at discharge and follow-up instructions given to the mother must be prepared and included in the medical record. The discharge note or summary must be authenticated by the attending or treating physician.
5. Hospitals shall comply with State Law and Health Department requirements for newborn testing. See *Rules Pertaining to Testing of Newborn Infants* and Ark. Code Ann. § 20-15-301 et seq.
6. Birth certificates shall be completed on all infants born in the hospital, or admitted as a result of birth in accordance with the requirements of Vital Records, Arkansas Department of Health.

SECTION 15: MEDICAL RECORD REQUIREMENTS FOR OUTPATIENT SERVICES, EMERGENCY ROOM AND OBSERVATION SERVICES.

- A. Outpatient Records. An Outpatient record shall be completed for each outpatient and shall include the following:
1. History and physical examination of the patient (not applicable if for diagnostic services and/or outpatient therapy services);
 2. Orders and reports of diagnostic services and outpatient therapy services;
 3. Patient's diagnosis and summary of treatment received recorded by the attending physician;
 4. Documentation of any medications administered;
 5. Progress notes for subsequent clinic visits recorded by applicable disciplines (practitioners);
 6. Outpatient surgery record requirements (See also item F. of Section 14, Health Information Services.); and
 7. Discharge instructions.
- B. Emergency Room Records. An Emergency Room Record shall be completed for each patient who presents for treatment at the Emergency Room and shall include the following:
1. Patient identification;
 2. Date and the following times:
 - a. Admission;
 - b. Time physician was notified of patient's presence in the Emergency Room;
 - c. Time of physician's arrival if applicable; and
 - d. Discharge.
 3. History (when the injury or onset of symptoms occurred);
 4. Vital signs;
 5. Nurses' assessment and physical findings;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

6. Diagnosis;
7. Record of treatment including documentation of verbal orders and of medication quantities administered with the initials of person(s) administering the medications. Also, type and amount of local anesthetic, if administered;
8. Diagnostic reports with specific orders noted;
9. Instructions to patients for follow-up care (e.g., do not drive after receiving sedatives, return to physician's office for removal of sutures in one week);
10. Disposition of case;
11. Signature of patient or his/her representative;
12. Signed and dated discharge order; and
13. The ambulance record shall be transferred with the patient.

NOTE: Emergency Room Records shall be completed within 24 hours of the patient's visit.

C. Observation Records. A record of every patient admitted to an observation status shall be maintained. The observation record shall include, at a minimum:

1. Patient identification data;
2. Physician's diagnosis and therapeutic orders dated and timed;
3. History and physical;
4. Physician's progress notes, including results of treatment;
5. Nursing assessment by a Registered Nurse;
6. Nursing observations;
7. Results of all diagnostic testing;
8. Medication Administration Record;
9. Allergies;
10. Patient education;
11. Plan for follow-up treatment; and

RULES FOR CRITICAL ACCESS HOSPITALS 2021

12. Referrals.

NOTE: Observation records shall be completed on patients who stay less than 24 hours.

D. Psychiatric Records. The basic medical record requirements for psychiatric patients shall be the same as for other patient records, with the following additions:

1. The identification data shall include the patient's legal status (on the face sheet);
2. A proper consent or authority for admission shall be included;
3. A psychiatric evaluation shall be completed by the attending physician within 60 hours of admission which includes the following:
 - a. The patient's chief complaints and/or reaction to hospitalization, recorded in patient's own words, if possible;
 - b. History of present illness including onset and reason for current admission;
 - c. Past history of any psychiatric problems and treatment, including a record of patient's activities (social, education, vocational, interpersonal and family relationships);
 - d. Past psychiatric history of patient's family;
 - e. Mental status which includes at least attitude and general behavior, affect, stream of mental activity, presence or absence of delusions and hallucinations, estimate of intellectual functions, judgment and an assessment of orientation and memory;
 - f. Strengths such as knowledge, interests, skills, aptitudes, experience, education and employment status written in descriptive terms to be used in developing the Master Treatment Plan; and
 - g. Diagnostic impressions and recommendations.
4. A history and physical examination shall be documented by a physician and shall include a neurological examination within 24 hours of admission.
5. Social service records, including report of interviews with patient, family members and others shall be included for each admission. Social assessment and plan of care shall be completed within 48 hours of admission.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

6. Reports of consultation, psychological evaluations, reports of electroencephalograms, dental records and reports of special studies shall be included in the records when applicable.
7. An Interdisciplinary Master Treatment Plan shall be developed for each patient and included in the medical record, within 60 hours of admission. The treatment plan shall involve all staff who have contact with the patient and shall include (as a minimum):
 - a. Problems and needs relevant to admission and discharge as identified in the various assessments, expressed in behavioral and descriptive terms;
 - b. Strengths (assets) including skills and interests;
 - c. Problems, both physical and mental, that require therapeutic management;
 - d. Long and short term goals describing the desired action or behavior to be achieved. Goals shall be relevant, observable and measurable;
 - e. Treatment modalities individualized in relation to patient's needs;
 - f. Evidence of patient's involvement in formulation of the plan;
 - g. Realistic discharge and aftercare plans;
 - h. Nursing assessment and progress notes integrated into the Master Treatment Plan. Reviews and revisions of the Nursing Plan of Care shall be as required under the Section 11, Patient Care Service;
 - i. Signatures of all staff involved;
 - j. Date Master Treatment Plan was implemented; and
 - k. Staff responsibilities.
8. The treatment received by the patient shall be documented in such a manner and with such frequency as to assure that all active therapeutic efforts such as individual and group psychotherapy, medication therapy, milieu therapy, occupational therapy, industrial or work therapy, nursing care and other therapeutic interventions are included.
9. Progress notes shall be recorded by the physician, social worker and others involved in active treatment modalities at least as often as the patient is seen. The notes shall contain recommendations for revisions in the treatment plan.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

10. Nursing notes shall be written as required under the Section 11, Patient Care Service.
11. The discharge summary shall include a recapitulation of the patient's hospitalization and recommendations from appropriate services concerning follow-up of aftercare, as well as a brief summary of the patient's condition on discharge.
12. The psychiatric diagnosis contained in the final diagnosis and included in the discharge summary shall be written in the terminology of the current American Psychiatric Association's Diagnostic and Statistical Manual.

SECTION 16: PHARMACY.

All hospitals shall have adequate provision for pharmaceutical services regarding the procurement, storage, distribution and control of all medications. There shall be compliance with all federal and state regulations, including Laws and Regulations – Arkansas State Board of Pharmacy.

A. Definitions.

1. Hospital Pharmacy means the place or places in which drugs, chemicals, medicines, prescriptions or poisons are prepared for distribution and administration for the use and/or benefit of patients in a hospital licensed by the Arkansas Department of Health. The Hospital Pharmacy shall also mean the place or places in which drugs, chemicals, medicines, prescriptions or poisons are compounded for the dispensing to hospital employees, members of the immediate families of hospital employees, patients being discharged, and other persons in emergency situations. Hospital Pharmacy shall also mean the provision of pharmaceutical services as defined in the Pharmacy Practice Act by a pharmacist to a patient of the hospital.
2. Hospital Employee means any individual employed by the hospital whose compensation for services or labor actually performed for a hospital is reflected on the payroll records of a hospital.
3. Qualified Hospital Personnel means persons other than Licensed Pharmacists who perform duties in conjunction with the overall hospital pharmaceutical services for inpatients.
4. Licensed Pharmacist means any person licensed to practice pharmacy by the Arkansas State Board of Pharmacy who provides pharmaceutical services as defined in the Pharmacy Practice Act to patients of the hospital.
5. Unit Dose Distribution System is a pharmacy-coordinated method of dispensing and controlling medications in hospitals in which medications are dispensed in single unit packages for a specific patient on orders of a physician where not more than a 24-hour supply of said medication is dispensed, delivered, or available to the patient.
6. Modified Unit Dose Distribution System is a system that meets the requirement of a "Unit Dose Distribution System," provided that up to a 72-hour supply may be sent to the floor once a week if the system has been reviewed and approved administratively by the Arkansas State Board of Pharmacy.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- B. Hospitals maintaining and using mechanical storage and delivery machines for legend drugs shall have such machines stocked only by Pharmacy Services. Drugs may be obtained from such machines only by licensed personnel in accordance with their Practice Act acting under the prescribed rules of safety procedures as promulgated by the individual hospital using said machine.

Limited amounts of Schedule II-V controlled substances may be stocked in the machines provided the following requirements are met:

1. Pharmacy Services possesses the only key necessary to stock the machine; and
2. Policies and Procedures specify the licensed personnel having access and responsibility for the medications.

The person removing a medication for administration shall record at least the patient's name and the name, strength, and amount of medication on a record that is maintained by the Pharmacy Department. The record shall also be signed by the person removing the medication. The removal of controlled substances shall comply with the record keeping requirements of Section 12, Medications. Pharmacy Services shall audit stock levels as needed to replace medications. Use of the machines shall not be to circumvent adequate pharmaceutical services.

- C. Compounding, Dispensing and Distributing.

1. Compounding. The act of selecting, mixing, combining, measuring, counting, or otherwise preparing a drug or medication.
2. Dispensing. A function restricted to licensed pharmacists, which involves the issuance of:
 - a. One or more doses of a medication in containers other than the original, with such new containers being properly labeled by the dispenser as to content and/or directions for use as directed by the prescriber;
 - b. Medication in its original container with a pharmacy prepared label that carries to the patient the directions of the prescriber as well as other vital information; and/or
 - c. A package carrying a label prepared for nursing station use. The contents of the container may be for one patient (individual prescription) or for several patients (such as a nursing station medication container).

RULES FOR CRITICAL ACCESS HOSPITALS 2021

3. **Distributing.** Distributing, in the context of this regulation, refers to the movement of a medication from a central point to a nursing station medication center. The medication shall be in the originally labeled manufacturer's container or in a prepackaged container labeled according to federal and state laws and regulations, by a pharmacist or under his direct and immediate supervision.
- D. **Pharmacy and Therapeutics Committee.** There is a committee of the Medical Staff to confer with the pharmacist in the formulation of policies, explained as follows:
1. A Pharmacy and Therapeutics (P&T) Committee, composed of at least one (1) physician, the Administrator or representative, the director of nursing service or representative, and the pharmacist is established in the hospital. It represents the organizational line of communication and the liaison between the Medical Staff and the pharmacist;
 2. The Committee assists in the formulation of broad, professional policies regarding the evaluation, appraisal, selection, procurement, storage, distribution, use, and safety procedures in conformance with Food and Drug Administration and manufacturers' bulletins on the safe administration of drugs and all other matters relating to drugs in hospitals;
 3. The Committee performs the following specific functions:
 - a. Serves as an advisory group to the hospital Medical Staff and pharmacist on matters pertaining to the choice of drugs;
 - b. Develops and approves the drug formulary and all drug lists annually and makes interim revisions as needed;
 - c. Establishes standards concerning the use and control of investigational drugs and research in the use of recognized drugs;
 - d. Evaluates clinical data concerning new drugs or preparations requested for use in the hospital;
 - e. Makes recommendations concerning drugs to be stocked on the nursing unit floors and emergency drug stocks;
 - f. Prevents unnecessary duplication in stocking drugs and drugs in combination having identical amounts of the same therapeutic ingredients; and
 - g. Reviews and approves drug-related policies and procedures; and
 4. The Committee develops and approves policies and procedures for all

RULES FOR CRITICAL ACCESS HOSPITALS 2021

nursing personnel assigned the responsibility of preparing and administering intravenous (IV) admixtures. The pharmacist shall be involved in the review of the drug order, calculations, and preparation whenever possible. The Committee should consider the appropriate category of personnel (Registered Nurse or LPN) and degree of training necessary to make judgments and calculations involved in IV admixture programs;

5. The Committee assures that medications dispensed to outpatients, Emergency Room patients and discharged patients comply with all federal and state laws and regulations;
 6. The Committee meets at least quarterly and reports to the Medical Staff by written report.
- E. Pharmacy Operations. The hospital has a pharmacy directed by a licensed pharmacist. The pharmacy is administered in accordance with accepted professional principles.
1. Pharmacy supervision. There is a pharmacy directed by a licensed pharmacist defined as follows:
 - a. The Director of Pharmacy is trained in the specialized functions of hospital pharmacy;
 - b. The Director of Pharmacy is responsible to the administration of the hospital and Board of Pharmacy for developing, supervising, and coordinating all the activities of the Pharmacy Department and all pharmacists providing professional services in the hospital; and
 - c. All licensed pharmacists who provide pharmaceutical services as defined by the Pharmacy Practice Act shall practice under policies, procedures, and protocols approved by the Director of Pharmacy. These policies, procedures, and protocols shall be subject to review and approval by the Board of Pharmacy.
- F. Physical Facilities. Facilities are provided for the storage, safeguarding, preparation, and dispensing of drugs, defined as follows:
1. Drugs are issued to floor units in accordance with approved policies and procedures;
 2. Drug cabinets on all units shall be checked monthly by qualified pharmacy personnel. All floor stocks are properly controlled;
 3. A careful determination of the functions of a department will regulate the space to be allocated, the equipment necessary to carry out the functions, and the number of personnel required to utilize the equipment and to render a given

RULES FOR CRITICAL ACCESS HOSPITALS 2021

volume of service, as these functions relate to the frequency or intensity of each function or activity. Adequate equipment shall specifically relate to services rendered and functions performed by the hospital pharmacy. Equipment lists will relate to the following services and functions:

- a. Medication preparation;
 - b. Library reference facilities;
 - c. Record and office procedures;
 - d. Sterile product manufacturing;
 - e. Bulk compounding (manufacturing);
 - f. Product control (assay, sterility testing, etc.); and
 - g. Product development and special formulations for medical staff.
4. Equipment and supplies necessary to the hospital pharmacy's safe, efficient, and economical operation shall include, but not be limited to:
- a. Graduates capable of measuring from 0.1 ml up to at least 500 ml;
 - b. Mortars and pestles;
 - c. Hot and cold running water;
 - d. Spatulas (steel and non-metallic);
 - e. Funnels;
 - f. Stirring rods;
 - g. Class A balance and appropriate weights;
 - h. Typewriter or other label printer;
 - i. Suitable apparatus for production of small-volume sterile solutions;
 - j. Suitable containers and labels; and

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- k. Adequate reference library to include at least the following:
- 1) American Hospital Formulary Service;
 - 2) Pharmacology text;
 - 3) Each hospital pharmacy shall have available for personal and patient use a current copy of:

The U.S.P. DI, three book set including "Drug Information for the Healthcare Professional" (two volumes) and "Advice for the Patient" (one volume)

or

The two volume set "Facts and Comparisons" (one volume) and "Patient Drug Facts" (one volume);
 - 4) Text on compatibility of parenteral products;
 - 5) Current professional journals, such as:
 - a) Drug Intelligence and Clinical Pharmacy;
 - b) Hospital Pharmacy; and
 - c) Journal of ASHP.
5. Special locked storage space is provided to meet legal requirements for storage of controlled drugs, alcohol, and other prescribed drugs; and
- G. Personnel. Personnel competent in their respective duties are provided in keeping with the size and activity of the department explained as follows:
1. The Director of Pharmacy is assisted by an adequate number of additional licensed pharmacists and other such personnel as the activities of the pharmacy may require to ensure quality pharmaceutical services; and
 2. The pharmacy, depending upon the size and scope of its operations, is staffed by the following categories of personnel:
 - a. Chief Pharmacist (Director of Pharmacy);
 - b. One or more assistant chief pharmacists (Assistant Director of Pharmacy);

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- c. Staff pharmacists;
 - d. Pharmacy residents (where program has been activated);
 - e. Trained non-professional pharmacy helpers (qualified hospital personnel); and
 - f. Clerical help.
- H. Emergency Pharmaceutical Services. Through the Administrator of the hospital, the P&T Committee shall establish policies and procedures that include, but are not limited to, the following:
- 1. Upon admission to the Emergency Room on an outpatient basis and when examined by the physician where medications are prescribed to be administered, a record shall be kept on file in the Emergency Room admission book or a copy of the Emergency Room medication order must be kept by the pharmacist to be readily accessible, for control and other purposes, as required by these rules;
 - 2. If the physician wishes the patient to have medication to be taken with them from the emergency room supplies, the amounts to be taken shall be sufficient to last until medication may be obtained from local pharmacies, in any case not to exceed a 48-hour supply. All state and federal laws shall be observed concerning all records, labeling, and outpatient dispensing requirements; and
 - 3. Take home prescriptions for anti-infectives issued to patients at the time of discharge from the Emergency Room, dispensed by a pharmacist shall be quantities consistent with the medical needs of the patient.
- I. Pharmacy Records and Labeling. Records are kept of the transactions of the pharmacy and correlated with other hospital records where indicated. All medication shall be properly labeled. Such record and labeling requirements are as follows:
- 1. The pharmacy establishes and maintains, in cooperation with the accounting department, a satisfactory system of records and bookkeeping in accordance with the policies of the hospital for:
 - a. Maintaining adequate control over the requisitioning and dispensing of all drugs and pharmaceutical supplies; and
 - b. Charging patients for drugs and pharmaceutical supplies.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

2. A record of procurement and disbursement of all controlled drugs is maintained in such a manner that the disposition of any particular item may be readily traced;
 3. The pharmacist shall receive and provide service pursuant to the perusal of the physician's original order or a direct copy thereof, except in emergency situations wherein the pharmacist may provide service pursuant to a verbal order or to an oral or written transcription of the physician's order provided that the pharmacist shall receive and review the original or direct copy;
 4. A record shall be maintained by the pharmacy and stored separately from other hospital records for each patient (inpatient or outpatient) containing the name of the patient, the prescribing physician, the name and strength of the drugs prescribed, the name and manufacturer (or trademark), the quantity and the pharmacist's initials for all medications dispensed;
 5. The label of each medication container prepared for administration to inpatients, shall bear the name and strength of the medication, the expiration date, and the lot or control number. The label on the medication or the container into which the labeled medication is placed shall bear the name of the patient and room number; and
 6. The label of each outpatient's individual prescription medication container bears the name of the patient, prescribing physician, directions for use, and the name and strength of the medication dispensed (unless directed otherwise by the physician) and the date of dispensing.
- J. Control of Toxic or Dangerous Drugs. Policies are established to control the administration of toxic or dangerous drugs with specific reference to the duration of the order and the dosage, explained as follows:
1. The Medical Staff has established a written policy that all toxic or dangerous medications not specifically prescribed as to the time or number of doses, will be automatically stopped after a reasonable time limit set by the staff;
 2. The classifications ordinarily thought of as toxic or dangerous drugs are controlled substances, anticoagulants, antibiotics, oxytocics, and cortisone products; and
 3. All deteriorated non-sterile, non-labeled, or damaged medication shall be destroyed by the pharmacist, with the exception of controlled substances. All controlled drugs (Schedule II, III, IV and V) shall be listed and a copy sent, along with drugs to the Arkansas Department of Health by registered mail or delivered in person for disposition.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- K. Drugs to be dispensed. Therapeutic ingredients of medications dispensed are included (or approved for inclusion) in the United States Pharmacopoeia, N.F. and U.S. Homeopathic Pharmacopoeia, or Accepted Dental Remedies (except for any drugs unfavorably evaluated therein) and drugs approved by Ark. Code Ann. § 17-92-503, or are approved for use by the P&T Committee of the hospital staff, explained as follows:
1. The pharmacist, with the advice and guidance of the P&T Committee, is responsible for the specifications as to quality, quantity, and source of supply of all drugs; and
 2. There is available a formulary or list of drugs accepted for use in the hospital which is developed and amended at regular intervals by the P&T.
- L. Policy and Procedure Manual.
1. A policy and procedure manual pertaining to the operations of the hospital pharmacy, with updated revisions adopted by the P&T Committee of each hospital shall be prepared and maintained at the hospital.
 2. The policy and procedure manual shall include at a minimum, the following:
 - a. Provisions for procurement, storage, distribution, and drug control for all aspects of pharmaceutical services in the hospital;
 - b. Specialized areas such as Surgery, Delivery, ICU and CCU units and Emergency Room stock and usage of medication shall be specifically outlined;
 - c. A system of requisitioning supplies and medications for nurses' stations stock shall be in written procedural form as to limits of medications to be stocked in each nursing unit;
 - d. Detailed job descriptions and duties of each employee by job title working in the Pharmacy Department shall be developed and made a part of these policies and procedures; and
 - e. The Pharmacy Policy and Procedure Manual shall be subject to review and approval by the Board of Pharmacy on request from the Board.
- M. Employee Prescription Medication.
1. There will be a prescription on file for all prescription drugs dispensed to hospital employees and their immediate families. These records will be kept

RULES FOR CRITICAL ACCESS HOSPITALS 2021

separate from all inpatient records.

2. The only person(s) entitled to have employee prescriptions filled will be the employee listed on the hospital payroll and members of their immediate family.
- N. Patient Discharge Medication. Any take-home prescription dispensed to patients at time of discharge from the hospital shall be for drugs and quantities consistent with the immediate needs of the patient.
- O. Licensed Pharmacist Personnel Requirements.
1. The minimum requirements for licensed pharmacists in hospitals are:
 - a. A general hospital, surgery and general medical care, maternal and general medical care hospital, chronic disease hospital, psychiatric hospital, and rehabilitative facility licensed for greater than 50 beds, as determined by the institution license issued by the Arkansas Department of Health, shall require the services of one pharmacist on the basis of 40 hours per week with such additional pharmacists as are necessary, in the opinion of the Arkansas State Board of Pharmacy, to perform required pharmacy duties as are necessary in keeping with the size and scope of the services of the hospital pharmacy's safe and efficient operation. Hospitals providing specialized or unique patient care services may request approval from the Arkansas State Board of Pharmacy to be exempt from the requirement of a pharmacist on duty 40 hours per week. The request for exemption shall provide adequate written documentation to justify the services of a pharmacist such hours as are necessary to perform required pharmacy services, followed by an appearance before the Arkansas State Board of Pharmacy for final approval of the request;
 - b. The above classified hospitals, licensed for 50 beds or less, as determined by the institution license issued by the Arkansas Department of Health, shall require the services of a pharmacist such hours as, in the opinion of the Arkansas State Board of Pharmacy and the Arkansas State Board of Health, are necessary to perform required pharmacy duties in keeping with the size and scope of the services of the hospital pharmacy safe, and efficient operation. The pharmacist shall be on site at least five days per week to perform and review pharmacy dispensing, drug utilization and drug distribution activities. A pharmacist shall be available to provide emergency services to the staff when the pharmacy is closed;
 - c. Recuperation Centers, Outpatient Surgery Centers and Infirmaries:
 - 1) If the infirmary, recuperation center, or outpatient surgery center has a pharmacy department, a licensed pharmacist shall be employed to administer the pharmacy in accordance with all state and federal laws

RULES FOR CRITICAL ACCESS HOSPITALS 2021

regarding drugs and drug control;

- 2) If the infirmary, recuperation center, or outpatient surgery center does not have a pharmacy department, it has provisions for promptly and conveniently obtaining prescribed drugs and biologicals from a community or institutional pharmacy;
 - 3) If the infirmary, recuperation center, or outpatient surgery center does not have a pharmacy department but does maintain a supply of drugs, a licensed pharmacist shall be responsible for the control of all bulk drugs and maintain records of their receipt and disposition. The pharmacist shall dispense drugs from the drug supply, properly labeled, and make them available to appropriate nursing personnel;
 - 4) All medication for patients shall be on individual prescription basis.
2. A pharmacist in charge, who is employed at any facility permitted by the Arkansas State Board of Pharmacy where a 40-hour work week is required, may also be the pharmacist in charge at a hospital licensed for 50 beds or less by the Arkansas Department of Health.

P. Responsibility of a Pharmacist in Hospital Pharmacy.

1. The pharmacist is responsible for the control of all medications distributed in the hospital where he practices and for the proper provision of all pharmaceutical services.
2. The following aspects of medication distribution and pharmaceutical service are functions involving professional evaluations or judgments and may not be performed by supportive personnel:
 - a. Selection of the brand and supplies of medication;
 - b. Interpretation and certification of the medication ordered. This involves a number of professional responsibilities such as the determination of:
 - 1) Accuracy and appropriateness of dose and dosage schedule;
 - 2) Such items as possible drug interactions, medication sensitivities of the patient, and chemical and therapeutic incompatibilities; and
 - 3) Accuracy of entry of medication order to patient's medication profile.
 - c. Final certification of the prepared medication.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

Q. Pharmacy Technicians.

1. Pharmacy technician refers to those individuals identified by the Arkansas State Board of Pharmacy. Exclusive of pharmacy interns, who are regular paid employees of the hospital and assist the pharmacist in pharmaceutical services.
2. Supervision means that the responsible pharmacist shall be physically present to observe, direct, and supervise the pharmacy technician at all times when the pharmacy technician performs acts specified in this regulation. The supervising pharmacist is totally and absolutely responsible for the actions of the pharmacy technician.
3. The pharmacist and pharmacy technician(s) shall comply with all applicable sections of Laws and Regulations of the Arkansas State Board of Pharmacy with regards to tasks, responsibilities, duties, ratios, and supervision in the hospital setting.
4. There shall be documentation by each technician of all duties and tasks performed in the preparation and processing of medication. The pharmacist shall be responsible for the final check and verification of all technician duties and tasks. The performance, check, and verification shall be recorded on a record maintained by the department which shall include the signature, initial(s), or other identifying mark of each person.

R. Operation of Pharmacy Department When Pharmacist is Not Present.

1. A limited supply of backup medications may be utilized for patient needs only at times when the pharmacist is not present. This stock shall be accessible only to approved licensed personnel. A record shall be maintained which identifies the medication obtained and the personnel obtaining it. The pharmacist shall then review this record when he returns to the facility to assure compliance with the physician's orders. Medications shall be replaced to stock as needed.
2. At no time will the hospital pharmacy be open and in operation unless a licensed pharmacist is physically present except:
 - a. Entrance may be obtained for emergency medication as set forth in the Pharmacy Policy and Procedure Manual when the pharmacy is closed outside its normal operation hours. The Medical Staff shall approve a method by which individual nursing personnel may be authorized by name and qualification to remove only one dose if the drug is not of the unit dose packaging type; or, if the medication is unit dosed, enough medication to last until the pharmacist returns can be removed. A record listing all medications obtained should be maintained, and the pharmacist shall check for compliance with the physician's orders when he returns to the facility. Controlled substances shall not be accessible unless daily counts are

RULES FOR CRITICAL ACCESS HOSPITALS 2021

performed and documented; and

- b. When the pharmacist is summoned away from the pharmacy and there are other qualified personnel left in the pharmacy, the personnel left in the pharmacy shall perform only those functions authorized within this regulation.
3. A pharmacist shall be available to provide medication consultation.
- S. Medication Utilization. The pharmacist, with the advice and guidance of the P&T Committee, shall participate in:
1. Discussions of reports of medication errors, with trends noted, conclusions made, and recommendations suggested. If there are no errors to report, this shall be stated;
 2. Discussions of adverse drug reactions with trends noted, conclusions made, and recommendations suggested. Proper reports of appropriate reactions shall be reported to the full Medical Staff and/or the FDA reporting system. If there are no adverse reactions to report, this shall be stated;
 3. Reviews of results of monitoring conducted according to approved criteria for antibiotics prescribed for prophylactic and therapeutic reasons;
 4. Reviews of other drug utilization in the facility, as appropriate; and
 5. Formulation of an official record of each meeting maintained as minutes. The written report shall be forwarded to the P&T Committee, QA/PI Committee, and/or the Medical Staff for review and consideration, with at least a quarterly frequency.
- T. Electronic Data Processing in Hospital Pharmacies. All hospitals utilizing electronic data processing systems shall comply with *Laws and Regulations of the Arkansas State Board of Pharmacy*.
- U. Maintenance and Retention of Drug Records. All drug records, including but not limited to, purchase invoices, official dispensing records, prescription and inventory records shall be kept in such a manner that all data is readily retrievable, and shall be retained as a matter of record by the pharmacist for at least two years.
- V. The American Society of Health-System Pharmacists Guidelines. The American Society of Health-System Pharmacists' most recent statement on hospital drug control systems and Guidelines for Institutional Use of Controlled Substances shall be required reading by hospital pharmacists

SECTION 17: FOOD AND NUTRITION SERVICES.

A. Administration.

1. The Food and Nutrition Services shall be under the daily, including weekends, onsite supervision of a qualified individual. The individual shall be at a minimum a certified dietary manager and:
 - a. Be responsible for the daily management of clinical and administrative dietetic aspects of the service by formulating, reviewing and revising policies and procedures for all Food and Nutrition Services practices;
 - b. Ensure that all personnel in the service are oriented in their respective duties;
 - c. Implement a maintenance program to ensure food service facilities, equipment and utensils are maintained in a safe, clean, sanitary manner and are replaced at specific intervals or as needed;
 - d. Participate on hospital-wide departmental committees as required;
 - e. Ensure that trained staff are maintained for daily administrative and clinical nutrition practices. A minimum of a two-week current work schedule shall be posted and reflect all positions, including the department director; and
 - f. Develop, implement and maintain a system for record keeping relating to all department functions dependent on the department's scope of services, e.g., patient assessments, counseling, diet instructions, temperatures, educational programs, etc.
 - g. A hospital within a hospital may contract with the host hospital for food and nutrition services. Contracted services shall:
 - 1) be under a current agreement; and
 - 2) meet all requirements of this section.
2. Policies and procedures shall have evidence of ongoing review and/or revision. The first page of each manual shall have the annual review date, signature of the department supervisor and/or person(s) conducting the review.
3. Policies and procedures shall include:
 - a. Job descriptions and performance evaluations;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- b. Orientation;
 - c. Preventive maintenance;
 - d. Infection prevention and control measures;
 - e. Safety practices; and
 - f. Cleaning of equipment and applicable areas.
4. Clinically relevant educational programs shall be conducted at regularly scheduled intervals with not less than 12 per year. There shall be evidence of program dates, attendance, and subject matter.
 5. Nutrition Services shall have an ongoing QA/PI Program that addresses both clinical and administrative issues. A mechanism for reporting results of audits shall be provided, to include: indicators monitored, thresholds/standards established, results, corrective plan/corrective action taken and follow-up.
 6. Time and duty schedules for all hourly employees shall be maintained.
 7. Diet Manual shall be authorized by the Medical Staff, reviewed and revised, as needed, to reflect current recognized dietary practices. A cover page shall be affixed with the date of review and appropriate signatures and a copy of the manual shall be located on each patient unit. Use of electronic diet manuals is acceptable.
 8. Menus shall:
 - a. Be planned/approved by the registered dietitian and meet the nutrition needs of the patients in accordance with the current recommended dietary guidelines of the Food and Nutrition Board, National Research Council and the currently approved facility diet manual in accordance with the written diet order.
 - b. Be dated at least one week in advance. The current week's menus shall be posted and available in the kitchen. The meals prepared and served shall correspond with the posted menu, or written diet orders.
 - c. Not be restrictive in nature (e.g., seasoning, fat, sodium, sugar content) unless required by a modified/therapeutic diet order.
 - d. Be of equivalent nutrition value when substitutions/changes are made. Menus/production schedules, showing all changes, shall be retained for at least 30 days.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

9. Diets shall be in writing and signed by a physician or a mid-level practitioner if privileged by the Medical Staff and Governing Body. Dietitians may issue orders for patient diets if authorized by the medical staff. Notification according to facility policy shall be made to the Nutrition Services Department on a timely basis, kept current and include current date, the patient's name, room number and diet order.
- B. Food Services.
1. At least three meal equivalents shall be served daily at regular intervals, approximately five hours apart. No more than 15 hours shall elapse between the serving of the evening meal and the morning meal. The meals shall be served at approximately the same hour each day.
 2. Food shall be prepared in accordance with approved menus and standardized recipes and in a manner to conserve nutritive value, flavor and appearance.
 3. Food shall meet patient needs and shall be attractive, palatable and served at proper temperatures.
 4. An identification system shall be implemented for patient trays to ensure that each patient receives the appropriate diet as ordered.
 5. Nourishing bedtime snacks, appropriate to the patient's needs, shall be made available
 6. Only foods prepared and stored under the direction of Nutrition Services, in accordance with the Rules Pertaining to Retail Food Service Establishments shall be served to patients.
 7. All individuals who assist patients in the preparation, heating, reheating, consumption of food, sanitation of food ware and kitchen equipment, etc., while in the facility or on the facility grounds, shall be under the direction of Nutrition Services and in compliance with the Rules Pertaining to Retail Food Service Establishments. Documentation of educational programs on food preparation, safety and sanitation shall be performed for all applicable personnel (e.g., Occupational Therapy, Nursing) by Nutrition Services at least annually.
 8. Food shall not be consumed in the kitchen.
 9. Food shall be transported in a manner that maintains safe food temperatures and prevents contamination. Food carts shall not block corridors/exits, emergency equipment or patient doorways.
 10. All storage containers/foodstuffs shall be stored a minimum of 6 inches above the floor on non-porous, easily cleaned racks, dollies or shelving, in a

RULES FOR CRITICAL ACCESS HOSPITALS 2021

manner that protects the food (or food contact surfaces) from splash and other contamination and permits easy cleaning of the storage area.

11. Plastic milk crates shall not be permitted for storing of food or equipment, except for the intended use for milk storage.
12. Temperature documentation of all food refrigerators/freezers in the kitchen and cafeteria shall be performed a minimum of three times per day at opening, mid-operation and closing of the department.
13. Temperature documentation of all nourishment refrigerators/freezers in patient care areas shall be performed at least daily
14. Proper temperatures of vending machines containing potentially hazardous foods shall be ensured daily by the facility. Vending machines shall be equipped with a thermometer, easily visible to food service personnel for the purposes of monitoring the temperature of the internal environment. These machines shall have the capacity to render themselves inoperable if temperatures in excess of 40 degrees Fahrenheit are maintained for more than two hours. Documentation of such downtime shall be maintained to include remedial action taken.
15. If, for any reason, the refrigeration equipment does not maintain the appropriate temperature, action shall be taken and a record of remedial action and downtime shall be recorded and maintained by the facility.
16. Temperature documentation of the dish machine shall be recorded with each meal and these records shall be maintained by the facility. If the temperatures (and, if applicable, dwell times) are not maintained properly, action shall be taken and a record of remedial action, back-up procedures used and downtime shall be maintained by the facility.
17. If the facility uses a chemical method for sanitizing food preparation and serving ware, a record of the water temperature, the chemical used and appropriate parts per million (ppm) shall be maintained by the facility at each use.
18. The temperature of the hot and cold potentially hazardous foods shall be recorded at least at the beginning and end of meal service that continues for more than 15 minutes. If meal service lasts for 15 minutes or less, food temperature documentation is required only at the beginning of food service.
19. Documentation of the testing/calibration of food/refrigeration/freezer thermometers shall be performed according to manufacturer's recommendations.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

20. Food thermometers shall be sanitized after each use and stored in a manner that prevents contamination.
21. Only dietary and authorized personnel shall be allowed in the kitchen.
22. Sanitation shall be in accordance with the Rules Pertaining to Retail Food Service Establishments.

C. Food Safety/Sanitation.

1. Whole eggs and raw meat shall be stored separately and in a way that prevents contamination of other food items in refrigerated units.
2. Reheated food shall attain a temperature above 165° Fahrenheit prior to placement in steam tables, warmers, or other hot food storage units. Steam tables, warmers or other food storage units shall not be used for the rapid heating of potentially hazardous food.
3. Disposable gloves shall be worn to eliminate direct handling of food. Gloves shall be properly discarded after being used, torn or contaminated.
4. Ground beef or ground beef products shall be cooked to an internal temperature of 160° Fahrenheit or higher.
5. Potentially hazardous food shall be tempered or thawed only:
 - a. In designated tempering units at a temperature not to exceed 45° Fahrenheit;
 - b. In general refrigeration units at a temperature not to exceed 40° Fahrenheit;
 - c. As part of the conventional cooking process; or
 - d. In a microwave, provided the food is immediately transferred to conventional cooking process.
6. Potentially hazardous food that is left over shall be labeled as such with the date and time it was removed from service.
7. Potentially hazardous food shall be chilled to a temperature below 40° Fahrenheit and retained for no longer than 48 hours.
8. Food contact surfaces, i.e., cutting boards, of all equipment and utensils, shall be sanitized by immersion for at least one-half minute in clean, hot water at a temperature of at least 180° Fahrenheit or by any other method approved by

RULES FOR CRITICAL ACCESS HOSPITALS 2021

Health Facility Services. Counter tops and other huge industrial equipment shall be washed down with concentrated solutions.

9. Clean linens, mopheads and cloths shall be stored in a manner to prevent contamination prior to use.
10. Soiled linens, etc., shall be stored covered, separately from clean linen, food storage, preparation and serving areas. Containers for holding such items shall be made of non- absorbent materials. Soiled linens shall be removed from the department daily.
11. Food inventory shall be handled on a first-in, first-out basis. A system for labeling and dating canned, dry and potentially hazardous foods shall be implemented.
12. Potentially hazardous frozen foods removed from freezer storage to be thawed shall be labeled with the date of pull from the freezer for thawing.
13. Supplies and perishable foods for a 24-hour period and nonperishable foods for a three-day period shall be on the premises to meet the requirements of the planned menus.

NOTE: These rules are referenced to the Arkansas Board of Health *Rules Pertaining to Retail Food Service Establishments*

D. Clinical Services.

1. Clinical Dietitian/Nutritionist.

Shall be a registered dietitian, or registry eligible, and evaluate and oversee the delivery of effective nutrition care based on current, recognized nutrition practices. If not full- time, make regularly scheduled visits to accomplish the following:

- a. Review, revise and approve a current diet manual for facility use;
- b. Review, revise, approve and implement nutrition care policy and procedures, standards of nutrition care, nutrition care protocols and the Nutrition Services QA/PI Program;
- c. Coordinate nutrition care through communication with other patient care services;
- d. Provide for the initiation of nutrition screening of all patients upon admission and periodic screening of patients during their hospital stay;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- e. Provide for the nutrition assessment of patients at nutrition risk, as defined by the Medical Staff, and collaborate with the physician on the findings of the evaluation;
 - f. Ensure competency of all nutrition services personnel who perform assessments, counseling, develop care plans and participate in discharge planning;
 - g. Provide to the facility evidence of continuing education hours;
 - h. Perform orientation, preceptorship and ongoing training/educational programs for staff;
 - i. Review and revise nutrition counseling/diet education practices that are individualized to patient needs;
 - j. Monitor the enforcement of all policies and procedures and practices relating to food safety and sanitation;
 - k. Develop, implement and maintain a system for recording data related to patient care;
 - l. Collaborate with Nursing and Pharmacy to provide food/drug interaction counseling; and
 - m. If the dietitian is a consultant, submit reports to the facility Administrator reflecting services performed at each regularly scheduled visit.
2. Nutrition Screening and Documentation.
- a. Nutrition Screening shall be completed within 24 hours of admission on all patients to determine nutrition risk and notify the physician and dietitian of any patients that are at nutrition risk.
 - b. Psychiatric, Alcohol and Drug and Rehabilitation patients shall be rescreened seven days from the initial screen and at least every 14 days thereafter.
3. Nutrition Care Process.
- a. A nutrition assessment of patients at nutrition risk, as reflected in the medical record, shall include as appropriate:
 - 1) Anthropometric measurements including height, weight, BMI, and goal weight

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- 2) Abnormal pertinent laboratory values;
 - 3) The patient's caloric and protein needs;
 - 4) nutrient intake compared to estimated needs;
 - 5) Determination of abnormal intake or recent weight loss/gain prior to admission;
 - 6) An objective evaluation of the patient's compliance with a physician ordered diet prior to admission;
 - 7) Pertinent food/drug interactions;
 - 8) An evaluation of the patient's special feeding/nutrient/fluid needs;
 - 9) Patient's food preferences, dislikes, allergies or intolerances; and
 - 10) Nutrition summary including identification of nutrition problems
- b. The patient care plan on all patients found to be at nutrition risk shall include the following nutrition components, as appropriate:
- 1) individualized nutrition counseling;
 - 2) discharge planning;
 - 3) comprehensive nutrition assessments to include further clinical, laboratory, social or nutrition data to assist with the ongoing evaluation;
 - 4) follow-up care to evaluate the effectiveness of the nutrition regimen; and
 - 5) Any requests for alterations or modifications to the ordered diet's nutrient content, consistency, administration route/method or meal pattern as served in the hospital in order to meet the nutrition needs and/or special feeding needs of the patient.
4. Nutrition Counseling. Documentation of nutrition counseling shall include:
- a. Description of the individualized nutrition counseling;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- b. Objective evaluation of the patient's and/or caregiver's understanding and ability to carry out the diet order; and
 - c. Plans for continued counseling and/or recommendations for post-discharge counseling and evaluation of patient diet compliance.
5. Nutrition Monitoring and Evaluation.
- a. Shall be performed when the patient is at nutrition risk and documented in the medical record. The frequency of follow-up nutritional care shall be determined by the patient's condition.
 - b. Shall be documented in the patient's medical record on all patients at nutrition risk.
 - c. Shall be documented to include an evaluation of the effectiveness of the prescribed nutrition regimen, changing nutrition status/needs, nutrition counseling and/or recommendations to improve patient nutrition care.

SECTION 18: INFECTION PREVENTION AND CONTROL.

A. General.

1. The facility shall develop and use a coordinated process that effectively reduces the risk of endemic and epidemic healthcare associated infections (HAI) in patients, health care workers and visitors.
2. There shall be a comprehensive list of communicable diseases for which patients shall be isolated and for which there are visitation restrictions. The list, and other policies and procedures for isolation, shall conform to the latest edition of the Centers for Disease Control and Prevention, Atlanta, Georgia (CDC) Guidelines.
3. It shall be the duty of the Administrator or his/her designee to report all infectious or communicable diseases in the facility to the Arkansas Department of Health, Epidemiology, as required by the Rules and Regulations Pertaining to Communicable Disease in Arkansas (Ark. Code Ann. §§ 20-7-109, 110) and CMS mandatory reporting requirements for Medicare certified facilities.
4. The Administrator shall designate a qualified individual who shall:
 - a. Coordinate the activities of the Infection Prevention and Control Committee;
 - b. Direct surveillance activities;
 - c. Ensure policies established by the Committee are carried out; and
 - d. Gather and report data regarding the hospital's HAI.
5. There shall be policies and procedures establishing and defining the Infection Prevention and Control program to include:
 - a. Definitions of HAI and communicable diseases based on the current CDC or National Healthcare Safety Network (NHSN) surveillance definitions;
 - b. Perform an annual facility-based risk assessment to determine the infections that are most likely to occur in the facility. Infections to be addressed include (but are not limited to) the following :
 - 1) Ventilator associated event (VAE);
 - 2) Clostridium difficle infection (CDI);

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- 3) Central line associated blood stream infection (CLABS); and
- 4) Catheter associated urinary tract infection (CAUTI).
- 7) Use of intravascular catheters.

NOTE: The facility's system for surveillance, calculation and evaluation of the incidence of HAI within the facility shall conform to CDC's National NHSN or CDC publications as applicable.

- c. Calculate HAI rates;
- d. Measures for assessing and identifying patients and health care workers at risk for HAI and communicable diseases;
- e. Methods for obtaining reports of infections and communicable diseases in patients and health care workers in a manner and time sufficient to limit the spread of infection;
- f. A plan for monitoring and evaluating at least the following areas or departments to ensure policies and procedures are followed:
 - 1) Inpatient and outpatient surgery;
 - 2) Delivery;
 - 3) Nursery;
 - 4) Central sterilization and supply;
 - 5) Housekeeping;
 - 6) Laundry;
 - 7) Food and Nutrition;
 - 8) Laboratory;
 - 9) Nursing;
 - 10) Maintenance;
 - 11) Invasive specialty laboratories (special procedures);

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- 12) Radiology; and
 - 13) Hemodialysis units.
- g. Measures for prevention of infections including but not limited to:
- 1) Intravenous (IV) devices;
 - 2) Indwelling urinary catheters;
 - 3) Ventilator care;
 - 4) Burns; and
 - 5) Immune suppressed patients.
- h. Measures for prevention of communicable disease outbreaks, especially Mycobacterium tuberculosis (TB). All plans for the prevention of transmission of TB shall conform to the most current CDC Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health Care Facilities;
- i. Isolation procedures and requirements for infected, immune suppressed patients and patients colonized or infected with resistant organisms. Procedures shall conform to the most current CDC Guidelines.
- j. Provisions for education of patients and their families concerning infections and communicable diseases to include hand hygiene and any isolation precautions;
- k. A plan for monitoring and evaluating all aseptic, isolation and sanitation techniques employed in the facility to ensure that approved infection prevention and control procedures are followed;
- l. Techniques for:
- 1) Hand hygiene including policies and procedures that reflect facility-selected national guidelines for soap and water as well as alcohol based hand rub if used;
 - 2) Respiratory protection including policies and procedures that reflect facility-selected national guidelines;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- 3) Asepsis/sterile technique;
 - 4) Sterilization;
 - 5) Sanitary food preparation;
 - 6) Disinfection;
 - 7) Housekeeping;
 - 8) Linen care;
 - 9) Liquid and solid waste disposal of both infectious and regular waste. Disposal of infectious waste shall conform to the latest edition of the Rules and Regulations Pertaining to the Management of Medical Waste from Generators and Health Care Related Facilities;
 - 10) Sharps safety;
 - 11) Separation of clean from dirty process; and
 - 12) Other means of limiting the spread of contagion.
- m. Authority and indications for obtaining microbiological cultures from patients;
 - n. Employee health; and
 - o. Visitation rules, especially for patients in isolation, critical care, pediatrics and other special care units, including postpartum care.
6. There shall be an orientation program for all new health care workers concerning the importance of infection prevention and control and each health care worker's responsibility in the hospital's infection prevention and control program.
 7. There shall be a plan for each employee to receive annual educational programs as indicated based on assessments of the Infection Prevention and Control process.
 8. Maintain a log of documentation of reportable diseases.
 9. No items shall be used past the expiration date.

B. Infection Prevention and Control Committee.

1. There shall be a multidisciplinary committee appointed by Administration to develop, implement and monitor direction for the Infection Prevention and Control program based on services impacting the infection prevention and control process.
2. The Medical Staff shall appoint a physician to serve as chairperson of the Infection Prevention and Control Committee. Additional physician members may be appointed.
3. The Infection Prevention and Control Committee shall meet at least quarterly. Minutes of the meetings shall reflect the Committee's actions in monitoring and directing the hospital's Infection Prevention and Control program.
4. The Infection Prevention and Control Committee shall fulfill the following responsibilities:
 - a. Assist in the development and approval of all infection prevention and control policies and procedures within the facility;
 - b. Ensure that an antibiogram is prepared at least annually and compared to the previous one to identify trends;
 - c. Monitor any contractual services relative to infection prevention and control (e.g. waste management and laundry) to ensure compliance with all applicable rules; and
 - d. Review any special infection prevention and control studies conducted within the facility; and
 - e. Provide oversight for disinfectants and sterilants.

C. Employee Health.

1. There shall be policies and procedures for screening health care workers for infectious/communicable diseases and monitoring for health care workers exposed to patients with any communicable diseases. The policies and procedures shall reflect facility-selected national guidelines.
2. There shall be employee health policies and procedures regarding preventing the transmission of infectious diseases. The policies and procedures shall reflect facility-selected national guidelines
3. There shall be policies which clearly state when health care workers shall not

RULES FOR CRITICAL ACCESS HOSPITALS 2021

render direct patient care.

4. There shall be a plan for ensuring that:
 - a. each health care worker is free from TB; and
 - b. The facility follows the latest tuberculosis screening and tuberculosis prevention guidelines approved by the Arkansas Department of Health (Rules Pertaining to: the Control of Communicable Diseases-Tuberculosis).
5. There shall be a plan for ensuring that all health care workers who are exposed to blood and other potentially infectious body fluids are offered immunizations for Hepatitis B.

SECTION 19: LABORATORY.

A. General.

1. Each Critical Access Hospital shall provide onsite laboratory services essential to the immediate diagnosis and treatment of patients served by the facility. Provision shall be made for the following laboratory services:
 - a. Chemistry and microscopic examination of urine;
 - b. Complete blood count including hemoglobin, hematocrit, red blood cells, white blood cells and platelets;
 - c. Routine chemistry procedures including blood glucose, blood urea nitrogen, sodium, potassium, chloride, arterial blood gases and cardiac enzyme(s);
 - d. Fecal occult blood;
 - e. Pregnancy tests;
 - f. Primary culturing for transmittal to a certified laboratory;
 - g. Procurement, safekeeping and transfusion of blood or blood products on an emergency basis either directly or through written arrangement with another facility.
2. The requirements of the most current rule of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) shall be met.
3. All laboratory testing that is performed at any site owned and/or operated by the facility shall be approved, in writing, by the Governing Body. The Governing Body shall authorize the director of the hospital laboratory to provide oversight of all testing to ensure the quality of the laboratory services provided. A comprehensive list of all testing sites shall be made available to the Medical Staff.
4. A laboratory shall refer specimens for testing only to a laboratory possessing a valid Clinical Laboratory Improvement Amendments (CLIA) certificate authorizing the performance of testing in the specialty or subspecialty of service for the level of complexity in which the referred test is categorized.
5. Only results from the Critical Access Hospital laboratory or from other approved laboratories, as determined by hospital policy, shall

RULES FOR CRITICAL ACCESS HOSPITALS 2021

be placed in the patient's medical record.

6. Laboratory tests shall be authorized by a physician or other persons authorized by the Medical Staff and the Governing Body to order laboratory examinations.
7. The laboratory shall maintain accurate counts of total patient procedures for each specialty in which tests are performed.
8. Current reference material, such as textbooks, shall be available for every laboratory category in which tests are performed.
9. The laboratory shall make available to the Medical Staff a list of all tests performed onsite, including the reference range for each test.

B. Personnel.

1. A member of the Medical Staff shall be appointed to act as a liaison between the laboratory and the Medical Staff.
2. The laboratory shall be under the oversight of a pathologist who is board certified or eligible. A pathologist who is not based at the hospital shall make at least a monthly visit and submit a monthly written report to the Hospital Administrator.

NOTE: A hospital which provides only limited laboratory services (e.g., blood gas laboratory only) shall not be subject to the requirement of oversight of a pathologist.

3. The laboratory director, as defined by CLIA 88, shall be responsible for the overall operation of the laboratory but may delegate specific responsibilities to supervisory personnel. However, the director remains responsible for ensuring that all duties are properly performed and documented. The laboratory director shall be responsible for the following:
 - a. Ensuring that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the pre-analytic, analytic and post-analytic phases of testing;
 - b. Ensuring that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical and biological hazards;
 - c. Ensuring that:

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- 1) The test methodologies selected have the capability of providing the quality of results required for patient care;
 - 2) Verification procedures used are adequate to determine the accuracy, precision and other pertinent performance characteristics of the method;
 - 3) Laboratory personnel are performing the test methods as required for accurate and reliable results;
- d. Ensuring that the laboratory is enrolled in a proficiency testing program approved by Health and Human Services (HHS) for the testing performed and that:
- 1) The proficiency testing samples are tested in the same manner as the patient samples;
 - 2) The results are returned within the time frames established by the proficiency testing program;
 - 3) All proficiency testing reports are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;
 - 4) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory;
- e. Ensuring that the quality control and quality assurance/performance improvement programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;
- f. Ensuring the establishment and maintenance of acceptable levels of analytical performance for each test system;
- g. Ensuring that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified and that patient test results are reported only when the system is functioning properly;
- h. Ensuring that reports of test results include pertinent information required for interpretation;
- i. Ensuring that consultation is available to the laboratory's clients and to the Medical Staff on matters relating to the quality of the

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- test results reported and interpretation concerning specific patient conditions;
- j. Ensuring there is a sufficient number of laboratory personnel with the appropriate education and either training or experience to provide appropriate consultation, properly supervise and accurately perform tests and report test results;
 - k. Ensuring all personnel have the appropriate education and experience, receive the appropriate training for the type of services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;
 - l. Ensuring there is documentation of training for laboratory personnel who perform special procedures such as arterial punctures and therapeutic phlebotomies;
 - m. Ensuring that qualified testing personnel are on duty or on call at all times;
 - n. Ensuring that policies and procedures are established for monitoring individuals who conduct pre-analytical, analytical and post-analytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. The procedures for evaluation of the competency of the staff shall include, but are not limited to the following:
 - 1) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;
 - 2) Monitoring the recording and reporting of test results;
 - 3) Review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records;
 - 4) Direct observation of performance of instrument maintenance and function checks;
 - 5) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples;
 - 6) Assessment of problem solving skills;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- 7) Evaluation and documentation of the performance of all personnel with at least the following frequency:
 - a) Semiannually during the first year of employment in the laboratory;
 - b) Annually after the first year;
 - c) Prior to reporting patient test results if test methodology or instrumentation changes;
 - o. Ensuring that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;
 - p. Ensuring there is a plan for providing continuing education for the laboratory staff and there is documentation of each employee's participation.
 - q. Specifying the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the pre- analytic, analytic and post-analytic phases of testing;
 - r. Specifying the examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results;
4. There shall be a supervisor accessible at all times when testing is performed.
 5. Personnel responsible for day-to-day supervision of the laboratory shall meet at least one of the following qualifications:
 - a. A bachelor's degree in medical technology from an accredited institution and at least one (1) year of clinical laboratory training or experience relative to the specialties being supervised;
 - b. A bachelor's degree in a chemical, physical, biological or clinical laboratory science from an accredited institution with at least two (2) years of clinical laboratory training or experience relative to the specialties being supervised;
 - c. An associate degree in a laboratory science or medical laboratory technology from an accredited institution with at least two (2) years of clinical laboratory training or experience relative to the specialties being supervised;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- d. A passing score on the Clinical Laboratory Technology Proficiency examination approved by HHS (HEW) and at least six (6) years of clinical laboratory experience with at least two (2) years of experience relative to the specialties being supervised;
 - e. Employment as a laboratory supervisor prior to January 1, 1995, in a hospital licensed by the Arkansas Department of Health.
6. Testing personnel shall meet at least the following qualifications:
- a. Have earned a high school diploma or equivalent;
 - b. Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. Such training shall ensure that the individual has the following:
 - 1) Skills required for proper patient preparation and specimen collection, to include the following:
 - a) Labeling;
 - b) Handling;
 - c) Preservation or fixation;
 - d) Processing or preparation;
 - e) Transportation and storage.
 - 2) The skills required for implementing all standard laboratory procedures;
 - 3) The skills required for performing each test method and for proper instrument use;
 - 4) The skills required for performing preventive maintenance, trouble-shooting and calibration procedures related to each test performed;
 - 5) A working knowledge of reagent stability and storage;
 - 6) The skills required to implement the quality control policies and procedures of the laboratory;
 - 7) An awareness of the factors that influence test results;
 - 8) The skills required to assess and verify the validity of patient

RULES FOR CRITICAL ACCESS HOSPITALS 2021

test results through the evaluation of quality control sample values prior to reporting test results.

C. Procedure Manual.

1. There shall be a procedure manual for the performance of all analytical methods used by the laboratory readily available and followed by laboratory personnel. Textbooks may be used as supplements but shall not be used in lieu of the laboratory's written procedures for testing or examining specimens. The procedure manual shall include, when applicable to the test procedure, the following:
 - a. Requirements for patient preparation, specimen collection and processing, labeling, preservation and transportation, including criteria for specimen rejection;
 - b. Procedures for microscopic examinations, including the detection of inadequately prepared slides;
 - c. Step-by-step performance of the procedure, including test calculations and interpretation of results;
 - d. Preparation of slides, solutions, calibrators, controls, reagents, stains and other materials used in testing;
 - e. Calibration and calibration verification procedures;
 - f. The reportable range for patient test results as verified by the laboratory;
 - g. Quality control procedures for each test to include the following:
 - 1) Type of control;
 - 2) Identity of control;
 - 3) Number of controls;
 - 4) Frequency of testing controls;
 - 5) Criteria for determining acceptability of control results.
 - h. Remedial actions to be taken when any of the following occur:
 - 1) Calibration results are unacceptable;
 - 2) Control results are unacceptable;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- 3) Equipment or test methodologies fail;
 - 4) Patient test values are outside the laboratory's reportable range of patient test results;
 - 5) The laboratory cannot report patient test results within its established time frames;
 - 6) Errors in reported patient test results are detected.
- i. Limitations in methodologies, including interfering substances;
 - j. Reference ranges (normal values);
 - k. A list of "panic values" with written instructions for reporting such values;
 - l. Pertinent literature references;
 - m. Appropriate criteria for specimen storage and preservation to ensure specimen integrity until testing is completed;
 - n. The laboratory's system for reporting patient test results;
 - o. Description of the course of action to be taken in the event that a test system becomes inoperable;
 - p. Criteria for the referral of specimens, including procedures for specimen submission and handling and for record keeping.
2. The procedure manual shall be reviewed, approved, signed and dated by the current director of the laboratory or by an individual designated by the director in compliance with the CLIA 88 requirements.
 3. Each revision or addition to the procedure manual shall be reviewed, approved, signed and dated by the current director of the laboratory or by an individual designated by the director in compliance with the CLIA 88 requirements.
 4. The laboratory shall maintain a copy of each discontinued procedure for two years, with the dates of initial use and discontinuance.
- D. Record System.
1. The laboratory shall have policies and procedures for a record system which shall assure positive identification of patient specimens from the time of specimen collection until the time of test completion and results reporting. The record system shall include provisions for test requisitions, test records

RULES FOR CRITICAL ACCESS HOSPITALS 2021

and test reports. The configuration of the system may be established by the laboratory, provided all of the required information is readily retrievable for at least two years.

2. The laboratory shall perform tests at the written or electronic request of an authorized person.
3. Records of test requisitions or test authorizations shall be retained for a minimum of two years.
4. The test requisition shall include:
 - a. Identification of the patient;
 - b. The name of the authorized person who ordered the test;
 - c. The test(s) requested;
 - d. The date the test is to be performed;
 - e. For Pap smears, the patient's last menstrual period, age or date of birth and indication of whether the patient had a previous abnormal report, treatment or biopsy;
 - f. Any additional information relevant and necessary to a specific test to assure accurate and timely testing and reporting of results (Examples: age, sex, current medications, time of specimen collection, diagnosis, type of specimen, fasting).
5. Records of patient testing, including instrument printouts, shall be retained for at least two years. Immune hematology records and transfusion records shall be retained for at least five years. (Exception: If an instrument is interfaced with a computer, and the electronic data cannot be edited, the instrument printouts do not have to be retained.)
6. Test records shall provide documentation of the information required for test requisitions as well as the following information:
 - a. Unique identification of the patient specimen;
 - b. The date and time of specimen receipt into the laboratory;
 - c. The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability;
 - d. The tests and date of performance of each;
 - e. The time of completion of testing;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- f. The identity of the person who performs each test.
7. The laboratory report shall be sent promptly to the authorized person who requested the test.
8. A duplicate of each test report, including both preliminary and final reports, shall be retained for at least two years. The duplicate may be retained electronically as long as it contains the exact information sent to the individual ordering the test and utilizing the test results. For test reports requiring an authorized signature or containing personnel identifiers, the exact duplicate must include the signature or identifiers. Immunohematology reports shall be retained for at least five years, and pathology reports shall be retained for at least 10 years.
9. The test report shall include the following:
 - a. Identification of the patient;
 - b. Date of specimen collection;
 - c. The test(s) performed;
 - d. Test results and, if applicable, the units of measurement;
 - e. Date results were reported;
 - f. The condition and disposition of specimens that do not meet the laboratory's criteria for acceptability;
 - g. Any additional information relevant and necessary for the interpretation of the results of a specific test (Examples: Type of specimen, time of specimen collection, fasting).
10. The laboratory shall have policies and procedures for referring patient specimens to reference laboratories, to include:
 - a. Current list of reference laboratories, with the following information:
 - 1) CLIA number;
 - 2) Specialties and subspecialties in which the laboratory is certified;
 - 3) Expiration date of CLIA certificate;
 - b. Specimen submission and handling;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- c. Record keeping system.
 11. The laboratory shall not revise results or information directly related to the interpretation of results provided by a reference laboratory.
 12. The laboratory shall retain an exact duplicate of each reference laboratory report, including each preliminary and corrected report, for at least two years. Pathology reports from reference laboratories shall be retained for 10 years, and immunohematology reports shall be retained for five years.
 13. The laboratory's report shall indicate the test(s) performed by a reference laboratory and the name and address of each laboratory location at which a test was performed.
- E. General Quality Control.
 1. The laboratory shall be constructed, arranged and maintained to ensure the space, ventilation and utilities necessary for conducting all phases of testing.
 2. The laboratory shall have appropriate and sufficient equipment, instruments, reagents, materials and supplies for the type and volume of testing performed and for the maintenance of quality during all phases of testing.
 3. The manufacturer's instructions shall be followed when using an instrument, kit or test system.
 4. Components of reagent kits of different lot numbers shall not be interchanged unless otherwise specified by the manufacturer.
 5. The laboratory shall define criteria for those conditions that are essential for proper storage of reagents and specimens and for accurate and reliable test system operation and test result reporting. These conditions shall include if applicable water quality, temperature, humidity and protection of equipment and instrumentation from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. There shall be documentation of the remedial actions taken to correct problems with these conditions.
 6. Reagents, solutions, culture media, control materials, calibration materials and other supplies, as appropriate, shall be labeled to indicate the following:
 - a. Identity and, when significant, titer, strength or concentration;
 - b. Recommended storage requirements;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- c. Preparation and expiration dates;
 - d. Other pertinent information required for proper use.
7. Reagents, solutions, culture media, control materials, calibration materials and other supplies shall be prepared, stored and handled in a manner to ensure that they are not used when the expiration date has been exceeded or when they have deteriorated or are of substandard quality.
8. The laboratory shall comply with the Food and Drug Administration (FDA) product dating requirements of 21 CFR 610.53 for blood, blood products and other biologicals and with labeling requirements in 21 CFR 809.10 for all other in vitro diagnostics. Any exception to the product dating requirements in 21 CFR 610.53 shall be granted by the FDA in the form of an amendment of the product license, in accordance with 21 CFR 610.53(d). All exceptions shall be documented by the laboratory.
9. Test methodologies and equipment shall be selected and testing performed in a manner that provides test results within the laboratory's stated performance specifications for each test.
10. Before the laboratory reports patient test values using a new method or device, it shall first verify or establish for each method the performance specifications for the following performance characteristics, as applicable:
- a. Accuracy;
 - b. Precision;
 - c. Analytical sensitivity and specificity, to include interfering substances;
 - d. Reportable range of patient test results;
 - e. Reference range (normal values);
 - f. Any other performance characteristics required for test performance;

The laboratory shall have documentation of the verification or establishment of all applicable test performance specifications and shall establish control and calibration procedures based upon those specifications.

11. The laboratory shall perform maintenance and function checks for all equipment, instruments and test systems according to the manufacturers' instructions. If the manufacturer does not define maintenance or function checks, the laboratory shall establish protocols ensuring equipment,

RULES FOR CRITICAL ACCESS HOSPITALS 2021

instruments or test systems perform accurately and reliably. Maintenance and function checks shall be performed with at least the frequency of the manufacturer's instructions.

12. All function checks and maintenance activities shall be documented. The function checks shall be within the laboratory's or manufacturer's established limits before patient testing is conducted.
13. For each method or device the laboratory shall perform calibration procedures:
 - a. At a minimum, in accordance with manufacturer's instructions, if provided, using calibration materials provided as specified, as appropriate, and with at least the frequency recommended by the manufacturer; and
 - b. In accordance with established laboratory criteria to include:
 - 1) The number, type and concentration of calibration materials, acceptable limits for calibration and the frequency of calibration; and
 - 2) Using calibration materials appropriate for the methodology and, if possible, traceable to a reference method or reference material of known value; and
 - c. Whenever calibration verification fails to meet the laboratory's established acceptable limits for calibration verification.
14. For each method or device the laboratory shall perform calibration verification procedures:
 - a. At a minimum, in accordance with the manufacturer's instructions, if provided; and
 - b. In accordance with established laboratory criteria to include:
 - 1) The number, type and concentration of calibration materials, acceptable limits for calibration verification, and frequency of calibration verification;
 - 2) Calibration materials appropriate for the methodology and, if possible, traceable to a reference method or reference material of known value;
 - 3) Verification of the laboratory's established reportable range of patient test results, which shall include at least a minimal (or zero) value, a mid-point value, and a maximum value at the

RULES FOR CRITICAL ACCESS HOSPITALS 2021

upper limit of that range;

- 4) Performance of calibration verification at least every six months or when the following occur:
 - a) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results and control values are not adversely affected by reagent lot number changes;
 - b) There is a major preventive maintenance or replacement of critical parts that may influence test performance;
 - c) Controls reflect an unusual trend or shift or are outside the laboratory's acceptable limits and other means of assessing and correcting unacceptable control values have failed to identify and correct the problem;
 - d) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification than specified by the manufacturer.
15. All calibration and calibration verification activities shall be documented.
16. Control Procedures - (Controls shall be performed as defined or as otherwise defined under a specific category heading.)
 - a. For each device the laboratory shall evaluate instrument and reagent stability and operator variance in determining the number, type and frequency of testing calibration or control materials and establish criteria for acceptability used to monitor test performance during a run of patient specimen(s). A run is an interval within which the accuracy and precision of a testing system is expected to be stable, but it cannot be greater than 24 hours or less than the frequency recommended by the manufacturer. For each procedure, the laboratory shall monitor test performance using calibration materials or control materials or a combination thereof. Controls shall be performed as follows:
 - 1) For qualitative tests, the laboratory shall include a positive and a negative control with each run of patient specimens. Internal procedural controls (both positive and negative) may be used to satisfy this requirement.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- 2) For quantitative tests, the laboratory shall include at least two samples of different concentrations of either calibration materials, control materials, or a combination thereof with the frequency not less than two levels per 24 hours of operation.
 - 3) If calibration and control materials are not available, the laboratory shall have an alternative mechanism to assure the validity of patient test results.
 - 4) Control samples shall be tested in the same manner as patient test specimens.
 - 5) When calibration or control materials are used, statistical parameters (e.g., mean and standard deviation) for each lot number of calibration or control material shall be determined through repetitive testing. Levy-Jennings plots or other visual representation methods shall be used to evaluate statistical data for trends and shifts. Weekly supervisory review is required. Control values shall be evaluated as follows:
 - a) The stated values of assayed control material may be used as the target values provided the stated values correspond to the methodology and instrumentation employed by the laboratory and are verified by the laboratory;
 - b) Statistical parameters for unassayed materials shall be established over time by the laboratory through concurrent testing with calibration materials or control materials having previously determined statistical parameters; and
 - c) Control results shall meet the laboratory's criteria for acceptability prior to reporting patient test results.
17. The laboratory shall document all control activities. Documentation shall be retained for a period of two years. Immunohematology quality control records shall be retained for a period of five years. Cytology and histopathology quality control records shall be retained for a period of 10 years.

| F. Chemistry.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

1. The following requirements apply only to blood gas analysis, regardless of the testing site:
 - a. Follow the manufacturer's instructions regarding calibration of the blood gas analyzer;
 - b. Test at least one (1) level of control material each eight hours of patient testing;
 - c. Rotate the order in which the controls are performed so that normal, alkalosis and acidosis levels are tested; and
 - d. Test one (1) sample of calibration material or control material each time patients are tested if the instrument does not internally verify calibration at least every 30minutes.
2. For electrophoretic determinations:
 - a. At least one control sample shall be used in each electrophoretic cell;
 - b. The control sample shall contain fractions representative of those routinely reported in the patient specimens.

G. Hematology.

1. There shall be at least two levels of controls for non-manual hematology testing systems each eight hours in which patient testing is performed.
2. There shall be at least one level of control for manual cell counts each eight hours in which patient testing is performed.
3. Manual cell counts shall be performed in duplicate with documentation of both counts. The laboratory shall establish criteria for the acceptable difference between duplicate counts.
4. There shall be two levels of controls for non-manual coagulation testing systems each eight hours in which patient testing is performed and each time a change in reagents occurs.
5. Each individual shall test two levels of controls before performing manual coagulation testing on patient samples and each time a change in reagents occurs.
6. Manual coagulation tests on both patient and control specimens shall be

RULES FOR CRITICAL ACCESS HOSPITALS 2021

performed in duplicate with documentation of both times. The laboratory shall establish criteria for the acceptable difference between duplicate times.

7. Background counts of diluents shall be performed daily and results recorded.
8. If the microhematocrit centrifuge is used, the maximum packing time shall be determined at least every six months.
9. The laboratory director shall establish written criteria for abnormal cell morphology requiring review by a qualified physician who is board-certified or board-eligible in either pathology or hematology.
10. The laboratory shall maintain a file of unusual hematology slides to be used in the orientation, training and continuing education of laboratory personnel.

H. Immunology.

1. The equipment, glassware, reagents, controls and techniques for tests for syphilis shall conform to manufacturers' specifications.
2. The laboratory shall run serologic tests on patient specimens concurrently with a positive serum control of known titer or controls of graded reactivity plus a negative control. (If patient results are reported in terms of graded reactivity, controls of graded reactivity shall be used; if patient results are reported as a titer, controls of known titer shall be used with results reported as a titer.)
3. The laboratory shall employ controls that evaluate all phases of the test system to ensure reactivity and uniform dosages when positive and negative controls alone are not sufficient.
4. A facility manufacturing blood and blood products for transfusion or serving as a referral laboratory for such a facility shall meet the following:
 - a. Syphilis serology testing requirements of 21 CFR 606.65(c&e) and 640.5(a);
 - b. HIV testing requirements of 21 CFR 610.45; and
 - c. Hepatitis testing requirements of 21 CFR 610.40.

I. Immunoematology.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

1. There shall be provision for prompt ABO blood grouping, D(Rho) typing, unexpected antibody detection, compatibility testing and laboratory investigation of transfusion reactions, either through the facility or under arrangement with an approved facility that is certified in Immunoematology and Transfusion Services and Blood Banking under the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88).
2. If the facility does not provide immunoematological or blood banking services onsite, there shall be a written agreement with an outside laboratory or blood bank that governs the procurement, transfer and availability of blood and blood products. The agreement shall be reviewed and approved by the laboratory director.
3. The laboratory shall perform and document ABO group and D(Rho) typing on all donor red cells received from outside sources prior to transfusing.
4. The laboratory shall perform ABO group and D(Rho) typing, unexpected antibody detection, antibody identification and compatibility testing in accordance with manufacturers' instructions, if provided, and as applicable, with 21 CFR Part 606 (with the exception of 21 CFR 606.20.a, Personnel) and 21 CFR 640 et seq.
5. The laboratory shall perform ABO group by concurrently testing unknown red cells with anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum shall be tested with known A1 and B red cells. All reactions shall be documented.
6. The laboratory shall determine the D(Rho) type by testing and documenting the reaction of unknown red cells with anti-D(Rho) blood grouping reagent.
7. If required in the manufacturer's package insert for anti-D(Rho) reagents, the laboratory shall employ a control system (Rh-hr control) capable of detecting false positive D(Rho) test results.
8. Each day of use the laboratory shall perform and document the following quality control checks for each vial of antisera and reagent red cells:
 - a. Positive control only for ABO antisera, ABO reagent red cells and antibody screening cells (at least one known antibody); and
 - b. Positive and negative controls for D(Rho) antisera, other antisera and anti-human globulin (Coombs serum).
9. Records shall identify the source and lot number of each reagent on each

RULES FOR CRITICAL ACCESS HOSPITALS 2021

day of use.

10. Policies and procedures to ensure positive identification of a blood or blood product recipient shall be established and followed.
11. Donor blood and blood products shall be stored or maintained for transfusion under conditions required to prevent deterioration and to ensure optimum integrity, whether in the blood bank or in a remote storage refrigerator.
12. Donor blood shall be stored in a refrigerator which meets the following criteria:
 - a. The refrigerator shall be connected to an emergency power source;
 - b. An audible alarm system shall monitor proper storage temperature and shall sound at a location that is staffed 24 hours per day;
 - c. The refrigerator shall not be used for the storage of hazardous or contaminated items;
 - d. The refrigerator shall have adequate space to provide for segregated storage of the following:
 - 1) Donor blood prior to completion of tests;
 - 2) Donor blood not suitable for use; and
 - 3) Autologous units;
 - e. A temperature recorder shall be connected to the refrigerator.
13. The high and low activation temperatures of the alarm system shall be checked and documented at least quarterly. The response to the activated alarm shall be documented.
14. The temperature recorder shall be compared daily to a thermometer in the refrigerator. Results of the temperature checks shall be documented.
15. The temperature recorder chart shall be changed weekly, and the individual who changes the chart shall initial and date it.
16. Written criteria shall be established for daily inspection of the blood storage unit for:
 - a. Outdated blood;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- b. Hemolysis;
 - c. Bacterial contamination; and
 - d. Unit integrity.
 - e. Blood shall be visually inspected at the time of issue. Results of all inspections shall be recorded.
17. Records shall be maintained of all blood or blood components received, cross matched, transfused, expired or returned to the supplier.
18. Patient's serum less than 72 hours old shall be used in the compatibility procedure.
19. All blood for transfusions, except for autologous transfusions, shall be tested for hepatitis and for HIV antibodies before it is transfused. The tests for hepatitis and/or HIV antibodies may be performed by the supplier or by the institution in which the blood is transfused.
20. Samples of both patient and donor blood shall be retained at least seven days following transfusion.
21. Procedures shall be established for the prompt investigation of all suspected transfusion reactions. The laboratory director shall review all suspected transfusion reactions, and a report shall be given to a committee of the Medical Staff.
22. Criteria shall be established for the reissuing of donor blood to ensure that the blood has been maintained under conditions required to ensure the safety of individuals being transfused within the facility.
23. Records of therapeutic phlebotomies shall be maintained, detailing the patient name, date, time, amount drawn, phlebotomist and disposition of the blood. Blood drawn as a therapeutic phlebotomy shall not be used for transfusion.
24. A committee of the Medical Staff shall fulfill the following responsibilities:
- a. Establish criteria for the proper use of blood and its components;
 - b. Monitor the transfusion of blood and its components to ensure the established criteria for proper use are met;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- c. Review the reports of suspected transfusion reactions;
 - d. Establish criteria for therapeutic phlebotomies.
25. Blood banking policies and procedures shall conform to the current Standards for Blood Banks and Transfusion Services of the American Association of Blood Banks.
- J. Urinalysis.
- 1. Routine urinalysis shall be performed within two hours of collection of the specimen unless the specimen is refrigerated.
 - 2. Manufacturers' instructions shall be followed for all tests.
 - 3. Two levels of controls shall be performed and documented each day of patient testing utilizing an automated strip reader.
 - 4. A refractometer for measuring urine specific gravity shall be checked each day of use with a low (1.000) and upper level standard or control.
- K. Microbiology.
- 1. Each day of use, the laboratory shall evaluate the detection phase of direct antigen systems using an appropriate positive and negative control organism or antigen extract. When direct antigen systems include an extraction phase, the system shall be checked, each day of use, using a positive organism.
 - 2. The laboratory shall check each batch or shipment of reagents, discs, stains, antisera and identification systems (systems using two or more substrates) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable.
 - 3. Unless otherwise specified, each day of use the laboratory shall test staining materials for intended reactivity to ensure predictable staining characteristics.
 - 4. The laboratory shall check fluorescent stains for positive and negative reactivity each time of use (unless otherwise specified).
 - 5. The laboratory shall check each batch or shipment of media for sterility, if it is intended to be sterile and sterility is required for testing. Media shall be checked for its ability to support growth and, as appropriate, selectivity/inhibition and/or biochemical response.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

6. The laboratory may use the manufacturer's control checks of media provided the manufacturers' product insert specifies that the manufacturer's quality control checks meet the National Committee for Clinical Laboratory Standards (NCCLS) for media quality control. The laboratory shall document that the physical characteristics of the media are not compromised and report any deterioration of the media to the manufacturer.
7. The laboratory shall follow the manufacturer's specifications for using the media and be responsible for the test results.
8. The following media shall be retested using NCCLS standards for growth, inhibition and selectivity, as applicable:
 - a. Campylobacter agar;
 - b. Media for the selective isolation of pathogenic Neisseria;
 - c. Media used to isolate parasites, viruses, Mycoplasma, Chlamydia;
 - d. Mueller-Hinton media used for antimicrobial susceptibility tests; and
 - e. Media commercially prepared and packaged as a unit or system consisting of two or more different substrates, primarily used for microbial identification.
9. The laboratory shall check positive and negative reactivity with control organisms as follows:
 - a. Each day of use for catalase, coagulase, beta-lactamase, and oxidase reagents and DNA probes;
 - b. Each week of use for Gram and acid-fast stains and for bacitracin, optochin, ONPG, X and V discs or strips;
 - c. Each month of use for antisera;
 - d. Each week of use the laboratory shall check XV discs or strips with a positive control;
 - e. For antimicrobial susceptibility tests, the laboratory shall check each new batch of media and each lot of antimicrobial discs or wells before or concurrent with initial use using approved reference organisms:

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- 1) The laboratory's zone sizes or minimum inhibitory concentrations (MIC) for reference organisms shall be within established limits before reporting patient test results;
 - 2) Each day tests are performed the laboratory shall use the appropriate control organisms to check the procedure unless adequate precision can be demonstrated. Once adequate precision is demonstrated, the controls may be performed each week of use. Documentation of precision studies is required.
10. Antibiotic sensitivities shall be performed using a recognized method. If the Kirby-Bauer method is utilized:
 - a. Proper sized petri dishes shall be used;
 - b. Disc zone sizes shall be measured and recorded, or a template shall be used; and
 - c. A standardized inoculum shall be used.
11. Records shall reflect all tests used to isolate and identify organisms.
12. For laboratories performing mycobacteriological testing, the laboratory shall:
 - a. Each day of use check the iron uptake test with at least one positive and one negative acid-fast control organism. Check all other reagents or test procedures used for identification with at least a positive acid-fast control organism.
 - b. Each week of use check the fluorochrome acid-fast stain's reactivity with a positive and a negative control organism;
 - c. Each week of use check the acid-fast stain's reactivity with a positive control organism; and
 - d. Each week of use, check the procedure for susceptibility tests performed on *Mycobacterium tuberculosis* isolated with a strain of *Mycobacterium tuberculosis* susceptible to all antimycobacterial agents tested.
13. For laboratories conducting mycological testing, the laboratory shall:

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- a. Each day of use, if using the auxanographic medium for nitrate assimilation, check the nitrate reagents with a peptone control;
 - b. Each week of use check the acid-fast stain's reactivity with a positive and a negative control organism; and
 - c. Each day of use test each drug for susceptibility tests with at least one control strain that is susceptible to the drug and ensure that patient test results are reported only when control results are within the laboratory's established control limits.
14. For laboratories performing parasitology tests, the laboratory shall:
- a. Have available a reference collection of slides or photographs and, if available, gross specimens for identification of parasites and use these references in the laboratory for appropriate comparison with diagnostic specimens;
 - b. Calibrate and use the calibrated ocular micrometer for determining the size of ova and parasites, if size is a critical parameter. Calibration of the micrometer shall be checked annually or after microscope repair or major maintenance. Documentation of the calibration is required; and
 - c. Check permanent stains each month of use using a fecal sample control that will demonstrate staining characteristics.
15. For laboratories performing virology tests, the laboratory shall:
- a. Have available host systems for the isolation of viruses and identification methods that cover the entire range of viruses that are etiologically related to clinical diseases for which services are offered;
 - b. Maintain records that reflect the systems used and the reactions observed; and
 - c. Simultaneously culture, for identification tests, uninoculated cells or cell substrate controls as a negative control to detect erroneous identification results.
16. A microbiological safety cabinet shall be used when mycobacteriology or mycology cultures are manipulated. The cabinet shall meet the following special requirements:
- a. Have a face velocity of at least 75 feet per minute;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- b. Be connected to an independent exhaust system;
 - c. Have filters with 99.97 percent efficiency (based on the dioctylphthalate (DOP) test method) in the exhaust system;
 - d. Be designed and equipped to permit the safe removal, disposal and replacement of contaminated filters; and
 - e. Be provided with a means of disinfection.
17. Mycology, mycobacteriology or virology cultures shall be disinfected prior to leaving the control of the laboratory.
- L. Pathology (Histopathology and Cytology).
- 1. The ventilation system shall be adequate to properly remove vapors, fumes and excessive heat.
 - 2. Staining dishes shall be properly labeled and covered when not in use.
 - 3. Flow charts that reflect the staining procedure used shall be available.
 - 4. A control slide of known reactivity shall be included with each slide or group of slides for differential or special stains. Reaction of the control slide with each special stain shall be documented.
 - 5. For cytology stains:
 - a. All gynecologic smears shall be stained using a Papanicolaou (PAP) or modified PAP staining method;
 - b. Effective measures shall be taken to prevent cross-contamination between gynecologic and non-gynecologic specimens during the staining process;
 - c. Non-gynecologic specimens that have a high potential for cross-contamination shall be stained separately from other non-gynecologic specimens, and the stains shall be filtered or changed following staining.
 - 6. All cytology slide preparations shall be retained for five years.
 - 7. For histopathology:
 - a. All stained slides shall be retained at least 10 years;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- b. All specimen blocks shall be retained at least two years; and
 - c. All remnants of tissue specimens shall be retained in a manner that assures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis has been made.
8. An exact duplicate of each test report shall be retained for at least 10 years.
9. The following reports shall be signed to reflect the review of a board-certified pathologist, or, as applicable, another individual meeting the qualifications specified in the CLIA requirements:
- a. All tissue pathology reports;
 - b. All non-gynecologic cytology reports;
 - c. All gynecologic cytology reports on smears containing cells exhibiting reactive or reparative changes, atypical squamous/glandular cells, premalignant or malignant condition.

NOTE: If an electronic signature is used, the laboratory shall ensure that only the authorized person can release the signature. Refer to Section 14, Health Information Services.

10. The laboratory shall compare clinical information, when available, with cytology reports and shall compare each malignant and premalignant gynecology report with the histopathology report, if available, and determine the causes of any discrepancies.
11. All tissues surgically removed shall be examined by an anatomic pathologist. The Medical Staff shall develop a list of tissues that need not be examined.
12. A frozen section diagnosis, as reported to the surgeon, shall be documented and signed by the pathologist at the time the frozen section is performed. The documentation may be on the requisition, a patient test log, or a report form.
13. Autopsy services shall be under the supervision of a board-certified pathologist.
14. Autopsy findings in a complete protocol shall be filed in the patient's medical record within 60 days of the autopsy. A provisional anatomical diagnosis shall be recorded within 72 hours after autopsy. A duplicate

RULES FOR CRITICAL ACCESS HOSPITALS 2021

copy of the autopsy report shall be maintained in the laboratory autopsy file.

M. Radiobioassay.

1. Background checks shall be performed each day at the proper window setting for each type of isotope being used, as applicable.
2. Criteria for unacceptable changes in background levels shall be established.
3. Safety precautions shall be written and appropriately displayed. Film badges and/or rings shall be worn, as applicable.
4. There shall be written procedures to assure reliability of testing and safety of patients and personnel.
5. All procedures for safety and disposal of radioactive waste shall conform to the most current Rules and Regulations for Control of Sources of Ionizing Radiation adopted and promulgated by the Arkansas State Board of Health.

N. Quality Assurance/Performance Improvement.

1. Each laboratory shall establish a Quality Assurance/Performance Improvement plan. The plan shall follow written policies and procedures for a comprehensive program which monitors and evaluates the ongoing and overall quality of the total testing process. The plan shall evaluate the effectiveness of the laboratory's policies and procedures, identify and correct problems, assure the accurate, reliable and prompt reporting of test results, and assure the adequacy and competency of the staff. As necessary, the laboratory shall revise policies and procedures based upon the results of those evaluations.
2. All Quality Assurance/Performance Improvement activities shall be documented.
3. The laboratory shall have an ongoing mechanism for monitoring and evaluating the following:
 - a. The criteria established for patient preparation, specimen collection, labeling, preservation and transportation;
 - b. The information solicited and obtained on the laboratory requisition for its completeness, relevance and necessity for testing patient specimens;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- c. The use and appropriateness of criteria established for specimen rejection;
 - d. The completeness, usefulness and accuracy of the test report information necessary for the interpretation or utilization of test results;
 - e. The timely reporting of test results based on testing priorities (STAT, routine, manufacturer's instructions, etc.);
 - f. The accuracy and reliability of test reporting and record storage and retrieval;
 - g. The effectiveness of corrective actions taken for:
 - 1) Problems identified during the evaluation of calibration and control data for each test method;
 - 2) Problems identified during the evaluation of patient test values for the purpose of verifying the reference range of a test method;
 - 3) Errors detected in previously reported test results.
 - h. The effectiveness of corrective actions taken for any unacceptable, unsatisfactory or unsuccessful proficiency testing results.
4. Laboratories that perform the same testing using different methodologies or instruments, or perform the same test at multiple testing sites, shall have a system that twice a year evaluates and defines the relationship between test results using different methodologies, instruments or test sites.
5. Laboratories that perform tests that are not challenged with a proficiency testing program shall have a system for verifying the accuracy and reliability of its test results at least twice per year.
6. The laboratory shall have a mechanism to identify and evaluate patient test results that appear inconsistent with relevant criteria such as patient age, sex, diagnosis or pertinent clinical data, when provided; distribution of patient test results, when available; and relationship with other test parameters, when available.
7. The laboratory shall have an ongoing mechanism to evaluate the effectiveness of its policies and procedures for assuring employee competence.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

8. The laboratory shall have a system in place to document problems that occur as a result of breakdowns in communication between the laboratory and the authorized individual who orders or receives the results of test procedures or examinations. Corrective actions shall be taken, as necessary, to resolve the problems and minimize communication breakdowns.
 9. The laboratory shall have a system in place to assure that all complaints and problems reported to the laboratory are documented. Investigations of complaints shall be made, when appropriate, and, as necessary, corrective actions shall be instituted.
 10. The laboratory shall have a mechanism for documenting and assessing problems identified during quality assurance/performance improvement reviews and discussing them with the staff. The laboratory shall take corrective actions that prevent reoccurrences.
 11. The laboratory shall maintain documentation of all quality assurance/performance improvement activities, including problems identified and corrective actions taken. All quality assurance/performance improvement records shall be available and maintained for a period of two years.
- O. Safety.
1. The physical plant and environmental conditions of the laboratory shall provide a safe environment in which employees, as well as all other individuals, are protected from physical, chemical and biological hazards.
 2. Safety precautions shall be established, posted and observed to ensure protection from physical, chemical, biochemical and electrical hazards as well as biohazardous materials.
- P. Point of Care Testing.
1. The requirements under this section apply only to the following tests which employ simple and accurate methodologies, as defined by the Centers for Disease Control and Prevention (CDC):
 - a. Dipstick or tablet reagent urinalysis;
 - b. Fecal occult blood;
 - c. Urine pregnancy tests (visual color comparison);

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- d. Hemoglobin by single analyte instrument with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout;
 - e. Whole blood glucose by devices approved for home use;
 - f. Spun microhematocrit;
 - g. Whole blood immunoassay for *Helicobacter pylori*;
 - h. Rapid test for Group A streptococcal antigen from throat swabs; and
 - i. Glycosylated hemoglobin (Hgb Alc).
2. All testing personnel shall have earned a high school diploma or equivalent.
 3. There shall be documentation that prior to testing patients' specimens each individual has received training for each test to be performed and has demonstrated the ability to perform all testing operations reliably.
 4. Manufacturer's instructions for each of the tests shall be available in each area in which the specific test is performed and shall be followed by all testing personnel.
 5. Components of reagent kits of different lot numbers shall not be interchanged unless otherwise specified by the manufacturer.
 6. Reagents, control and calibration materials and other supplies shall be stored and handled in a manner to ensure that they are not used when the expiration date has been exceeded or when they have deteriorated or are of substandard quality.
 7. Quality control procedures shall be performed in accordance with the manufacturer's instructions, at a minimum. Additional quality control procedures shall be performed as determined by the director of the hospital laboratory.
 8. Maximum packing time of the microhematocrit centrifuge shall be determined at least every six months.
 9. The test record system shall include at least the following:
 - a. Identification of the patient;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- b. Name of the authorized person who ordered the test;
 - c. Test performed;
 - d. Date and time of test performance;
 - e. Identity of the person who performed the test;
 - f. Test results; and
 - g. Any additional information relevant and necessary for the interpretation of the results of a specific test.
10. The configuration of the test system shall be determined by the facility.
11. All required records shall be readily retrievable for at least two (2) years.
12. Point of Care Testing shall be included in the hospital laboratory's Quality Assurance/Performance Improvement program.
13. Any tests other than those specified in P(1) above shall be subject to all of the requirements of Section 19.

SECTION 20: RADIOLOGICAL SERVICES.

- A. Radiology.
1. Each hospital shall have shock-proof diagnostic X-ray facilities.
 2. Radiological Services shall be under the direction of a physician, who is a member of the Medical Staff.
 - a. The physician director shall be certified (or eligible for examination) by the American Board of Radiology.
 - b. At a minimum, a board certified radiologist shall be available on a consultative basis. Documentation of the radiologist's visits shall be required.
 3. Radiological Services shall be supervised by a technologist who is qualified by experience or education and has at least two years technical experience.
 4. A radiologic technologist with at least two years training shall be on duty 24 hours or on call at all times.
 5. Radiologic staff who use the radiologic equipment and administer procedures shall have written verification of training and shall have approval in writing by the physician director.
 6. Radiologic technologists shall not independently perform fluoroscopic procedures.
 7. Radiologic staff who administer agents for diagnostic purposes shall have written verification of training. A current list of radiology employees who administer agents for diagnostic purposes shall be approved by the physician director and maintained by the facility.
 8. Radiology personnel who participate in direct patient care shall maintain competency in life support measures or the equivalent.
 9. Clinically relevant educational programs shall be conducted at regularly scheduled intervals with not less than 12 per year. There shall be evidence of program dates, attendance, and subject matter.
 10. Policies and procedures for the department shall have evidence of ongoing review and/or revision. The first page of each manual shall have the annual review date, signature of the department and/or person(s) conducting the review. Policies and procedures shall include:

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- a. Job descriptions for every type employee;
 - b. A written list of all tests/procedures performed by the Radiology Department and the list shall be available to the Medical Staff;
 - c. Infection prevention and control measures;
 - d. The holding of patients;
 - e. Orientation practices for new employees;
 - f. Operation of equipment;
 - g. Management of an adverse reaction;
 - h. Cleaning and disinfecting procedures; and
 - i. Posting of signs.
11. Radiology personnel shall receive yearly instruction in:
- a. Safety precautions; and
 - b. Managing emergency radiation hazards and accidents.
12. A documented preventive maintenance and quality control program shall include:
- a. Radiology personnel shall follow the dosimetry requirements identified in the *Rules for Control of Sources of Ionizing Radiation*.
 - b. Preventive maintenance for all diagnostic and therapeutic radiologic equipment to assure a safe working condition. Safety and calibration checks shall be made according to manufacturer's directions, not exceeding one year intervals;
 - c. Annual inspection of all leaded gloves, aprons and similar protective devices at least once a year with documentation to include: the name of the examiner, identification of the protective device examined and the results plus corrective action taken;
 - d. Documentation of safety, calibration, and inspection checks maintained for the life of the equipment; and
 - e. Remedial and corrective action recorded in response to equipment "down

RULES FOR CRITICAL ACCESS HOSPITALS 2021

time," with documentation to include: the piece of equipment involved, time/date malfunction occurred, action taken, time/date when the equipment became operational.

13. X-ray films shall not be stored in radiologic examination rooms.
 14. X-ray films shall be filed according to a recognized filing system.
 15. X-ray prescription/work requests shall be authorized by a written and signed physician's order and shall include the following:
 - a. Identification of the patient;
 - b. Date the test was ordered;
 - c. Physician's name;
 - d. Concise statement as to the reason why the X-ray/test was ordered; and
 - e. Originator's signature.
 16. The radiologic report shall be signed by a physician and shall be placed in the medical record.
 17. The Radiological Services shall have an ongoing QA/PI program that addresses patient care issues. A mechanism for reporting results of audits shall be provided, to include: indicators monitored, thresholds/standards, results, corrective plan/corrective action taken and follow-up.
 18. This section establishes requirements for radiology that are in addition to, not in substitution of the Rules for Control of Sources of Ionizing Radiation.
 19. Actual X-ray film shall be retained for five years.
 20. X-ray films and reports shall be stored in a room that is equipped with a smoke detection system. An extinguishing system shall be made available.
 21. Locked security shall be ensured for the written reports maintained in the X-ray file when the storage area is not under the direct supervision of radiology personnel.
 22. Dual image viewing shall be available in the OR, ER & Radiology areas.
 23. Facilities shall maintain the capacity to view x-ray films.
- B. Nuclear Medicine Services.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

1. Nuclear Medicine procedures shall be under the direction of a physician, qualified in Nuclear Medicine, who is a member of the Medical Staff.
2. Nuclear Medicine services shall be supervised by a nuclear medicine technologist who has completed certification requirements and has at least two years technical experience.
3. Nuclear Medicine staff who use the equipment and administer procedures shall have written verification of training and shall have approval in writing by the physician director and Medical Staff.
4. All radioactive materials shall be purchased, stored, administered and disposed of in a manner consistent with the requirements of the Rules for Control of Sources of Ionizing Radiation or with the specific condition of a Radioactive Material License issued pursuant to these rules.
5. The policy and procedure manual shall be reviewed annually and revised as necessary. Included in the manual shall be a cover page with signatures of those reviewing the manual and a month/day/year of review. The policies and procedures shall include:
 - a. Job description for each employee;
 - b. A list of tests/procedures performed by Nuclear Medicine;
 - c. Safety practices;
 - d. Management of an adverse reaction;
 - e. Orientation for new employees;
 - f. Operation of equipment;
 - g. Cleaning and disinfecting procedures;
 - h. Posting of signs;
 - i. Quality control;
 - j. Quality Assurance/Performance Improvement;
 - k. Clean up of spills;
 - l. Receipt/disposal of radioactive materials; and

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- m. Radiation safety plan.
6. All nuclear medicine personnel who participate in direct patient care shall maintain competency in life support measures.
 7. There shall be a documented preventive maintenance and quality control program:
 - a. Monitoring of nuclear medicine personnel for exposure to radiation shall be integrated over a period not to exceed one month;
 - b. Nuclear medicine personnel shall follow the dosimetry requirements identified in the *Rules and Regulations for Control of Sources of Ionizing Radiation*;
 - c. All nuclear medicine equipment shall be maintained in safe working condition. Preventive maintenance, safety and calibration checks shall be made according to manufacturer's directions, not to exceed one-year interval;
 - d. Documentation of all safety, calibration and inspection checks shall be maintained for the life of the equipment; and
 - e. Remedial and corrective action shall be recorded in response to equipment "down time." Documentation shall include: the piece of equipment involved, time/date malfunction occurred, action taken, and time/date when equipment became operational again.
 8. The nuclear medicine "hot lab" shall be kept locked when not under the direct supervision of authorized personnel.
 9. There shall be an emergency eye wash available in the nuclear medicine "hot lab".
 10. All nuclear medicine staff who administer agents for diagnostic purposes shall have written verification of training and approval by the physician director and individual(s) supervising the training.
 11. Clinically relevant educational programs shall be conducted on regularly scheduled intervals at not less than 12 per year. There shall be evidence of program dates, attendance, and subject matter.
 12. All nuclear medicine requests shall be authorized by a written and signed physician's order and shall include the following:
 - a. Identification of the patient;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- b. Date;
 - c. Physician's name;
 - d. Originator's signature; and
 - e. Reason/justification for the test.
13. The nuclear medicine report shall be signed by a physician. The original shall be placed in the medical record.
 14. Films shall not be stored in radiologic or nuclear medicine examination rooms.
 15. The storage of nuclear medicine films shall comply with the guidelines under Section 20, Radiological Services.
- C. Guidelines for Mobile Services. The Governing Body and Medical Staff shall approve the provisions for establishing services in accordance with the following criteria:
1. General Considerations.
 - a. The installation is governed by the following Arkansas Department of Health publications:
 - 1) Rules for Hospitals and Related Institutions in Arkansas, Section 20, Radiological Services; and
 - 2) Rules for Control of Source of Ionizing Radiation.
 - b. Approvals shall be granted by the Arkansas Department of Health:
 - 1) Health Facility Services; and
 - 2) Radiation Control and Emergency Management.
 - c. The mobile service provider shall maintain fire, theft, general and professional liability insurance.
 2. Operating Policies.
 - a. All examinations shall be authorized by a written and signed physician's order;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- b. Examinations shall be performed under the direction of and interpreted by a qualified physician, with documented training or experience, who is a member of the hospital's Medical Staff;
 - c. Examinations shall be performed by a licensed radiologic technologist;
 - d. The Radiology Department shall maintain current policies and procedures for use of the mobile units to include infection prevention and control and safety;
 - e. All personnel who administer agents for diagnostic purposes shall have written verification of training and approval by the physician director and individual(s) supervising the training;
 - f. Hospital personnel shall transport patients to and from the mobile unit according to hospital safety policies;
 - g. Oxygen and emergency medical supplies shall be maintained and readily available;
 - h. The hospital Pharmacy may provide necessary medical supplies including contrast media, but proper handling and control of dated items shall be ensured;
 - i. A log of all patients shall be maintained;
 - j. Films shall be maintained in the same manner as X-ray films;
 - k. Personnel who participate in direct patient care shall be competent in life support measures; and
 - l. Contracted services shall be under current agreement and the contractor shall fulfill all requirements of this section.
3. Refer to Section 52, Physical Facilities, Imaging Suite

SECTION 21: PHYSICAL THERAPY.

Licensed physical therapist means any person licensed to practice physical therapy by the Arkansas State Board of Physical Therapy.

The practice of licensed physical therapy assistants shall be performed under the supervision of the licensed physical therapist. The supervising therapist shall be readily available for consultations, evaluations and establishment of each program prior to delegation of any treatments and determination of patient discharge.

If physical therapy services are rendered by an individual who does not meet at least the assistant-level qualifications (aide/technician), a qualified physical therapist shall be on the premises and immediately available to provide assistance and direction throughout the time the services are rendered.

- A. Physical therapy services shall be provided under the direction of a physician member of the Medical Staff.
- B. Physical therapy services shall be supervised by a physical therapist licensed by the Arkansas State Board of Physical Therapy. Physical therapy assistants and aides shall comply with all state licensure requirements.
- C. A policy and procedure manual for Physical Therapy shall be developed. The manual shall have evidence of ongoing review and/or revision. The first page of each manual shall have the annual review date, signature of the department supervisor and/or person(s) conducting the review.
- D. There shall be written policies and procedures which shall include:
 - 1. Job descriptions for each type of employee;
 - 2. Infection prevention and control measures;
 - 3. Standards of care;
 - 4. Criteria for assuring continuous communication of the patient's therapy and progress to the physician;
 - 5. Assembly and operation of equipment;
 - 6. Physical therapy services provided and a list of services made available to the Medical Staff;
 - 7. Documentation specifying who may perform special procedures and give patient instruction; this shall be verified by the physician director;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

8. Safety practices;
 9. Orientation practices for new employees; and
 10. Cleaning, disinfecting and sterilizing procedures.
- E. There shall be an adequate supply of reference material for the physical therapist which shall include current literature.
- F. All physical therapy prescriptions/work requests shall be authorized by a written and signed physician's order.
- G. Equipment shall be adequate for the services offered and maintained in good repair.
1. Equipment shall be serviced, calibrated and operated according to the manufacturer's directions.
 2. All physical therapy equipment shall be under the control of the physical therapy supervisor.
 3. A preventive maintenance program shall be implemented with periodic inspection of all equipment and appropriate records maintained for the life of each piece of equipment.
 4. All temperature-dependent patient use equipment shall have the temperature checked and recorded before each patient use or at least daily, if used, to ensure patient safety.
- H. Physical therapy records for each patient shall include:
1. Current written plan of care;
 2. Statement of treatment objectives;
 3. Statement of patient's short-term and long-term rehabilitation potential;
 4. Functional limitations;
 5. Justification of continued rehabilitative care; and
 6. Documentation of daily treatments.
- I. Clinically relevant educational programs shall be conducted on a regularly scheduled interval not less than 12 times per year. There shall be evidence of program dates, attendance and subject matter.
- J. All physical therapy personnel who participate in direct patient care shall be

RULES FOR CRITICAL ACCESS HOSPITALS 2021

competent in life support measures.

- K. There shall be an ongoing QA/PI program.
- L. Hospitals which have swimming pools shall comply with applicable sections of Rules Pertaining to Swimming Pools and Other Related Facilities.
- M. Contracted physical therapy services shall be under current agreement and the contractor shall fulfill all requirements of this Section.

SECTION 22: OCCUPATIONAL THERAPY.

In facilities with an organized Occupational Therapy Department, the following shall apply:

- A. Occupational Therapy Services shall be under the direction of a physician member of the Medical Staff.
- B. Occupational Therapy Services shall be supervised by a currently licensed therapist in the field of rehabilitation services.
- C. There shall be sufficient occupational therapy supportive technical staff to provide authorized Occupational Therapy Services.
- D. The policy and procedure manual shall have evidence of ongoing review and/or revision. The first page of each manual shall have the annual review date, signature of the department supervisor and/or person(s) conducting the review.
- E. There shall be written policies and procedures which shall include:
 - 1. Job descriptions for every type of employee;
 - 2. Documentation specifying who may perform special procedures and give patient instructions. This shall be verified by the physician director;
 - 3. Orientation practices for new employees;
 - 4. Occupational therapy services provided and a list of services provided to the Medical Staff; and
 - 5. Safety practices.
- F. Current reference material shall be available for the occupational therapist.
- G. All occupational therapy prescriptions/work requests shall be authorized by a written and signed physician's order.
- H. Equipment shall be adequate for the services offered and maintained in good repair.
 - 1. Equipment shall be serviced, calibrated and operated according to the manufacturer's directions.
 - 2. All occupational therapy equipment shall be under the control of the occupational therapy supervisor.
 - 3. A preventive maintenance program shall be implemented with periodic

RULES FOR CRITICAL ACCESS HOSPITALS 2021

inspection of all equipment and appropriate records maintained for the life of each piece of equipment.

4. All temperature-dependent patient use equipment shall have the temperature checked and recorded before each patient use.

When appropriate elements are planned and arranged for shared use by physical therapy patients and staff, one or both services shall be responsible for the preventive maintenance program and the retention of records.

- I. Occupational therapy records for each patient shall include:
 1. Current written plan of care;
 2. Statement of treatment objectives;
 3. Statement of patient's short-term and long-term rehabilitation potential;
 4. Justification of any continued rehabilitation care; and
 5. Documentation of the patient's condition and response to treatments.
- J. Clinically relevant educational programs shall be conducted on a regularly scheduled basis at not less than 12 per year. There shall be evidence of program dates, attendance, and subject matter.
- K. All occupational therapy personnel shall maintain competency in life support measures.
- L. There shall be an ongoing QA/PI program.
- M. Contracted occupational therapy services shall be under current agreement and the contractor shall fulfill all requirements of this Section.

SECTION 23: SPEECH PATHOLOGY/AUDIOLOGY SERVICES.

In facilities with an organized Speech Language Pathology/Audiology Services Department, the following shall apply:

- A. Speech Pathology/Audiology Services shall be under the direction of a physician member of the Medical Staff.
- B. Speech Pathology/Audiology Services shall be supervised by a therapist who is currently licensed.
- C. There shall be sufficient supportive personnel to provide authorized speech pathology/audiology services.
- D. There shall be documentation, verified by the physician director, of who may perform special procedures and give patient instructions.
- E. Policies and procedures shall have evidence of ongoing review and/or revision. The first page of each manual shall have the annual review date, signature of the department supervisor and/or person(s) conducting the review.
- F. There shall be written policies and procedures which shall include:
 - 1. Job descriptions for every type of employee;
 - 2. Orientation procedures for new employees;
 - 3. Infection prevention and control measures;
 - 4. A listing of services/treatments available to the Medical Staff; and
 - 5. Safety practices.
- G. Equipment shall be in good repair and under the control of the therapist supervisor. Documentation of preventive maintenance shall be maintained for the life of each piece of equipment.
- H. Current reference material shall be available for the department.
- I. Clinically relevant educational programs shall be conducted on a regularly scheduled basis at not less than 12 per year. There shall be evidence of program dates, attendance, and subject matter.
- J. All speech pathology/audiology prescriptions/work requests shall be authorized by a written and signed physician's order.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- K. Speech Pathology/Audiology Services records for each patient shall include:
 - 1. Current written plan of care;
 - 2. Statement of treatment objectives;
 - 3. Statement of patient's short-term and long-term rehabilitation potential;
 - 4. Justification of any continued rehabilitation care; and
 - 5. Documentation of progress notes following treatment given to patients.
- L. All Speech Pathology/Audiology personnel shall maintain competency in life support measures.
- M. There shall be an ongoing QA/PI program.
- N. Contracted Speech Pathology/Audiology Services shall be under current agreement and the contractor shall fulfill all requirements of this Section.

SECTION 24: RECREATIONAL THERAPY.

In facilities with organized Recreational Therapy Services, the following shall apply:

- A. Recreational Therapy Services shall be under the direction of a physician member of the Medical Staff.
- B. Recreational Therapy Services shall be supervised by a therapist with current certification.
- C. There shall be sufficient Recreational Therapy supportive staff to provide authorized Recreational Therapy Services.
- D. There shall be documentation, verified by the physician director, of who may perform special procedures and give patient instructions.
- E. The policy and procedure manual shall have evidence of ongoing review and/or revision. The first page of the manual shall have the annual review date, signature of the department supervisor and/or person(s) conducting the review.
- F. There shall be written policies and procedures which shall include:
 - 1. Job descriptions;
 - 2. Infection prevention and control measures;
 - 3. Recreational Therapy Services provided and a list of services shall be made available to the Medical Staff;
 - 4. Orientation practices for new employees and volunteer personnel;
 - 5. Assembly, operation and maintenance of all equipment;
 - 6. Safety practices;
 - 7. Security of supplies and tools; and
 - 8. Activities off-campus.
- G. All equipment, tools and machines shall be in good repair and under the control of the therapist supervisor. Documentation of preventive maintenance shall be maintained for the life of each piece of equipment.
- H. Current reference material shall be available for the department.
- I. Clinically relevant educational programs shall be conducted on a regularly scheduled

RULES FOR CRITICAL ACCESS HOSPITALS 2021

basis at not less than 12 per year. There shall be evidence of program dates, attendance, and subject matter.

- J. All recreational therapy prescriptions/work requests shall be authorized by a written and signed physician's order and shall include:
 - 1. Identification of the patient;
 - 2. Date;
 - 3. Physician's name;
 - 4. Type, frequency and duration of treatment; and
 - 5. Originating signature.
- K. Recreational Therapy Service records for each patient shall include:
 - 1. Current written plan of care;
 - 2. Documentation of attendance by the therapist in team meetings and the contribution by the therapist to the treatment plan;
 - 3. Statement of treatment objectives;
 - 4. Statement of patient's short-term and long-term rehabilitation potential;
 - 5. Record of daily activity participation;
 - 6. Justification of any continued rehabilitation care; and
 - 7. Progress notes.
- L. All Recreational Therapy personnel shall maintain competency in life support measures.
- M. There shall be an ongoing QA/PI program.
- N. If food and/or nutritional service functions are offered, infection prevention and control, storage and supervision shall be coordinated with the Dietary Department of the facility.
- O. Contracted Recreational Therapy Services shall be under current agreement and the contractor shall fulfill all requirements of this Section.

SECTION 25: PET THERAPY PROGRAM

Definitions.

“Program” means Pet Therapy Program.

“Pet” means an animal that has been specifically screened, trained, and authorized by the hospital to participate in the Program.

“Handler” means an individual who has been specifically credentialed and authorized by the hospital to participate in, and to accompany and control pets participating in, the Program.

- A. The Program shall be approved by the Governing Body, Medical Staff, and the Infection Prevention and Control Committee.
- B. The Infection Prevention and Control Committee shall, in conjunction with a licensed Veterinarian, establish the Medical Criteria that each pet shall meet in order to participate in the Program.
- C. The hospital shall establish the Behavioral Criteria that each pet shall meet before participating in the Program.
- D. A licensed Veterinarian shall certify that a participating pet:
 1. Meets the hospital’s medical criteria; and
 2. Is free of zoonotic communicable disease causing organisms.
- E. A licensed Veterinarian, a local protection society or a pet therapy association or society shall certify that a participating pet meets the Hospital’s Behavioral Criteria.
- F. Pets found to have a communicable disease shall be excluded from the Pet Therapy Program until the pet is treated and has one negative culture, if culturing of the causative agent is feasible. Pets expressing behavioral problems will be excluded from the program until the behavioral problem is remedied.
- G. Pets shall be bathed and groomed before each hospital visit. Pets shall be free of fleas while visiting the hospital.
- H. The hospital shall establish an orientation program for the Handlers. Handlers shall attend this program before participating in the Program. The orientation program shall include, at least, patient confidentiality, appropriate infection prevention and control measures, safety, and appropriate emergency protocols. Records of the orientation program shall be kept.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- I. The hospital shall keep records of each visit the Pet makes. The records shall include, at least, the date, the identity of the Pet, the identity of the Handler, all the patients visited; the area in which the patient visits were made, and any infectious condition the patient had or any type isolation the patient was in at the time of the visit.
- J. The pet and handler shall be escorted at all times by a staff member appropriate to the area visited. Patient safety and confidentiality shall be maintained at all times.
- K. The Pet shall be under the direct supervision of the handler at all times and shall be on a leash or in a crate at all times while in the hospital. Other patients, visitors, and employees shall be discouraged from petting the pet.
- L. The Hospital shall provide an area to walk the pet. There shall be procedures for immediate cleanup of all accidents.
- M. There shall be procedures for patient hand washing, visit area clean up and cleaning of the patient's room. If a pet visits a patient in bed, the bed linens will be changed immediately after the visit. A barrier shall be placed over the bed if the pet is placed directly on the patient's bed.
- N. The attending physician in conjunction with the Infection Control Officer, will determine the appropriateness of the pet visits. The attending physician shall approve and order each Pet visit. The orders shall be documented in the medical record.

SECTION 26: SPECIALIZED SERVICES: SURGICAL SERVICES.

- A. Organization and Supervision.
1. An organizational plan shall be developed.
 2. Surgical Services shall be under the medical direction of a qualified physician or a physician committee.
 3. A Surgical Services Registered Nurse supervisor shall be accountable and responsible for patient care.
 4. Surgical Services shall have written policies and procedures that include:
 - a. Operative and special consents;
 - b. Fire and disaster plans;
 - c. Environmental control;
 - d. Visitor and traffic control to include allowance for no one other than staff or professionals without the expressed consent of the physician and operating room supervisor;
 - e. Safety practices;
 - f. Infection prevention and control measures;
 - g. Care and disposition of surgical specimens, cultures and foreign bodies;
 - h. Care of special equipment including preventive maintenance contracts and records;
 - i. Emergency management;
 - j. Orientation of all personnel; and
 - k. Medication accountability. (Refer to Section 11, Patient Care Service and Section 16, Pharmacy.)
 5. Clinically relevant educational programs shall be conducted on a regularly scheduled basis not less than 12 per year. There shall be evidence of program dates, attendance, and subject matter.
 6. A surgery schedule shall be maintained in the surgery suite.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

7. There shall be a continuous QA/PI program that is specific to the patient care administered.
 8. A current roster of physicians and dentists with a delineation of each physicians and dentists surgical privileges shall be accessible and available in the confidential files of the Surgical Services Registered Nurse and in the files of the hospital administrator.
 9. The following information shall be maintained in the surgery services log:
 - a. Patient's full name;
 - b. Hospital number;
 - c. Surgeon;
 - d. Assistant surgeon;
 - e. Type of anesthetic and person administering;
 - f. Pre and postoperative diagnoses;
 - g. Circulating nurse;
 - h. Scrub nurse(s);
 - i. Procedures;
 - j. Complications;
 - k. Sponge, needle, and instrument count;
 - l. Time of beginning and ending of case; and
 - m. Other persons present.
- B. Environment, Equipment and Supplies.
1. A safe operating room environment shall be established, controlled and consistently monitored.
 2. At a minimum, the following general equipment and supplies shall be in the surgical suite:
 - a. Call-in system;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- b. Crash cart;
 - c. Cardiac monitor
 - d. Defibrillator;
 - e. Resuscitating equipment;
 - f. Suction equipment; and
 - g. Thoracotomy set.
3. Equipment and supplies necessary to meet the requirements of the services provided:
- a. Stretcher;
 - b. Anesthetic equipment and supplies;
 - c. Adjustable operating table with waterproof pad;
 - d. Side tables;
 - e. Approved surgical light;
 - f. Medical gases;
 - g. 24-hour supply of sterile linen;
 - h. Wall clock; and
 - i. Equipment and supplies for timed scrubbing technique.
- C. Staffing.
1. Surgical personnel including a Registered Nurse shall be available to provide emergency surgical services on a 24-hour basis.
 2. A Registered Nurse shall be present in the operating room for the duration of the surgical procedure. Additional auxiliary personnel shall be available as necessary.
 3. Only qualified Registered Nurses may perform circulating duties in the operating room.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

4. There shall be documentation of training and/or experience for all operating room personnel assigned to surgical procedures.

SECTION 27: SPECIALIZED SERVICES: POSTANESTHESIA CARE UNIT.

- A. Postanesthesia Care Unit (PACU) Services shall be provided in a well-organized manner under the direction of a qualified physician and under the supervision of a Registered Nurse.
- B. Policies and procedures shall have evidence of ongoing review and/or revision. The first page of each manual shall have the annual review date, signature of the department supervisor and/or person(s) conducting the review. Policies and procedures shall include:
 - 1. Lines of authority and nursing supervision;
 - 2. Transfer of patients from the Operating Room to Postanesthesia Care Unit;
 - 3. Criteria for discharge of patients from the Postanesthesia Care Unit; and
 - 4. The care of patients in the event the Postanesthesia Care Unit closes (including provisions of adequate nursing staff).
- C. There shall be adequate nursing staff in attendance with every patient during anesthesia recovery.
- D. A physician shall order the discharge of the patient from the Postanesthesia Care Unit.
- E. Equipment shall be available in accordance with services provided.
- F. The Registered Nurse shall assess and document assessment of each PACU patient.
- G. Clinically relevant educational programs shall be conducted on a regularly scheduled basis not less than 12 per year. There shall be evidence of program dates, attendance, and subject matter.
- H. There shall be an ongoing QA/PI program that is specific to the patient care administered.

SECTION 28: SPECIALIZED SERVICES: AMBULATORY SURGERY SERVICES.

- A. There shall be policies and procedures specific to Ambulatory Surgery Services. Policies and procedures for the department shall have evidence of ongoing review and/or revision. The first page of each manual shall have the annual review date, signature of the department supervisor and/or person(s) conducting the review.
- B. Policies and procedures shall include:
 - 1. Scheduling of patients for surgery;
 - 2. Admission and discharge criteria;
 - 3. Perioperative patient care;
 - 4. Operative and special consents;
 - 5. Obtaining a documented history and physical on the patient's medical record prior to the procedure;
 - 6. Preoperative assessment procedures required by the Medical Staff; and
 - 7. Medication accountability. (Refer to Section 11, Patient Care Service, Section 12, Medications and Section 16, Pharmacy.)
- C. A physician shall order the discharge of the patient from the facility.
- D. For additional requirements refer to Patient Care Service, Section 11, Specialized Services: Surgical Services, Section 26 and Specialized Services: Post anesthesia Care Unit, Section 27.

SECTION 29: SPECIALIZED SERVICES: ANESTHESIA SERVICES.

- A. Organization and Staffing. Anesthesia Services shall be provided in a well-organized manner under the direction of a qualified physician. The service is responsible for all anesthesia administered.
- B. Those administering anesthesia shall be credentialed by Medical Staff and approved by the Governing Body. A current roster, with delineation of privileges for those administering anesthesia, shall be maintained and readily available.
- C. Anesthesia shall be administered by the following:
 - 1. Anesthesiologist;
 - 2. Physician qualified to administer anesthesia; or
 - 3. Certified Registered Nurse Anesthetist (CRNA) ~~under the supervision of a physician.~~
- D. Written policies and procedures specific to Anesthesia Services shall have evidence of ongoing review and/or revision. The first page of the manual shall have the annual review date, signature of the department supervisor and/or person(s) conducting the review.
- E. Policies and procedures shall include:
 - 1. Preanesthesia evaluation;
 - 2. Approved anesthesia agents;
 - 3. Methods of delivery of anesthesia;
 - 4. Intraoperative anesthesia record;
 - 5. Post anesthesia follow-up report;
 - 6. Mechanism for routine checking and maintenance of anesthesia machines and equipment for safe use;
 - 7. Medication accountability. See Section 16, Pharmacy, Section 11, Patient Care Service, and Section 12, Medications;
 - 8. Responsibilities in the discharge of patients from the Post anesthesia Care Unit. See Section 27, Post anesthesia Care Unit; and
 - 9. Infection prevention and control measures.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

062921

- F. All medications and anesthetic agents administered to the patient shall be ordered by the prescriber and/or anesthesia provider. This includes preoperative as well as intraoperative and postoperative medications.
- G. There shall be an ongoing QA/PI program that is specific to the patient care administered.

SECTION 30: SPECIALIZED SERVICES: LABOR, DELIVERY, LABOR DELIVERY RECOVERY (LDR), LABOR DELIVERY RECOVERY POST PARTUM (LDRP), POST PARTUM AND MATERNAL-CHILD EDUCATION.

A. Labor Room and/or LDR, LDRP Room.

1. Provisions shall be made for patients in labor in either a designated labor room and/or birthing room. Rooms used only for labor shall be in close proximity to the delivery room. Furniture, washable wallpaper, pictures, radio, television, and other items may be used as long as the needs of the mother and baby are not compromised. Items selected shall be made of durable materials, with a smooth, impervious surface which can be easily cleaned and disinfected.
2. All beds used for labor shall be equipped with side rails.
3. There shall be equipment and supplies available for the examination and preparation of patients in labor, which shall consist of the following:
 - a. Precipitous delivery tray;
 - b. Stethoscope;
 - c. Suction equipment;
 - d. Sterile gloves;
 - e. Emergency medications as approved by the Pharmacy and Therapeutics Committee and supplies to include laryngoscopes, airways, endotracheal tubes and infant ambu bags; and
 - f. Fetal monitoring device.
4. A physician shall be immediately available when Oxytocin is administered. "Immediately available" shall be determined by the hospital's administrative staff, Medical Staff and Governing Body.
5. Father or support persons may be allowed with the patient during labor unless medically contraindicated.

B. Delivery Areas.

1. Hospitals offering delivery and maternity services shall comply with the requirements of this section. (See Section 14, Health Information Services and Section 11, Patient Care Service.)

RULES FOR CRITICAL ACCESS HOSPITALS 2021

08202021

2. General operating rooms may not be used for deliveries, except for major surgical deliveries. Delivery rooms shall be separate from operating rooms and shall not be used for any other purpose, with the exception of a tubal ligation immediately following a delivery. Delivery rooms may be used for Caesarean sections provided the usual operating room equipment is used, and surgical policies and procedures related to the delivery are made a part of the labor and delivery manual.
3. The following equipment and supplies shall be provided:
 - a. Supply of medications as approved by the Pharmacy and Therapeutics Committee;
 - b. Infant identification and supplies. Identification shall be done in the delivery room at the time of birth and shall remain in place during the entire period of hospitalization. Identification information shall be sufficient to identify the infant(s) with one mother. Identification bands shall be waterproof plastic with tag inserts written in waterproof ink;
 - c. Heated bassinet, crib, or incubator;
 - d. Supply of prophylaxis medication for the prevention of infant blindness. The medication shall be administered within one and one-half hours of the time of birth per written order of the physician;
 - e. Commercially manufactured delivery table/birthing bed with a waterproof non-conductive table pad;
 - f. Side tables for instruments and other necessary equipment;
 - g. Approved surgical light;
 - h. Wall clock;
 - i. Equipment and supplies for timed scrub technique and an approved disinfectant soap;
 - j. Apgar score chart;
 - k. Suction equipment (infant and adult);
 - l. Sphygmomanometer; and
 - m. Fetal monitoring device.

C. Organization.

1. Delivery services shall be under the direction of a qualified physician and under the supervision of a Registered Nurse. A Registered Nurse shall be present during labor, delivery and post-delivery of each patient. The birth shall be attended by a physician or a certified nurse midwife with hospital privileges.
2. Patients shall be provided with direct care by a Registered Nurse during labor, delivery, recovery and postpartum.
 - a. All patients in active labor shall be attended and/or monitored.
 - b. Qualified nurses, in adequate numbers shall be provided to meet the needs of each patient.
3. An on-call schedule shall be provided to ensure that a physician with obstetrical privileges is readily available to perform obstetrical services at all times. "Readily available" shall be determined by the hospital's Administrative Staff, Medical Staff and Governing Body.
4. Qualified Registered Nurses shall always be available in-house for labor and delivery patients. When there are no patients, on-call staff may be utilized if approved by the Medical Staff and Governing Body.
5. Procedures for obtaining the mother's Rh factor shall be provided by the facility or documented by the mother's attending physician upon admission.
6. When a patient presents to the hospital for evaluation, the physician shall be notified.
7. Policies and procedures shall include:
 - a. Immediate delivery;
 - b. Obstetrical emergencies;
 - c. Setting up and cleaning the delivery room, LDR or LDRP room, and C-section room;
 - d. Equipment requirements;
 - e. Visitation;
 - f. Climate control (physical);

RULES FOR CRITICAL ACCESS HOSPITALS 2021

08202021

- g. Infection prevention and control measures;
 - h. Aseptic techniques;
 - i. Intermittent rooming in;
 - j. Anesthesia;
 - k. Deliveries occurring outside the delivery area;
 - l. Infectious patients; and
 - m. Infant security.
8. A permanent record of all deliveries shall be maintained. There shall be a reasonable attempt to collect current information to include the following:
- a. Mother's name, date of birth, maiden name, father's name if available, hospital number, gravida-para, ABO type, Rh factor, mother's Hepatitis C status and length of gestational period;
 - b. Baby's sex, race, date of birth, time of birth, weight, apgar score, and baby identification band number;
 - c. The healthcare provider shall record in the medical record if the pregnant women declines to be tested for Hepatitis C.

D. Anesthesia.

- 1. Only a physician, anesthesiologist or Certified Registered Nurse Anesthetist (CRNA) shall be permitted to initiate and reinject continual epidural or caudal anesthesia and to initiate or continue general or regional anesthesia.
- 2. A physician shall be immediately available for consultation if CRNAs are administering anesthesia. "Immediately available" shall be determined by the hospital's Administrative Staff, Medical Staff and Governing Body.
- 3. The permanent record shall contain the names of the physician, anesthesiologist, anesthetist or CRNA.

E. Postpartum Care.

- 1. Policies and procedures shall be developed specific to the care of maternity patients.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

08202021

2. Maternity patients shall not be routinely cared for in rooms with patients admitted for diagnosis other than maternity.
 3. After an observation period, the infant may stay in the room with the mother for the duration of the hospital stay.
 4. Mothers with infection, fever or other condition that could adversely affect the safety and welfare of others shall be immediately segregated and isolated in a separate room.
- F. Maternal-Child Education. The hospital shall develop an educational program for the care of the obstetrical patient and infant. Policies and procedures shall include:
1. Personal hygiene;
 2. Dietary instruction;
 3. Care of episiotomy and perineum;
 4. Care of incision;
 5. Breast care;
 6. Exercise program;
 7. Car seat safety (Ark. Code Ann. § 27-34-101 et seq.);
 8. Preventive health;
 9. Referral services;
 10. Infant care; and
 11. Distributing educational materials for shaken baby syndrome (Ark. Code Ann. § 20-9-1401 et seq.).
 12. Hepatitis C counseling.

SECTION 31: NURSERY SERVICES.

The newborn nursery shall be under the direct supervision of a Registered Nurse with clinical skills in newborn nursing. The newborn nursery shall be located within or adjacent to the postpartum unit. The following requirements shall apply to all nurseries:

- A. Nurseries shall not be used for any other purpose and shall never be left unattended when occupied.
- B. Infants born outside the hospital or with proven or potential infections shall be isolated from other infants in the Nursery. Infants with infections, skin rash or diarrhea shall be immediately separated and isolated.
- C. Isolettes shall not serve as a sole means of isolation. Provisions for isolation shall be provided.
- D. The following equipment shall be provided in nurseries:
 - 1. Individual approved type hospital bassinets. Wicker or woven type bassinets shall not be used;
 - 2. Metal or approved plastic diaper and waste containers. The lids on these containers shall be operated by a foot control or equivalent device;
 - 3. Infant scales;
 - 4. Blankets and linen;
 - 5. Suction equipment; and
 - 6. Incubators suitable for the care of premature infants provided in the ratio of at least one incubator to 20 bassinets.
- E. Infant emergency supplies:
 - 1. Emergency medications approved by the Pharmacy and Therapeutics Committee;
 - 2. Infant laryngoscope;
 - 3. Suction catheters;
 - 4. Endotracheal tubes;
 - 5. Stylets; and
 - 6. Infant airways and IV supplies.

F. Newborn testing for critical congenital heart defects shall include the performance of pulse oximetry testing all newborns before discharge Ark. Code Ann. § 20-15-103. Performance of a pulse oximetry test on a newborn is not required if the parent or legal guardian of the newborn object to the testing on medical, religious, or philosophical grounds.

G. Newborn testing for genetic illnesses shall be in accordance with Arkansas Rules Pertaining to Testing of Newborn Infants Ark. Code Ann. § 20-15-301.

H. Newborn testing for early detection of hearing loss shall be in accordance with Arkansas Rules Pertaining to the Universal Newborn/Infant Hearing Screening, Tracking and Intervention Program Ark. Code Ann. 20-15-1501.

~~F.I.~~ Strict hand hygiene techniques shall be maintained by all personnel. A clean barrier shall be used by anyone handling the infant.

~~G.J.~~ Infant clothing shall be furnished by the hospital; however, if the mother wishes to provide clothing for the infant, hospital personnel shall examine the clothing to make sure it meets hospital requirements. Diapers shall be available in necessary quantities.

~~H.K.~~ Formula Feedings.

1. Any individually packaged, presterilized formula delivered by an outside source shall be approved by the facility.
2. There shall be an adequate supply of sterile disposable ready-to-use formula bottles available.
3. Formulas shall be stored in enclosed cabinets.
4. The expiration date shall be checked on each bottle prior to infant feeding.
5. Policies and procedures shall be developed in conjunction with the Infection Prevention and Control Committee regarding the handling, labeling and storing (separately) of breast milk.
6. Individual nipple shields and breast pumps used in infant feeding shall be cleaned according to hospital infection prevention and control policies and procedures.
7. If the facility has a breast milk bank the policies and procedures shall be submitted to and approved by the Arkansas Department of Health and hospital Infection Prevention and Control Committee.

- I. Rooming-In Service. Hospitals providing a newborn nursery may provide rooming in for infants on an intermittent or 24-hour basis based on the mother's request.

SECTION 32: SPECIALIZED SERVICES: CRITICAL CARE.

A Critical Care Unit is a section of the hospital where intensive care nursing, necessary monitoring and treatment equipment and supplies are provided to those patients who, in the opinion of the attending physician, require such specialized services.

A. Staffing.

1. Critical Care Units shall be staffed with a Registered Nurse each shift.
2. All critical care nursing staff shall be oriented and trained in life support measures, interpretation of dysrhythmias and shall demonstrate competency in critical care nursing specific to patient types. Competency in the specific areas shall be maintained.

B. Policies and Procedures. Procedures shall include:

1. Admission and continuing stay criteria;
2. Discharge criteria;
3. Triage/transfer;
4. Use of protocols; and
5. Definition of the clinical scope of the hospital's critical care service.

C. Equipment. Equipment shall include:

1. Suction;
2. Diagnostic monitoring equipment to include electrocardiographic monitoring;
3. "Crash Cart" containing emergency medications and supplies;
4. Defibrillator;
5. Wall clock;
6. Accommodations to maintain privacy; and
7. Weighing device for bed patients.

D. Isolation. An isolation room shall be available for the treatment of potentially infectious or immune suppressed critical care patients.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- E. Pediatric Critical Care. If the facility offers critical care for the pediatric patient there shall be:
1. Policies, procedures and equipment specific to the needs of pediatric patients; and
 2. Nursing staff oriented and trained in life support measures, interpretation of dysrhythmias and competency in critical care nursing specific to the pediatric patient.

SECTION 33: SPECIALIZED SERVICES: DENTAL SERVICES.

- A. Dental Services shall comply with the requirements of this section. (See Section 14, Health Information Services, Section 11, Patient Care Services, Section 16, Pharmacy and all applicable Sections.)
- B. Patients admitted to the hospital for dental care shall be given the same medical appraisal as those admitted to other services. The care of dental patients shall be the dual responsibility of the dentist and a physician on the hospital staff.
- C. Dental services shall be under the direction of a dentist.
- D. Policies and procedures shall be provided.

SECTION 34: SPECIALIZED SERVICES: CENTRAL STERILIZATION AND SUPPLY.

- A. Each hospital shall provide central medical and surgical supply services with facilities that are responsible for processing, sterilizing, storing, distributing supplies and equipment to all units of the hospital. (Refer to Section 66, Physical Facilities, Central Medical and Surgical Supply Department, for space and equipment requirements.)
- B. The central sterilization and supply service shall be under the direct supervision of a Registered Nurse or other qualified person who is trained in management, aseptic procedures, supply processing and control methods which are applicable to central sterilization and supply service.
- C. Policies and procedures shall have evidence of ongoing review and/or revision. The first page of each manual shall have the annual review date, signature of the department and/or person(s) conducting the review.
- D. Policies and procedures shall include:
 - 1. Job descriptions;
 - 2. Infection prevention and control measures;
 - 3. Assembly and operation of equipment;
 - 4. Safety practices;
 - 5. Orientation for new employees;
 - 6. Care and cleaning of equipment;
 - 7. Evaluation of:
 - a. Cleaning effectiveness; and
 - b. Sterilizing effectiveness.
 - 8. Receiving, decontaminating, cleaning, preparing, disinfecting and sterilizing reusable items;
 - 9. Assembling and wrapping of packs (to include the double-wrapped techniques);
 - 10. Storage and distribution of sterile equipment/medical supplies;
 - 11. Use of chemical indicators and biological spore tests for sterilizers;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

12. Recalling and disposing/reprocessing of outdated sterile supplies;
 13. Cleaning and disinfecting of surfaces, utensils, and equipment;
 14. Specifications for cold-liquid sterilization and gas sterilization (if used); and
 15. Collection and disposal of supplies recalled by the manufacturer.
- E. There shall be an ongoing QA/PI program specific to the area.
- F. Precautions shall be exercised to prevent the mixing of sterile and unsterile supplies and equipment. The precautions shall be set forth in written policies.
- G. Procedures shall be developed for unloading and transporting flash sterilized items. The procedures shall be developed with the assistance of the Infection Prevention and Control Committee and shall provide for the aseptic transfer within the physical constraints of the facility.
- H. Relevant educational programs shall be conducted on a regularly scheduled basis not less than 12 per year. There shall be written documentation with employee signature, program title/subject, presenter, date and outline or narrative of presented program.
- I. A liaison with the Infection Prevention and Control Committee shall be maintained.
- J. Records shall be maintained of all autoclave loads, both routine and immediate use or “flash,” which shall include the date, time, lot number (on routine loads), the time at temperature (where a recorder is not available), item(s) sterilized and shall identify the person performing the task.
1. Autoclaves shall meet the following requirements:
 2. The efficacy of autoclaves, both for routine and immediate use or “flash” use, shall be determined weekly through the use of biological spore monitors:
 3. The results of all biological spore monitoring shall be reported to the Infection Prevention and Control Committee; and
 4. Failures of the biological spore test shall be brought to the attention of the Infection Prevention and Control Officer or designee immediately so the appropriate surveillance measures can be initiated.

NOTE: All materials sterilized from the date of the biological spore monitor failure to the last successful biological spore monitor shall be re-sterilized before use.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- K. All autoclaves within the facility shall be maintained in accordance with the manufacturer’s written directions. Records shall be maintained of all maintenance and repairs for the life of the equipment.
- L. Chemical indicators for sterility shall be used with each cycle
- M. The facility shall validate compliance and efficacy of the sterilization policy through the quality review process. The sterilization policy shall describe the mechanism used to determine the shelf life of sterilized packages. The policy shall:
 - 1. Be consistent with published industry standards (AAMI and APIC).
 - 2. Stress that sterility is related to integrity of pack regardless of whether expiration dating or event-related expiration is utilized.
- N. Event-related dating of sterile packs is acceptable.

ALLOWABLE SHELF LIFE

Double-wrapped Muslin	Use for rapid turn-around items only in well controlled environment, < 30 days
Double-wrapped Muslin Placed in a Plastic Dust Cover Then Heat Sealed or Bonded	Event related
Paper or Polypropylene Peel Pack (Paper, Plastic or Tyvek/Mylar)	Event related and/or per manufacturer’s instructions
Rigid Containers, Caskets, etc.	Per manufacturer’s instructions

NOTE:

- 1. Sterile storage areas shall maintain a temperature of no more than 75°F and a relative humidity of no more than 70%. Ventilation shall be 10 air changes per hour and shall follow clean to dirty flow.
- 2. The interior of the dust cover shall not be considered sterile.
- 3. Packages that are wet, dropped on the floor, compressed or torn shall be rejected.
- 4. The lot number or control number and expiration statement shall be visible through the package or another tag shall be placed on the outside.
- 5. Containers for sterilization systems shall be scientifically proven suitable for the

RULES FOR CRITICAL ACCESS HOSPITALS 2021

specific sterilization cycle used; the container system shall be verified as the correct one for the cycle. (Manufacturer's instructions shall be followed.)

- 6. Double-wrapped shall mean the end results of the wrapping technique will yield a two-ply covering.
- 7. The date of sterilization and load control number shall be placed on each sterilized pack.
- O. Immediate use or “flash” (autoclaving) shall be restricted to unplanned or emergency situations. Flash sterilization shall never be used as a convenience to compensate for inadequate inventories of instruments or implantables. Flash sterilization of implantables shall be restricted to the direst circumstances.
- P. Items which are to be immediate use flash sterilized shall be cleaned and decontaminated before the sterilization process.
- Q. Traffic areas in which immediate use or flash sterilization is carried out shall be restricted to authorized personnel wearing surgical attire consisting of surgical scrubs, shoe covers, masks and hair covers. The sterilizer shall not be located adjacent to any potential sources of contamination such as scrub sinks, clinical sinks or hoppers, wash sinks, linen or trash disposal areas.
- R. For immediate use or flash sterilization, minimal time at effective temperature shall conform to the following:

AUTOCLAVE	LOA	MINIMAL TIME AT TEMPERATURE
Gravity	Nonporous (Simple Metal Instruments)	3 minutes at 132EC (270EF)
Gravity	Porous (Towels, Rubber, Plastic) Nonporous Mix	10 minutes at 132EC (270EF)
Gravity	Nonporous with Lumens, Deep Grooves, Sliding Parts	10 minutes at 132EC (270EF)
Gravity/Prevacuum	Complex Devices, Air-powered Drills	Per Manufacturer's Instructions
Prevacuum	Nonporous	3 minutes at 132EC (270EF)
Prevacuum	Porous/Nonporous	4 minutes at 132EC (270EF)

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- S. Items that previously have been packaged, sterilized, and issued, but not used may be returned to the sterile storage area if the integrity of the packaging has not been compromised and there is no evidence of contamination; such items may be dispensed when needed.

Items that previously have been packaged, sterilized and issued to the patient care units or other areas where the environment is not controlled shall be discarded if they are single use items, or unwrapped and reprocessed through decontamination if they are reusable.

- T. Sterile materials shall be stored eight to ten inches from the floor and at least 18 inches from the ceiling and at least two inches from outside walls. Items shall be positioned so that packages are not crushed, bent, compressed, or punctured and sterility is not compromised.
- U. All sterilization techniques other than steam (plasma, ethylene oxide, chemical, etc.) shall follow the manufacturer's directions and meet all state and federal regulations.

SECTION 35: SPECIALIZED SERVICES: RESPIRATORY CARE.

- A. Respiratory Care Services shall be under the direction of a physician member of the Medical Staff.
- B. Respiratory Care Services, including equipment, shall be supervised by a qualified and trained respiratory therapist.
- C. There shall be sufficient personnel qualified and trained in respiratory care to provide respiratory care services.
 - 1. Services may be performed by an assistant only when a qualified and trained respiratory therapist is readily available for consultation; and
 - 2. Personnel qualified and trained in respiratory care shall be on the premises whenever continuous ventilatory support is provided to patients.
- D. All respiratory care personnel shall maintain competency in:
 - 1. Life support measures;
 - 2. Isolation techniques; and
 - 3. Safety techniques for oxygen and oxygen equipment.
- E. The policy and procedure manual shall have evidence of ongoing review and/or revision. The first page of the manual shall have the annual review date and signature of the department supervisor and/or person(s) conducting the review.
- F. Policies and procedures shall include:
 - 1. Job descriptions;
 - 2. Documentation, verified by the physician director, of who may perform special procedures and give patient instructions;
 - 3. Safety practices;
 - 4. Handling, storage and dispensing of therapeutic gases;
 - 5. Infection prevention and control measures;
 - 6. Assembly and operation of equipment;
 - 7. Respiratory care services provided and a list of services shall be available to the Medical Staff;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

8. Steps to take in the event of an adverse reaction;
 9. Cleaning, disinfecting and sterilizing procedures; and
 10. Orientation policies for new employees.
- G. Clinically relevant educational programs shall be conducted on a regularly scheduled basis not less than 12 per year. There shall be evidence of program dates, attendance, and subject matter.
- H. If arterial blood gases are performed the Respiratory Care department shall subscribe to a nationally recognized proficiency testing program for blood gases and meet the quality control requirements for clinical laboratories.
- I. The Respiratory Care Service shall have sufficient equipment and adequate facilities appropriate for safety and effective provision of care.
1. Equipment shall be serviced calibrated, and operated according to manufacturers' directions.
 2. An approved safety system shall be used with therapeutic gases.
 3. Resuscitation, ventilatory and oxygenation support equipment shall be available for patients of all sizes.
 4. Ventilators for continuous assistance or controlled breathing shall be equipped with alarm systems.
 5. A preventive maintenance program shall be implemented and records maintained for the life of the equipment.
- J. All Respiratory Care prescription/work requests shall specify the type, frequency and duration of each treatment, and, as required, the type and dose of medication and the type of diluent and oxygen or medical air.
- K. Respiratory Care reports of blood gas results shall be prepared in duplicate and signed by the therapist responsible for the procedure/test. The original shall be placed in the patient's medical record and the copy retained in the department file.
- L. Accurate records shall be maintained regarding the type and duration of each treatment given. These records shall be correlated with the patient's medical record.
- M. Respiratory Care documentation for each patient shall include:

RULES FOR CRITICAL ACCESS HOSPITALS 2021

1. Current written plan of care to include goals and objectives;
 2. Instructions to patient or patient's family; and
 3. Type and duration of the treatment given.
- N. When oxygen is being administered to a patient:
1. Patients, visitors and personnel shall be apprised of the fire hazard; and
 2. If the patient is in a tent, alcohol or rub-on lotion shall not be used.
- O. Oxygen shall be humidified in accordance with physician's orders.
- P. If reusable reservoirs are used to humidify the oxygen, the reservoirs shall be cleaned and disinfected to a high-level of disinfection. (A high-level disinfection can be expected to kill all microorganisms with the exception of high numbers of bacterial endospores. Only sterile solutions and diluents shall be used in humidification and nebulizing equipment. Nebulizers (in-line and hand-held), between treatments on the same patient, shall be disinfected to a high level and rinsed in sterile water or, if a small volume medication nebulizer, air dried. All other semicritical equipment shall be cleaned and disinfected in accordance with the Center for Disease Control and Prevention's Guidelines.
- Q. After use, all equipment shall be returned to a central location for thorough cleaning, servicing and disinfecting before use on another patient.
- R. There shall be an ongoing QA/PI program.
- S. Contracted Respiratory Care Services shall be under current agreement and the contractor shall fulfill all requirements of this section.
- NOTE: The National Fire Protection Association Vol. 99, Health Care Facilities, is a mandatory reference for developing safety regulations for Respiratory Care Services.

SECTION 36: SPECIALIZED SERVICE: EMERGENCY SERVICES.

NOTE: Federal EMTALA requirements apply

- A. Every licensed hospital shall have a dedicated emergency department. The following hospitals are excepted:
 - 1. Psychiatric hospitals;
 - 2. Rehabilitation hospitals;
 - 3. Long term acute care hospitals; and
 - 4. Prison hospitals.

- B. The hospital's emergency department shall have organized services, procedures, and nationally recognized protocols for emergencies.

- C. Diagnostic and treatment equipment, medications, supplies and space shall be adequate in terms of the size and scope of services provided. Resuscitation and life support equipment shall include but not be limited to:
 - 1. Airway control and ventilation equipment including laryngoscope and endotracheal tubes, valve-mask resuscitator, sources of oxygen, pulse oximeter, CO2 monitoring;
 - 2. Suction devices;
 - 3. Standard IV fluids and administration devices, including IV catheters;
 - 4. Intravenous fluid and blood warmers;
 - 5. Sterile surgical sets for standard ED procedures;
 - 6. Gastric lavage equipment; and
 - 7. Blood pressure monitoring equipment.

- D. Each emergency department shall have diagnostic imaging and diagnostic laboratory capabilities available twenty-four (24) hours per day, seven (7) days per week. Such laboratory services shall include:
 - 1. Standard analyses of blood, urine, and other body fluids;
 - 2. Blood typing and cross-matching;

RULES FOR CRITICAL ACCESS IN ARKANSAS 2021

3. Coagulation studies;
 4. Comprehensive blood bank or access to a community central blood bank and adequate hospital storage facilities; and
 5. Blood gases and pH determination.
- E. An inventory list of all supplies and equipment including all items on the crash cart, shall be checked each shift and after each use.
- F. The location and telephone number of the nearest poison control center and a list of poison antidotes shall be posted in the emergency department.
- G. Screening examination
- Each patient presenting to the emergency department (“ED”) shall have a medical screening examination by a qualified medical personnel. The examination shall be completely documented.
- H. Treatment and Disposition
1. If a patient is screened as having an emergency medical condition, a physician shall be contacted to discuss the assessment findings and patient’s condition. A physician shall determine disposition of the patient.
 2. If a patient is screened as having a non-emergency medical condition, a hospital may allow treatment and disposition of the patient by a physician or non-physician licensed medical professional. This individual must be appropriately credentialed by the medical staff with approval by the governing body to provide non-emergent medical care in the Emergency Department.
- I. Physician availability
1. Arrangements shall be provided, such as a duty or on-call roster, to ensure a physician is available for all emergency patients as determined by the screening examination.
 2. Arrangements shall be made for obtaining specialized medical services.
- J. Staffing.
1. The Emergency Service shall be under the supervision of a Registered Nurse.
 2. All patient care personnel assigned to the emergency department shall receive orientation and be competent in life support measures.

RULES FOR CRITICAL ACCESS IN ARKANSAS 2021

3. An Advanced Cardiac Life Support (ACLS) or Pediatric Advanced Life Support (PALS) (as appropriate) trained person shall be in-house and immediately available.
4. The Registered Nurse shall assume the responsibility for the nursing functions of the Emergency Services. This includes:
 - a. Supervision;
 - b. Evaluation of the patient's emergency nursing care needs;
 - c. The assignment of nursing care for each patient to other nursing personnel in accordance with the patient's needs and the preparation and competence of the nursing staff;
 - d. Supplies and equipment;
 - e. The emergency department record (See Section 7, General Administration and Sections 15, Medical Record Requirements for Outpatient Services, Emergency Room and Observation Services.); and
 - f. Maintenance of an emergency department log.
5. Emergency Medical Technician (EMT). Pursuant to the Arkansas Emergency Medical Service Act Ark. Code Ann. §§20-13-201 et.seq., if a hospital allows an Arkansas Certified Emergency Medical Technician to perform specified procedures within the Emergency Room or be a member of a hospital code team the following action shall be taken:
 - a. The Medical Staff shall approve the privileges granted to the individual EMT with concurrence of the hospital's Governing Body. Specific policies governing the supervision and the procedures to be performed by an EMT shall be developed by the Medical Staff and approved by the hospital's Governing Body. In no event shall an EMT perform a procedure that he/she is not certified to do by the Office of Emergency Services of the Arkansas Department of Health;
 - b. Approved EMT's shall function in accordance with physician's orders and under the direct supervision of either the physician or Registered Nurse responsible for Emergency Services;
 - c. Students in EMT training programs approved by the Office of Emergency Medical Services of the Arkansas Department of Health shall be trained by qualified instructors within the hospital

RULES FOR CRITICAL ACCESS IN ARKANSAS 2021

under guidelines established by the Medical Staff and approved by the Governing Body; and

- d. A roster with the delineation of privileges shall be maintained and readily available.
- K. Medications. (See Section 16, Pharmacy and Section 12, Medications.)
- L. Off-Campus Emergency Departments (off-campus EDs). Off-campus EDs shall meet all requirements for hospital EDs. Off-campus EDs shall:
- 1. Function as a department of the parent hospital.
 - 2. Be fully integrated into the parent hospital's systems and operations.
 - a. Medical staff must be part of the parent hospital's single organized medical staff.
 - b. Nursing personnel must be part of the hospital's single organized nursing service.
 - c. Emergency laboratory and imaging services must be available 24 hours/day, 7 days/week.
 - d. Quality assessment/performance improvement (QAPI) program must be integrated into the parent hospital's QAPI program.
 - e. Records must be maintained as part of the hospital's single medical record system.
 - f. Infection prevention and control practices must meet the requirements of the parent hospital's infection control policies and practices.
 - g. Emergency services must meet accepted standards of practice for hospital emergency department.
 - h. Patients who require further care must have access to all services of the main hospital.
 - 3. Be open 24 hours per day, 7 days per week.
- M. Emergency Services Facility. The Arkansas Department of Health may license under Ark. Code Ann. § 20-9-218, hospitals which have discontinued inpatient services to continue to provide emergency services if there is no other hospital Emergency Service in the community.

RULES FOR CRITICAL ACCESS IN ARKANSAS 2021

1. The Emergency Services Facility shall be subject to inspection and to all other provisions of Ark. Code Ann. §§ 20-9-201 et. seq. and 20-13-201 et. seq., as amended.
2. The Emergency Services Facility shall have agreements with licensed hospitals to accept patients who are in need of inpatient hospital services.
3. An emergency facility shall not have licensed inpatient beds, however, at least one holding/observation bed shall be provided for patient use not to exceed 24 hours.
4. Emergency Service Facilities shall provide, or contract to provide emergency ambulance services licensed by the Arkansas Department of Health, that include radio communication and patient telemetry. It is further required that contractual agreements be made for patient air transport services.
5. Policies and procedures shall be developed and approved by Health Facility Services of the Arkansas Department of Health, prior to issuance of a license, and the facility may not provide services without a license.
6. Clinically relevant educational program shall be conducted on a regularly scheduled basis not less than 12 per year. There shall be evidence of program dates, attendance, and subject matter.
7. There shall be an ongoing QA/PI program that is specific to the patient care administered.

SECTION 37: SPECIALIZED SERVICE: PSYCHIATRIC SERVICES.

- A. Psychiatric care units in general hospitals shall meet the construction requirements of Section 48, Psychiatric Nursing Unit, and shall in all respects comply with the requirements of Section 42, Physical Facilities, Patient Accommodations (Adult Medical, Surgical, Communicable or Pulmonary Disease) except furniture, equipment and supplies may be modified by the attending physician on an individual patient basis as verified by signed orders.
- B. General Requirements.
1. Each psychiatric care unit shall have a written plan describing the organization of services or the arrangement for the provision of such services to meet patient needs.
 2. The services shall include, but not be limited to, diagnostic evaluation, individual or group therapy, consultation and rehabilitation.
 3. The unit shall be under the direction and management of a psychiatrist who is qualified by training and experience for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry and licensed in the State of Arkansas.
 4. The Program Director of the unit shall be an individual with at least two years administrative experience.
 5. The unit shall furnish, through the use of qualified personnel, psychological services, social work services, occupational therapy, recreational therapy and psychiatric nursing.
 6. The unit shall have a qualified Director of Nursing with a Master's Degree or be qualified by education and experience in the care of the mentally ill. If the director does not meet the qualifications, there shall be regular documented consultation by a qualified Registered Nurse.
 7. Staffing for the unit shall ensure the presence in the unit of a Registered Nurse at all times. There shall be adequate numbers of Registered Nurses, Licensed Practical Nurses, and mental health workers to provide the care necessary under each patient's active treatment program.
 8. The unit shall provide or have available, psychological services to meet the needs of the patients.
 9. There shall be a social service staff to provide services in accordance with accepted standards of practice and established policies and procedures.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

10. The unit shall provide a therapeutic activities program. The program shall be appropriate to the needs and interests of the patients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.
 11. There shall be a procedure for referrals for needed services.
 12. There shall be adequate space, equipment and supplies for services to be provided effectively and efficiently in functional surroundings that are readily accessible to the patients. All space, equipment and facilities, both within the psychiatric facility and those utilized outside the facility, shall be well maintained and shall meet applicable federal, state and local requirements for safety, fire, health and sanitation.
 13. Policies and procedures shall have evidence of ongoing review and/or revision. The first page of each manual shall have the annual review date, signature of the department director and/or person(s) conducting the review.
 14. Clinically relevant educational program shall be conducted on a regularly scheduled basis not less than 12 per year. There shall be evidence of program dates, attendance, and subject matter.
 15. Staff meetings shall be held at least monthly. Dated minutes of each meeting shall be kept in writing.
 16. There shall be an ongoing program for orientation of staff.
 17. All psychiatric services personnel shall maintain competency in life support measures.
 18. There shall be an ongoing QA/PI program.
- C. Medical records shall include at least:
1. Identification data including patient's legal status;
 2. Admitting psychiatric diagnosis as well as diagnoses of medical problems;
 3. Reason for the patient's admission;
 4. Social service records including reports of interviews with patients, family members and others and a social history and assessment;
 5. Psychiatric evaluation (See Section 15, Medical Record Requirements for Outpatient Services, Emergency Room, Observation Services and Psychiatric Records); and

RULES FOR CRITICAL ACCESS HOSPITALS 2021

6. Treatment plan (See Section 15, Medical Record Requirements for Outpatient Services, Emergency Room, Observation Services and Psychiatric Records).
- D. Medications. (See Section 16, Pharmacy.)
 - E. Food and Nutritional Services. (See Section 17, Food and Nutrition Services.)
 - F. Organization of psychiatric nursing units and services in general hospitals:
 1. Medical direction shall be provided by a qualified psychiatrist and under the supervision of a Registered Nurse, qualified by training and experience in psychiatric nursing.
 2. In addition to the requirements set forth for Nursing Services in Section 11, Patient Care Service, policies and procedures shall be developed specific to the care of the psychiatric patient.
 - G. Supplies and equipment shall be commensurate with the type of services offered.
 - H. Medical Records (See Section 15, Medical Record Requirements for Outpatient Services, Emergency Room, Observation Services and Psychiatric Records).

SECTION 38: SPECIALIZED SERVICE: CARE OF PATIENTS WITH PULMONARY DISEASE IN CRITICAL ACCESS HOSPITALS.

- A. In addition to the Patient Care Services requirements set forth in Section 11, the policies and procedures shall include specialized procedures specific to respiratory disease patients and shall include:
1. Collection of sputum;
 2. Utilization of respiratory care;
 3. Skin test procedures;
 4. Tuberculosis control program for personnel;
 5. Follow-up service for patients after discharge from the hospital; and
 6. Provision for individual patient's plan of care.

SECTION 39: OUTPATIENT PSYCHIATRIC CENTERS.

Any facility in which psychiatric services are offered for a period of 8 to 16 hours a day, and where, in the opinion of the attending psychiatrist, hospitalization, as defined in the present licensure law, is not necessary, is considered an Outpatient Psychiatric Facility. This definition does not include Community Mental Health Clinics and Centers as they now exist. Such facilities shall conform with applicable sections if those services are provided within the facility. Such facilities shall conform with applicable sections of Section 75, Physical Facilities, Outpatient Care Facilities.

A. General Requirements.

1. Each psychiatric facility shall have a written plan describing the organization of outpatient services or the arrangement for the provision of such services to meet patient needs.
2. The outpatient services shall include, but not be limited to, diagnostic evaluation, individual or group therapy, consultation and rehabilitation.
3. The center shall be under the direction and management of a psychiatrist who is qualified by training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry and licensed in the State of Arkansas.
4. The Program Director of the Outpatient Center shall be an individual with at least two years of administrative experience.
5. The center shall furnish, through the use of qualified personnel, psychological services, social work services, occupational therapy, recreational therapy and psychiatric nursing.
6. The center shall have a qualified Director of Nursing with a Master's Degree or be qualified by education and experience in the care of the mentally ill. If the director does not meet the qualifications, there shall be regular documented consultation by a qualified Registered Nurse.
7. Staffing for the center shall insure the presence in the center of a Registered Nurse during the hours the unit is open. There shall be adequate numbers of Registered Nurses, Licensed Practical Nurses and mental health workers to provide the care necessary under each patient's active treatment program.
8. The center shall provide or have available, psychological services to meet the needs of the patients.
9. There shall be a social service staff to provide services in accordance with accepted standards of practice and established policies and procedures.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

10. The center shall provide a therapeutic activities program. The program shall be appropriate to the needs and interests of the patients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.
 11. There shall be a procedure for referrals for needed services that are not provided directly by the facility.
 12. There shall be adequate space, equipment and supplies for outpatient services to be provided effectively and efficiently in functional surroundings that are readily accessible and acceptable to the patients and community services. All space, equipment and facilities, both within the psychiatric facility and those utilized outside the facility, shall be well maintained and shall meet applicable federal, state and local requirements for safety, fire, health and sanitation.
 13. Policies and procedures shall have evidence of ongoing review and/or revision. The first page of each manual shall have the annual review date, signature of the department supervisor and/or person(s) conducting the review.
 14. Clinically relevant educational program shall be conducted on a regularly scheduled basis not less than 12 per year. There shall be evidence of program dates, attendance, and subject matter.
 15. Regular staff meetings shall be held at least monthly. Dated minutes of each meeting shall be kept in writing.
 16. There shall be an ongoing program for orientation of staff.
 17. There shall be an ongoing QA/PI program.
- B. Medical records shall include at least:
1. Identification data including patient's legal status;
 2. Admitting psychiatric diagnosis as well as diagnoses of medical problems;
 3. The reasons for the patient's admission to this level of care;
 4. Social service records including reports of interviews with patients, family members and others and a social history and assessment;
 5. Psychiatric evaluation (See Section 37, Specialized Services: Psychiatric Services.);
 6. Treatment plan (See Section 37, Specialized Services: Psychiatric Services.); and

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- C. Medications. Outpatient Services utilizing medications in therapeutic programs shall fulfill the requirements in Section 16, Pharmacy.
- D. Food and Nutritional Services. (See Section 17, Food and Nutrition Services.)
- E. Physical Facilities. The Outpatient Psychiatric Centers shall comply with Section 75, Physical Facilities, Outpatient Care Facilities.

SECTION 40: REHABILITATION HOSPITALS AND UNITS.

A. General Requirements.

1. Rehabilitation Hospital means a hospital or a distinct part of a hospital as designated in Section 3, Definitions, of these rules which is used for the primary purpose of providing rehabilitative services as so defined and shall comply with Sections 1, Authority, through Section 38, Specialized Services: Care of Patients with Pulmonary Disease in General Hospitals. Each hospital or unit shall have the capability of providing or arranging for emergency services 24 hours per day, seven days per week.
2. Any comprehensive physical rehabilitative program shall provide through the use of qualified professional personnel, at a minimum, the following clinical services:
 - a. Physical therapy;
 - b. Occupational therapy;
 - c. Speech therapy; and
 - d. Social services or psychological services.

NOTE: May be provided under contract or arrangement on an as needed basis.

3. A physician qualified by training, experience and knowledge of rehabilitative medicine shall be appointed as the Medical Director.
4. Nursing Services shall be under the direct supervision of a Registered Nurse who has a Master's Degree or be qualified by education and experience in Rehabilitative Nursing. If the Registered Nurse does not have the required credentials, a Master's prepared Registered Nurse shall be available as a consultant. The number of Registered Nurses, Licensed Practical Nurses and other nursing personnel shall be adequate to formulate and carry out the nursing components of the individual treatment plan for each patient. There shall be a Registered Nurse on duty 24 hours per day, seven days per week, to plan, assign, supervise and evaluate nursing care and to provide for the delivery of nursing care to patients.
5. A physician licensed in the State of Arkansas shall be responsible for each patient's general medical condition as needed. Medical services shall be available 24 hours per day, seven days per week as needed. Upon admission there shall be written orders for the immediate care of the

patient.

6. Policies and procedures shall be developed. The manual shall have evidence of ongoing review and/or revision. The first page of the manual shall have the annual review date, signature of the department supervisor and/or person(s) conducting the review.
 7. Clinically relevant educational programs shall be conducted on a regularly scheduled basis not less than 12 per year. There shall be evidence of program dates, attendance, and subject matter.
 8. Regular staff meetings shall be held at least monthly. Dated minutes of each meeting shall be kept in writing.
 9. There shall be an ongoing QA/PI program.
- B. Special Medical Record Requirements. (Refer also to Section 14, Health Information Services.) The medical record shall include:
1. Reason for referral to physical rehabilitation services or admission to the comprehensive physical rehabilitation program;
 2. History and physical examination including patient's clinical condition, functional strengths and limitations, indications and contra-indications for specific physical rehabilitative services and prognosis;
 3. Goals of treatment and the treatment plan, including any problem that may affect the outcome of physical rehabilitation services, and criteria for the discontinuation of services;
 4. Interdisciplinary treatment plans to include measurable goals of treatment and criteria for discharge. The plan shall include ongoing assessments as required by the patient's medical condition. Documentation of patient and family in the development of the treatment plan and resolution of problems and rehabilitation potential;
 5. A discharge summary that includes recommendations for further care; and
 6. Patient evaluation procedures, including treatment plan for each patient based on the functional assessment and evaluation. The initial treatment plan shall be developed within 24 hours, and a comprehensive individualized plan developed no later than one week after admission and updated at least monthly. The plan shall state the rehabilitative problem, goals and required therapeutic services, as well as prognosis, anticipated length of stay and discharge disposition.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- C. Physical Environment. The Rehabilitation Facility shall comply with Section 42, Physical Environment.
- D. Physical Facilities. The Rehabilitation Facility shall comply with Section 76, Physical Facilities, and Rehabilitation Facilities.

SECTION 41: RECUPERATION CENTERS.

Any facility which includes inpatient beds with an organized Medical Staff, and with medical services including physician services and continuous nursing services to provide treatment for patients who are not in an acute phase of illness but who currently require primarily convalescent or restorative services, shall be considered a recuperation center and shall comply with applicable Sections 1, Authority, through 72, Physical Facilities, Electrical Standards.

- A. Quality Assurance/Performance Improvement, Infection Prevention and Control, Pharmacy and Therapeutics, and Utilization Review.
 - 1. The Recuperation Center shall maintain a Quality Assurance/Performance Improvement Committee consisting of the Nurse Manager, Medical Director, and at least three other members of the center's staff, which shall meet at least quarterly to provide oversight and direction for the center's quality assurance/performance improvement activities. Minutes of the Quality Assurance/Performance Improvement Committee shall be maintained.
 - 2. QA/PI activities shall include ongoing monitoring, with identification of opportunities for improvement, actions taken, and evaluation of the results of actions. QA/PI activities shall be reported at least quarterly to the Medical Staff and Governing Body through the hospital-wide QA/PI program.
 - 3. Reporting of all infection prevention and control, medication and utilization review issues specific to the center shall be evident in the minutes of the hospital-wide Infection Prevention and Control, Pharmacy and Therapeutics and Utilization Review Committees. Frequency of reporting shall be defined in policies and procedures consistent with State laws.
- B. Patient identification. Patient armbands shall not be routinely used. Reasonable measures shall be used to identify patients.
- C. Restraints. See Section 13, Restraints.
- D. Documentation Requirements.
 - 1. An assessment of the patient's needs shall be completed by a Registered Nurse on admission.
 - 2. Each assessment shall be coordinated with all health professionals.
 - 3. The interdisciplinary team shall develop a comprehensive care plan based

RULES FOR CRITICAL ACCESS HOSPITALS 2021

on the patient's identified needs, measurable goals of treatment, methods of intervention, and documentation of resolution or continuance. There shall be documentation of the patient and family's participation in the development of the care plan.

4. Verbal/telephone orders shall be reduced to writing and countersigned by the physician.
- E. Physical Environment. The requirements in Section 44, Physical Facilities, Patient Accommodations (Adult Medical, Surgical, Communicable or Pulmonary Disease) shall apply to recuperation centers with the following exceptions:
1. The patient dining, recreation, and day room(s) may be in separate or adjoining rooms and shall have a total of 35 square feet per patient bed.
 2. Patient corridors shall have handrails on both sides of the corridors. A clear distance of one and one-half inches shall be provided between the handrail and the wall. The top of the gripping surface of handrails shall be 32 inches minimum and 36 inches maximum above the finish floor. Ends of handrails and grab bars shall be constructed to prevent snagging the clothes of patients. Exception, special care areas such as those serving children.
- F. Health Information Services. Applicable parts of item D. of Section 14, Health Information Services and Section 15, Medical Record Requirements for Outpatient Services, Emergency Room, Observation Services and Psychiatric Records.
- G. Nursing Services. A Registered Nurse shall observe each patient at least once per shift and the observations shall be documented in the patient's medical record.

SECTION 42: PHYSICAL ENVIRONMENT.

A. Building and Grounds.

1. The building and equipment shall be maintained in a state of good repair at all times.
2. Facilities and their premises shall be kept clean, neat and free of litter, rubbish.
3. Rooms for gas fired equipment shall not be used for storage except for noncombustible materials.
4. Portable equipment shall be supervised by the department having control of such equipment and shall be stored in areas which are not accessible to patients, visitors, or untrained personnel.
5. Exit Access Corridors shall be maintained clear and unobstructed of stationary and non-patient related portable equipment. Stationary or portable non-patient care furnishings or equipment shall not be stored in an Exit Access Corridor. Any portable equipment such as a gurney, wheelchair, linen care, etc. that is not actively used within a 30-minute time period is considered "Stored". The facility's fire plan and training program shall address the relocation of these items during a fire. Exit Access Corridors for Health Care Occupancies are those aisles, corridors and ramps required for exit access that are located outside of a "suite of sleeping rooms" greater than 5,000 sq. ft. or "suite of rooms" greater than 10,000 sp. Ft (area is defined as occupiable net floor space). Encroachments on the width of the means of egress in an Exit Access Corridor by stationary objects or furnishings shall not be allowed. The width of the means of egress in an Exit Access Corridor shall be defined by physical means such as corridor walls, columns, or other approved methods. The means of egress may provide both visual and physical barrier design characteristics conducive to establishing a common egress that provides for either a change in floor texture or self-illumination in the dark.

Alternative consideration: the Means of Egress Requirements for Health Care Occupancies of NFPA 101 (or equivalency per Section 43 of these rules).

6. Each hospital shall develop a written preventive maintenance plan. This plan shall be available to the Department for review at any time. Such plans shall provide for maintenance as recommended by manufacturer, applicable codes, or designer.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

7. The hand washing facilities in visitors' rest rooms and the handwashing facilities used by staff personnel shall be equipped with a soap dispenser, and a towel dispenser.
 8. A supply of hot water for patient use shall be available at all times. A weekly hot water temperature log shall be maintained.
 9. Heating, ventilating and air-conditioning (HVAC) systems shall be operated, and maintained in a manner to provide a comfortable and safe environment for patients, personnel, and visitors. An air filter change out log shall be maintained.
- B. Maintenance and Engineering.
1. The physical plant and equipment maintenance programs shall be under the direction of a person qualified by training and/or experience and licensed where required.
 2. Equipment Management Program (EMP). There shall be a preventive maintenance program designed to assure the electrically powered patient care equipment used to monitor, diagnose, or provide therapy, performs properly and safely. This program shall be administered by individuals qualified through training and/or experience or by procuring a contractual maintenance agreement. The following are minimum program elements:
 - a. A current list of electrically powered patient care equipment shall be maintained regardless of location or ownership;
 - b. Each device, or identical group of devices, shall have a procedure establishing minimum criteria against which performance and safety are measured. The elements of these procedures shall be based on the manufacturer's directions;
 - c. Each device shall be tested at intervals of not more than six months unless there is documented evidence that less frequent testing is justified;
 - d. Historical records documenting acceptable performance as established by the procedures shall be maintained;
 - e. A program to identify and repair equipment failures shall be maintained;
 - f. User or owner departments shall be notified of the status of their equipment when it will be out of service more than 24 hours;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

4. Life Safety Management Program (LSM). There shall be a preventive maintenance program designed to assure that all circuits of fire alarm and detection systems shall be inspected, tested and maintained in accordance with NFPA 72. Analog detection devices that provide automatic self-testing are exempt from the quarterly testing requirement. This program shall be administered by individuals qualified through training and/or experience or by procuring a contractual maintenance agreement. This program shall consist of the following minimum elements:
 - a. A list of all fire protection equipment or component groups shall be maintained;
 - b. Equipment and/or component groups, shall have a procedure establishing minimum criteria against which performance and safety are measured. The elements of these procedures shall be based on the manufacturer's recommendations and/or the experience of the repair technician or operator;
 - c. Fans or dampers in air handling and smoke management systems shall be reliable and functional at all times;
 - d. Automatic fire extinguishing systems shall be inspected and tested annually; actual discharge of the fire extinguishing system is not required. Records documenting acceptable performance as established by the procedures shall be maintained;
 - e. A program to identify and repair equipment and/or component group failures shall be maintained;
 - f. Systems for transmitting fire alarms to the local fire department shall be reliable and functional at all times;
 - g. There shall be operator and maintenance instructions for each piece of equipment and/or component group on the list;
 - h. Individuals shall be trained to operate and maintain all equipment and/or component group on the list; and
 - i. Portable fire extinguishers shall be clearly identified.
5. Emergency Procedures Program (EPP). There shall be written emergency procedures or a disaster management plan for utility system disruptions or failures which address the specific and concise procedures to follow in the event of a utility system malfunction or failure of the water supply, hot water system, medical gas system, sewer system, bulk waste disposal system, natural gas system, commercial power system, communication system, boiler or steam

delivery system.

- a. These procedures shall be kept separate from all other policy and procedure manuals as to facilitate their rapid implementation.
 - b. These procedures shall contain but are not limited to the following information:
 - 1) A method of obtaining alternative sources of essential utilities;
 - 2) A method of shutoff and location of valves for malfunctioning systems;
 - 3) A method of notification of hospital staff in affected areas; and
 - 4) A method of obtaining repair services.
6. Policies and procedures shall include job descriptions and orientation practices for employees.
 7. Policies and procedures shall have evidence of ongoing review and/or revision. The first page of each manual shall have the annual review date, signature of the department supervisor and/or person(s) conducting the review.
 8. Relevant educational programs shall be conducted at regularly scheduled intervals with no less than six per year. There shall be evidence of program dates, attendance and subject matter.
 9. The department director shall ensure that all employees annually attend mandatory educational programs on the fire safety, back safety, infection prevention and control, universal precautions, emergency procedures and disaster preparedness or make provisions to conduct these departmentally.
 10. There shall be sufficient supervisory and support personnel to provide maintenance services in relation to the size and complexity of the facility and the services that are provided.
 11. An ongoing QA/PI program with a liaison with the Infection Prevention and Control and Safety Committees.
- C. Environmental Services.
1. The environmental services shall be under the direction of a person qualified by training and/or experience and licensed where required.
 2. There shall be written policies and procedures which include:

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- a. Cleaning of the physical plant;
 - b. The use, care, and cleaning of equipment; and
 - c. Specific cleaning methods used for:
 - 1) Operating rooms;
 - 2) Delivery rooms;
 - 3) Nurseries/infant care units;
 - 4) Emergency rooms;
 - 5) Isolation areas; and
 - 6) Other units as appropriate.
 - d. Job descriptions;
 - e. Orientation practices;
 - f. Safety practices;
 - g. Infection prevention and control measures;
 - h. Methods used for evaluation of cleaning effectiveness;
 - i. Personal hygiene;
 - j. The selection of housekeeping and cleaning supplies; and
 - k. The proper use of housekeeping and cleaning supplies.
3. The policy and procedure manual shall have evidence of ongoing review and/or revision. The first page of each manual shall have the annual review date, signature of the department and/or person(s) conducting the review.
 4. Relevant in-service educational programs shall be conducted at regularly scheduled intervals with no less than six per year. There shall be written documentation with employee signatures, program title/subject, presenter, date, and outline or narrative of presented program.
 5. Expendable supplies (i.e., soap, paper products, etc.) shall be stored in a manner

RULES FOR CRITICAL ACCESS HOSPITALS 2021

that shall prevent their contamination prior to use.

6. Solutions, cleaning compounds, disinfectants, vermin control chemicals, and all other potentially hazardous substances that are used in connection with environmental services shall be:
 - a. Kept in containers which accurately reflect at least the following:
 - 1) Content name;
 - 2) Concentration of solution;
 - 3) Expiration date and lot number;
 - b. Stored in a secured area. Under no circumstances shall these substances be stored in or near food storage or food preparation areas;
 - c. Selected by the director of environmental services or other appointed qualified person. The Infection Prevention and Control Committee shall initially approve the list of chemicals used in the facility and thereafter, any additions or deletions to the list.
 7. A designee from this department shall be a member of the Infection Prevention and Control Committee.
 8. The use of common towels and common drinking utensils shall be prohibited.
 9. Dry, or untreated dusting, sweeping, or mopping, except vacuum type cleaning shall be prohibited within the facility.
 10. There shall be an ongoing QA/PI Program with a mechanism for reporting results.
- D. Linen Services.
1. Laundry services shall be under the direction of a person qualified by training and/or experience and licensed where required.
 2. There shall be sufficient support personnel to provide linen services in relation to the size and complexity of the facility and the services that are provided.
 3. There shall be written policies and procedures which include:
 - a. Collection of soiled, wet, and contaminated linen;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- b. Transporting of soiled, wet, and contaminated linen to the laundry service or to a designated area for commercial pick-up;
 - c. Storage of soiled, wet, and contaminated linen until laundering or being picked up by the commercial laundry;
 - d. Storage of clean linen; and
 - e. Specific laundry requirements (type detergent, sours, bleach, time and temperatures used) for washing:
 - 1) New linen;
 - 2) Diapers;
 - 3) Soiled, wet, and contaminated linen.
 - f. Personal hygiene;
 - g. Evaluation of washing/cleaning effectiveness;
 - h. Job descriptions;
 - i. Orientation practices for new employees;
 - j. Safety practices; and
 - k. Infection prevention and control measures.
4. Policies and procedures for Linen Services shall have evidence of ongoing review and/or revision. The first page of the manual shall have the annual review date, signature of the department supervisor and/or person(s) conducting the review.
5. Relevant in-service educational programs shall be conducted at regularly scheduled intervals with no less than six per year. There shall be written documentation with employee signature, program title/subject, presenter, date and outline or narrative of presented program.
6. Facility linen service:
- a. Sorting of soiled laundry shall be done in a designated area;
 - b. Tables or bins shall be provided for sorting of soiled laundry;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- c. Lint traps shall be provided on dryers and shall be cleaned regularly;
- d. Prerinsing shall be done in the laundry service not in showers, bathtubs or lavatories;
- e. Removal of solid soil shall be done in soiled utility rooms or rooms that are designated for this purpose;
- f. Patient clothing may be washed in the patient area if a separate equipped laundry room is available;
- g. A rinsing sink shall be provided in the soiled linen area of the laundry;
- h. Hot water supplied to laundry areas shall be in accordance with Table 9 of the Appendix;
- i. Linen contained in hot water soluble plastic bags (identified as being contaminated) shall be placed directly into the washing machine without being removed from the bag for sorting;
- j. A lavatory equipped with wrist action controls, a soap dispenser and a towel dispenser shall be provided in the laundry for use by the personnel;
- k. Personnel with infectious disease or open wounds shall not be permitted in the laundry; and
- l. Personnel assigned to laundry duties shall wash their hands:
 - 1) After handling wet or soiled laundry;
 - 2) Before leaving the laundry;
 - 3) After using the toilet; and
 - 4) As often as is necessary to maintain good hygiene.

NOTE: Laundry equipment and installation requirements are set forth in Section 64, Physical Facilities, Linen Service.

- 7. Soiled linen from isolation areas, surgical cases, etc., shall be placed into impervious bags and, if leakage occurs, bagged into a second bag with proper identification. Suitable precautions shall be taken in transport,

RULES FOR CRITICAL ACCESS HOSPITALS 2021

handling, and processing.

8. Soiled, wet, and contaminated linens shall be transported in a closed container.
9. Soiled, wet, and contaminated linens shall be stored in closed containers or impervious bags in designated areas off the floor. Areas for storage of soiled, wet, and contaminated linens shall have forced ventilation to the outside of the building.
10. All new clothing, linen and diapers shall be laundered before being used.
11. There shall be a designated area for the storage of clean linens.
12. The linen service within the facility shall have a capacity sufficient to process a continuous supply of clean laundry ready for use.
13. Temperature used in the dryer will depend on the type fabric. An employee shall be present at all times when the dryer is in operation.
14. There shall be an ongoing QA/PI Program with a mechanism for reporting results.
15. Linen Service shall include a written contingency plan indicating an alternative provision that may be followed in the event the laundry is unable to meet the production demand of the facility.
16. Separate containers for the disposal of infectious waste and sharps shall be located in the soiled linen sorting area.
17. Laundry workers handling infectious linens shall wear protective equipment, including but not limited to waterproof, puncture-resistant gloves, protective over-clothing, and where necessary, face shields or goggles.
18. Facilities which do not have linen services:
 - a. The facility shall determine that all launderable items are processed in a commercial laundry in accordance with standards set forth in this section and shall conduct annual onsite inspections of the commercial laundry and shall require written verification of compliance by the laundry.
 - b. Soiled, wet, and contaminated laundry shall be stored in a the commercial laundry;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- c. A designated clean area shall be provided for receiving clean laundry and shall be separate from the soiled linen area;
 - d. Clean linen shall be packaged and protected from contamination during transportation and storage.
19. Refer to Section 18, Infection Prevention and Control, for additional requirements.
- E. Safety Services.
- 1. There shall be an effective program to enhance safety within the facility and grounds. The program shall be monitored by a Safety Committee appointed by the Administrator. Committee members may be selected from areas such as Administration, Nursing, Maintenance, Housekeeping, Laboratory, Respiratory Care, Rehabilitation Services, the Medical Staff and others as appropriate.
 - 2. The Safety Committee shall meet a minimum four times per year to fulfill safety objectives. Minutes of each meeting shall be recorded and kept in the facility.
 - 3. The Administrator shall designate a specific individual to carry out policies established by the Committee and to gather data for the Committee to study safety related incidents.
 - 4. Safety policies and procedures shall have evidence of ongoing review and/or revision. The first page of each manual shall have the annual review date, signature of the department supervisor and/or person(s) conducting the review. Safety policies and procedures shall include:
 - a. Facility wide hazard surveillance program;
 - b. Response to medical-device recalls and hazard notices;
 - c. Safety education;
 - d. Reporting of all accidents, injuries, and safety hazards;
 - e. External and internal disaster plans;
 - f. Fire safety; and
 - g. Safety devices and operational practices.
 - 5. The orientation program for the facility shall include the importance of general safety, fire safety and the responsibility of each individual to the program.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

6. The Safety Committee shall have the following functions:
 - a. Monitoring the results of the safety program and analyzing the effectiveness of the program annually;
 - b. Monitor fire drills and disaster drills at required intervals;
 - c. Conclusions, recommendations, and actions of the committee shall be reported to the Board at a minimum annually; and
 - d. Ensuring each department or service shall have a safety policy and procedure manual within their own area that is a part of the overall facility safety manual and establishes safety policies and procedures specific to each area.
7. Fire extinguishers shall be provided in adequate numbers, of the correct type, and shall be properly located and installed. Personnel shall be trained in the proper use of fire extinguishers and equipment. Personnel shall follow procedures in fire containment and evacuating patients in case of fire or explosion. There shall be an annual check of all fire extinguishers by qualified persons in accordance with the applicable sections of the National Fire Protection Association's Standard 10 (NFPA 10). The date the check was made and the initials of the inspector shall be recorded on the fire extinguisher or on a tag attached to the extinguisher.
8. Any fire or disaster event at the facility shall be reported immediately to the Arkansas Department of Health by telephone 501-661-2201 during regular working hours or to 501-661-2136 after normal working hours, holidays and weekends. If any fire(s) or disaster is not reported to the Department, the facility is subject to a fine, refer to item J. of Section 4, Licensure and Codes.
9. There shall be policies and procedures governing the routine methods of handling and storing flammable and explosive agents, particularly in operating rooms, delivery rooms, laundries and in areas where oxygen therapy is administered.
10. There shall be keys available to assure prompt access to all locked areas. All doors shall be devised so they can be opened from the inside of the locked area. Special door locking devices are acceptable in limited areas. Usage is subject to all codes and regulations.
11. All required exit doors shall remain unlocked per NFPA requirements.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

12. A list of Material Safety Data Sheets (MSDS) for solutions, cleaning compounds, disinfectants, vermin control chemicals, and other potentially hazardous substances used in connection with the facility shall be readily available to the Safety Committee, Emergency Room, Environmental Services and as directed by facility policy and procedures.

SECTION 43: PHYSICAL FACILITIES.

A. General Considerations.

1. The requirements set forth herein have been established by the Department and constitute minimum requirements for the design, construction, renovation, and repair of facilities requiring licensure under these rules.
2. Facilities shall be accessible to the public, staff, and patients with physical disabilities. Minimum requirements shall be those set forth by the Arkansas State Building Services, Minimum Standards and Criteria – Accessibility for the Physically Disabled Standards.
3. Projects involving renovation and additions to existing facilities shall be programmed and phased to minimize disruption of the existing functions. Access, exits and fire protection shall be maintained for the occupant's and the facility's safety.
4. Codes and Standards. Nothing stated herein shall relieve the owner from compliance with building codes, ordinances, and regulations which are enforced by city, county, or other State jurisdictions. Where such codes, ordinances, and regulations are not in effect, the owner shall consult the state building codes for all components of the building type which are not specifically covered by these minimum requirements. In location where there is a history of tornadoes, floods, earthquakes or other regional disasters, planning and design shall consider the need to protect the occupants and the facility.

B. Occupancy: Each licensed facility or portion of a licensed facility shall be classified as indicated below:

1. **General Hospital:** A facility or portion of a facility licensed by the Department as a General Hospital that provide for patient care, treatment, or diagnosis on a 24-hour basis and provides treatment or anesthesia for patients that renders the patients incapable of taking action for self-preservation under emergency conditions without the assistance of others.
2. **Mobile, Transportable, and Relocatable Unit:** A portion of a facility licensed by the Department that meets the definitions provided in Section 54 for mobile, transportable, and relocatable units.
3. **Outpatient Care Facility:** A portion of a facility licensed by the Department that provides patient care, treatment or diagnosis on a less than 24-hour basis and does not provide treatment or anesthesia for patients that renders the patients incapable of taking action for self-preservation under emergency conditions without the assistance of others.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

Outpatient care facilities may be utilized on occasion by hospital inpatients provided that such use is limited to a less than 24 hour basis.

4. Rehabilitation Facility: A facility or portion of a facility licensed by the Department as a Rehabilitation Facility.
 5. Non-Healthcare Occupancy: A portion of a licensed facility that does not contain areas intended for patient care, treatment, or diagnosis and does not contain equipment (mechanical, electrical, plumbing, communication, fire alarm, etc.) that serves areas intended for patient care, treatment, or diagnosis.
- C. Multiple Occupancy: Facilities may contain more than one occupancy (as described above) provided each different occupancy is separated from all other occupancies by a 2-hour fire resistive rated smoke barrier.
- D. Construction Projects: Each construction project shall be classified as indicated below:
1. Addition: A project that increases the floor area of a licensed facility.
 2. Repair: A project that provides for the repair or renewal of a licensed facility or portion of a licensed facility solely for the purpose of its maintenance.
 3. Simple Renovation: A project other than repair that meets all of the criteria listed below:
 - a. The project does not increase the floor area of a licensed facility.
 - b. The project does not change the occupancy of a licensed facility or portion of a licensed facility.
 - c. The project does not involve more than two (2) smoke compartments.
 - d. The smoke compartments affected by the project were completely protected by an automatic sprinkler system prior to the project or the project provides for the installation of a complete automatic sprinkler system in all smoke compartments that are affected by the project.
- E. Applicable Requirements Based upon Occupancy:
1. Existing Facilities: Existing facilities that do not comply with these rules shall be permitted to continue in service, provided the lack of conformity with these rules does not present a serious hazard to the occupants as

RULES FOR CRITICAL ACCESS HOSPITALS 2021

determined by Health Facility Services or other authorities having jurisdiction.

2. General Hospital: Facilities or portions of facilities classified as a General Hospital occupancy shall be designed, constructed, and renovated in accordance with the Sections of these rules listed below and all publications and Appendices referenced by these Sections.
 - a. Section 42
 - b. Section 43
 - c. Section 44 through 53
 - d. Sections 54 through 76
3. Mobile, Transportable, and Relocatable Unit: Facilities or portions of facilities classified as a Mobile, Transportable, and Relocatable Unit occupancy shall be designed, constructed, and renovated in accordance with the Sections of these rules listed below and all publications and Appendices referenced by these Sections.
 - a. Section 42
 - b. Section 43
 - c. Section 54
4. Outpatient Care Facility: Facilities or portions of facilities classified as Outpatient Care Facility occupancy shall be designed, constructed, and renovated in accordance with the Sections of these rules listed below and all publications and Appendices referenced by these Sections.
 - a. Section 42
 - b. Section 43
 - c. Section 75
5. Rehabilitation Facility: Facilities or portions of facilities classified as an Outpatient Care Facility occupancy shall be designed, constructed, and renovated in accordance with the Sections of these rules listed below and all publications and Appendices referenced by these Sections.
 - a. Section 42
 - b. Section 43

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- c. Section 76
6. Non-Healthcare Occupancy Facilities or portions of facilities classified as a Non-Healthcare occupancy shall be designed, constructed, and renovated in accordance with the Sections of these rules listed below and all publications and Appendices referenced by these Sections.
 - a. Section 42
 - b. Section 43
- F. Applicable Requirements Based upon the Type of Project:
 1. General:
 - a. Where renovation work is done within an existing facility, all new work, or additions, or both, shall comply, insofar as practical with applicable sections of these rules and appropriate sections of National Fire Protection Association (NFPA) 101 Life Safety Code covering new occupancies. Where major structural elements make total compliance impractical or impossible, exceptions will be considered.
 - b. In renovation projects and projects involving additions to existing facilities, only that portion of the total facility affected by the project shall comply with applicable sections of these rules and with appropriate parts of NFPA 101 covering new occupancies. Existing portions of the facility that are not included in the project but essential to the functioning of a complete facility shall comply (at a minimum) with the appropriate sections of NFPA 101 covering existing occupancies. Existing portions of the facility that receive less than substantial amounts of new work, shall also comply (at a minimum) with the appropriate sections of NFPA 101 covering existing occupancies.
 - c. Facilities or portions of facilities shall be permitted to be occupied during construction, renovation, and repair only where required means of egress and required fire protection features are in place and continuously maintained for the portion occupied or where alternate life safety measures acceptable to Health Facility Services and other authorities having jurisdiction are in place.
 2. Addition, Simple Renovation, and Complex Renovation shall be designed, constructed, and renovated in accordance with the applicable Sections of these rules and all Appendices and publications referenced by these Sections.
 3. Repair projects shall be designed and constructed in a manner that does not

RULES FOR CRITICAL ACCESS HOSPITALS 2021

diminish the safety level that existed prior to the start of the work.

G. Project Review and Approval Process.

1. Coordination: Health Facilities Services will coordinate the review and approval process for all offices of the Department.
2. Addition or Complex Renovation Projects shall be reviewed and approved by Health Facility Services as indicated below:
 - a. Drawing Review and Approval Process:
 - 1) Submission of Plan Review Fee: A plan review fee in the amount of one percent of the total cost of construction or \$500.00, whichever is less, shall be paid for the review of plans and specifications. The plan review fee check is to be made payable to Arkansas Department of Health. A detailed estimate shall accompany the plans unless the maximum fee of \$500.00 is paid.
 - 2) Submission of Functional Program: Refer to Section 43, Paragraph H.
 - 3) Submission of Site Location: Refer to paragraph Section 43, Paragraph I.
 - 4) Submission of Preliminary Plans: Refer to Section 43, Paragraph J.
 - 5) Review of Functional Program, Site Location, and Preliminary Plans: Health Facility Services shall review the Functional Program, Site Location, and Preliminary Plans and forward a written response with comments to the Facility.
 - 6) Submission of Final Construction Documents: Refer to Section 43, Paragraph K.
 - 7) Review and Approval of Final Construction Documents: Health Facility Services shall review the Final Construction Documents and forward a written response with comments to the Facility and the Design Professional. Health Facility Services shall have a minimum of six (6) weeks to review Final Construction Documents. The written response shall indicate whether or not the Final Construction Documents are approved. If the Final Construction Documents are not approved, the written response shall indicate the design modifications required to secure approval.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- 8) Plans may be certified by a Licensed Architect or Professional Engineer with respect to compliance with the applicable codes, rules, and standards.
 - b. Approval to Begin Construction: Facilities may proceed with Addition and Complex Renovation projects after receiving a letter from Health Facility Services stating that the Final Construction Documents have been reviewed and approved and after receiving approval from other authorities having jurisdiction.
 - c. Site Inspections During Construction: Refer to Section 43, Paragraph L.
 - d. Final Site Inspection: Refer to Section 43, Paragraph M.
2. Repair: Repair projects do not require Health Facility Services review and approval.
 3. Simple Renovation Projects submitted to Health Facility Services shall be reviewed and approved by Health Facility Services as indicated below:
 - a. Drawing Review and Approval Process:
 - 1) Submission of Plan Review Fee: A plan review fee in the amount of one percent of the total cost of construction or \$500.00, whichever is less, shall be paid for the review of plans and specifications. The plan review fee check is to be made payable to the Arkansas Department of Health. A detailed estimate shall accompany the plans unless the maximum fee of \$500.00 is paid.
 - 2) Submission of Functional Program: Refer to Section 43, Paragraph H.
 - 3) Submission of Final Construction Documents: Refer to Section 43, Paragraph K.
 - 4) Review and Approval of Final Construction Documents: Health Facility Services shall review the Final Construction Documents and forward a written response with comments to the Facility. Health Facility Services shall have a minimum of six (6) weeks to review Final Construction Documents. The written response shall indicate whether or not the Final Construction Documents are approved. If the Final Construction Documents are not approved, the written response shall indicate the design modifications required to secure approval.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- 5) Plans may be certified by a Licensed Architect or Professional Engineer with respect to compliance with the applicable codes, rules, and standards.
 - b. Approval to Begin Construction: Facilities may proceed with Simple Renovation projects after receiving a letter from Health Facility Services stating that the Final Construction Documents have been reviewed and approved and after receiving approval from other authorities having jurisdiction.
 - c. Site Inspections During Construction: Refer to Section 43, Paragraph L.
 - d. Final Site Inspection: Refer to Section 43, Paragraph M.
- H. Functional Program.

The facility shall supply for each project (other than repair project) a functional program that describes the purpose of the project and indicates the estimated cost of construction.

I. Site Location.

1. Location.

- a. The site of any medical facility should be easily accessible to the community and to service vehicles such as fire protection apparatus.
- b. Facilities should be located with due regard to the accessibility by public transportation for patients, staff, and visitors, and availability of competent medical and surgical consultation.
- c. The facility should have security measures for patients, personnel, and the public consistent with the conditions and risks inherent in the location of the facility. These measures shall include a program designed to protect human and capital resources.
- d. The facility should be located to provide reliable utilities (water, natural gas, sewer and electricity).
- e. The site should afford good drainage and shall not be subject to flooding nor be located near insect breeding areas, excessive noise, nor other nuisance producing locations, nor near airports, railways, air pollution, penal institutions (except prison infirmaries), or a cemetery.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

2. Roads and Parking.
 - a. Paved roads and walks shall be provided within the lot lines to provide access to the main entrance and service entrance, including loading and unloading docks for delivery trucks. Hospitals having an organized emergency services department shall have the emergency entrance well marked to facilitate entry from the public roads or streets serving the site. Access to the emergency entrance shall not conflict with other vehicular traffic or pedestrian traffic. Paved walkways shall be provided for necessary pedestrian traffic.
 - b. Each facility shall have parking spaces to satisfy the minimum needs of patients, employees, staff, and visitors. In the absence of a formal parking study, each facility shall provide not less than one space for each day shift staff member and employee plus one space for each patient bed. This ratio may be reduced in an area convenient to a public transportation system or to a public parking facility if proper justification is given and provided that approval of any reduction is obtained from the Department. Additional parking shall be required to accommodate outpatient and other services when they are provided. Space shall be provided for emergency and delivery vehicles.
3. Subsoil Investigation. Subsoil investigation shall be made to determine the subsurface soil and water conditions. The investigation shall include a sufficient number of test pits or test borings to determine, in the judgment of the architect and the structural engineer, the true subsurface conditions. Results of the investigation shall be available in the form of a soil investigation report or a foundation engineering report. The investigation shall be made in close cooperation with the architect and structural engineer and shall contain detailed recommendations for foundation design and gradings. The following is a general outline of the suggested scope of soil investigation:
 - a. The borings or test pits shall extend into stable soils well below the bottom of any proposed foundations. A field log of the borings shall be made and the thickness, consistency, and character of each layer recorded;
 - b. The amount and elevation of groundwater encountered in each pit or boring and its probable variation with the seasons and effect on the subsoil shall be determined. High or low water levels of nearby bodies of water affecting the ground level shall also be determined;
 - c. Laboratory tests shall be performed to determine the safe bearing value and compressibility characteristics of the various strata encountered in each pit or boring;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- d. Maximum depth of frost penetration below surface of the ground shall be recorded;
 - e. Tests shall be made to determine whether the soil contains alkali in sufficient quantities to affect concrete foundations;
4. Approval. The new building site shall be inspected and approved by the Department before construction begins.
- J. Preliminary Plans: Preliminary plans submitted to Health Facility Services shall include minimum the following information:
1. Floor plans drawn to scale that indicate room names, room dimensions, corridor dimensions, locations of fire resistive rated partitions, and locations of rated smoke barriers.
 2. An existing floor plan indicating existing spaces and exits and their relationship to the new construction (renovation projects only)
 3. Building sections that establish the proposed construction type and fire rating. Sections shall be drawn at a scale sufficiently large to clearly present the proposed construction system.
 4. A site plan that indicates the location of proposed roads, walks, service and entrance courts, parking and orientation.
 5. Simple horizontal and vertical space diagrams that indicate the relationship of various departments and services to each other the general room arrangement in each department.
 6. A narrative description of proposed mechanical, electrical, and fire protection systems.
- K. Final Construction Documents.
1. Construction Documents shall be prepared by an architect and/or professional engineer licensed by the State of Arkansas.
 2. Architectural construction documents shall be prepared by an architect and engineering construction documents (structural, mechanical, electrical, and civil) shall be prepared by a qualified engineer. The documents shall be stamped with appropriate seals for each discipline.
 3. Periodic observations of construction shall be provided and documented by each design professional. Design professionals shall verify that the construction is in accordance with the construction documents and that the Record Drawings are properly maintained.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

4. The construction contract shall contain a provision to withhold progress payments to the contractor until the Record Drawings are current.
5. Final Construction Documents shall include drawings and specifications. Separate drawings and specifications shall be prepared for each of the following branches of work: architectural, structural, mechanical, electrical, life safety and fire protection.
6. The drawings shall include the following information:
 - a. Architectural.
 - 1) Approved plan showing all new topography, newly established levels and grades, existing structures on the site (if any), new buildings and structures, roadways, walks, and the extent of the areas to be planted. All structures and improvements removed under the construction contract. A print of the survey included with the working drawings.
 - 2) Plan of each floor, roof, and all intermediate levels.
 - 3) Elevations of each exterior wall.
 - 4) Sections through building.
 - 5) Scale details as necessary to properly indicate portions of the work.
 - 6) Schedule of finishes.
 - b. Equipment.
 - 1) Large scale drawings of typical and special rooms indicating all fixed equipment and major items of furniture and movable equipment.
 - 2) The furniture and movable equipment not included in the construction contract shall be indicated by dotted lines.
 - c. Structural.
 - 1) Plans of foundations, floors, roofs, and all intermediate levels shall show a complete design with sizes, sections, and the relative location of the various members and schedule of beams, girders, and columns.
 - 2) Dimensional floor levels, column centers and offsets.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- 3) Special openings.
 - 4) Details of all special connections, assemblies, and expansion joints.
 - 5) Name of the governing building code.
- d. Mechanical.
- 1) Heating, piping, and air-conditioning systems:
 - a) Steam heated equipment, such as sterilizers, warmers, and steam tables;
 - b) Heating and steam mains and branches with pipe sizes;
 - c) Diagram of heating and steam risers with pipe sizes;
 - d) Sizes, types, and heating surfaces of boilers and oil burners, if any;
 - e) Pumps, tanks, boiler breeching and piping, and boiler room accessories;
 - f) Air-conditioning systems with required equipment, water refrigerant piping, and ductwork showing required fire smoke/dampers;
 - g) Air quantities for all room supply, return, and exhaust ventilating duct openings;
 - h) A ventilation schedule specifying the following information: room number, room name, room volume (ft³), required room air changes, required outside air changes, required air movement relative to adjacent area, required air filtration (% efficiency), required room total supply air quantity (CFM), required room exhaust air quantity (CFM), design room total supply air quantity (CFM), design room return air quantity (CFM), design outside air quantity (CFM), design room exhaust air quantity (CFM), design room air filtration (% efficiency), room design summer (°F) dry bulb/wet bulb (DB/WB), room design winter (°F) DB/WB, outside

RULES FOR CRITICAL ACCESS HOSPITALS 2021

air design summer ('F) DB/WB, and outside air design winter ('F) DB/WB.

- i) Air filter design pressure drop both clean and dirty.
- 2) Plumbing, drainage, and standpipe systems:
 - a) Size and elevation of street sewer, house sewer, house drains, and street water main;
 - b) Locations and size of soil, waste, and vent stacks with connections to house drains, clean outs, fixtures and equipment;
 - c) Size and location of hot and cold circulating mains, branches, and risers from the service entrance and tanks;
 - d) Riser diagram to show all plumbing stacks with vents, water risers, and fixture connections;
 - e) Gas, oxygen, and special connections;
 - f) Standpipe and sprinkler systems;
 - g) Plumbing fixtures and equipment which require water and drain connections;
 - 3) Elevators and dumbwaiters: Details and dimensions of shaft, pit and machine room, pit sumps with alarms when required, sizes of car platform and doors.
 - 4) Kitchens, laundry, refrigeration, and laboratories detailed at a satisfactory scale (1/4 inch scale) to show the location, size, and connection of all fixed and moveable equipment.
- e. Electrical.
- 1) All electrical wiring, outlets, smoke detectors, and equipment which require electrical connections.
 - 2) Electrical service entrance with switches, and feeders to the public service feeders, characteristics of the light and power current and transformers and their connections, if located in the building.
 - 3) Plan and diagram showing main switchboard power panels,

light panels and equipment. Diagram of feeder and conduit sizes with a schedule of feeder breakers or switches.

- 4) Light outlets, receptacles, switches, power outlets, and circuits.
 - 5) Telephone layout showing service entrance, telephone switchboard, terminal boxes, and telephone outlets.
 - 6) Nurse call systems with outlets for beds, nurse's stations, door signal lights, annunciators, and wiring diagrams.
 - 7) Staff paging and doctor's in-and-out registry systems with all equipment wiring, if provided.
 - 8) Fire alarm and or security system with stations, signal devices, control board, and wiring diagrams.
 - 9) Emergency electrical system with outlets, transfer switch, source of supply, feeders, and circuits.
 - 10) Medical gas alarm systems.
 - 11) All other electrically operated systems and equipment.
- f. Life Safety and Fire Protection.
- 1) Limits of each smoke compartment.
 - 2) Location of each smoke barrier wall.
 - 3) Dimensions and gross areas of each smoke compartment.
 - 4) Location of each fire rated wall or partition, fire separation wall and horizontal exit.
 - 5) Location of each exit sign, fire pull station, and extinguisher cabinet and extinguisher.
 - 6) Travel distance(s) from the most remote location(s) in the building to an exit as defined by NFPA 101 (i.e., horizontal exit, exit passageway, enclosed exit stair, exterior exit door).
- g. Specifications.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- 1) Specifications shall supplement the drawings to fully describe types, sizes, capacities, workmanships, finishes, and other characteristics of all materials and equipment and shall include the following:
 - a) Cover or title sheet with architectural seal;
 - b) Index;
 - c) General conditions;
 - d) General requirements;
 - e) Sections describing material and workmanship in detail for each class of work.
- h. All construction documents and specifications shall be approved by the Department prior to the beginning of construction and a letter shall be issued from the licensing agency granting approval to commence with construction. The Department shall have a minimum of six weeks to review construction documents and specifications. Health Facility Services shall coordinate the plan review with other Divisions in the Department. Penalties for starting construction without Department approval see Section 4.I, Licensure and Codes.
- L. Site Inspection During Construction. The Department shall inspect the project during the construction process as indicated below:
 1. This Department is to be notified when construction begins and a construction schedule shall be submitted to determine inspection dates.
 2. Representatives from the Department shall have access to the construction premises and the construction project for purposes of making whatever inspections deemed necessary throughout the course of construction.
 3. Any deviation from the accepted construction documents shall not be permitted during construction, until the written request for change(s) in the construction is approved by this Department.
- M. Final Site Inspection.
 1. Upon completion of construction and prior to the approval by the Department to occupy and use the facility, the owner shall be furnished a complete set of recorded drawings and a complete set of installation, operation, and maintenance manuals and parts lists for the installed

equipment.

2. A list of final site inspection items has been provided in the Table 5 of the Appendix.
3. No facility shall occupy any new structure or major addition or renovation space until the appropriate permission has been received from the local building and fire authorities and licensing agency.

N. Referenced Publications.

1. General: These rules include references to other codes and standards. The most current codes and standards adopted at the time of this publication are used. Later issues will normally be acceptable where requirements for function and safety are not reduced; however, editions of different dates may have portions renumbered or re-titled. Care shall be taken to ensure that appropriate sections are used.
2. Publications adopted in whole by these rules are as listed below:
 - a. American National Standards Institute (ANSI) Standard A17.1, "American National Standard Safety Code for Elevators, Dumbwaiters, Escalators and Moving Stairs."
 - b. American Society of Civil Engineers, (ASCE), "Minimum Design Loads for Buildings and Other Structures."
 - c. Arkansas Building Authority, Minimum Standards and Criteria – Accessibility for the Physically Disabled Standards.
 - d. National Council on Radiation Protection (NCRP), Report No. 33, "Medical X-ray and Gamma Ray Protection for Energies Up to 10 MeV Equipment Design and Use, 1986."
 - e. National Council on Radiation Protection (NCRP), Report No. 49, "Medical X-ray and Gamma Ray Protection for Energies up to 10 MeV Structural Shielding Design and Evaluation, 1976."
 - f. National Council on Radiation Protection (NCRP), Radiation Protection Design Guidelines for 0.1pi29100, MeV Particle Accelerator Facilities.
 - g. National Fire Protection Association 101, "Life Safety Code, 2000 Edition". Note that "Mandatory References" are listed in Chapter 2 of this document.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

Government Printing Office (GPO), Washington, DC 20402. Copies of non-government publications can be obtained at the addresses listed below.

1. Air Conditioning and Refrigeration Institute, 1501 Wilson Boulevard, Arlington, VA 22209.
2. American National Standards Institute, 1430 Broadway, New York, NY 10018.
3. American Society of Civil Engineers, 345 East 47 10017 Street, New York, NY
4. American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.
5. American Society of Heating, Refrigerating, and Air Conditioning, 1741 Tullie Circle, NE, Atlanta GA 30329.
6. Arkansas State Building Services, 1515 West 7th Street, Suite 700, Little Rock, AR 72201.
7. Arkansas Department of Labor, 10421 West Markham, Little Rock, AR 72205.
8. Illuminating Engineering Society of North America (IESNA), 120 Wall Street, 17th Floor, New York, NY 10005.
9. National Council on Radiation Protection and Measurement, 7910 Woodmont Avenue, Suite 1016, Bethesda, MD 20814.
10. National Fire Protection Association, 1 Batterymarch Park, Post Office Box 9101, Quincy, MA 02269-9101.
11. International Building Code Congress International, Inc., 900 Montclair Road, Birmingham, AL 35213.

P. Interpretations of Requirements.

1. Memorandum of Understanding: Conflicts between the Arkansas Fire Prevention Code and NFPA 101 Life Safety Code are to be resolved using the Memorandum of Understanding as indicated below:
 - a. The Arkansas Fire Prevention Code is the fire prevention code for the State of Arkansas.
 - b. When the Arkansas State Fire Prevention Code conflicts with the chapters of NFPA 101 Life Safety Code governing new and existing

RULES FOR CRITICAL ACCESS HOSPITALS 2021

health care and ambulatory health care occupancies (Chapters 18, 19, 20, and 21), the provisions of the Life Safety Code shall govern.

- c. Requirements found only in the Arkansas Fire Prevention Code (requirements not addressed by NFPA 101) may be provided at the option of the facility (compliance with these requirements is not mandatory).
2. Safety Improvement Plans: Nothing in these rules shall be construed as restrictive to a facility that chooses to do work as a part of a long-range safety improvement plan. These rules do not prohibit a single phase of improvement. All hazards to life and safety all areas of noncompliance should be corrected as soon as possible.
3. Provisions in Excess of Regulatory Requirements: Nothing in these rules shall be construed to prohibit a better type of building construction, an additional means of egress, or an otherwise safer condition than that specified by the minimum requirements of these rules.
4. Equivalency:
 - a. Insofar as practical, these minimum standards have been established to obtain a desired performance result. Prescriptive limitations, when given, such as exact minimum dimensions or quantities, describe a condition that is recognized as a practical standard for normal operation.
 - b. It is the intent of these rules to permit and promote equivalency concepts. Nothing in these rules shall be construed as restricting innovations that provide an equivalent level of performance with these rules in a manner other than that which is prescribed by these rules, provided that no other safety element or system is compromised in order to establish equivalency.
 - c. Health Facility Services may approve alternate methods, procedures, design criteria, and functional variations from these rules, because of extraordinary circumstances, new programs, new technology, or unusual conditions when the facility can effectively demonstrate that the intent of the rules is met and that the variation does not reduce the safety or operational effectiveness of the facility below that required by the exact language of the rules.
 - d. When contemplating equivalency allowances, Health Facility Services may use a variety of expert sources to make equivalency findings. Health Facility Services will document the reasons for approval or denial of equivalency to the facility.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- e. National Fire Protection Association (NFPA) document 101A is a technical standard for evaluating equivalency to certain Life Safety Code 101 requirements. The Fire Safety Evaluation System (FSES) is a widely recognized method for establishing a safety level equivalent to the Life Safety Code. The use of the FSES process may be useful for evaluating existing facilities that will be affected by renovation.

SECTION 44: PHYSICAL FACILITIES, PATIENT ACCOMMODATIONS (ADULT MEDICAL, SURGICAL, COMMUNICABLE OR PULMONARY DISEASE).

NOTE: See other sections of this document for Special-Care area units such as Post anesthesia Care Unit, Critical Care Units, Rehabilitation Units, Pediatric Units, Postpartum Care Units and/or other specialty units.

- A. Patient Rooms. Each patient room shall meet the following requirements.
1. Maximum room capacity shall be two patients.
 2. In new construction, patient rooms shall have a minimum of 100 square feet of clear floor area per bed in semi-private rooms and 120 square feet of clear floor are for single-bed rooms, exclusive of toilet rooms, closets, lockers, wardrobes, alcoves or vestibules. The dimensions and arrangement of rooms shall be such that there is a minimum of three feet between the sides and foot of the bed and any wall, other fixed obstruction or another bed. In semi-private bed rooms, a clearance of four feet shall be available at the foot of each bed to permit the passage of equipment and beds.

Minor encroachments, including columns and lavatories, that do not interfere with functions may be ignored when determining space requirements for patient rooms. Where renovation work is undertaken, every effort shall be made to meet the above minimum standards.
 3. Each patient room shall have a window with outside exposure and where the operation of windows or vents requires the use of tools or keys, such devices shall be on the same floor and easily accessible to staff. The windowsills shall not be higher than three feet above the floor and shall be above the grade. Patient rooms in new construction intended for 24 hour occupancy shall have windows. If operable windows are installed, such devices shall be permanently secured or restricted to inhibit possible escape or suicide.
 4. Nurse patient communication station shall be provided in accordance with item G. of Section 72, Physical Facilities, Electrical Standards.
 5. Hand washing stations shall be provided to serve each patient room. These hand washing stations shall be located in the toilet room.
 6. Each patient shall have access to a toilet room without having to enter the general corridor area. One toilet room shall serve no more than four patient beds and no more than two patient rooms. In new construction, an additional hand washing station or sanitizing station shall be placed in the

RULES FOR CRITICAL ACCESS HOSPITALS 2021

patient room where the toilet room serves more than one bed. The toilet room shall contain a water closet and a hand washing station and the door shall swing outward or be double acting.

7. Each patient shall have within the room a separate wardrobe or closet that is suitable for hanging full length garments and for storing personal items.
 8. Visual privacy from casual observation by other patients and visitors shall be provided for each patient in semi-private rooms with cubicle curtains or equivalent built-in or movable dividers. Provisions for privacy is not required within psychiatric or alcohol and drug units. The method for providing privacy shall not obstruct passage of other patients either to the entrance, toilet or lavatory. All curtains shall have a flame spread of 0 to 25 and shall comply with NFPA 13 requirements for clear space below sprinklers.
 9. Each room shall communicate directly with a corridor without passage through another patient's room.
 10. Rooms existing partially below grade level shall not be used for patients unless they are dry, well ventilated and are otherwise suitable for occupancy.
 11. Beds shall be arranged to provide adequate room for all patient care procedures and to prevent the transmission of infections.
 12. Individual approved hospital type beds shall be provided. Bed rails shall be provided on beds for children.
 13. A reading light shall be provided for each patient bed. The location and design shall be such that the light is not annoying to other patients.
 14. A bedside table with drawer shall be provided for each bed. The lower portion of the table and/or enclosed shelves shall be provided for individual nursing care equipment.
- B. Service Areas. Each service area may be arranged and located to serve more than one nursing unit but at least one such service area shall be provided on each nursing floor. Some of the service areas may be combined in a single space. The following service areas shall be located in or readily available to each nursing unit:
1. Nursing Station. Facilities for charting, clinical records, work counter, communication system, space for supplies and convenient access to hand washing stations shall be provided. It may be combined with or include centers for reception and communication.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

2. Dictation area shall be provided. This area shall be adjacent to but separate from the nurses' station;
3. Toilet room(s) for staff convenient to nurses' station (may be unisex).
4. Lounge facilities for staff. These facilities may be on another floor.
5. Individual closets or compartments for the safekeeping of coats and personal effects of nursing personnel. These shall be located convenient to the nurses' station of personnel or in a central location;
6. Multi-purpose room(s) for staff, patients, patients' families for patient conferences, reports, education, training sessions, and consultation. The rooms shall be accessible to each nursing unit. One such room may serve several nursing units and/or departments.
7. Examination/treatment room(s). Such rooms may be omitted if all patient rooms are single-bed rooms. It shall have a minimum floor area of 120square feet excluding space for vestibule, toilet, closets, and work counters (whether fixed or movable). Centrally located examination and treatment room(s) may serve more than one nursing unit on the same floor. The room shall contain a lavatory or sink equipped for handwashing, work counter, storage facilities, and a desk, counter or shelf space for writing. The emergency treatment room may be used for this purpose if it is conveniently located to the patient rooms.
8. Clean workroom or clean supply room. If the room is used for preparing patient care items, it shall contain a work counter, a handwashing fixture and storage facilities for clean and sterile supplies. If the room is used only for storage and holding as part of a system for distribution of clean and sterile materials, the work counter and handwashing fixture may be omitted. Soiled and clean workrooms or holding rooms shall be separated and have no direct connection.
9. Soiled workroom or soiled holding room. This room shall be separate from the clean workroom. The soiled workroom shall contain a clinical sink (or equivalent flushing-rim fixture). The room shall contain a lavatory (or handwashing fixture). The above fixtures shall both have a hot and cold mixing faucet. The room shall have a work counter and space for separate covered containers for soiled linen and waste. Rooms used only for temporary holding of soiled material may omit the clinical sink and work counter. If the flushing-rim clinical sink is eliminated, facilities for cleaning bedpans shall be provided elsewhere.
10. Medication Station. Provisions shall be made for distribution of

medications. This may be done from a medicine preparation room or unit, from a self-contained medicine dispensing unit, or by another approved system

- a. Medicine preparation room. This room shall be designed to allow for visual supervision by the nursing staff. It shall contain a work counter, a sink adequate for handwashing, refrigerator, and locked storage for controlled drugs. When a medicine preparation room is to be used to store one or more self-contained medicine dispensing units, the room shall be designed with adequate space to prepare medicines with the self-contained medicine dispensing unit(s) present.
 - b. Self-contained medicine dispensing unit. A self-contained medicine dispensing unit may be located at the nurses' station, in the clean workroom, or in an alcove, provided the unit has adequate security for controlled drugs and adequate lighting to easily identify drugs. Convenient access to handwashing stations shall be provided. (Standard cup-sinks provided in many self-contained units are not adequate for handwashing.)
11. Clean Linen Storage. A separate closet or a designated area within the clean workroom shall be provided. If a closed cart system is used, storage may be in an alcove. Carts shall be out of the path of traffic.
 12. Nourishment Station. This shall contain a sink equipped for handwashing, equipment for serving nourishment between scheduled and unscheduled meals, refrigerator, storage cabinets, and ice maker units to provide ice for patients' service and treatment. Ice for human consumption shall be from self-dispensing units. Handwashing stations shall be in or immediately accessible to the nourishment station;
 13. Equipment Storage Room. This shall be for equipment such as I.V. stands, inhalators, air mattresses, and walkers;
 14. Parking for stretchers and wheelchairs. This shall be located out of path of normal traffic;
 15. Showers and bathtubs. When individual bathing facilities are not provided in patient rooms, there shall be at least one shower and/or bathtub for each 12 beds without such facilities. Each bathtub or shower shall be in an Individual room or enclosure that provides privacy for bathing, drying, and dressing. Special bathing facilities, including space for attendant, shall be provided for patients on stretchers, carts, and wheelchairs at the ratio of one per 100 beds or a fraction thereof. This may be on a separate floor if convenient for use.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

16. Emergency Equipment Storage. Space for emergency equipment such as a "crash cart" shall be provided and shall be under control of the nursing staff;
 17. Environmental Services Closet. See Section 65, Physical Facilities, Cleaning and Sanitizing Carts and Environmental Services, for detailed requirements.
- C. Airborne Infection Isolation Room(s). Rooms for patients who are suffering from infections shall be provided at the rate of 1 for each 30 beds or fraction thereof. These may be located within each nursing unit or placed together in a separate unit. See also Section 32, Physical Facilities, Critical Care Unit for the requirements of Critical Care Units. Psychiatric and Alcohol/Drug Unit(s) beds need not be included in the bed count ratio to establish the number of rooms. Each isolation room shall be a single-bed room and planned as required for a normal patient room except as follows:
1. Each airborne infection isolation room shall have an anteroom for handwashing, gowning, and storage of clean and soiled materials located directly outside the entry door to the patient room.
 2. Airborne infection isolation room perimeter walls, ceiling, and floors, including penetrations, shall be sealed tightly so that air does not infiltrate the environment from the outside or from other spaces.
 3. Airborne infection isolation room(s) shall have self-closing devices on all room exit doors
 4. Separate toilet, bathtub (or shower) and handwashing stations are required for each airborne infection isolation room.
 5. Airborne infection isolation rooms may be used for noninfectious patients when not needed for patients with airborne infectious disease.
 6. Windows shall not be operable without the use of a key or tool controlled by the nursing staff.
 7. Each room shall have a permanently installed visual mechanism to constantly monitor the pressure status of the room when occupied by patients with an airborne infectious disease.
- D. Protective Isolation Rooms. In facilities where procedures such as organ transplants, burn therapy, and immunosuppressive treatments are performed, special design provisions, including special ventilation, may be necessary to meet the needs of the functional program. Refer to Table 4 of the Appendix for air

RULES FOR CRITICAL ACCESS HOSPITALS 2021

pressure and ventilation. Each protective isolation room shall be a single-bed room and planned as required for a normal patient room except as follows:

1. Each protective isolation room shall have an anteroom for handwashing, gowning, and storage of clean and soiled materials located directly outside the entry door to the patient room.
 2. Protective isolation room perimeter walls, ceiling, and floors, including penetrations, shall be sealed tightly so that air does not infiltrate the environment from the outside or from other spaces.
 3. Protective isolation room(s) shall have self-closing devices on all room exit doors.
 4. Separate toilet, bathtub (or shower), and handwashing stations are required for each protective isolation room.
 5. Protective isolation rooms may be used for nonimmunosuppressed patients, except airborne infectious patients are prohibited.
 6. Windows shall not be operable without the use of a key or tool controlled by the nursing staff.
- E. Seclusion Rooms. Each hospital shall provide one or more single-bed rooms for patients needing close supervision if suitable psychiatric facilities are not available elsewhere in the community. Such rooms shall comply with the applicable requirements in Section 48, Physical Facilities, Psychiatric Nursing Unit.
- F. Observation Rooms. Patients in observation status may be accommodated within the facility:
1. In private, semi-private or multi-patient rooms. Furniture shall be arranged to provide adequate room for patient care procedures and to prevent the transmission of infection;
 2. Cubicle curtains, privacy screens or an approved equivalent shall be provided for patient privacy in all multi-patient rooms. The utilization of such curtains or screens shall be such that each patient shall have privacy;
 3. Each room or cubicle shall be provided with (a) oxygen; (b) vacuum; and (c) a nurse call button unless direct observation is afforded and maintained;
 4. Hand hygiene facilities shall be available within the area;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

5. Hospital grade furniture shall be provided. Bed rails shall be provided on beds;
6. For each area in which a patient bed is utilized, a reading light shall be provided for each bed. The location and design shall be such that the light is not annoying to other patients;
7. Patient toilets shall be provided and accessible to all patients; and
8. Adequate space shall be provided for medical supplies.

SECTION 45: PHYSICAL FACILITIES, CRITICAL CARE UNIT.

The Critical care units require special space and equipment considerations for effective staff functions. In addition, space arrangement shall include provisions for immediate access of emergency equipment from other departments. Critical care units shall comply in size, number and type with these standards and with the functional program. The following standards are intended for the more common types of critical care services and shall be appropriate to needs defined in functional programs. Where specialized services are required, additions and/or modifications shall be made as necessary for efficient, safe, and effective patient care.

- A. Critical Care (General). The following shall apply to all types of critical care units unless otherwise noted. Each unit shall comply with the following provisions:
1. The location shall offer direct access by the emergency, respiratory care, laboratory, radiology, surgery, and other essential departments and services as defined by the functional program. It shall be located so that the medical emergency resuscitation teams may be able to respond promptly to emergency calls within minimum travel time. The location shall be arranged to eliminate the need for through traffic.
 2. In new construction, where elevator transport is required for critically ill patients, the size of the cab and mechanisms and controls shall meet the specialized needs.
 3. In new construction, each patient room (or multiple bed space for neonatal or pediatric units) shall have a minimum of 200 square feet of clear floor area with a minimum headwall width of 113 feet per bed, exclusive of anterooms, vestibules, toilet rooms, closets, lockers, wardrobes, and/or alcoves. In renovation of existing critical care units, every effort shall be made to meet the above minimum standards. If it is not possible to meet the above square foot standards, the Entity having jurisdiction may grant approval to deviate from this requirement. In such cases, rooms shall be no less than 130square feet.
 4. View panels to the corridor shall be required and shall have means to provide visual privacy. Where only one door is provided to a bed space, it shall be at least four feet wide and arranged to minimize interference with movement of beds and large equipment. Sliding doors shall not have floor tracks and shall have hardware that minimizes jamming possibilities. Where sliding doors are used for access to cubicles within a suite, a three-foot-wide swinging door may also be provided for personnel communication. The sliding doors shall swing out.
 5. Each patient bed area shall have space at each bedside for visitors and provisions for visual privacy from casual observation by other patients and visitors. For both adult and pediatric units, there shall be a minimum of eight feet between beds.
 6. Each patient bed shall have visual access, other than skylights, to the outside

RULES FOR CRITICAL ACCESS HOSPITALS 2021

environment with not less than one outside window in each patient bed area. In renovation projects, clerestory windows with windowsills above the heights of adjacent ceilings may be used, provided they afford patients a view of the exterior and are equipped with appropriate forms of glare and sun control. Distance from the patient bed to the outside window shall not exceed 50 feet. When partitioned cubicles are used, patients' view to outside windows may be through no more than two separate clear vision panels.

7. Nurse/patient communication shall be provided in accordance with item G. of Section 72, Physical Facilities, Electrical Standards. The communication station for the unit shall include provisions for an emergency code resuscitation alarm to summon assistance from outside the critical care unit.
8. Handwashing fixtures shall be convenient to nurse stations and patient bed areas. There shall be at least one handwashing fixture for every three beds in open plan areas, and one in each patient room. The handwashing fixture or sanitizing station shall be located near the entrance to the patient cubicle or room, shall be sized to minimize splashing water onto the floor, and shall be equipped with hands-free operable controls.
9. Nurses' station shall have space for counters and storage. It may be combined with or include centers for reception and communication. There shall be direct or remote visual observation between the nurses' station and all patient beds in the critical care unit.
10. Each unit shall contain equipment for continuous monitoring, with visual displays for each patient at the bedside and at the nurses' station. Monitors shall be located to permit easy viewing and access but not interfere with access to the patient.
11. Emergency equipment storage space that is easily accessible to the staff shall be provided for emergency equipment such as a emergency cart.
12. Medication Station. Provisions shall be made for distribution of medications. This may be done from a medicine preparation room or unit, from a self-contained medicine dispensing unit, or by another approved system:
 - a. Medicine preparation room. This room shall be designed to allow for visual supervision by the nursing staff. It shall contain a work counter, a sink adequate for handwashing, refrigerator, and locked storage for controlled drugs. When a medicine preparation room is to be used to store one or more self-contained medicine dispensing units, the room shall be designed with adequate space to prepare medicines with the self-contained medicine dispensing unit(s) present.
 - b. Self-contained medicine dispensing unit. A self-contained medicine

dispensing unit may be located at the nurses' station, in the clean workroom, or in an alcove, provided the unit has adequate security for controlled drugs and adequate lighting to easily identify drugs. Convenient access to handwashing stations shall be provided. (Standard cup-sinks provided in many self-contained units are not adequate for handwashing.)

13. At least one airborne infection isolation room with anteroom shall be provided. The number of airborne infection isolation rooms shall be determined based on an infection control risk assessment; as per the primary catchment area by the facility. Each room shall contain only one bed and shall comply with the requirements of item C. of Section 44, Physical Facilities, Patient Accommodations (Adult Medical, Surgical, Communicable or Pulmonary Disease). However, the requirement for the bathtub (or shower) may be eliminated. Compact, modular toilet/sink combination units may replace the requirement for a "toilet room." Special ventilation requirements are found in Table 4.
14. The following additional service spaces shall be immediately available within each critical care area (Note: These additional spaces may be shared by more than one critical care unit provided that direct access is available from each unit.):
 - a. Securable closets or cabinet compartments for the unit personnel;
 - b. Clean workroom or clean supply room. If the room is used for preparing patient care items, it shall contain a work counter, a handwashing fixture and storage facilities for clean and sterile supplies. If the room is used only for storage and holding as part of a system for distribution of clean and sterile supply materials, the work counter and handwashing fixture may be omitted. Soiled and clean workrooms or holding rooms shall be separated and have no direct connection;
 - c. Clean linen storage. There shall be a designated area for clean linen storage. This may be within the clean workroom, a separate closet or an approved distribution system on each floor. If a closed cart system is used, storage may be in an alcove. It shall be out of the path of normal traffic and under staff control;
 - d. Soiled workroom or soiled holding room. This room shall be separate from the clean workroom. The soiled workroom shall contain a clinical sink or equivalent flushing-rim fixture. The room shall contain a lavatory or handwashing fixture. The above fixtures shall have a hot and cold mixing faucet. The room shall have a work counter and space for separate covered containers for soiled linen and a variety of waste types. Rooms used only for temporary holding of soiled material may omit the

RULES FOR CRITICAL ACCESS HOSPITALS 2021

clinical sink and work counter. If the flushing-rim clinical sink is eliminated, facilities for cleaning bedpans shall be provided elsewhere;

- e. Nourishment Station. There shall be a nourishment station with sink, work counter, refrigerator, storage cabinets, and equipment for hot and cold nourishments between scheduled meals. The nourishment station shall include space for trays and dishes used for nonscheduled meal service. Provisions and space shall be included for separate temporary storage of unused and soiled dietary trays not picked up at meal time. Handwashing stations shall be in or immediately accessible from the nourishment station;
 - f. Ice machine. There shall be available equipment to provide ice for treatments and nourishment. Ice-making equipment may be in the clean work room or at the nourishment station. Ice intended for human consumption shall be from self-dispensing ice makers;
 - g. Equipment storage room or alcove. Appropriate room(s) or alcove(s) shall be provided for storage of large items of equipment necessary for patient care and as required by the functional program. Its location shall not interfere with the flow of traffic; and
 - h. X-ray viewing equipment.
15. The following shall be provided and may be located outside the unit if conveniently accessible.
- a. A visitors' waiting room shall be provided with access to telephones and toilets. One waiting room may serve several critical care units.
 - b. Staff lounge(s) and toilet(s) shall be located so that staff may be recalled quickly to the patient area in emergencies. The lounge shall have telephone or intercom and emergency code alarm connections to the critical care unit it serves. One lounge may serve adjacent critical care areas.
 - c. A special procedures room shall be provided if required by the functional program.
 - d. Multipurpose room(s) for staff, patients, and patients' families for patient conferences, reports, education, training sessions, and consultation shall be provided. These rooms shall be accessible to each nursing unit.
 - e. A housekeeping room shall be provided within or immediately adjacent to the critical care unit. It shall not be shared with other nursing units or departments. It shall contain a service sink or floor receptor and

RULES FOR CRITICAL ACCESS HOSPITALS 2021

provisions for storage of supplies and housekeeping equipment.

- f. Storage space for stretchers and wheelchairs shall be provided in a strategic location, without restricting normal traffic.
- g. Laboratory, radiology, respiratory care, and pharmacy services shall be available. These services may be provided from the central departments or from satellite facilities as required by the functional program.

B. Coronary Critical Care Unit. In addition to the standards set forth in Section 45, Physical Facilities, Critical Care Unit, the following standards apply to the coronary critical care unit:

- 1. Each coronary patient shall have a separate room for acoustical and visual privacy.
- 2. Each coronary patient shall have access to a toilet in the room. (Portable commodes may be used in lieu of individual toilets, but provisions shall be made for their storage, servicing, and odor control.)

C. Pediatric Critical Care. If a facility has a specific pediatric critical care unit, the functional program shall include consideration for staffing, isolation, and the safe transportation of critically ill pediatric patients, along with life support and environmental systems, from other areas. In addition to the standards previously listed for critical care units, each pediatric critical care unit shall include:

- 1. Space at each bedside for family, visitors and nursing staff;
- 2. In new construction, each patient space (whether separate rooms, cubicles, or multiple bed space) shall have a minimum of 200 square feet of clear floor area with a minimum headwall width of 13 feet per bed, exclusive of anterooms, vestibules, toilet rooms, closets, lockers, wardrobes, and/or alcoves;
- 3. Consultation/demonstration room within, or convenient to, the pediatric critical care unit for private discussions;
- 4. Provisions for formula storage. These may be outside the pediatric critical care unit but shall be available for use at all times;
- 5. Separate storage cabinets or closets for toys and games for use by the pediatric patients; and
- 6. Examination and treatment room(s).

D. Newborn Intensive Care Units. Each Newborn Intensive Care Unit (NICU) shall include or comply with the following:

RULES FOR CRITICAL ACCESS HOSPITALS 2021

1. The NICU shall have a clearly identified entrance and reception area for families. The area shall permit visual observation and contact with all traffic entering the unit. A scrub area shall be provided at each public entrance to the patient care area(s) of the NICU. All sinks shall be hands-free operable and large enough to contain splashing;
2. At least one door (44inches minimum) to each room in the unit to accommodate portable X-ray equipment;
3. There shall be controlled access systems to the unit from the Labor and Delivery area, the Emergency Room or other referral entry points;
4. When viewing windows are provided, provision shall be made to control casual viewing of infants;
5. Noise control shall be a design factor;
6. Provisions shall be made for indirect lighting in all nurseries. Provisions shall be made for multiple lighting levels;
7. A central area shall serve as a nurses' station, shall have space for counters and storage, and shall have convenient access to handwashing stations. It may be combined with or include centers for reception and communication and patient monitoring;
8. Each patient care space shall contain a minimum of 120 square feet per bassinette excluding sinks and aisles. There shall be an aisle for circulation adjacent to each patient care space with a minimum width of three feet;
9. An airborne infection isolation room is required in at least one level of nursery care. The room shall be enclosed and separated from the nursery unit with provisions for observation of the infant from adjacent nurseries or control area(s);
10. Blood gas lab facilities shall be immediately accessible;
11. A respiratory care work area and storage room shall be provided;
12. A consultation/demonstration/breast feeding room shall be provided convenient to the unit;
13. Charting and dictation space for physicians shall be provided;
14. Medication station shall be provided;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

15. Clean workroom or clean supply room shall be provided. See Section 44.B.8, Physical Facilities, Patient Accommodations (Adult Medical, Surgical, Communicable or Pulmonary Disease);
16. Soiled workroom or soiled holding room shall be provided. See Section 44.B.9, Physical Facilities, Patient Accommodations (Adult Medical, Surgical, Communicable or Pulmonary Disease);
17. A lounge, locker room and staff toilet within or adjacent to the unit suite for staff use shall be provided;
18. Space shall be provided for emergency equipment that is under direct control of the nursing staff, such as a emergency cart. This space shall be located in an area appropriate to the functional program, but out of normal traffic;
19. One environmental services closet shall be provided for the unit. It shall be directly accessible from the unit and be dedicated for the exclusive use of the neonatal critical care unit. It shall contain a service sink or floor receptor and provisions for storage of supplies and housekeeping equipment; and
20. Space shall be provided for the following:
 - a. A visitors' waiting room;
 - b. Nurses' station; and
 - c. Multipurpose room(s) for staff, patients and patients' families for patient conferences, reports, education, training sessions, and consultation. These rooms shall be accessible to each nursing unit. They may be on other floors if convenient for regular use. One such room may serve several nursing units and/or departments.

SECTION 46: PHYSICAL FACILITIES, NURSERY UNITS.

Normal newborn infants shall be housed in nurseries that comply with the standards below. All nurseries other than pediatric nurseries shall be convenient to the postpartum nursing unit and obstetrical facilities. The nurseries shall be located and arranged to preclude the need for nonrelated pedestrian traffic. No nursery shall open directly into another nursery. There should be one breastfeeding/pumping room readily available for mothers of NICU babies to pump breastmilk.

- A. General. Each nursery shall contain the following:
1. At least one lavatory, equipped with hands-free handwashing station, for each eight infant stations;
 2. Glazed observation windows to permit the viewing of infants from public areas, workrooms, and adjacent nurseries;
 3. Convenient, accessible storage for linens and infant supplies at each nursery room;
 4. A consultation/demonstration/breast feeding or pump room shall be provided convenient to the nursery. Provision shall be made, either within the room or conveniently located nearby, for sink, counter, refrigeration and freezing, storage for pump and attachments, and educational materials. The area provided for the unit for these purposes, when conveniently located, may be shared;
 5. Enough space shall be provided for parents to stay 24hours;
 6. An airborne infection isolation room is required in or near at least one level of nursery care. The room shall be enclosed and separated from the nursery unit with provisions for observation of the infant from adjacent nurseries or control area(s). All airborne infection isolation rooms shall comply with the requirements of Section 44.C, Patient Accommodations (Adult Medical, Surgical, Communicable or Pulmonary Disease), except for separate toilet, bathtub, or shower;
 7. Workroom(s). Each nursery room shall be served by a connecting workroom. The workroom shall contain scrubbing and gowning facilities at the entrance for staff and housekeeping personnel, work counter, refrigerator, storage for supplies and a hands-free handwashing fixture. One workroom may serve more than one nursery room provided that required services are convenient to each. The workroom serving the full-term and continuing care nurseries may be omitted if equivalent work and storage areas and facilities, including those for scrubbing and gowning, are provided within that nursery. Space required for work areas located within

the nursery is in addition to the area required for infant care. Adequate provision shall be made for storage of emergency cart(s) and equipment out of traffic and for the sanitary storage and disposal of soiled waste.

- a. When the functional program includes a mother-baby couplet approach to nursing care, the workroom functions described above may be incorporated in the nurse station that serves the postpartum patient rooms.
 - b. Neonate examination and treatment areas. Such areas, when required by the functional program, shall contain a work counter, storage facilities and a hands-free handwashing station. c. Neonate formula facilities. Where infant formula is prepared on-site, direct access from the formula preparation room to any nursery room is prohibited. The room may be located near the nursery or at other appropriate locations in the hospital, but shall include
 - 1) Cleanup facilities for washing and sterilizing supplies. This area shall include a handwashing station, facilities for bottle washing, a work counter and sterilization equipment.
 - 2) Separate room for preparing infant formula. This room shall contain warming facilities, refrigerator, work counter, formula sterilizer, storage facilities and a handwashing station.
 - 3) Refrigerated storage and warming facilities for infant formula accessible for use by nursery personnel at all times.
 8. Commercial neonate formula. If a commercial infant formula is used, the separate cleanup and preparation rooms may be omitted. The storage and handling may be done in the nursery workroom or in another appropriate room in the hospital that is conveniently accessible at all hours. The preparation area shall have a work counter, a handwashing station and storage facilities.
 9. Housekeeping/environmental services room. A housekeeping/environmental services room shall be provided for the exclusive use of the nursery unit. It shall be directly accessible from the unit and shall contain a service sink or floor receptor and provide for storage of supplies and housekeeping equipment.
 10. Charting space. Charting facilities shall have linear surface space to ensure that staff and physicians may chart and have simultaneous access to information and communication systems.
- B. Newborn Nursery

RULES FOR CRITICAL ACCESS HOSPITALS 2021

1. Each newborn nursery room shall contain no more than 16 stations. The minimum floor areas shall be 24 square feet per bassinet, exclusive of auxiliary work areas. When a rooming-in program is used, the total number of bassinets provided in these units may be appropriately reduced, but the newborn nursery shall not be omitted in its entirety from any facility that includes delivery services. (When facilities use a rooming-in program in which all infants are returned to the nursery at night, a reduction in nursery size may not be practical.)
 2. Baby holding nurseries may replace traditional nurseries with baby holding nurseries in postpartum and labor-delivery-recovery-postpartum (LDRP) units. The minimum floor area per bassinet, ventilation, electrical, and medical vacuum and gases shall be the same as that required for a full-term nursery. These holding nurseries should be next to the nurse station on these units. The holding nursery shall be sized to accommodate the percentage of newborns who do not remain with their mothers during the postpartum stay.
- C. Continuing Care Nursery For hospitals that provide continuing care for infants requiring close observation (for example, low birth-weight babies who are not ill but require more hours of nursing than do normal neonates), the minimum floor space shall be 50 square feet per bassinet, exclusive of auxiliary work areas, with provisions for at least 4 feet between and at all sides of each bassinet.
- D. Pediatric Nursery To minimize the possibility of cross infection, each nursery room serving pediatric patients shall contain no more than eight bassinets; each bassinet shall have a minimum clear floor area of 40 square feet. Each room shall contain a lavatory equipped for hands-free handwashing, a nurse's emergency calling system and a glazed viewing window for observing infants from public areas and workrooms. (Limitation on number of patients in a nursery room does not apply to the pediatric critical care unit.)

SECTION 47: PHYSICAL FACILITIES, PEDIATRIC AND ADOLESCENT UNIT.

The unit shall meet the following standards:

- A. Patient Rooms. Each patient room shall meet the following standards:
1. Maximum room capacity shall be four patients.
 2. The space requirements for pediatric patient beds shall be the same as for adult beds due to the size variation and the need to change from cribs to beds and vice-versa. See Section 44, Patient Accommodations (Adult Medical, Surgical, Communicable or Pulmonary Disease), for requirements. Additional provisions for hygiene, toilets, sleeping, and personal belongings shall be included where the program indicates that parents will be allowed to remain with young children. See Sections 45, Physical Facilities, Critical Care Unit and 46, Physical Facilities, Newborn Nursery Units for pediatric critical care units and for newborn nurseries.
 3. Each patient room shall have a window in accordance with Section 44, Physical Facilities, Patient Accommodations (Adult Medical, Surgical, Communicable or Pulmonary Disease).
- B. Examination/Treatment Rooms. This room shall be provided for pediatric and adolescent patients. A separate area for infant examination and treatment may be provided within the pediatric nursery workroom. Examination/treatment rooms shall have a minimum floor area of 120square feet. The room shall contain a handwashing fixture; storage facilities; and a desk, counter, or shelf space for writing. This room is not required if all rooms are private.
1. Multipurpose or individual room(s) shall be provided within or adjacent to areas serving pediatric and adolescent patients for dining, education and developmentally appropriate play and recreation, with access and equipment for patients with physical restrictions. If the functional program requires, an individual room shall be provided to allow for confidential parent/family comfort, consultation, and teaching. Insulation, isolation and structural provisions shall minimize the transmission of impact noise through the floor, walls or ceiling of these multipurpose room(s).
 2. Space for preparation and storage of infant formula shall be provided within the unit or other convenient location. Provisions shall be made for continuation of special formula that may have been prescribed for the infant prior to admission or readmission.
 3. Patient toilet room(s) with handwashing stations in each room, in addition to those serving bed areas, shall be conveniently located to multipurpose

room(s) and to each central bathing facility.

4. Storage closets or cabinets for toys and educational and recreational equipment shall be provided.
5. Storage space shall be provided to permit exchange of cribs and adult beds. Provisions shall also be made for storage of equipment and supplies (including cots or recliners, extra linen, etc.) for parents who stay with the patient overnight.
6. A least one airborne infection isolation room shall be provided in each pediatric unit. The total number of infection isolation rooms shall be determined by an infection prevention and control risk assessment. Airborne infection isolation room(s) shall comply with the requirements of item C. of Section 44, Physical Accommodations (Adult Medical, Surgical, Communicable or Pulmonary Disease).
7. Separate clean and soiled workrooms or holding rooms shall be provided as described in Section 44 B.8 and B.9, Physical Accommodations (Adult Medical, Surgical, Communicable or Pulmonary Disease).

SECTION 48: PHYSICAL FACILITIES, PSYCHIATRIC NURSING UNIT.

When part of a general hospital, these units shall be designed for the care of inpatients. Non-ambulatory inpatients may be treated in a medical unit until their medical condition allows for transfer to the psychiatric nursing unit. Provisions shall be made in the design for adapting the area for various types of psychiatric therapies.

The environment of the unit should be characterized by a feeling of openness with emphasis on natural light and exterior views. Various functions should be accessible from common areas while not compromising desirable levels of patient privacy. Interior finishes, lighting and furnishings should suggest a residential rather than an institutional setting. These should, however, conform with applicable fire safety codes. Security and safety devices should not be presented in a manner to attract or challenge tampering by patients.

Where glass fragments pose a hazard to certain patients, safety glazing and/or other appropriate security features shall be used.

Details of such facilities should be as described in the approved functional program. Each nursing unit shall provide the following:

- A. Patient Rooms. The patient room requirements noted in Section 44, Physical Accommodations (Adult Medical, Surgical, Communicable or Pulmonary Disease), shall be applied to patient rooms in psychiatric nursing units except as follows:
 - 1. A nurses' call system is not required; but if it is included, provisions shall be made for easy removal or for covering call button outlets;
 - 2. Bedpan-flushing devices shall be omitted from patient room toilets;
 - 3. Handwashing stations are not required in patient rooms;
 - 4. Visual privacy in multibed rooms (e.g., cubicle curtains) is not required;
 - 5. The ceiling and the air distribution devices, lighting fixtures, sprinkler heads, and other appurtenances shall be of a tamper-resistant type;
 - 6. Each patient room shall be provided with a private toilet that meets the following requirements:
 - a. The door shall not be lockable from within;
 - b. The door shall be capable of swinging outward; and
 - c. The ceiling shall be of tamper-resistant construction and the air distribution devices, lighting fixtures, sprinkler heads and other appurtenances shall be of the tamper-resistant type.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

7. Patient rooms, exclusive of toilet rooms, closets, lockers, wardrobes, alcoves, or vestibules, shall be at least 100 square feet for single-bed rooms and 80 square feet per bed for multiple-beds rooms. The dimensions and room arrangement criteria of Section 44 does not apply.
- B. Service Areas. The standards noted in Section 44, Physical Accommodations (Adult Medical, Surgical, Communicable or Pulmonary Disease), shall apply to services areas for psychiatric nursing units with the following modifications:
1. A secured storage area shall be provided for patients' belongings that are determined to be potentially harmful (e.g., razors, nail files, cigarette lighters); this area shall be controlled by staff.;
 2. Medication station shall include provisions for security against unauthorized access;
 3. Food service within the unit may be one, or a combination, of the following:
 - a. A nourishment station;
 - b. A kitchenette designed for patient use with staff control of heating and cooking devices; and
 4. Storage space for stretchers and wheelchairs may be outside the psychiatric unit, provided that provisions are made for convenient access as needed for disabled patients;
 5. In psychiatric nursing units, a bathtub or shower shall be provided for each six beds not otherwise served by bathing facilities within the patient rooms. Bathing facilities shall be designed and located for patient convenience and privacy;
 6. A separate charting area shall be provided with provisions for acoustical privacy. A viewing window to permit observation of patient areas by the charting nurse or physician may be used if the arrangement is such that patient files cannot be read from outside the charting space;
 7. At least two separate social spaces, one appropriate for noisy activities and one for quiet activities shall be provided. The combined area shall be a minimum of 40 square feet per patient with a minimum of 120 square feet for each of the two spaces. This space may be shared by dining activities;
 8. Space for group therapy shall be provided. This may be combined with the quiet space noted above in item 7 when the unit accommodates not more than 12 patients, and when at least 225 square feet of enclosed private space is available

RULES FOR CRITICAL ACCESS HOSPITALS 2021

for group therapy activities;

9. Patient laundry facilities with an automatic washer and dryer shall be provided. The following elements shall also be provided, but may be either within the psychiatric unit or immediately accessible to it unless otherwise dictated by the functional program;
 10. Rooms (s) for examination and treatment shall have a minimum floor area of 120 square feet. Examination and treatment room(s) for medical-surgical patients may be shared by the psychiatric unit patients. (These may be on a different floor if conveniently accessible.)
 11. Separate consultation room(s) with minimum floor space of 100 square feet each, provided at a room-to-bed ratio of one consultation room for each 12 psychiatric beds. The room(s) shall be designed for acoustical and visual privacy and constructed to achieve a noise reduction of at least 45 decibels. This room is not required if all rooms are private;
 12. Psychiatric units each containing 15 square feet of separate space per patient for patient therapy/multipurpose use, with a minimum total area of at least 200 square feet, whichever is greater. Space shall include provision for handwashing, work counter(s), storage, and displays. This space may serve more than one nursing unit. When psychiatric nursing unit(s) contain less than 12 beds, the therapy and other functions may be performed within the noisy activities area, if at least an additional 10 square feet per patient served is included; and
 13. A conference and treatment planning room for use by the psychiatric unit.
- C. Seclusion Treatment Room. There shall be at least one seclusion room for up to 24 beds or a major fraction thereof. If a facility has more than one psychiatric nursing unit, the number of seclusion rooms shall be a function of the total number of psychiatric beds in the facility. Seclusion rooms may be grouped together.
1. The seclusion room is intended for short-term occupancy by a violent or suicidal patient. The room(s) shall be located for direct nursing staff supervision. Each room shall be for only one patient. It shall have an area of at least 60 square feet and shall be constructed to prevent patient hiding, escape, injury or suicide. Where restraint beds are required by the functional program, 80 square feet shall be required.
 2. Room doors shall be designed with hardware that will permit the doors to swing out. Outside corners shall be omitted where possible. The ceiling shall be of tamper-resistant construction and the air distribution devices, lighting fixtures, sprinkler heads, and other appurtenances shall be of the tamper-resistant type. The walls shall be completely free of objects. Special fixtures and hardware for electrical circuits shall be used. Minimum ceiling height shall be nine feet. Doors shall be three feet eight inches wide and shall permit staff observation of the

RULES FOR CRITICAL ACCESS HOSPITALS 2021

patient while also maintaining provisions for patient privacy. Seclusion treatment rooms shall be accessed by an anteroom or vestibule which also provides direct access to a toilet room. The toilet room and anteroom shall provide for safe management of the patient.

3. Where the interior of the seclusion room is padded with combustible materials, these materials shall be of a type acceptable to NFPA standards. The room area, including floor, walls, ceilings, and all openings shall be protected with not less than one-hour-rated construction.

SECTION 49: PHYSICAL FACILITIES, SURGICAL FACILITIES

- A. General Operating Room(s). At least one general operating room shall be provided for each 50 beds or major fraction thereof up to 200 beds. Over 200 beds, additional operating room needs shall be based on the projected surgical workload. In new construction, each room shall have a minimum clear area of 400 square feet exclusive of fixed or wall-mounted cabinets and built-in shelves, with a minimum of 20 feet clear dimension between fixed cabinets and built-in shelves, and a system for emergency communication with the surgical suite control station. X-ray film illuminators for handling at least four films simultaneously shall also be provided. In renovation projects, every effort shall be made to meet the floor space requirements indicated above. In no event shall the clear floor area be less than 360 square feet with a minimum dimension of 18 feet.
- B. Specialty Operating Rooms for cardiovascular, orthopedic, neurological, and other procedures that require additional personnel and/or large equipment. When included, this room shall have, in addition to the above requirements for general operating rooms, a minimum clear area of 600 square feet, with a minimum of 20 feet clear dimension exclusive of fixed or wall-mounted cabinets and built-in shelves. When open-heart surgery is performed, an additional room in the restricted area of the surgical suite shall be designated as a pump room where extra corporeal pump(s), supplies and accessories are stored and serviced. When complex orthopedic and neurosurgical surgery is performed, additional rooms shall be in the restricted area of the surgical suite which shall be designated as equipment storage rooms for the large equipment used to support these procedures. Appropriate plumbing, medical gases, and electrical connections shall be provided in the pump storage room. When included, a room for orthopedic surgery shall, in addition to the above, have enclosed storage space for splints and traction equipment. Storage outside the operating room shall be conveniently located. If a sink is used for the disposal of casting material, an appropriate trap shall be provided. In renovation projects, every effort shall be made to meet the floor space requirements indicated above. In no event shall the clear floor area be less than 400 square feet (except for Orthopedic procedures shall be 360 square feet) with a minimum dimension of 18 feet.
- C. Room(s) for Surgical Cystoscopic and Endo-Urologic Procedures. When provided and/or required by the written functional program, the cystoscopic and endo-urologic procedures room(s) shall follow these requirements. A scrub sink or large lavatory shall be provided within or adjoining the cystoscopy room. In new construction, these rooms shall have a minimum clear area of 350 square feet, exclusive of fixed or wall-mounted cabinets and built-in shelves with a minimum of 15 feet clear dimension between fixed cabinets and built-in shelves.

Additional clear space may be required by the functional program to accommodate special functions in one or more of these rooms. An emergency

communications system shall connect with the Surgical Suite control station. Facilities for the disposal of liquid wastes shall be provided. If a floor drain is installed to provide for disposal of liquid wastes, it shall be completely insulated from ground by means of an insulating type floor drain and nonconductive waste connections. The drain shall also be provided with a flushing device. X-ray viewing capability to accommodate at least four films simultaneously shall be provided. In renovation projects, every effort shall be made to meet the clear floor space requirements indicated above for construction. In no event shall the clear floor space be less than 250 square feet.

D. Endoscopy

The endoscopy suite may be divided into three major functional areas: the procedure room(s), instrument processing room(s), and patient holding/preparation and recovery room or area.

NOTE: When invasive procedures are to be performed in this unit on persons who are known or suspected of having airborne infectious diseases, these procedures should not be performed in the operating suite. These procedures shall be performed in a room meeting airborne infections isolation ventilation requirements or in a space using local exhaust ventilation.

1. Procedures Room(s)
 - a. Each procedure room shall have a minimum clear area of 200 square feet (15.58 square meters) exclusive of fixed cabinets and built-in shelves.
 - b. A freestanding handwashing fixture with hands-free controls shall be available in the suite.
 - c. Refer to Table 11 for medical gas station outlets.
 - d. Floor covering shall be monolithic and joint free.
 - e. A system for emergency communication shall be provided.
 - f. Procedure rooms shall be designed for visual and acoustical privacy for the patient.
2. Instrument Processing Room(s)
 - a. Dedicated processing room(s) for cleaning and disinfecting

instrumentation shall be provided. In an optimal situation, cleaning room(s) shall be located between two procedure rooms. However, one processing room may serve multiple procedure rooms. Size of the cleaning room(s) is dictated by the amount of equipment to be processed.

Cleaning rooms shall allow for flow of instrumentations from the contaminated area to the clean area, and finally to storage. The clean equipment rooms, including storage, should protect the equipment from contamination.

- b. The decontamination room shall be equipped with the following:
 - 1) Two utility sinks remote from each other.
 - 2) One freestanding handwashing fixture.
 - 3) Work counter space(s).
 - 4) Space and plumbing fixtures for automatic endoscope cleaners, sonic processor, and flash sterilizers (where required).
 - 5) Ventilation system. Negative pressure shall be maintained and minimum of 10 air changes per hour shall be maintained. A hood is recommended over the work counter. All air shall be exhausted to the outside to avoid recirculation within the facility.
 - 6) Outlets for vacuum and compressed air.
 - 7) Floor covering shall be monolithic and joint free.
3. Patient Holding/Prep/Recovery Area. The following elements shall be provided in this area:
 - a) Each patient cubicle shall be equipped with oxygen and suction outlets.
 - b) Cubicle curtains for patient privacy.
 - c) Medication preparation and storage with handwashing stations.
 - d) Toilet facilities (may be accessible from patient holding or directly from procedure room(s) or both).

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- e) Change areas and storage for patients' personal effects.
 - f) Nurses reception and charting area with visualization of patients.
 - g) Clean utility room or area.
 - h) Environmental Services closet.
- E. Service Areas. Individual rooms shall be provided when so noted; otherwise alcoves or other open spaces which shall not interfere with traffic may be used. Services, except the soiled workroom and the janitor's closet, may be shared with and organized as part of the obstetrical facilities if the approved functional program reflects this sharing concept. Service areas shall be arranged to avoid direct traffic between the Operating and Delivery Suites. The following areas shall be provided.
1. Control station located to permit visual surveillance of all traffic which enters the Operating Suite.
 2. A supervisor's office or station. The number of offices, stations, and teaching areas in the surgical suite shall depend upon the functional program.
 3. Sterilizing facilities conveniently located to serve all operating rooms. The sterilizing facility shall have work counter space and a handwashing sink. When the functional program indicates that adequate provisions have been made for replacement of sterile instruments during surgery, sterilization facilities in the Surgical Suite shall not be required.
 4. Medication Distribution. Provisions shall be made for storage and distribution of medications. This may be done from a medication preparation room or unit, from a self-contained medication dispensing unit, or by another system approved by the Department. If used, a medication preparation room or unit shall be under visual control of nursing staff. It shall contain a work counter, sink, refrigerator, and double-locked storage for controlled substances with convenient access to handwashing stations provided. Each blood bank refrigerator shall be on an emergency power circuit.
 5. Scrub Facilities. Two scrub stations shall be provided near the entrance to each operating room; however, two scrub stations may serve two operating rooms if the scrub stations are located adjacent to the entrance of each operating room. Scrub facilities shall be arranged to minimize any incidental splatter on nearby personnel or supply carts. In new construction, view windows at scrub stations permitting observation of room interiors shall be provided. The scrub sinks

RULES FOR CRITICAL ACCESS HOSPITALS 2021

shall be recessed into an alcove out of the main traffic areas. Equipment and supplies for timed scrub technique shall be available at each scrub sink with manual and/or automatic two way controls.

6. **Soiled Workroom.** An enclosed soiled workroom (or soiled-holding room that is part of a system for the collection and disposal of soiled material) for the exclusive use of the surgical suite shall be provided. It shall be located in the restricted area. The soiled workroom shall contain a flushing-rim clinical sink or equivalent flushing-rim fixture, a work counter, a handwashing fixture, and space for waste receptacles, and soiled linen receptacles. Rooms used only for temporary holding of soiled material may omit the flushing-rim clinical sink and work counters. However, if the flushing-rim clinical sink is omitted, other provisions for disposal of liquid waste shall be provided. This room shall not have direct connection with operating rooms or other sterile activity rooms. Soiled and clean work or holding rooms shall be separated.
7. **Clean Workroom or a Clean Supply Room.** A clean workroom is required when clean materials are assembled within the surgical suite prior to use, or following the decontamination cycle. It shall contain a work counter, a handwashing fixture, storage for clean supplies, and space to package reusable items. The storage for sterile supplies shall be separated from this space. If the room is used only for storage and holding as part of a system for distribution of clean and sterile supply materials, the work counter and handwashing fixture may be omitted. Storage space for sterile and clean supplies shall be adequate for the functional plan. The space shall be moisture and temperature controlled and free from cross traffic.
8. **The location of sterilization for surgical instruments and the direction of flow from the decontamination location to the sterile location shall be addressed by the written functional program.**
 - a. An operating room suite design with a sterile core shall provide for no cross traffic of staff and supplies from the decontaminated/soiled areas to the sterile/clean areas.
 - b. The use of facilities outside the operating room for soiled/decontaminated processing and clean assembly and sterile processing shall be designed to move the flow of goods and personnel from dirty to clean/sterile without compromising standard precautions or aseptic techniques in both departments. This room shall have no direct opening into an operating room.
9. **Anesthesia storage shall be provided in accordance with NFPA 99.**
10. **Medical gas storage facilities.** Main storage of medical gases may be outside or inside the facility in accordance with NFPA99. Provision shall be made for

RULES FOR CRITICAL ACCESS HOSPITALS 2021

additional separate storage of reserve gas cylinders necessary to complete at least one day's procedures.

11. An anesthesia workroom for testing and storing anesthesia equipment shall contain a work counter, sink and racks for cylinders.
12. Equipment storage room(s) for equipment and supplies used in the Surgical Suite. Each surgical suite shall provide sufficient storage area to keep the exit access corridor free of equipment and supplies, but not less than 150 square feet or 50 square feet per OR, whichever is greater.
13. Staff Dressing Room. Appropriate room(s) shall be provided for males and females working within the Surgical Suite. The room(s) shall contain lockers, showers, toilets, lavatories equipped for handwashing, and space for donning scrub suits and boots. These room(s) shall be arranged to provide a one-way traffic pattern so personnel entering from outside the Surgical Suite can change, shower, gown, and move directly into the Surgical Suite.
14. Stretcher storage area out of direct line of traffic.
15. Staff lounge and toilet facilities. Separate or combined lounges for males and females shall be provided. Lounge(s) shall be located to permit use without leaving the Surgical Suite and to provide convenient access to the Recovery Room
16. Dictation and report preparation area. This may be accessible from the lounge area.
17. Phase II recovery. Where outpatient surgeries are to be part of the surgical suite, and where outpatients receive Class B or Class C sedation, a second Phase II or step-down recovery room shall be provided. The room shall contain handwashing stations, a nurse station with charting facilities, clinical sink, provision for bedpan cleaning, and storage space for supplies and equipment. In addition, the design shall provide a minimum of 50 square feet for each patient in a lounge chair with space for additional equipment described in the functional program and for clearance of 4 feet between the sides of the lounge chairs and the foot of the lounge chairs. Provisions shall be made for the isolation of infectious patients. Provisions for patient privacy such as cubicle curtains shall be made. In new construction, at least one door shall access the PACU without crossing unrestricted corridors of the hospital. A patient toilet shall be provided with direct access to the Phase II recovery unit for the exclusive use of patients. A staff toilet shall be provided with direct access to the working area to maintain staff availability to patients. Handwashing stations with hands-free operable controls shall be available with at least one for every four lounge chairs uniformly distributed to provide equal access from each patient bed.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

18. Change areas for outpatients and same-day admissions. If the functional program defines outpatient surgery as part of the surgical suite, a separate area shall be provided where outpatients may change from street clothing into hospital gowns and be prepared for surgery. This would include a waiting room, locker(s), toilet(s), and clothing change or gowning area. Changing may also be accommodated in a private holding room or cubicle
19. Provisions shall be made for patient examination, interviews, preparation, testing, and obtaining vital signs of patients for outpatient surgery.
20. Patient holding area. In facilities with two or more operating rooms, an area shall be provided to accommodate stretcher patients waiting for surgery. This holding area shall be under the visual control of the nursing staff.
21. Storage areas for portable X-ray equipment, stretchers, fracture tables, warming devices, auxiliary lamps, etc. These areas shall be out of corridors and traffic.
22. Emergency equipment storage under direct control of the nursing staff and not obstructing the corridor.
23. Environmental Services closet. See Section 65, Physical Facilities, Cleaning and Sanitizing Carts and Environmental Services, for detailed requirements.
24. Area for preparation and examination of frozen sections. This may be part of the general laboratory if immediate results are obtainable without unnecessary delay in the completion of surgery.
25. Ice machine. An ice machine shall be provided to provide ice for treatments and patient use. Ice intended for human consumption shall be from self-dispensing ice makers.
26. A waiting room, with toilets, telephones, and drinking fountains conveniently located. The toilet room shall contain handwashing stations. If outpatients, as defined by the written functional program, are required to wait in this area, then a separate area shall be provided. Provisions shall be made for examinations, interviews, testing, and obtaining vital signs.
A separate area shall be provided where outpatients may change from street clothing into hospital gowns.
27. Ethylene Oxide Sterilization Facilities. Where ethylene oxide is used for sterilization, provisions shall be made for complete exhaust of gases to the exterior. When the door is opened, arrangement shall ensure that gases are pulled away from the operator. Provisions shall be made for appropriate

aeration of supplies. Aeration cabinets shall be vented to the outside. Where aeration cabinets are not used in ethylene oxide processing, provision for isolated area mechanically vented to the outside for aeration, OSHA standards shall be met.

F. Preoperative Patient Holding Area.

1. Preoperative Patient Holding Area(s). In facilities with two or more operating rooms, areas shall be provided to accommodate stretcher patients as well as sitting space for ambulatory patients not requiring stretchers. These areas shall be under the direct visual control of the nursing staff and may be part of the recovery suite to achieve maximum flexibility in managing surgical case loads. Each stretcher station shall be a minimum of 80 square feet and shall have a minimum clearance of 4 feet on the sides of the stretchers and the foot of the stretcher. Provisions shall be made for the isolation of infectious patients. Provisions for patient privacy such as cubicle curtains shall be made.

G. Post-anesthetic care units (PACUs):

1. Each PACU shall contain a medication station; handwashing stations; nurse station with charting facilities; clinical sink; provisions for bedpan cleaning; and storage space for stretchers, supplies, and equipment. Additionally, the design shall provide a minimum of 80 square feet for each patient bed with a space for additional equipment described in the functional program, and for clearance of at least 5 feet between patient beds and 4 feet between patient bedsides and adjacent walls. Provisions shall be made for the isolation of infectious patients. Provisions for patient privacy such as cubicle curtains shall be made. In new construction, at least one door to the recovery room shall access directly from the surgical suite without crossing public hospital corridors.
2. An airborne infection isolation room is not required in a PACU. Provision for the recovery of a potentially infectious patient with an airborne infection shall be determined by the Infection Prevention and Control Risk Assessment.
3. A staff toilet shall be located within the working area to maintain staff availability to patients.
4. Handwashing stations with hands-free operable controls shall be available with at least one for every four beds uniformly distributed to provide equal access from each patient bed.

SECTION 50: PHYSICAL FACILITIES, OBSTETRICAL FACILITIES.

General obstetrical unit shall be located and designated to prohibit non-related traffic through the unit. When delivery and operating rooms are in the same suite, access and service arrangements shall be such that neither staff nor patients need to travel through one area to reach the other. Except as permitted otherwise herein, existing facilities being renovated shall, as far as practicable, provide all the required support services.

A. Postpartum Unit.

1. Postpartum Room.

- a. A postpartum room shall have a minimum of 100square feet of clear floor area per bed in multi-bedded rooms and 120square feet of clear floor area in single-bed rooms. These areas shall be exclusive of toilet rooms, closets, alcoves, or vestibules. Where renovation work is undertaken, every effort shall be made to meet the above minimum standards. If it is not possible to meet the above square –foot standards, the authorities having jurisdiction may grant approval to deviate from this requirement. In such cases, existing postpartum patient rooms shall have no less than 80 square feet of clear floor area per bed in multiple-bed rooms and 100 square feet in single-bed rooms.
- b. In multi-bedded rooms there shall be a minimum clear distance of four feet between the foot of the bed and the opposite wall, three feet between the side of the bed and nearest wall, and four feet between beds.
- c. The maximum number of beds per room shall be two.

2. The following support services for this unit shall be provided.

- a. Nurses' station.
- b. Nurse office.
- c. Charting facilities.
- d. Toilet room for staff.
- e. Staff lounge.
- f. Lockable closets or cabinets for personal articles of staff.
- g. Consultation/conference room(s).

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- h. Patients' lounge. The patients' lounge may be omitted if all rooms are single-bedded rooms
- i. Clean workroom or clean supply room. A clean workroom is required if clean materials are assembled within the obstetrical suite prior to use. It shall contain a work counter, a handwashing fixture, and storage facilities for clean and sterile supplies. If the room is used only for storage and holding as part of a system for distribution of clean and sterile supply materials, the work counter and handwashing fixtures may be omitted. Soiled and clean workrooms or holding rooms shall be separated and have no direct connection.
- j. Soiled workroom or soiled holding room for the exclusive use of the obstetrical suite. This room shall be separate from the clean workroom. The soiled workroom shall contain a clinical sink (or equivalent flushing-rim fixture) and a handwashing fixture. The above fixtures shall have a hot and cold mixing faucet. The room shall have work counter and space for separate covered containers for soiled linen and waste. Rooms used only for temporary holding of soiled material may omit the clinical sink and work counter. If the flushing-rim clinical sink is omitted, facilities for cleaning bedpans shall be provided elsewhere.
- k. Medication station. Provision shall be made for storage and distribution of drugs and routine medications. This may be done from a medicine preparation room or unit, from a self-contained medicine dispensing unit, or by another approved system. If used, a medicine preparation room or unit shall be under visual control of nursing staff. It shall contain a work counter, sink, refrigerator, and double-locked storage for controlled substances. Convenient access to handwashing stations shall be provided. (Standard cup-sinks provided in many self-contained units are not adequate for handwashing.)
- l. Clean linen storage may be part of a clean workroom or a separate closet. When a closed cart system is used, the cart shall be stored out of the path of normal traffic.
- m. Nourishment station shall contain sink, work counter, ice dispenser, refrigerator, cabinets, and equipment for serving hot or cold food. Space shall be included for temporary holding of unused or soiled dietary trays.
- n. Equipment storage room. Each unit shall provide sufficient storage

area(s) located on the patient floor to keep its required corridor width free of equipment and supplies, but not less than 10 square feet per postpartum room and 20 square feet per each LDR or LDRP outside of the patient room.

- o. Storage space for stretchers and wheelchairs shall be provided in a strategic location, out of corridors and away from normal traffic.
 - p. When bathing facilities are not provided in patient rooms, there shall be at least one shower and/or bathtub for each six beds or fraction thereof.
 - q. A housekeeping room shall be provided for the exclusive use of the obstetrical suite. It shall be directly accessible from the suite and shall contain a service sink or floor receptor and provisions for storage of supplies and housekeeping equipment.
 - r. Examination/treatment room and/or multipurpose diagnostic testing room shall have a minimum clear floor area of 120square feet. When utilized as a multipatient diagnostic testing room, a minimum clear floor area of 80square feet per patient shall be provided. An adjoining toilet room shall be provided for patient use.
 - s. Emergency equipment storage shall be located in close proximity to the nurses' station.
4. Airborne infection isolation room(s). An airborne infection isolation room is not required for the obstetrical unit. Provisions for the care of the perinatal patient with an airborne infection shall be determined by the Infection Prevention and Control Risk Assessment.

B. Cesarean/Delivery Suite.

- 1. Caesarean/delivery room(s) shall have a minimum clear floor area of 360 square feet with a minimum dimension of 16 feet exclusive of built-in shelves or cabinets. There shall be a minimum of one such room in every obstetrical unit.
- 2. Delivery room(s) shall have minimum clear area of 300 square feet exclusive of fixed cabinets and built-in shelves. An emergency communication system shall be connected with the obstetrical suite control station.
- 3. Infant resuscitation shall be provided within the cesarean/delivery room(s) and delivery rooms with a minimum clear floor are of 40 square feet in addition to

RULES FOR CRITICAL ACCESS HOSPITALS 2021

the required area of each room or may be provided in a separate but immediately accessible room with a clear floor area of 150 square feet. Six single or three duplex electrical outlets shall be provided for the infant in addition to the facilities required for the mother.

4. Labor room(s) (LDR or LDRP rooms may be substituted). In renovation projects, existing labor rooms may have a minimum clear area of 100 square feet per bed.

Where LDRs or LDRPs are not provided, a minimum of two labor beds shall be provided for each Caesarean room and/or delivery room. In facilities that have only one Caesarean delivery room, two labor rooms shall be provided. Each room shall be designed for either one or two beds with a minimum clear area of 120square feet per bed. Each labor room shall contain a handwashing fixture and have access to a private toilet room. One toilet room may serve two labor rooms. Labor rooms shall have controlled access with doors that are arranged for observation from a nurses' station. At least one shower (which may be separate from the labor room if under staff control) for use of patients in labor shall be provided. Windows in labor rooms, if provided, shall be located, draped, or otherwise arranged to preserve patient privacy from causal observation from outside the labor room.

5. Recovery room(s). (LDR or LDRP rooms may be substituted.) Each recovery room shall contain at least two beds and have a nurses' station with charting facilities located to permit visual control of all beds. Each room shall include stations for handwashing and dispensing medicine. A clinical sink with bedpan flushing device shall be available, as shall storage for supplies and equipment. There shall be enough space for baby and crib and a chair for the support person. There shall be the ability to maintain visual privacy of the new family.
6. Service Areas.

- a. Individual rooms shall be provided as indicated in the following standards; otherwise, alcoves or other open spaces that do not interfere with traffic may be used.
- b. The following services shall be provided:
 - 1) A control/nurse station located to restrict unauthorized traffic into the suite.
 - 2) Soiled workroom or soiled holding room. This room shall be separate from the clean workroom. The soiled workroom shall contain a clinical sink (or equivalent flushing-rim fixture). The room shall contain a handwashing fixture. The above fixtures shall have a hot and cold mixing faucet. The room shall have a

work counter and space for separate covered containers for soiled linen and waste. Rooms used only for temporary holding of soiled material may omit the clinical sink and work counter. If the flushing-rim clinical sink is eliminated, facilities for cleaning bedpans shall be provided elsewhere.

- 3) Fluid waste disposal.
- c. The following services may be shared with the surgical facilities if the functional program reflects this concern. Where shared, areas shall be arranged to avoid direct traffic between the delivery and operating rooms.
- 1) A supervisor's office or station.
 - 2) A waiting room, with toilets, telephones, and drinking fountains conveniently located. The toilet room shall contain handwashing stations.
 - 3) Sterilizing facilities with high-speed sterilizers convenient to all Caesarean/delivery rooms. Sterilization facilities shall be separate from the delivery area and adjacent to clean assembly. High-speed autoclaves shall only be used in an emergency situation (i.e., a dropped instrument and no sterile replacement readily available). Sterilization facilities would not be necessary if the flow of materials were handled from a central service department based on the usage of the delivery room (DR).
 - 4) A drug distribution station with handwashing stations and provisions for controlled storage, preparation, and distribution of medication.
 - 5) Scrub facilities for Caesarean and delivery rooms. Two scrub stations shall be provided adjacent to entrance to each Caesarean/delivery room. Scrub facilities should be arranged to minimize any splatter on nearby personnel or supply carts. In new construction, view windows at scrub stations to permit the observation of room interiors.
 - 6) Clean workroom or clean supply room. A clean workroom shall be provided if clean materials are assembled within the obstetrical suite prior to use. If a clean workroom is provided it shall contain a work counter, sink equipped for handwashing and space for storage of supplies. A clean supply room may be provided when the narrative program defines a

RULES FOR CRITICAL ACCESS HOSPITALS 2021

system for the storage and distribution of clean and sterile supplies.

- 7) Medical gas storage facilities. Main storage of medical gases may be outside or inside the facility in accordance with NFPA99. Provision shall be made for additional separate storage of reserve gas cylinders necessary to complete at least one day's procedures.
 - 8) A clean sterile storage area readily available to the delivery room: size to be determined on level of usage, functions provided, and supplies from the hospital central distribution area.
 - 9) An anesthesia workroom for cleaning, testing, and storing anesthesia equipment. It shall contain a work counter, sink, and provisions for separation of clean and soiled items.
 - 10) Equipment storage room(s) for equipment and supplies used in the obstetrical suite.
 - 11) Staff clothing change areas. The clothing change area shall be designed to encourage one-way traffic and cross-traffic between clean and contaminated personnel. The area shall contain lockers, showers, toilets, handwashing stations, and space for donning and disposing scrub suits and booties.
 - 12) Male and female support persons change area (designed as described above).
 - 13) Lounge and toilet facilities for obstetrical staff convenient to delivery, labor, and recovery areas. The toilet room shall contain handwashing stations.
 - 14) An on-call room(s) for physician and/or staff may be located elsewhere in the facility.
 - 15) Environmental Services Closet. See Section 65, Physical Facilities, Cleaning Sanitizing Carts and Environmental Services for detailed requirements.
 - 16) An area for storing stretchers out of the path of normal traffic.
- C. LDR and LDRP Facilities. When provided by the narrative program, delivery procedures in accordance with birthing concepts may be performed in the LDR or LDRP rooms. LDR room(s) may be located in a separate LDR suite or as part of the

RULES FOR CRITICAL ACCESS HOSPITALS 2021

Caesarean/Delivery suite. The postpartum unit may contain LDRP rooms. These rooms shall have a minimum of 250square feet of clear floor area with a minimum dimension of 13feet, exclusive of toilet room, closet, alcove, or vestibules. There should be enough space for crib and reclining chair for support person. An area within the room but distinct from the mothers area shall be provided for infant stabilization and resuscitation. See Table 4 of the Appendix for medical gas outlets. These outlets shall be located in the room so that they are accessible to the mother's delivery area and infant resuscitation area. When renovation work is undertaken, every effort shall be made to meet the above minimum standards. If it is not possible to meet the above square-foot standards, the authorities having jurisdiction may grant approval to deviate from this requirement. In such cases, existing LDR or LDRP rooms may have a minimum clear area of 200 square feet.

Each LDR or LDRP room shall be for single occupancy and have direct access to a private toilet with shower or tub. Each room shall be equipped with handwashing facilities (handwashing stations with hands-free operation area acceptable for scrubbing). Examination lights may be portable, but shall be immediately accessible.

Finishes shall be selected to facilitate cleaning and with resistance to strong detergents. Window(s) shall be provided for LDRP room(s). Windows or doors within a normal sightline that would permit observation into the room shall be arranged or draped as necessary for patient privacy. Additional requirements for windows are provided above in A2.a.

SECTION 51: PHYSICAL FACILITIES, EMERGENCY SUITE.

A. General. The following shall be provided:

1. Grade-level well-marked, illuminated, and covered entrance with direct access from public roads for ambulance and vehicle traffic. Entrance and driveway shall be clearly marked. If a raised platform is used for ambulance discharge, a ramp shall be provided for pedestrian and wheelchair access. The emergency vehicle entry cover shall provide shelter for both the patient and the emergency medical crew during transfer from an emergency vehicle into the building.
2. Paved emergency access to permit discharge of patients from automobiles and ambulances, and temporary parking convenient to the entrance.
3. Reception, triage, and nurses' station shall be located to permit staff observation and control of access to treatment area, pedestrian and ambulance entrances, and public waiting area. The triage area requires special consideration. As the point of entry and assessment for patients with undiagnosed and untreated airborne infections, the triage area shall be designed and ventilated to reduce exposure of staff, patients and families to airborne infectious diseases. If determined by the infection prevention and control risk assessment, one or more separate, enclosed spaces designed and ventilated as airborne infection isolation rooms shall be required.
4. Wheelchair and stretcher storage shall be provided for arriving patients. This shall be out of traffic with convenient access from emergency entrances.
5. Public waiting area with toilet facilities, drinking fountains, and telephones shall be provided. The hospital shall conduct infection prevention and control risk assessment to determine if the emergency department waiting area shall require special measures to reduce the risk of airborne infection transmission. These measures may include enhanced general ventilation and air disinfection similar to inpatient requirements for airborne infection isolation rooms.
6. Communication center shall be convenient to nurses' station and have radio, telephone, and intercommunication systems.
7. Examination and Treatment Room(s). Examination and treatment room(s) shall have minimum floor area of 120 square feet. The room shall contain work counter(s); cabinets; handwashing stations; supply storage facilities; examination lights; a desk, counter, or shelf space for writing; and a vision panel adjacent to and/or in the door. When treatment cubicles are in open multiple-bed areas, each cubicle shall have a minimum of 80square feet of clear floor space and shall be separated from adjoining cubicles by curtains. Handwashing stations shall be provided for each four treatment cubicles or

RULES FOR CRITICAL ACCESS HOSPITALS 2021

major fraction thereof in multiple-bed areas. For oxygen and vacuum requirements, see Table 4 of the Appendix. Treatment/exam rooms used for pelvic exams should allow for the foot of the examination table to face away from the door.

8. Trauma/cardiac rooms for emergency procedures, including emergency surgery, shall have at least 250 square feet of clear floor space. Each room shall have cabinets and emergency supply shelves, X-ray film illuminators, examination lights, and counter space for writing. Additional space with cubicle curtains for privacy may be provided to accommodate more than one patient at a time in the trauma room. Provisions shall be made for monitoring the patient. There shall be storage provided for immediate access to attire used for universal precautions. Doorways leading from the ambulance entrance to the cardiac trauma room shall be a minimum of five feet wide to simultaneously accommodate stretchers, equipment, and personnel. In renovation projects, every effort shall be made to have existing cardiac/trauma rooms meet the above minimum standards.
9. Orthopedic and cast work. These may be in separate room(s) or in the trauma room. They shall include storage for splints and other orthopedic supplies, traction hooks, X-ray film illuminators, and examination lights. If a sink is used for the disposal of plaster of paris, a plaster trap shall be provided. The clear floor space for this area shall depend on the functions program and the procedures and equipment accommodated here.
10. Scrub stations located in or adjacent and convenient to each trauma and/or orthopedic room.
11. Convenient access to radiology and laboratory services.
12. Poison Control Center and EMS Communications Center may be part of the work and charting area.
13. Provisions for disposal of solid and liquid waste. This may be a clinical sink with bedpan flushing device within the soiled workroom.
14. Storage area out of line of traffic for stretchers, wheelchairs and emergency equipment;
15. A toilet room for patients. Where there are more than eight treatment areas, a minimum of two toilet facilities, with handwashing stations(s) in each toilet room, will be required.;
16. Soiled workroom for the exclusive use of the emergency suite. This room shall be separate from the clean workroom. The soiled workroom shall

RULES FOR CRITICAL ACCESS HOSPITALS 2021

contain a clinical sink or equivalent flushing type fixture, work counter, sink equipped for handwashing, waste receptacle and linen receptacle. This room shall be separate from the clean workroom and shall have separate access doors.

17. Clean workroom or clean supply room. A clean work room is required if clean materials are assembled within the emergency suite prior to use. It shall contain a work counter, a handwashing fixture, and storage facilities for clean and sterile supplies. If the room is used only for storage and holding as part of a system for distribution of clean and sterile supply materials, the work counter and handwashing fixtures may be omitted. Soiled and clean workrooms or holding rooms shall be separated and have no direct connection.
18. Nurses' Station(s). Facilities for charting, clinical records, work counter, communication system, space for supplies and convenient access to handwashing stations shall be provided. Visual observation of all traffic into the suite, where feasible.
19. Securable closets or cabinet compartments for personnel.
20. Staff lounge. Convenient and private access to staff toilets, lounge, and lockers shall be provided.
21. Housekeeping room. A housekeeping room shall be directly accessible from the unit and shall contain a service sink or floor receptor and provisions for storage of supplies and housekeeping equipment.
22. Security station. A security system should be located near the emergency entrances and triage/reception area. The non-selective 24-hour accessibility of the emergency dictates that a security system reflecting local community needs be provided.
23. At least one airborne infection isolation room shall be provided. The need for additional airborne infection isolation rooms or for protective environment room shall be as determined by the Infection Prevention and Control Risk Assessment. See Section 44.C for requirements.
24. Bereavement Room shall be located within or adjacent to the emergency suite. A telephone shall be provided.
25. Secured holding room in accordance with the functional program. At least one holding/seclusion room of 80 square feet shall be provided. This room shall allow for security, patient and staff safety, patient observations, and soundproofing.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

26. Decontamination area. A decontamination area shall be provided. The functional program shall define the location of the area and the types of exposure (i.e., nuclear, biological, chemical) to be considered. The location of the area shall be permitted to be on the exterior perimeter of the facility adjacent to the ambulance entrance or built within the walls of the facility.

SECTION 52: PHYSICAL FACILITIES, IMAGING SUITE.

A. General.

1. Equipment and space shall be as required by the functional program.
2. A certified physicist or other qualified expert shall specify the type, location, and amount of radiation protection to be installed in accordance with the final approved department layout and equipment selections. Where protected alcoves with view windows are required, a minimum of one foot six inches between the view window and the outside partition edge shall be provided. Radiation protection requirements shall be incorporated into the specifications and the building plans.
3. Radiation Control and Emergency Management shall be notified when any existing and/or new equipment has been relocated or introduced into the facility. Radiation Control approval for the equipment(s) and space(s) shall be obtained prior to use.

B. Angiography.

1. Space shall be provided as required by the functional program.
2. A control room shall be provided as necessary to meet the needs of the functional program. A view window in the control room shall be provided to permit full view of the patient.
3. A viewing area shall be provided.
4. A scrub sink located outside the staff entry to the procedure room shall be provided for use by staff.
5. A patient holding area shall be provided.
6. Storage for portable equipment and supplies shall be provided.
7. Provision shall be made within the facility for extended post-procedure observation of outpatients.

C. Computerized Tomography (CT) Scanning.

1. A control room shall be provided which is designed to accommodate the computer and other controls for the equipment. A view window shall be provided to permit full view of the patient. The angle between the control and equipment centroid shall permit the control operator to see the patient's head.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

2. The control room shall be located to allow convenient film processing.
 3. A patient toilet room shall be convenient to the procedure room, and if directly accessible to the scan room, arranged so that a patient may leave the toilet without having to reenter the scan room.
- D. Diagnostic X-ray (e.g., Tomography, Radiography/Fluoroscopy Rooms, Mammography). Radiology rooms shall be of a size to accommodate the functional program. Each X-ray room shall include a shielded control alcove. This area shall be provided with a view window designed to provide full view of the examination table and the patient at all times, including full view of the patient when the table is in the tilt position or the chest X-ray is being utilized. For mammography machines with built-in shielding for the operator, the alcove may be omitted when approved by the certified physicist or state radiation protection agency.
- E. Magnetic Resonance Imaging (MRI).
1. Space shall be provided as required by the functional program.
 2. A control room shall be provided with full view of the MRI.
 3. A computer room shall be provided.
 4. A patient holding area should be located near the MRI unit.
 5. Cryogen venting shall comply with manufacturer's recommendations.
- F. Ultrasound.
1. Space shall be provided as required by the functional program.
 2. A patient toilet room, accessible from the procedure room, shall be provided.
- G. Support Spaces. The following spaces are common to the imaging department and are minimum requirements unless stated otherwise.
1. Patient Waiting Area. The area shall have a seating capacity in accordance with the functional program.
 2. Control Desk and Reception Area.
 3. Holding Area. A convenient holding area under staff control shall be provided to accommodate patients on stretchers or beds.
 4. Patient Toilet Rooms. Toilet rooms shall be provided convenient to the waiting rooms and shall be equipped with an emergency call system. Separate toilets with

handwashing stations shall be provided with direct access from each radiography/fluoroscopy room so that a patient may leave the toilet without having to reenter the radiography/fluoroscopy room. Rooms used only occasionally for fluoroscopy procedures may utilize nearby patient toilets if they are located for immediate access.

5. Patient Dressing Rooms. Dressing rooms shall be provided convenient to the waiting areas and X-ray rooms. Each room shall include a seat or bench, mirror, and provisions for hanging patients' clothing.
6. Staff Facilities. Toilets may be outside the suite but shall be convenient for staff use. In larger suites of three or more procedure rooms, toilets internal to the suite shall be provided.
7. Image Storage. Provisions shall be provided by the facility for the active and inactive image storage. A room with cabinet or shelves for filing patient image for immediate retrieval shall be provided. A room or area for inactive image storage shall be provided. It may be outside the imaging suite, but shall be under imaging's administrative control and properly secured to protect films against loss or damage.
8. Storage for Unexposed Image. Storage facilities for unexposed images shall include protection of film against exposure or damage and shall not be warmer than the air of adjacent occupied spaces.
9. Provisions for image viewing, individual consultation, clerical spaces and charting shall be provided.
10. Contrast Media Preparation. This area shall be provided with sink, counter, and storage to allow for mixing of contrast media. One preparation area, if conveniently located, may serve any number of rooms. When prepared media is used, this area may be omitted, but storage shall be provided for the media.
11. Image Processing Room. A darkroom shall be provided for image processing unless the processing equipment normally used does not require a darkroom for loading and transfer. When daylight processing is used, the darkroom may be minimal for emergency and special uses. Image processing shall be located convenient to the procedure rooms and to the quality control area.
12. Quality Control Area. An area shall be provided near the processor for viewing film immediately after it is processed. All view boxes shall be illuminated to provide light of the same color value and intensity for appropriate comparison of several adjacent images.
13. Cleanup Facilities. Provisions for cleanup shall be located within the suite for

convenient access and use and shall include service sink or floor receptacle as well as storage space for equipment and supplies. If automatic film processors are used, a receptacle of adequate size with hot and cold water for cleaning the processor racks shall be provided.

14. Handwashing Stations. Handwashing stations shall be provided within each procedure room unless the room is used only for routine screening such as chest X-rays where the patient is not physically handled by the staff. Handwashing stations shall be provided convenient to the MRI room, but need not be within the room.
15. Clean Storage. Provisions shall be made for the storage of clean supplies and linens. If conveniently located, storage may be shared with another department.
16. Soiled Holding. Provisions shall be made for soiled holding. Separate provisions for contaminated handling and holding shall be made. Handwashing stations shall be provided.
17. Provision shall be made for locked storage of medications and drugs.

H. Cardiac Catheterization Lab.

Note: The number of procedure rooms and the size of the prep, holding, and recovery areas shall be based on expected utilization.

1. The cardiac catheterization lab is normally a separate suite, but may be within the imaging suite when the appropriate sterile environment is provided. It may be combined with angiography in low usage situations.
2. The procedure room shall be a minimum of 400square feet exclusive of fixed and movable cabinets and shelves.
3. A control room or area for the efficient functioning of the X-ray and image recording equipment. A view window permitting full view of the patient from the control console shall be provided.
4. An equipment room or enclosure large enough to contain x-ray transformers, power modules, and associated electronics and electrical gear shall be provided.
5. Scrub facilities with hands free operable controls shall be provided adjacent to the entrance of procedure rooms, and shall be arranged to minimize incidental splatter on nearby personnel, medical equipment, or supplies.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

6. The following shall be available for use by the cardiac catheterization suite:
 - a. A viewing room;
 - b. A film file room.
7. Staff change area(s) shall be provided and arranged to ensure a traffic pattern so that personnel entering from outside the suite can enter, change their clothing, and move directly into the cardiac catheterization suite.
8. A patient preparation, holding, and recovery area or room shall be provided and arranged to provide visual observation before and after the procedure.
9. A clean workroom or clean supply room shall be provided. If the room is used for preparing patient care items, it shall contain a work counter and handwashing sink. If the room is used only for storage and holding of clean and sterile supply materials, the work counter and handwashing stations may be omitted.
10. A soiled workroom shall be provided which shall contain a handwashing and a clinical sink (or equivalent flushing rim fixtures). When the room is used for temporary holding of soiled materials, the clinical sink may be omitted.
11. A housekeeping closet containing a floor receptor or service sink and provisions for storage of supplies and housekeeping equipment shall be provided.

SECTION 53: PHYSICAL FACILITIES, NUCLEAR MEDICINE.

- A. Equipment and space shall be provided to accommodate the functional program.
- B. A certified physicist or other qualified expert representing the owner shall specify the type, location, and amount of radiation protection to be installed in accordance with final approved department layout and equipment selection. These specifications shall be incorporated into the plans.
- C. Floors and walls shall be constructed of materials that are easily decontaminated in case of radioactive spills.
- D. If radiopharmaceutical preparation is performed onsite, an area adequate to house a radiopharmacy shall be provided with appropriate shielding. This area should include adequate space for storage of radionuclides, chemicals for preparation, dose calibrators, and record keeping. Floors and walls should be constructed of easily decontaminated materials. Vents and traps for radioactive gases should be provided if such are used. Hoods for pharmaceutical preparation shall meet applicable standards. If pre-prepared materials are used, storage and calculation area may be considerable smaller than that for on-site preparation. Space shall provide adequately for dose calibration, quality assurance, and record keeping. This area may still require shielding from other portions of the facilities.
- E. Nuclear medicine area when operated separately from the imaging department shall include the following as required to accommodate the functional program:
 - 1. Space adequate to permit entry of stretchers, beds, and able to accommodate imaging equipment, electronic consoles, and if present, computer terminals;
 - 2. A darkroom onsite available for film processing. The darkroom should contain protective storage facilities for unexposed film that guard the film against exposure or damage;
 - 3. When the functional program requires a centralized computer area, it should be a separate room with access terminals available within the imaging rooms.
 - 4. Provisions for cleanup located within the suite for convenient access and use. It shall include service sink or floor receptacle as well as storage space for equipment and supplies;
 - 5. Film storage with cabinets or shelves for filing patient film for immediate retrieval;
 - 6. Inactive film storage under the departmental administrative control and properly secured to protect film against loss or damage;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

7. A consultation area with view boxes illuminated to provide light of the same color value and intensity for appropriate comparison of several adjacent films;
 8. Provisions for physicians, assistants and clerical office space, individual consultation, viewing, and charting of film;
 9. Waiting areas out of traffic, under staff control, with seating capacity in accordance with the functional program. If the department is routinely used for outpatients and inpatients at the same time, separate waiting areas with screening or visual privacy between the waiting areas;
 10. A private area for dose administration located near the preparation area;
 11. A holding area for patients on stretchers or beds which may be provided and may be combined with the dose administration area with visual privacy between the areas;
 12. Patient dressing rooms convenient to the waiting area and procedure rooms. Each dressing room shall include a seat or bench, a mirror, and provisions for hanging patient's clothing;
 13. Toilet rooms convenient to waiting and procedure rooms;
 14. Staff toilet(s) convenient to the nuclear medicine laboratory;
 15. Handwashing stations within each procedure room;
 16. Control desk and reception area;
 17. Storage area for clean linen with a handwashing station;
 18. Provisions shall be made for holding soiled material. Such provision shall include a handwashing station.
 19. Separate provision shall be made for holding contaminated material (exposed to radiation).
- F. Positron Emission Tomography (PET).
1. Space should be provided as necessary to accommodate the functional program.
 2. PET scanning is generally used in experimental settings and requires space for a scanner and for a cyclotron. The scanner room should be a

RULES FOR CRITICAL ACCESS HOSPITALS 2021

minimum of 300 square feet.

3. Where a cyclotron room is required, it should be a minimum of 225 square feet with a 16 square foot space safe for storage of parts, which may need to cool down for a year or more.
4. Both a hot (radioactive) lab and a cold (nonradioactive) lab may be required, each a minimum of 250 square feet.
5. A blood lab of a minimum of 80 square feet should be provided.
6. A patient holding area to accommodate two stretchers should be provided.
7. A gas storage area large enough to accommodate bottles of gas should be provided. Each gas will be piped individually and may go to the cyclotron or to the lab. Ventilation adequate for the occupancy is required. Compressed air may be required to pressurize a water circulation system.
8. Significant radiation protection may be required since the cyclotron may generate high radiation.
9. Special ventilation systems together with monitors, sensors, and alarm systems may be required to vent gases and chemicals.
10. The heating, ventilating, and air conditioning system will require particular attention; highest pressures should be in coldest (radiation) areas and exhaust should be in hottest (radiation) areas. Redundancy may be important.
11. The cyclotron is water cooled with de-ionized water. A heat exchanger and connection to a compressor or connection to chilled water may be required. A redundant plumbing system connected to a holding tank may be required to prevent accidental leakage of contaminated water into the regular plumbing system.

G. Radiotherapy.

1. Rooms and spaces shall be provided as required by the functional program. Equipment manufacturers recommendations should be sought and followed, since space requirements may vary from one machine to another and one manufacturer to another. The radiotherapy suite may contain one or both electron beam therapy and radiation therapy.
2. Cobalt, linear accelerators, and simulation rooms require radiation protection. A certified physicist representing the owner or appropriate state

RULES FOR CRITICAL ACCESS HOSPITALS 2021

agency shall specify the type, location, and amount of protection to be installed in accordance with final approved department layout and equipment selection. This information shall be incorporated into the floor plans.

3. Cobalt rooms and linear accelerators shall be sized in accordance with equipment requirements and shall accommodate a stretcher for litter-borne patients. Layouts shall provide for preventing the escape of radioactive particles. Openings into the room, including doors, ductwork, vents, and electrical raceways and conduits, shall be baffled to prevent direct exposure to other areas of the facility.
 4. Simulator, accelerator, and cobalt rooms shall be sized to accommodate the equipment with patient access on a stretcher, medical staff access to the equipment and patient, and service access.
 5. Flooring shall be adequate to meet load requirements for equipment, patients, and personnel. Provision for wiring raceways, ducts, or conduit should be made in floors and ceilings. Ceiling mounted equipment should have properly designed rigid support structures located above the finished ceiling. The ceiling height is normally higher than 8'-0" (2.44 meters). A lay-in type of ceiling should be considered for ease of installation, service, and remodeling.
 6. Additional Support Areas for Linear Accelerator:
 - a. Mold room with exhaust hood and handwashing facility.
 - b. Block room with storage. The block room may be combined with the mold room.
 7. Additional Support Areas for Cobalt Room:
- H. General Support Areas. The following areas shall be provided unless they are accessible from other areas such as imaging:
1. A stretcher holding area adjacent to the treatment rooms, screened for privacy which may be combined with a seating area for outpatients;
 2. Exam rooms as specified by the functional program. Each shall be a minimum of 120square feet and equipped with a handwashing station;
 3. Darkroom convenient to the treatment room(s) and the quality control area. Where daylight processing is used, the darkroom may be minimal for emergency use. If automatic film processors are used, a receptacle of adequate size with hot and cold water for cleaning the processor racks shall be provided either in the darkroom or nearby;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

4. Patient gowning area with provision for safe storage of valuables and clothing. At least one space should be large enough for staff-assisted dressing;
 5. Business office and/or reception/control area;
 6. Housekeeping room equipped with service sink or floor receptor and large enough for equipment or supplies storage;
 7. Image file area; and
 8. A storage area for unprocessed media.
- I. Optional Support Area. The following areas may be required by the functional program:
1. Quality control area with view boxes illuminated to provide light of the same color value and intensity;
 2. Computer control area normally located just outside the entry to the treatment room(s);
 3. Dosimetry equipment area;
 4. Hypothermia room (may be combined with an exam room);
 5. Consultation room;
 6. Oncologist's office (may be combined with consultation room);
 7. Physicist's office (may be combined with treatment planning);
 8. Treatment planning and record room; and
 9. Work station/nutrition station.

SECTION 54: PHYSICAL FACILITIES, MOBILE, TRANSPORTABLE, AND RELOCATABLE UNITS.

- A. General. This section applies to mobile, transportable, and relocatable structures.
- B. Definitions.
 - 1. Mobile Unit - Any premanufactured structure, trailer, or self-propelled unit equipped with a chassis on wheels and intended to provide medical services on a temporary basis.
 - 2. Transportable Unit - Any premanufactured structure or trailer, equipped with a chassis on wheels, intended to provide medical services on an extended basis.
 - 3. Relocatable Unit - Any structure, not on wheels, built to be relocated at any time and provide medical services.
- C. General Considerations.
 - 1. Classifications. These facilities shall be classified as either a small outpatient facility, large outpatient facility, ambulatory surgery center, or a hospital based upon the definitions provided in the Rules, the program functional and construction type.
 - 2. Applicable Requirements. Facilities classified as a small outpatient clinic shall be designed in accordance with the requirements stipulated in Section 75, Physical Facilities, Outpatient Care Facilities. Facilities classified as a large outpatient facility shall be designed in accordance with the requirements stipulated in item F. of Section 75, Physical Facilities, Outpatient Care Facilities. Facilities classified as a hospital shall be designed in accordance with the requirements stipulated in Section 43, Physical Facilities.
 - 3. These requirements shall be applicable to mobile, transportable, and relocatable structures, when such structures are used to provide shared medical services on an extended or a temporary basis.
 - 4. When any mobile unit, transportable and relocatable unit(s) are situated in a fixed location and rendered immobile they shall be classified and designed as a health care facility.
- D. Common Elements for Mobile, Transportable, and Relocatable Units.
 - 1. Site Conditions.
 - a. Access for the unit to arrive shall be taken into consideration for space planning. Turning radius of the vehicles, slopes of the approach (six (6)

RULES FOR CRITICAL ACCESS HOSPITALS 2021

percent maximum), and existing conditions shall be addressed.

- b. Gauss fields of various strengths of magnetic resonance imaging (MRI) units shall be considered for the environmental effect on the field homogeneity and vice versa. Radio frequency interference shall be considered when planning the site.
 - c. Sites shall be provided with properly sized power, including emergency power, water, waste, telephone, and fire alarm connections.
 - d. Site shall have level concrete pads or piers and be designed for the structural loads of the facility.
 - e. Site utilizing MRI systems shall consider providing adequate access for cryogen-servicing of the magnet. Storage of dewars also shall be included in space planning.
 - f. It is recommended that each site provide a covered walkway or enclosure to ensure patient safety from the outside elements.
 - g. Diesel exhaust of the tractor and/or unit generator shall be 25feet away from the fresh air intake of the facility.
 - h. Each facility shall provide a means of preventing unit movement, either by blocking the wheels or by providing pad anchors.
 - i. Sites shall provide hazard-free patient drop-off zones and adequate parking.
 - j. The facility shall provide waiting space for patient privacy and patient and staff toilets as close to the unit docking area as possible.
 - k. Each site shall provide access to the unit for wheelchair/stretchers patients.
 - l. Mobile units shall be provided with handwashing stations unless each site can provide handwashing stations within a 25foot proximity to the unit. Transportable and relocatable units shall be provided with handwashing stations.
- E. General Standards for Details and Finishes for Unit Construction.
- 1. Horizontal sliding doors and power-operated doors shall comply with NFPA

RULES FOR CRITICAL ACCESS HOSPITALS 2021

101.

2. Units shall be permitted a single means of egress as permitted by NFPA 101.
3. All glazing in doors shall be safety or wire glass.
4. Units shall be equipped with fire detection and alarm systems. In relocatable and transportable units these systems shall be connected to the central fire alarm system.
5. Radiation protection for X-ray and gamma ray installations shall be in accordance with Arkansas Rules and Regulations for Control of Sources of Ionizing Radiation.
6. Interior finish materials shall be class A as defined in NFPA 101.
7. Textile materials having a napped, tufted, looped, woven, nonwoven, or similar surface shall be permitted on walls and ceilings provided such materials have a class A rating and rooms or areas are protected by an automatic extinguishment or sprinkler system.
8. Fire retardant coatings shall be permitted in accordance with NFPA 101.
9. Curtains and draperies shall be noncombustible or flame retardant and shall pass both the large and small scale tests required by NFPA 101. Fire retardant coatings shall be permitted in accordance with NFPA 101.

F. Mechanical Standards.

1. Air conditioning, heating, ventilating, ductwork, and related equipment shall be installed in accordance with NFPA 90A, Standard for the Installation of Air Conditioning and Ventilation systems.
2. Plumbing Standards.
 - a. Plumbing and other piping systems shall be installed in accordance with the Arkansas State Plumbing Code.
 - b. Mobile units, requiring sinks, shall not be required to be vented through the roof. Ventilation of waste lines shall be permitted to be vented through the sidewalls or other acceptable locations. Transportable and relocatable units shall be vented through the roof per model plumbing codes.
 - c. Backflow prevention shall be installed at the point of water connection

on the unit.

- d. Medical gases and suction systems, if installed, shall be in accordance with NFPA 99.

G. Electrical Standards

1. All electrical material and equipment, including conductors, controls, and signaling devices, shall be installed in compliance with applicable section of NFPA 70 and NFPA 99 and shall be listed as complying with available standards of listing agencies or other similar established standards where such standards are required.
2. The electrical installations, including alarm, nurse call, and communication systems, shall be tested to demonstrate that equipment installation and operation is appropriate and functional. A written record of performance tests on special electrical systems and equipment shall show compliance with applicable codes and standards.
3. Data processing and/or automated laboratory or diagnostic equipment, if provided, may require safeguards from power line disturbances.
4. Main switchboards shall be located in an area separate from plumbing and mechanical equipment and shall be accessible to authorized persons only. Switchboards shall be convenient for use, readily accessible for maintenance, away from traffic lanes, and located in dry, ventilated spaces free of corrosive or explosive fumes, gases, or any flammable material. Overload protective devices shall operate properly in ambient room temperatures.
5. Panelboards serving normal lighting and appliance circuits shall be located on the same level as the circuits they serve.
6. Lighting shall be engineered to the specific application.
7. The Illuminating Engineering Society of North America (IES) has developed recommended lighting levels for health care facilities. The reader should refer to the IES Handbook (1993).
8. Approaches to buildings and parking lots and all occupied spaces shall have fixtures for lighting that can be illuminated as necessary.
9. Consideration should be given to the special needs the elderly. Excessive contrast in lighting levels that make effective sight adaptation difficult should be minimized.
10. A portable or fixed examination light shall be provided for

RULES FOR CRITICAL ACCESS HOSPITALS 2021

examination, treatment, and trauma rooms.

11. Duplex grounded-type receptacles (convenience outlets) shall be installed in all areas in sufficient quantities for tasks to be performed as needed. Each examination and work table shall have access to a minimum of two duplex receptacles.
12. At inhalation anesthetizing locations, all electrical equipment and devices, receptacles, and wiring shall comply with applicable sections of NFPA 99 and NFPA 70.
13. Fixed and mobile x-ray equipment installations shall conform to articles 517 and 660 of NFPA 70.
14. Emergency lighting and power shall be provided for in accordance with NFPA 99, NFPA 101, AND NFPA 110.
15. The fire alarm system shall be as described in NFPA 101 AND WHERE APPLICABLE NFPA 72.
16. Terminating devices for telecommunications and information systems wiring shall be located on the unit that the terminating devices serve. These terminating devices shall be accessible to authorized personnel only.
17. Special air conditioning and voltage regulation shall be provided when recommended by the manufacturer.

SECTION 55: PHYSICAL FACILITIES, LABORATORY SERVICES.

- A. Facilities necessary for providing laboratory services described in the narrative program shall be provided. The laboratory shall be constructed, arranged and maintained to ensure adequate space, ventilation and utilities necessary for conducting all phases required of testing in accordance with current CLIA regulations refer to Section 19.
- B. Specimen collection facilities shall be provided. These facilities may be located outside the laboratory suite. The blood collection area shall have a work counter, space for patient seating, and handwashing facilities. Urine and feces collection room(s) shall be equipped with a water closet and a lavatory.
- C. Provisions shall be made for safety from physical, chemical and biological hazards. There shall be eye flushing devices, appropriate storage of flammable liquids, emergency spill kit(s) and fire extinguishers as required by NFPA 99.
- E. Locker and toilet facilities for laboratory staff shall be located convenient to the laboratory area.

SECTION 56: PHYSICAL FACILITIES, REHABILITATION THERAPY DEPARTMENT.

- A. Common Elements. Each rehabilitative therapy department shall include the following, which may be shared or provided as separate units for each service:
1. Office and clerical space with provisions for filing and retrieval of patient records.
 2. Reception and control station(s) with visual control of waiting and activities area. (This may be combined with office and clerical space.)
 3. Patient waiting area(s) out of traffic with provision for wheelchair patients.
 4. Patient toilets with handwashing stations accessible to wheelchair patients.
 5. Space(s) for storing wheelchairs and stretchers out of traffic while patients are using the services. These spaces may be separate from the service area but shall be conveniently located.
 6. A conveniently accessible housekeeping room and service sink for housekeeping use.
 7. Locking closets or cabinets within the vicinity of each work area for securing staff personal effects.
 8. Convenient access to toilets and lockers.
 9. Access to a demonstration/conference room.
 10. Lockable storage for medications.
- B. Physical Therapy. If physical therapy is part of the service, the following at least, shall be included:
1. Individual treatment area(s) with privacy screens or curtains. Each such space shall have not less than 70 square feet of clear floor area.
 2. Handwashing stations for staff either within or at each treatment space (one handwashing station may serve several stations).
 3. Exercise area and facilities.
 4. Clean linen and towel storage.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

5. Storage for equipment and supplies.
 6. Separate storage for soiled items.
 7. Patient change area. (If required by the functional program.)
- C. Occupational Therapy. If this service is provided, at least the following shall be included:
1. Work areas and counters suitable for wheelchair access.
 2. Handwashing stations.
 3. Storage for supplies and equipment.
 4. An area for daily living activities shall be provided. It shall contain an area for a bed, kitchen counter with appliances and sink, bathroom, and a table/chair.
- D. Prosthetics and Orthotics. If this service is provided, at least, the following shall be included:
1. Work space for technicians;
 2. Space for evaluating and fitting, with provisions for privacy;
 3. Space for equipment, supplies and storage.
- E. Recreation Therapy. NOTE: Recreation therapy assists patients in the development and maintenance of community living skills through the use of leisure-time activity tasks. These activities may occur in a recreation therapy department, in specialized facilities (e.g., gymnasium), multipurpose space in other areas (e.g., the nursing unit), or outdoors. If this service is provided, at least, the following shall be included:
1. Activity areas suitable for wheelchair access;
 2. Handwashing stations if required by the program;
 3. Storage for supplies and equipment;
 4. Secured storage for supplies and equipment potentially harmful;
 5. Remote electrical switching for equipment potentially harmful.
- F. Speech, Hearing, and Audio Therapy. If this service is provided, at least, the following shall be included:

RULES FOR CRITICAL ACCESS HOSPITALS 2021

1. Space for evaluation and treatment of patients. The space shall be protected with acoustical treatment of walls and finishes.
 2. Space for equipment storage and supplies.
- G. Respiratory Care. If respiratory care is part of the service, the following, at least, shall be included as a minimum:
1. Storage of equipment and supplies.
 - a. Space and utilities for cleaning and sanitizing equipment. Provide physical separation of the space for receiving and cleaning soiled materials from the space for storage of clean equipment and supplies. Appropriate local exhaust ventilation shall be provided if glutaraldehyde or other noxious disinfectants are used in the cleaning.
 - b. If respiratory services, such as testing and demonstration for outpatients are part of the program, additional facilities and equipment shall be provided as necessary for the appropriate function of the service, including but not limited to:
 - 1) Patient waiting area with provision for wheelchairs;
 - 2) Reception and control station;
 - 3) Patient toilets and handwashing facilities;
 - 4) Room(s) for patient education and demonstration;
 2. Cough-Inducing and Aerosol-Generating Procedures. All cough-inducing procedures performed on patients who may have suspected or active infectious Mycobacterium tuberculosis shall be performed in rooms that meets the requirements for airborne infection control.

SECTION 57: PHYSICAL FACILITIES, MORGUE AND NECROPSY.

These facilities shall be directly accessible to an outside entrance and shall be located to avoid movement of bodies through public areas. The following elements shall be provided when autopsies are performed within the hospital:

- A. Refrigerated facilities for body-holding;
- B. Autopsy Room. This room shall contain:
 - 1. Work counter with sink equipped for handwashing;
 - 2. Storage space for supplies, equipment, and specimens;
 - 3. Autopsy table;
 - 4. A deep sink for washing of specimens;
 - 5. A housekeeping service sink or receptor for cleanup and housekeeping.

NOTE: If autopsies are performed outside the facility, only a well ventilated, temperature- controlled, body-holding room need be provided.

SECTION 58: PHYSICAL FACILITIES, PHARMACY.

The size and type of services to be provided in the pharmacy can largely depend upon the type of medication distribution system used, number of patients to be served, and extent of shared or purchased services. This shall be described in the functional program. The pharmacy room or suite shall be located for convenient access, staff control, and security. Facilities and equipment shall be as necessary to accommodate the functions of the program. See Section 16, Pharmacy, for additional requirements. (Satellite facilities, if provided, shall include those items required by the program.) As a minimum, the following elements shall be included:

- A. Dispensing.
 - 1. A pickup and receiving area.
 - 2. An area for reviewing and recording.
 - 3. An extemporaneous compounding area that includes a sink and sufficient counter space for medication preparation.
 - 4. Work counters and space for automated and manual dispensing activities.
 - 5. An area for temporary storage, exchange, and restocking of carts.
 - 6. Security provisions for medications and personnel in the dispensing counter area.
- B. Manufacturing.
 - 1. A bulk compounding area.
 - 2. Provisions for packaging and labeling.
 - 3. A quality control area.
- C. Storage (may be cabinets, shelves, and/or separate rooms or closets).
 - 1. Bulk storage.
 - 2. Active storage.
 - 3. Refrigerated storage.
 - 4. Volatile fluids and alcohol storage constructed according to applicable fire safety codes for the substances involved.
 - 5. Double-locked storage for controlled substances.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

6. Storage for general supplies and equipment not in use.

D. Administration.

1. An area for education and training (may be in a multipurpose room shared with other departments).
2. An area for patient counseling and instruction (may be in a room separate from the pharmacy).
3. A separate area for office functions.

E. Other.

1. Handwashing stations shall be provided within each separate room where open medication is handled and readily accessible.
2. Provide for convenient access to toilet and locker.
3. If unit dose procedure is used, provide additional space and equipment for supplies, packaging, labeling, and storage, as well as for the carts.
4. If IV solutions are prepared in the pharmacy, provide a sterile work area with a laminar-flow work station designed for product protection. The laminar-flow system shall include a nonhydroscopic filter (HEPA) rated at 99.97 percent, as tested by DOP tests and have a visible pressure gauge for detection of filter leaks or defects.
5. Hoods used for chemotherapy shall be 100percent exhausted to the exterior.
6. As a minimum the partitions enclosing the pharmacy shall extend from the floor to the deck above, with gypsum board on both sides of metal studs.

SECTION 59: PHYSICAL FACILITIES, DIETARY FACILITIES.

Construction, equipment, and installation shall comply with the standards specified in FDA U.S. Public Health Service Food Code. Food service facilities shall be designed and equipped to meet the requirements of the functional program. These may consist of an onsite conventional food preparing system, a convenience food service system, or an appropriate combination of the two. The following shall be provided:

- A. Receiving/Control Areas. Provide an area for the receiving and control of incoming dietary supplies. This area shall be separated from the general receiving area and shall contain the following: a control station, and a breakout for loading, uncrating, and weighing supplies;
- B. Storage Spaces. A minimum of four days' supplies shall be stocked. (In remote area s, this number may be increased to accommodate length of delivery in emergencies). All food shall be stored clear of the floor. Lowest shelf shall not be less than 12 inches above the floor or shall be closed in and sealed tight for ease of cleaning;
- C. Cleaning supplies storage. Provide a separate storage room for the storage of non-food items such as cleaning supplies that might contaminate edibles.
- D. Food Preparation Facilities. Conventional food preparation systems shall have adequate space and equipment for preparing, cooking, and baking. Convenience food preparation systems shall have adequate space for equipment for thawing, portioning, cooking, and/or baking. These areas shall be as close as possible to the user (i.e., tray assembly and dining);
- E. Assembly and Distribution Areas. A patient tray assembly area shall be located within close proximity to the food preparation and distribution areas;
- F. Food Service Carts. A cart distribution area shall provide space for storage, loading, distribution, receiving, and sanitizing of food service carts. The cart traffic shall be designed to eliminate any danger of cross circulation between outgoing food carts and incoming, soiled carts, and the cleaning and sanitizing process. Cart circulation shall not traffic through food processing areas;
- G. Handwashing Stations. These shall be operable without the use of hands and be readily accessible at locations throughout the dietary department;
- H. Dining Area. There shall be dining space for ambulatory patients, staff, and visitors which is separate from the food preparation and distribution areas;
- I. Area for Receiving, Scraping, and Sorting Soiled Tableware. Area shall be adjacent to

RULES FOR CRITICAL ACCESS HOSPITALS 2021

ware washing and separate from food preparation areas. A handwashing fixture shall be conveniently available;

- J. Dishwashing Space. An area shall be located in a room separate from food preparation and serving areas. Commercial-type dishwashing equipment shall be provided. Clean and soiled dish areas shall be separated with an opening in the partition between the clean and soiled dish area large enough for the dishwasher and ventilation of the area. The clean dish area may be either a separate room or a portion of the kitchen. A lavatory shall be conveniently available. The soiled dish area shall be so located as to prevent soiled dishes from being carried through the food preparation area;
- K. Ware Washing Facilities. They shall be designed to prevent contamination of clean wares with soiled wares through cross-traffic. The clean wares should be transferred for storage or use in the dining area without having to pass through food preparation areas;
- L. Pot Washing Facilities including multi-compartmented sinks of adequate size for intended use shall be provided convenient to using service. Supplemental heat for hot water to clean pots and pans may be by booster heater or by steam jet.
- M. Waste Storage Room. A food waste storage room shall be conveniently located to the food preparation and ware washing areas but not within the food preparation area.
It shall have direct access to the hospital's waste collection and disposal facilities.
- N. Storage Rooms and Areas. A room for cans, carts, mobile tray conveyors, and cleaning and sanitizing carts shall be provided. There shall be a separate storage room for the storage of non-food items that might contaminate edibles (i.e., cleaning supplies). A separate space or room for the storage of cooking wares, extra trays, flatware, plastic and paper products, and portable equipment is required;
- O. Toilets and Locker Spaces. Lockers, if provided in the dietary facility, shall be for the exclusive use of the dietary staff. Toilets and lockers shall not open directly into the food preparation areas, but shall be in close proximity to them;
- P. Office(s). Dietary service manager/supervisor offices shall be conveniently located for visual control of receiving area and food preparation areas;
- Q. Environmental Closet. A closet shall be provided for the exclusive use of the dietary department to contain a floor sink and space for mops, pails, and supplies. Where hot water or steam is used for general cleaning, additional space within the room shall be provided for the storage of hoses and nozzles;
- R. Ice Making Equipment. Equipment shall be convenient for service and easily cleaned. It shall be provided for both drinks (self-dispensing equipment), and for general use (storage bin type equipment);

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- S. Commissary or Contract Services from Other Areas. If a service is used, above items may be reduced as appropriate. The process of food delivery shall insure freshness, retention of hot and cold, and avoidance of contamination. If delivery is from outside sources, protection against weather shall be provided. Provisions shall be made for thorough cleaning and sanitizing of equipment to avoid mix of soiled and clean equipment;

- T. Equipment. Mechanical devices shall be heavy duty, suitable for intended use and easily cleaned. Movable equipment shall have heavy duty locking casters. If equipment is to have fixed utility connections, it shall not be equipped with casters. Walk-in coolers, refrigerators, and freezers shall be insulated at floor, walls and top. Coolers and refrigerators shall be capable of maintaining a temperature down to freezing. Freezers shall be capable of maintaining a temperature of 20°below zero Fahrenheit. Coolers, refrigerators, and freezers shall be thermostatically controlled to maintain desired temperature settings in increments of two degrees or less. Interior temperatures shall be visible from the exterior. Controls may include audible and visible high and low temperature alarm. Time of alarm shall be automatically recorded. Walk-in units may be lockable from outside but shall have release mechanism for exit from inside at all times. Interior shall be lighted. All shelving shall be corrosion resistant, easily cleaned, and constructed and anchored to support a loading of at least 100pounds per linear foot. All cooking equipment shall be equipped with automatic shut off devices to prevent excessive heat buildup. Under counter conduits, piping, and drains shall be arranged to not interfere with cleaning of floor below or of the equipment;

SECTION 60: PHYSICAL FACILITIES, ADMINISTRATION AND PUBLIC AREAS.

The following areas shall be provided:

- A. Facility entrance, at grade level, sheltered from the weather, and able to accommodate wheelchairs;
- B. Lobby, which shall include:
 - 1. Reception and information counter or desk;
 - 2. Waiting space(s);
 - 3. Public toilet facilities (one for each sex);
 - 4. Public telephone(s);
 - 5. Drinking fountain(s);
- C. Interview space(s) for private interviews relating to social service, credit, and admissions;
- D. General or individual office(s) for business transactions, medical and financial records, and administrative and professional staffs;
- E. Multipurpose room(s) with provisions for the use of visual aids for conferences, meetings, and health education. One multipurpose room may be shared by several services;
- F. Storage for office equipment and supplies; and
- G. Staff toilet facilities.

SECTION 61: PHYSICAL FACILITIES, HEALTH INFORMATION UNIT.

The following rooms and areas shall be provided:

- A. Health Information Director's office or space;
- B. Review and dictating room(s) or spaces;
- C. Work area for sorting, recording, or microfilming records;
- D. Medical record storage (Refer to Section 61A.26); and

Rooms for patient medical records and archived patient medical records that remain onsite shall be kept in a one hour fire rated enclosure or protected by a sprinkler system; protected by a security system and a smoke detection system. Circulating records at the nurses' station or in active working areas are excluded from this requirement. The records shall be protected against undue destruction from dust, vermin, water, etc

SECTION 62: PHYSICAL FACILITIES, CENTRAL MEDICAL AND SURGICAL SUPPLY DEPARTMENT.

The following areas shall be provided:

A. Separate Soiled and Clean Work Areas

1. Soiled Workroom. This room shall be physically separated from all other areas of the department. Work space shall be provided to handle the cleaning and initial sterilization/disinfection of all medical/surgical instruments and equipment, work tables, sinks, flush-type devices, and washer/sterilizer decontaminators. Pass-through doors and washer/sterilizer decontaminators shall deliver into clean processing area/workrooms.
2. Clean Assembly/Workroom. This workroom shall contain handwashing stations, workspace, and equipment for terminal sterilizing of medical and surgical equipment and supplies. Clean and soiled work areas shall be physically separated.

B. Storage Areas

Clean/Sterile Medical/Surgical Supplies. A room shall be provided for the breakdown of clean/sterile bulk supplies. Storage for packs etc., shall include provisions for ventilation, humidity, and temperature control.

C. Administrative/Changing Room

If required by the functional program, this room shall be separate from all other areas and provide for staff to change from street clothes into work attire. Lockers, sink, and showers shall be made available within the immediate vicinity of the department.

D. Storage Room for Patient Care and Distribution Carts

This area shall be adjacent, easily available to clean and sterile storage, and close to main distribution point to keep traffic to a minimum and to ease work flow.

SECTION 63: PHYSICAL FACILITIES, CENTRAL SUPPLY AND RECEIVING.

In addition to supply facilities in individual departments, a central storage area shall also be provided. General stores may be located in a separate building onsite with provisions for protection against inclement weather during transfer of supplies. The following shall be provided:

- A. Off-street unloading facilities;
- B. Receiving area;
- C. General Storage Room(s). General storage rooms(s) with a total area of not less than 20 feet per inpatient bed shall be provided. Storage may be in separate, concentrated areas within the institution or in one or more individual buildings onsite. A portion of this storage may be provided offsite; and
- D. Additional Storage Room(s). Additional storage areas for outpatient facilities shall be provided in an amount not less than five percent of the total area of the outpatient facilities. This may be combined with and in addition to the general stores or be located in a central area within the outpatient department. A portion of this storage may be provided offsite.

SECTION 64: PHYSICAL FACILITIES, LINEN SERVICES.

Each facility shall have provisions for storing and processing of clean and soiled linen for appropriate patient care. Processing may be done within the facility, in a separate building on- or off-site, or in a commercial or shared laundry.

- A. Facility Processing. Facilities and equipment shall be as required for cost effective operation as described in the functional program. At a minimum, the following elements shall be included:
 - 1. A separate room for receiving and holding soiled linen until ready for pickup or processing.
 - 2. A central, clean linen storage and issuing room(s), in addition to the linen storage required at individual patient units.
 - 3. Cart storage area(s) for separate parking of clean- and soiled-linen carts out of traffic.
 - 4. A clean linen inspection and mending room or area. If not provided elsewhere, a clean linen inspection, delinting, folding, assembly and packaging area should be provided as part of the linen services. Mending should be provided for in the linen services department. A space for tables, shelving, and storage should be provided.
 - 5. Handwashing stations in each area where unbagged, soiled linen is handled.
- B. If linen is processed in a laundry facility that is not part of the licensed facility provisions shall also be made for:
 - 1. A service entrance, protected from inclement weather, for loading and unloading of linen.
 - 2. Control station for pickup and receiving.
 - 3. The hospital is responsible to insure the commercial laundry does comply with Section 42, Physical Environment.
- C. If linen is processed in a laundry facility that is part of the licensed facility, the following shall be provided in addition to that of Section 64 A:
 - 1. A receiving, holding, and sorting room for control and distribution of soiled linen. Discharge from soiled linen chutes may be received within this room or in a separate room.
 - 2. Laundry processing room with commercial type equipment that can

RULES FOR CRITICAL ACCESS HOSPITALS 2021
06/17/19

process at least a seven-day supply within the regular scheduled workweek. This may require a capacity for processing a seven-day supply in a 40-hour week.

3. Storage for laundry supplies.
4. Employee handwashing stations in each room where clean or soiled linen is processed and handled.
5. Arrangement of equipment that will permit an orderly workflow and minimize cross-traffic that might mix clean and soiled operations.
6. Conveniently accessible staff lockers, showers, and lounge.

SECTION 65: PHYSICAL FACILITIES, CLEANING AND SANITIZING CARTS, EMPLOYEE FACILITIES AND ENVIRONMENTAL CLOSETS.

- A. Facilities shall be provided to clean and sanitize carts serving the central medical and surgical supply department, dietary facilities, and linen services. These may be centralized or departmentalized or offsite as required by the written narrative.
- B. Lockers, lounges, toilets, etc. should be provided for employees and volunteers. These should be in addition to, and separate from, those required for medical staff and public.
- C. Each environmental services closet shall contain a floor receptor and/or services sink and storage space for environmental services equipment (cart, bucket, etc.) and supplies. There shall be at least one environmental services closet for each floor.

SECTION 66: PHYSICAL FACILITIES, ENGINEERING SERVICE AND EQUIPMENT AREAS.

Space shall be included in all mechanical and electrical equipment rooms for proper maintenance of equipment. Provisions shall also be made to provide for equipment removal and replacement. The following shall be provided:

- A. Boilers, mechanical equipment, and electrical equipment shall be located in ventilated rooms or buildings except as noted below:
 - 1. Rooftop air conditioning and ventilation equipment installed in weatherproof housings;
 - 2. Standby generators where the engine and appropriate accessories (i.e., batteries) are properly heated and enclosed in a weatherproof housing as recommended by the manufacturer;
 - 3. Cooling towers and heat rejection equipment;
 - 4. Electrical transformers and switchgear where required to serve the facility and where installed in a weatherproof housing;
 - 5. Medical gas parks and equipment;
 - 6. Air cooled chillers where installed in a weatherproof housing;
 - 7. Waste processing equipment. Site lighting, post indicator valves, and other equipment normally installed on the exterior of the building;
 - 8. Site lighting, post indicator valves, and other equipment normally installed on the exterior of the building; and
 - 9. Exhaust fans.
- B. Engineer's office with file space and provisions for secured storage of facility drawings, records, manuals, etc. The engineer's office shall be a separate and distinct space dedicated for the purpose;
- C. General maintenance shop(s) for repair and maintenance as required by the functional program;
- D. Storage room for building maintenance supplies. Storage for solvents and flammable liquids shall comply with applicable NFPA codes;
- E. Yard equipment and supply storage shall be located so equipment may be moved directly to exterior without interfering with other work;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

06/17/19

- F. Separate area or room specifically for storage, repair, and testing of electronic and other medical equipment. The amount of space and type of utilities will vary with the type of equipment involved and types of outside contracts used.

SECTION 67: PHYSICAL FACILITIES, WASTE PROCESSING SERVICES.

- A. Hazardous Waste and Antineoplastic Agent Disposal. The facility shall have policies and procedures for the identification, segregation, labeling, storage, transport and disposal of hazardous waste. The policies and procedures shall conform with the latest edition of Hazardous Waste Management Regulation 23, Arkansas Department of Environmental Quality, Little Rock, Arkansas. Within the facility, hazardous waste, especially antineoplastic agents, shall be labeled in a manner that it shall be easily recognized from all other waste. The facility shall compile a list of all antineoplastic agents used in the facility. The facility shall have policies and procedures for the cleanup of spills, decontamination and treatment of personnel exposed to hazardous waste and antineoplastic agents.
- B. Radioactive Waste Disposal. The facility shall have policies and procedures for the identification, segregation, labeling, storage, transport and disposal of radioactive waste and materials. All policies and procedures shall conform to the most current Rules and Regulations for Control of Sources of Ionizing Radiation, Arkansas Department of Health, Little Rock, Arkansas. The facility shall maintain records of all radioactive waste and materials which have been disposed.
- C. Regulated Medical Waste (Infectious Waste) Disposal. The facility shall have policies and procedures for the identification, segregation, labeling, storage, transport and disposal of Regulated Medical Waste. All policies and procedures shall conform to the latest edition of the. The facility shall have policies and procedures for the cleanup of spills, and for decontamination and treatment of personnel exposed to regulated medical waste.
- D. Solid Waste Disposal (Non-Infectious Waste). The facility shall have policies and procedures for the identification, segregation, labeling, storage, transport and disposal of solid waste. Policies and procedures shall conform with the latest edition of the Solid Waste Management Regulation 22, Arkansas Department of Environmental Quality, Little Rock, Arkansas.
- E. Nuclear Waste Disposal: The facility shall have policies and procedures for the identification, segregation, labeling, storage, transport and disposal of nuclear waste. All policies and procedures shall conform to the Code of Federal Regulations; title X, parts 20 and 35, concerning the handling and disposal of nuclear materials in health care facilities.
- F. Containers of hazardous and antineoplastic agent waste, radioactive waste, and regulated medical waste shall be closed except when receiving waste. Containers have swinging lids or lids that are easily contaminated are prohibited. Open containers shall be emptied between patients and the container disinfected. Containers shall be kept closed except when receiving waste.

- G. Other Waste. The facility shall have policies and procedures for the identification, segregation, labeling, storage, transport, and disposal of any waste not specifically mentioned in this section.

SECTION 68: PHYSICAL FACILITIES, DETAILS AND FINISHES.

All details for alteration or expansion projects as well as for new construction shall comply with the following.

A. Details.

1. Compartmentation, exits, automatic extinguishing systems, and other details relating to fire prevention and fire protection shall comply with requirements listed in the NFPA referenced codes and be shown on the Fire Protection Plan. The Fire Safety Evaluation System (FSES) is an acceptable means of determining Life Safety Code compliance.
2. Minimum corridor width shall be eight feet clear without projections. Increased width shall be provided at elevator lobbies and other places where conditions may demand more clearance. All service or administrative corridors shall not be less than 44 inches in width. Doors to patient rooms shall be a minimum door size of three feet eight inches wide and seven feet high to provide clearance for movement of beds and other equipment. Alternatively, NFPA 101 shall be deemed to meet requirements.
3. Items such as drinking fountains, telephone booths, and vending machines, shall be located so as not to project into exit access corridors. Incidental items shall be determined by the licensing agency.
4. Rooms containing bathtubs, sitz baths, showers, and water closets, subject to occupancy by patients, shall be equipped with doors and hardware which shall permit access from the outside in any emergency.
5. All doors between corridors, rooms, or spaces subject to occupancy, except elevator doors, shall be of the swing type. Openings to showers, baths, patient toilets, ICU patient compartments with the breakaway feature, and other such areas not leading to fire exits shall be exempt from this standard.
6. All patient room doors located on exit access corridors shall have positive latching hardware.
7. Doors to patients' toilet rooms and other rooms needing access for wheelchairs shall have a minimum width of 36 inches for new facilities. Alcoves and similar spaces which generally do not require doors are excluded from this requirement.
8. Windows shall be designed so that persons cannot accidentally fall out of them when they are open or shall be provided with security screens. Operation of windows shall be restricted to inhibit possible escape or suicide. Where the operation of windows or vents require the use of tools

RULES FOR CRITICAL ACCESS HOSPITALS 2020

or keys, tools or keys shall be on the same floor and easily accessible to staff.

9. Glass doors, lights, sidelights, borrowed lights, and windows located within 12 inches of a door jamb (with a bottom frame height of less than 60 inches above the finished floor) shall be constructed of safety glass, wired glass, or plastic, break resistant material that creates no dangerous cutting edges when broken. Similar materials shall be used for wall openings in active areas such as recreation rooms and exercise rooms, unless otherwise required for fire safety. Safety glass-tempered or plastic glazing materials shall be used for shower doors and bath enclosures. Plastic and similar materials used for glazing shall comply with the flame- spread ratings of NFPA 101. Safety glass or plastic glazing materials, as noted above, shall also be used for interior windows and doors, including those in pediatric and psychiatric unit corridors. In renovation projects, only glazing within 18 inches of the floor shall be changed to safety glass, wire glass, or plastic, break-resistant material. NFPA 101 contains additional requirements for glazing in exit corridors, etc., especially in buildings without sprinkler systems.
10. Where labeled fire doors are required, these shall be certified by an independent test laboratory as meeting the construction requirements equal to those for fire in NFPA Standard 80. Reference to a labeled door shall be construed to include labeled frame and hardware.
11. Trash chutes shall be in accordance with NFPA standard 82. In addition, linen and refuse chutes shall meet or exceed the following requirements:
 - a. Service openings to chutes shall not be located in corridors or passageways but shall be located in a room which complies with NFPA 101;
 - b. Service openings to chutes shall have approved self-closing Class B one and one-half hour labeled fire doors;
 - c. Minimum cross-sectional dimensions of gravity chutes shall not be less than two feet;
 - d. Chutes shall discharge directly into collection rooms separate from incinerator, laundry, or other services. Separate collection rooms shall be provided for trash and for linen. Chute discharge into collection rooms shall comply with NFPA 101;
 - e. Gravity chutes shall extend through the roof with provisions for continuous ventilation as well as for fire and smoke ventilation. Openings for fire and smoke ventilation shall have an effective area of not less than

RULES FOR CRITICAL ACCESS HOSPITALS 2020

that of the chute cross-section and shall be not less than four (4) feet above the roof and not less than six (6) feet clear of other vertical surfaces. Fire and smoke ventilating openings may be covered with single strength sheet glass.

11. Dumbwaiters, conveyors, and material handling systems shall comply with NFPA 101.
12. Thresholds and expansion joint covers shall be installed flush with the floor surface to facilitate use of wheelchairs and carts. Expansion and seismic joints shall be constructed to restrict the passage of smoke.
13. Grab bars shall be provided in all patients' toilets, showers, tubs, and sitz baths. The bars shall have one and one-half inch clearance to walls and shall have sufficient strength and anchorage to sustain a concentrated load of 250pounds.
14. Soap dishes, soap dispensers and/or other devices shall be provided at showers, bath tubs, and all handwashing stations except scrub sinks.
15. Location and arrangement of handwashing stations shall permit proper use and operation. All sinks, except public toilets, janitor closets, and sinks used by patients only, shall have foot, knee, or wrist blade faucets. Particular care shall be given to the clearances required for blade-type operating handles.
16. Mirrors shall not be installed at handwashing fixtures in food preparation areas, nurseries, clean and sterile supply areas, scrub sinks, or other areas where asepsis is essential. Provisions for hand drying shall be included at all handwashing stations except scrub sinks. Paper units shall be enclosed to protect against dust or soil and to insure single unit dispensing.
17. Lavatories and handwashing stations shall be securely anchored to withstand an applied downward vertical load of not less than 250pounds on the front of the fixture.
18. Radiation protection requirements of X-ray and gamma ray installations shall conform with Rules and Regulations for Control of Sources of Ionizing Radiation, Arkansas Department of Health.
19. The minimum ceiling height shall be seven feet ten inches with the following exceptions:
 - a. Boiler rooms shall have ceiling clearances not less than two feet six inches above the main boiler header and connecting piping.
 - b. Ceilings in radiographic, operating and delivery rooms, and other rooms containing ceiling-mounted equipment or ceiling-mounted surgical light

RULES FOR CRITICAL ACCESS HOSPITALS 2020

- fixtures shall be of sufficient height to accommodate the equipment or fixtures and their normal movement.
- c. Ceilings in corridors, storage rooms, and toilet rooms shall be not less than seven feet eight inches in height. Ceiling heights in small, normally unoccupied spaces may be reduced.
 - d. Seclusion treatment rooms shall have a minimum ceiling height of nine feet.
- 20. Recreation rooms, exercise rooms, and similar spaces where impact noises may be generated shall not be located directly over patient bed area, delivery or operating suites, unless special provisions are made to minimize such noise.
 - 21. Rooms containing heat-producing equipment (such as boiler or heater rooms and laundries) shall be insulated and ventilated to prevent any floor or partition surface from exceeding a temperature of 10°Fahrenheit above ambient room temperature.
 - 22. Noise reduction criteria shown in Table 2 of the Appendix shall apply to partition, floor, and ceiling construction in patient areas. (Careful attention shall be given to penetrations.)
 - 23. Approved fire extinguishers shall be provided in locations throughout the building in accordance with NFPA Standard No. 10. Extinguishers located in exit corridors shall be recessed.
 - 24. Offsite buildings or freestanding buildings used for storage of archived patient medical records shall be built of noncombustible materials and provide security and smoke detection systems for the records. Records shall be arranged in an accessible manner and stored at least six inches above the floor. Records shall be protected against undue destruction from dust, vermin, water, etc. X-ray film storage are not required to meet the above requirements.
 - 25. Light fixtures shall be provided with protective covers in food preparation, serving areas, and patient care and treatment spaces. Protective light fixture covers are not required in corridors.
 - 26. Minimum distance between patient room windows and adjacent structures shall be 30 feet (new construction only).
 - 27. A panic bar releasing device shall be provided for all required exit doors subject to patient traffic (new construction only).
 - 28. Doors in smoke barrier partitions shall comply with NFPA 101.

RULES FOR CRITICAL ACCESS HOSPITALS 2020

29. Fire rated roof-ceiling assemblies shall be listed with a nationally recognized laboratory.
 30. Mechanical smoke door coordinators shall not be used. Adjustable hydraulic closures or the full length header type shall be used.
 31. Corridor partitions, smokestop partitions, horizontal exit partitions, exit enclosures, and fire rated walls required to have protected openings shall be effectively and permanently identified with signs or stenciling in a manner acceptable to Health Facility Services. Such identification shall be above any decorative ceiling and in concealed spaces.
- B. Finishes.
1. Cubicle curtains and draperies shall be noncombustible or rendered flame retardant and shall pass both the large and small scale tests of NFPA Standard 701 and the requirements of NFPA 13 when applicable.
 2. Flame spread, fuel contributed, smoke density, and critical radiant flux of finishes shall comply with NFPA 101.
 3. Floors in areas and rooms in which anesthetic agents are stored or administered to patients shall comply with NFPA Standard 99. Conductive flooring may be omitted in anesthetizing areas where a written resolution is signed by the hospital board stating that no flammable anesthetic agents shall be used and appropriate notices are permanently and conspicuously affixed to the wall in each such area and room.
 4. Floor materials shall be easily cleanable and have wear resistance appropriate for the location involved. Floors in areas used for food preparation or food assembly shall be water resistant and grease-proof. Joints in tile and similar material in such areas shall be resistant to food acids. In all areas frequently subject to wet cleaning methods, floor-materials shall not be physically affected by germicidal and cleaning solutions. Floors that are subject to traffic while wet (such as shower and bath areas, kitchens, and similar work areas) shall have a non-slip surface. Any facility designed to install carpet shall have prior approval from the Arkansas Department of Health. The prior approval in part shall be contingent upon submission of a laboratory test report from an approved independent laboratory indicating that the proposed carpet meets or exceeds the requirements listed in NFPA 101 and agreement by the Department as to the specific areas in which carpet is to be used. In all carpet installations no rubber backings or rubber padding shall be permitted except in cases where the carpet and backing are tested as an integral component and the integral component meets the requirements listed in NFPA 101. Carpet shall not be allowed in the following areas or rooms: operating rooms, delivery rooms,

RULES FOR CRITICAL ACCESS HOSPITALS 2020

emergency rooms, intensive care units, nursery, recovery, kitchens, laboratories, LDR and LDRP rooms, clean and soiled holding/workrooms, and isolation rooms. Operating rooms shall have a seamless floor.

5. Wall bases in kitchens, operating rooms, soiled workrooms, and other areas which are frequently subject to wet cleaning methods shall be made integral and coved with the floor, tightly sealed within the wall, and constructed without voids that can harbor insects.
6. Wall finishes shall be washable. In the vicinity of plumbing fixtures, shall be smooth and water resistant.
7. Floors and walls penetrated by pipes, ducts, and conduits shall be tightly sealed to minimize entry of rodents and insects.
8. Ceilings in food-preparation and storage areas, shall be cleanable with routine housekeeping equipment.
9. Operating rooms, trauma rooms, delivery rooms for Caesarean sections, and protective isolation rooms shall have ceilings with a smooth finish plaster or gypsum board surface with a minimum of fissures equipped with access panels where needed.
10. In psychiatric patient rooms, toilets, and seclusion rooms, ceiling construction shall be smooth finish plaster or gypsum board surface with a minimum of fissures. Ceiling-mounted air and lighting devices shall be security type. Ceiling-mounted sprinkler heads shall be of the concealed type.
11. Ceilings shall be cleanable and in the following areas shall be washable, waterproof, smooth finish plaster or gypsum board or vinyl faced acoustic panels: cardiac cath labs, surgical suite corridors, delivery suite corridors, central sterilization suite, autopsy rooms, bacteriology, mycology, media preparation rooms, glass washing rooms located in the labs, soiled holding rooms, soiled and clean utility rooms, emergency suite-treatment rooms and trauma rooms.
12. Finished ceilings may be omitted in mechanical, electrical, equipment spaces and shops.
13. Finished ceilings shall be provided for corridors in patient areas.
14. Sound sensitive areas such as neonatal intensive care may have special floor and ceiling treatments.

SECTION 69: PHYSICAL FACILITIES, CONSTRUCTION, INCLUDING FIRE RESISTIVE REQUIREMENTS.

- A. Design. Every building and every portion thereof shall be designed and constructed to sustain all dead and live loads in accordance with American Society of Civil Engineers, (ASCE), "Minimum Design Loads for Buildings and Other Structures."
- B. Foundations. Foundations shall rest on natural solid bearing if a satisfactory bearing is available at reasonable depths. Proper soil-bearing values shall be established in accordance with recognized standards. If solid bearing is not encountered at practical depths, the structure shall be supported on drive piles or drilled piers designed to support the intended load without detrimental settlement, except that one story buildings may rest on a fill designed by a soils engineer. When engineered fill is used, site preparation and placement of fill shall be performed under the direct full-time supervision of the soils engineer. The soils engineer shall issue a final report on the compacted fill operation and certification of compliance with the job specifications. All footings shall extend to a depth not less than one foot below the estimated maximum frost line.

C. Construction.

- 1. Construction shall comply with the applicable requirements of NFPA 101, and the Arkansas Fire Protection Code Volumes I and II and Arkansas State Building Services, Minimum Standards and Criteria - Accessibility for the Physically Disabled Standards.

NOTE: NFPA 101 generally covers fire/safety requirements only, whereas most model codes also apply to structural elements. The fire/safety items of NFPA 101 would take precedence over other codes in case of conflict. In the event NFPA 101 does not specifically address a life safety requirement found only in the Arkansas Fire Prevention Code, compliance with the requirement is not mandatory. Appropriate application of each would minimize problems. For example, some model codes require closers on all patient doors. NFPA 101 recognizes the potential fire/safety problems of this requirement and stipulates that if closers are used for patient room doors, smoke detectors shall also be provided within each affected patient room.

- 2. For renovation projects, the extent of new construction shall be determined by the licensing agency. Construction shall comply with applicable requirements of NFPA 101.

D. Free-standing Buildings (For Patient Use). Buildings of this element category are considered to be greater than 30feet from the hospital or separated from the hospital by two-hour fire resistance rated construction. Buildings housing non-sleeping patient

RULES FOR CRITICAL ACCESS HOSPITALS 2021

areas shall comply with NFPA 101.

- E. Free-standing Buildings. Separate free-standing buildings over 30 feet from an inpatient facility housing the boiler plant, laundry, shops, or general storage shall be built in accordance with applicable building codes for such occupancy.
- F. Interior Finishes. Interior finish materials shall comply with the limitations as indicated in NFPA 101. If a separate underlayment is used with any floor finish materials, the underlayment and the finish material shall be tested as a unit. Tests shall be performed by an approved independent testing laboratory.
- G. Insulation Materials. Building insulation materials, unless sealed on all sides and edges, shall have a flame spread rating of 25 or less and a smoke developed rating of 150 or less when tested in accordance with NFPA 255.
- H. Flood Protection. Executive Order No 11296 was issued to minimize financial loss from flood damage to facilities constructed with federal assistance. In accordance with that order, possible flood effects shall be considered when selecting and developing the site. Insofar as possible, new facilities shall not be located on designated flood plains. Where this is unavoidable, consult with the Corps of Engineers regional office for the latest applicable regulations pertaining to flood insurance and protection measures that may be required.
- I. Elevators. All hospitals having patient facilities (such as bedrooms, dining rooms, or recreation areas) or critical services (such as operating, delivery, diagnostic, or therapeutic) located on other than the grade-level entrance floor shall have electric or hydraulic elevators. Installation and testing of elevators shall comply with ANSI/ASME A17.1 for new construction and ANSI/ASME A17.3 for existing facilities. (See ASCE 7-93 for seismic design and control systems requirements for elevators.)
 - 1. In the absence of an engineered traffic study the following guidelines for number of elevators shall apply:
 - a. At least one hospital-type elevator shall be installed when one to 59 patient beds are located on any floor other than the main entrance floor.
 - b. At least two hospital-type elevators shall be installed when 60 to 200 patient beds are located on floors other than the main entrance floor, or where the major inpatient services are located on a floor other than those containing patient beds. (Elevator service may be reduced for those floors providing only partial inpatient services.)
 - c. At least three hospital-type elevators shall be installed where 201 to 350 patient beds are located on floors other than the main entrance floor,

RULES FOR CRITICAL ACCESS HOSPITALS 2021

or where the major inpatient services are located on a floor other than those containing patient beds. (Elevator service may be reduced for those floors which provide only partial inpatient services.)

- d. For hospitals with more than 350 beds, the number of elevators shall be determined from a study of the hospital plan and the expected vertical transportation requirements.
2. Hospital-type elevator cars shall have inside dimensions that accommodate a patient bed with attendants. Cars shall be at least five feet eight inches wide by nine feet deep. Car doors shall have a clear opening of not less than four feet wide and seven feet high. In renovations, existing elevators that can accommodate patient beds used in the facility will not be required to be increased in size.

NOTE: Additional elevators installed for visitors and material handling may be smaller than noted above, within restrictions set by standards for disabled access.

3. Elevators shall be equipped with a two-way automatic level-maintaining device with an accuracy of one-fourth inch.
4. Each elevator, except those for material handling, shall be equipped with an independent keyed switch for staff use for bypassing all landing button calls and responding to car button calls only.
5. Elevator call buttons and controls shall not be activated by heat or smoke. Light beams, if used for operating door reopening devices without touch, shall be used in combination with door-edge safety devices and shall be interconnected with a system of smoke detectors. This is so the light control feature will be overridden or disengaged should it encounter smoke at any landing.
6. Field inspections and tests shall be made and the owner shall be furnished with written certification stating the installation meets the requirements set forth in this section as well as all applicable safety regulations and codes.

SECTION 70: PHYSICAL FACILITIES, MECHANICAL REQUIREMENTS.

A. General.

1. Prior to acceptance of the facility, all mechanical systems shall be tested and operated to demonstrate to the owner or his designated representative that the installation and performance of these systems conform to design intent. Test results shall be documented for maintenance files.
2. Upon completion of the special systems equipment installation contract, the owner shall be furnished with a complete set of manufacturers' operating, maintenance, and preventive instructions, parts list, and complete procurement numbers and descriptions. Operating staff shall be provided with instructions for proper operation of systems and equipment.
3. Rotating mechanical equipment, shall be mounted on vibration isolators as required to prevent unacceptable structure-borne vibration.
4. Supply and return mains and risers for cooling, heating, and steam systems shall be equipped with valves to isolate the various sections of each system and each piece of equipment.

B. Thermal and Acoustical Insulation.

1. Insulation within the building shall be provided to conserve energy, protect personnel, prevent vapor condensation, and reduce noise.
2. Insulation on cold surfaces shall include an exterior vapor barrier. Material that will not absorb or transmit moisture will not require a separate vapor barrier.
3. Insulation, including finishes and adhesives on the exterior surfaces of ducts, piping, and equipment, shall have a flame-spread rating of 25 or less and a smoke-developed rating of 50 or less as determined by an independent testing laboratory in accordance with NFPA 255.
4. Interior duct linings shall not be used. This requirement shall not apply to air terminals and sound attenuation devices that have special coverings over such linings.
5. Existing accessible insulation within areas that are renovated shall be inspected and addressed, as appropriate.

C. Steam and Hot Water Systems and Pressure Vessels.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

1. All pressure vessels shall meet the requirements of the Arkansas Boiler Inspector, Arkansas Department of Labor.

D. Air Conditioning, Heating and Ventilating Systems.

1. The systems shall be designed to provide the dry bulb temperatures noted in Table 3 of the appendix. The systems shall be designed and operated to provide the relative humidity noted in Table 3 of the appendix.
2. All rooms and areas in the facility used for patient care shall have provisions for ventilation. The ventilation rates shown in Table 4 shall be used only as minimum standards; they do not preclude the use of higher, more appropriate rates. Fans serving exhaust systems shall be located at the discharge end and shall be readily serviceable. Air supply and exhaust in rooms for which no minimum total air change rate is noted may vary down to zero in response to room load. For rooms listed in Table 4 where VAV systems are used, minimum total air change shall be within limits noted. Temperature control shall also comply with these standards. To maintain asepsis control, airflow supply and exhaust should generally be controlled to ensure movement of air from "clean" to: less clean" areas, especially in critical areas. The ventilation systems shall be designed and balanced according to the requirements shown in Table 4 and in the applicable notes.
3. Exhaust systems may be combined to enhance the efficiency of recovery devices required for energy conservation. Local exhaust systems shall be used whenever possible in place of dilution ventilation to reduce exposure to hazardous gases, vapors, fumes, or mists. Airborne infection isolation rooms shall not be served by exhaust systems incorporating energy recovery devices that permit cross-contamination.
4. Fresh air intakes shall be located at least 25feet from exhaust outlets of ventilating systems, combustion equipment stacks, medical-surgical vacuum systems, plumbing vents, or areas that may collect vehicular exhaust or other noxious fumes. (Prevailing winds and/or proximity to other structures may require greater clearances.) Plumbing and vacuum vents that terminate at a level above the top of the air intake may be located as close as 10feet. The bottom of outdoor air intakes serving central systems shall be as high as practical, but at least six feet above ground level, or, if installed above the roof, three feet above roof level. Exhaust outlets from areas that may be contaminated shall be above roof level and arranged to minimize recirculation of exhaust air into the building.
5. In new construction and major renovation work, air supply for operating and delivery rooms (excluding LDR/LDRP rooms) shall be from ceiling outlets near the center of the work area. Return air shall be near the floor level. Each operating and delivery room shall have at least two return-air

inlets located as remotely from each other as practical. (Design should consider turbulence and other factors of air movement to minimize fall of particulates onto sterile surfaces.) Where extraordinary procedures, such as organ transplants, justify special designs, installation shall properly meet performance needs as determined by applicable standards. These special designs should be reviewed on a case-by-case basis. Temperature shall be individually controlled for each operating and cesarean section room.

6. The operating and delivery room (excluding LDR/LDRP rooms) room ventilation systems should operate at all times to maintain the “air movement relationship to adjacent areas.” The cleanliness of the spaces is compromised when the ventilation system is shut down, e.g., airflow from a less clean space such as the corridor can occur, and standing water can accumulate in the ventilation system (near humidifiers or cooling coils).
7. In new construction and major renovation work, air supply for rooms used for invasive procedures such as autopsy rooms, cardiac cath labs, cystoscopic rooms, trauma rooms, endoscopy rooms, bronchoscopy rooms, and/or rooms where anesthesia gases are used shall be from ceiling outlets near the center of the room and/or work area. Return or exhaust air inlets shall be near the floor level. Exhaust inlets for anesthesia evacuation and other special applications shall be permitted to be installed in the ceiling.
8. Each space routinely used for administering inhalation anesthesia and inhalation analgesia shall be served by a scavenging system to vent waste gases. If a vacuum system is used, the gas-collecting system shall be arranged so that it does not disturb patients' respiratory systems. Gases from the scavenging system shall be exhausted directly to the outside. The anesthesia evacuation system may be combined with the room exhaust system, provided the part used for anesthesia gas scavenging exhausts directly to the outside and is not part of the recirculation system. Scavenging systems are not required for areas where gases are used only occasionally, such as the emergency room, offices for routine dental work, etc.
9. The bottoms of ventilation openings shall be at least three inches above the floor.
10. The space above ceilings in new construction shall not be used as plenum space to supply to, return air from, or to exhaust air from any patient room, operating room, trauma room, critical care room, delivery room, endoscopy room, cardiac cath lab, bronchoscopy room, autopsy room, exam room, treatment room, airborne infection isolation room, protective environment room, radiology suite, laboratory suite, soiled workroom, soiled holding, physical therapy and hydrotherapy, ETO-sterilizer room, sterilizer equipment room, and central

medical and surgical supply areas or rooms. Plenum return air space conforming to NFPA 90A requirements shall be acceptable in areas where it is not listed above.

11. All central ventilation or air conditioning systems shall be equipped with filters with efficiencies equal to, or greater than, those specified in Table 1 of the Appendix. Where two filter beds are required, filter bed number one shall be located upstream of the air conditioning equipment and filter bed number two shall be downstream of any fan or blowers. Filter efficiencies, tested in accordance with ASHRAE 52-92, shall be average. Filter frames shall be durable and proportioned to provide an airtight fit with the enclosing ductwork. All joints between filter segments and enclosing ductwork shall have gaskets or seals to provide a positive seal against air leakage. A manometer or equal equivalent method of monitoring high and low pressure drop shall be installed across each filter bed having a required efficiency of 90 percent or more including hoods requiring HEPA filters.
12. If duct humidifiers are located upstream of the final filters, they shall be located in a manner to prevent condensation on the surface of the filters. Ductwork with duct-mounted humidifiers shall have a means of water removal. An adjustable high-limit humidistat shall be located downstream of the humidifier to reduce the potential of condensation inside the duct. All duct take-offs should be sufficiently downstream of the humidifier to ensure complete moisture absorption. Steam humidifiers shall be used. Reservoir-type water spray or evaporative pan humidifiers shall not be used.
13. Air-handling duct systems shall be designed with accessibility for duct cleaning, and shall meet the requirements of NFPA 90A.
14. Ducts that penetrate construction intended to protect against X-ray, magnetic, RFI, or other radiation shall not impair the effectiveness of the protection.
15. Fire and smoke dampers shall be constructed, located, and installed in accordance with the requirements of NFPA 101, 90A, and the specific damper's listing requirements. Fans, dampers, and detectors shall be interconnected so that damper activation will not damage ducts. Maintenance access shall be provided at all dampers. All damper locations shall be indicated on design drawings. Dampers should be activated by fire or smoke sensors, not by fan cutoff alone. Switching systems for restarting fans may be installed for fire department use in venting smoke after a fire has been controlled. However, provisions should be made to avoid possible damage to the system due to closed dampers. When smoke partitions are required, heating, ventilation, and air conditioning zones shall be coordinated with compartmentation insofar as practical to minimize need to penetrate fire and smoke partitions.
16. Hoods and safety cabinets may be used for normal exhaust of a space provided

that minimum air change rates are maintained. If air change standards in Table 4 of the Appendix do not provide sufficient air for proper operation of exhaust hoods and safety cabinets (when in use), supplementary makeup air (filtered and preheated) shall be provided around these units to maintain the required airflow direction and exhaust velocity. Use of makeup air will avoid dependence upon infiltration from outdoor and/or from contaminated areas. Makeup systems for hoods shall be arranged to minimize "short circuiting" of air and to avoid reduction in air velocity at the point of contaminant capture.

17. Laboratory hoods shall meet the following general standards:
 - a. Have an average face velocity of at least 75 feet per minute.
 - b. Have an exhaust fan located at the discharge end of the system.
 - c. Have an exhaust duct system of noncombustible corrosion-resistant material as needed to meet the planned usage of the hood.
18. Laboratory exhaust and ventilation systems shall comply with NFPA 45.
19. Laboratory hoods shall meet the following special standards:
 - a. Fume hoods, and their associated equipment in the air stream, intended for use with perchloric acid and other strong oxidants, shall be constructed of stainless steel or other material consistent with special exposures, and be provided with a water wash and drain system to permit periodic flushing of duct and hood. Electrical equipment intended for installation within such ducts shall be designed and constructed to resist penetration by water. Lubricants and seals shall not contain organic materials. When perchloric acid or other strong oxidants are only transferred from one container to another, standard laboratory fume hoods and the associated equipment may be used in lieu of stainless steel construction.
 - b. In new construction and major renovation work, each hood used to process infectious or radioactive materials shall have a minimum face velocity of 90 feet per minute with suitable pressure-independent air modulating devices and alarms to alert staff of fan shutdown or loss of airflow. Each shall also have filters with 99.97 percent efficiency (based on dioctyl-phthalate (DOP) test method) in the exhaust stream, and be designed and equipped to permit the safe removal, disposal, and replacement of contaminated filters. Filters shall be as close to the hood as practical to minimize duct contamination. Fume hoods intended for use with radioactive isotopes shall be constructed of stainless steel or other material suitable for the particular exposure and shall comply with NFPA 801,

RULES FOR CRITICAL ACCESS HOSPITALS 2021

Facilities for Handling Radioactive Materials. Radioactive isotopes used for injections, etc. without probability of airborne particulates or gases may be processed in a clean-workbench-type hood where acceptable to the Nuclear Regulatory Commission.

20. Exhaust hoods handling grease-laden vapors in food preparation centers shall comply with NFPA 96. All hoods over cooking ranges shall be equipped with grease filters, fire extinguishing systems, and heat-actuated fan controls. Cleanout openings shall be provided every 20feet and at changes in direction in the horizontal exhaust duct systems serving these hoods. (Horizontal runs of ducts serving range hoods should be kept to a minimum.
21. The ventilation system for anesthesia storage rooms shall conform to the requirements of NFPA 99.
22. The ventilation system for the space that houses ethylene oxide (ETO) sterilizers should be designed to:
 - a. Provide a dedicated (not connected to a return air or other exhaust system) exhaust system. Refer to 29 CFR Part 1910.1047.
 - b. All source areas shall be exhausted, including the sterilizer equipment room, service/aeration areas, over the sterilizer door, and the aerator. If the ETO cylinders are not located in a well-ventilated, unoccupied equipment space, an exhaust hood shall be provided over the cylinders. The relief valve shall be terminated in a well-ventilated, unoccupied equipment space, or outside the building. If the floor drain which the sterilizer(s) discharges to is not located in a well-ventilated, unoccupied equipment space, an exhaust drain cap shall be provided (coordinate with local codes).
 - c. Ensure that general airflow is away from sterilizer operator(s).
 - d. Provide a dedicated exhaust duct system for ETO. The exhaust outlet to the atmosphere should be at least 25feet away from any air intake.
23. An audible and visual alarm shall activate in the sterilizer work area, and a 24hour staffed location, upon loss of airflow in the exhaust system.
24. Rooms with fuel-fired equipment shall be provided with sufficient outdoor air to maintain equipment combustion rates.
25. Gravity exhaust may be used, where conditions permit, for nonpatient areas such as boiler rooms, central storage, etc.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

26. The energy-saving potential of variable air volume systems is recognized and these standard herein are intended to maximize appropriate use of that system. Any system utilized for occupied areas shall include provisions to avoid air stagnation in interior spaces where thermostat demands are met by temperatures of surrounding areas.
27. Special consideration shall be given to the type of heating and cooling units, ventilation outlets, and appurtenances installed in patient-occupied areas of psychiatric units. The following shall apply:
 - a. All air grilles and diffusers shall be of a type that prohibits the insertion of foreign objects. All exposed fasteners shall be tamper-resistant.
 - b. All convector or HVAC enclosures exposed in the room shall be constructed with round corners and shall have enclosures fastened with tamper-resistant screws.
 - c. HVAC equipment shall be of a type that minimizes the need for maintenance with the room.
28. Rooms or booths used for sputum induction, aerosolized pentamidine treatments, and other high-risk cough-inducing procedures shall be provided with local exhaust ventilation. See Table 4 of the Appendix for ventilation requirements.
29. Non-central air handling systems, i.e., individual room units that are used for heating and cooling purposes (fan-coil units, heat pump units, etc.) in areas permitted by Table 4 to utilize air recirculated by means of a room unit shall be equipped with permanent (cleanable) or replaceable filters. The filters shall have a minimum efficiency of 68percent weight arrestance. These units may be used as recirculating units only. All outdoor air requirements shall be met by a separate central air handling system with the proper filtration, as noted in Table 1 of the Appendix.
30. For special needs pharmacy work area and equipment requirements refer to Laws and Regulations - Arkansas State Board of Pharmacy.

SECTION 71: PHYSICAL FACILITIES, PLUMBING AND OTHER PIPING SYSTEMS.

All plumbing systems shall be designed and installed in accordance with the requirements of the latest edition of the Arkansas State Plumbing Code and the latest edition of the Laws, Rules, and Regulations Governing Boiler Inspection, Arkansas Department of Labor.

A. Plumbing Fixtures.

1. The material used for plumbing fixtures shall be nonabsorbent acid-resistant material.
2. The water supply spout for lavatories and sinks required in patient care areas (except patient rooms) shall be mounted so that the discharge point is a minimum distance of five inches above the rim of the fixture.
3. All fixtures used by medical and nursing staff and all lavatories used by patients and food handlers shall be trimmed with valves which can be operated without the use of hands. Where blade handles are used for this purpose, they shall not exceed four and one-half inches in length, except that handles on clinical sinks shall be not less than six inches long. (Automatic controls are acceptable.) Scrub sinks shall be trimmed with foot, knee or ultrasonic controls.
4. Clinical sinks shall have an integral trap in which the upper portion of the water trap provides a visible seal.
5. Shower bases and tubs shall provide non-slip walking surfaces.

B. Potable Water Supply Systems.

1. Systems shall be designed to supply water at sufficient pressure to operate all fixtures and equipment during maximum demand periods.
2. Each water service main, branch main, riser, and branch to a group of fixtures shall be valved. Stop valves shall be provided at each fixture. Appropriate panels for access shall be provided at all valves where required.
3. Backflow preventers (vacuum breakers) shall be installed on hose bibs, laboratory sinks, janitors' sinks, bedpan flushing attachments, autopsy tables, and on all other fixtures to which hoses or tubing can be attached.
4. Bedpan flushing devices shall be provided in each inpatient toilet room. Installation is optional in psychiatric and alcohol-abuse units

where patients are ambulatory

5. The following standards shall apply to hot water systems:
 - a. The water-heating system shall have sufficient supply capacity at the temperatures and amounts indicated in Table 9 of the Appendix. Water temperature is measured at the point of use or inlet to the equipment.
 - b. Hot-water distribution systems serving patient care areas shall be under constant recirculation to provide continuous hot water at each hot water outlet. The temperature of hot water for showers and bathing shall be appropriate for safe and comfortable use. (See table 9 of the Appendix) .
 6. Water distribution systems shall be arranged to provide hot water at each hot water outlet at all times. (See table 9 of the Appendix).
- C. Drainage Systems. The following standards shall apply to drainage systems:
1. Drain lines used for acid waste disposal shall be made of acid-resistant material.
 2. Drain lines serving some types of automatic blood-cell counters shall be of carefully selected material that will eliminate potential for undesirable chemical reactions
 3. Drainage piping should not be installed within the ceiling or exposed in operating and delivery rooms, nurseries, food preparation centers, food serving facilities, food storage areas, central services, electronic data processing areas, electric closets, and other sensitive areas. Where exposed overhead drain piping in these areas is unavoidable, special provisions shall be made to protect the space below from leakage, condensation, or dust particles.
 4. Floor drains shall not be installed in operating and delivery rooms.
 5. If a floor drain is installed in cystoscopy, it shall contain a nonsplash, horizontal-flow flushing bowl beneath the drain plate. Note: Floor drains in cystoscopy operating rooms have been shown to disseminate heavily contaminated spray during flushing. Unless regularly with large amounts of fluid, the trap tends to dry out and permit passage of gases, vapors, odors, insects and vermin directly into the operating room. For new construction, if a floor drain is insisted upon by the users, the drain plate should be located away from the operative preferably with a closed system of drainage. Alternative methods include (a) an aspirator/trap installed in a wall connected to the collecting trough of the operating table by a closed,

RULES FOR CRITICAL ACCESS HOSPITALS 2021

disposable tube system, or (b) a closed system using portable collecting vessels. (See NFPA 99.)

6. Drain systems for autopsy tables shall be designed to positively avoid splatter or overflow onto floors or back siphonage and for easy cleaning and trap flushing.
 7. Building sewers shall discharge into community sewage. Where such a system is not available, the facility shall treat sewage in accordance with local and state regulations.
 8. Kitchen grease traps shall be located and arranged to permit easy access without the need to enter food preparation or storage areas. Grease traps shall be of capacity required and shall be accessible from outside of the building without need to interrupt any services.
 9. Where plaster traps are used, provisions shall be made for appropriate access and cleaning.
 10. In dietary areas, floor drains and/or floor sinks shall be of a type that can be easily cleaned by removal of cover. Provide floor drains or floor sinks at all "wet equipment" (i.e., ice machines) and as required for wet cleaning of floors. Provide removable stainless steel mesh in addition to gridded drain cover to prevent entry of large particles of waste which might cause stoppages. Location of floor drains and floor sinks shall be coordinated to avoid conditions where locations of equipment make removal of covers for cleaning difficult.
- D. The installation, testing, and certification of nonflammable medical gas and air systems shall comply with the requirements of NFPA 99. (See Table 11 of the Appendix for rooms that require station outlets.)
- E. Clinical vacuum system installations shall be in accordance with NFPA 99. (See Table 11 of the Appendix for rooms that require station outlets.)
- F. All piping, except control-line tubing, shall be identified. All valves shall be tagged, and a valve schedule shall be provided to the facility owner for permanent record and reference.
- G. When the functional program includes hemodialysis, continuously circulated filtered cold water shall be provided.
- H. Provide condensate drains for cooling coils of a type that may be cleaned as needed without disassembly. Provide air gap where condensate drains empty into floor drains. Provide heater elements for condensate lines in freezer or other areas where freezing may be a problem.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- I. No plumbing lines may be exposed overhead or on walls where possible accumulation of dust or soil may create a cleaning problem or where leaks would create a potential for food contamination.

SECTION 72: PHYSICAL ENVIRONMENT, ELECTRICAL STANDARDS.

A. General.

1. All electrical material and equipment, including conductors, controls, and signaling devices, shall be installed in compliance with and maintained per applicable sections of NFPA 70 and NFPA 99 and shall be listed as complying with available standards of listing agencies, or other similar established standards where such standards are required. Maintenance and testing of receptacles in patient care areas shall be performed at initial installation, replacement or servicing of devices. Records shall be maintained of all tests, rooms or areas tested, with itemized pass/fail indicators.
2. The electrical installations, including alarm, nurse call, and communication systems, shall be tested to demonstrate that equipment installation and operation is appropriate and functional. A written record of performance tests on special electrical systems and equipment shall demonstrate compliance with applicable codes and standards.
3. Shielded isolation transformers, voltage regulators, filters, surge suppressors, and other safeguards shall be provided as required where power line disturbances are likely to affect data processing and/or automated laboratory or diagnostic equipment.

B. Main switchboards shall be located in an area separate from plumbing and mechanical equipment and shall be accessible to authorized persons only. Switchboards shall be convenient for use, readily accessible for maintenance, away from traffic lanes, and located in dry, ventilated spaces free of corrosive or explosive fumes, gases, or any flammable material. Overload protective devices shall operate properly in ambient room temperatures.

C. Lighting.

1. The Illuminating Engineering Society of North America (IES) has developed recommended lighting levels for health care facilities. The reader should refer to the IES Handbook.
2. Approaches to buildings and parking lots, and all occupied spaces within buildings shall have fixtures that can be illuminated as necessary.
3. Patient rooms shall have general lighting and night lighting. A reading light shall be provided for each patient. Reading light controls shall be readily accessible to the patient(s). Incandescent and halogen light sources which produce heat shall be avoided to prevent burns to the patient and/or bed

RULES FOR CRITICAL ACCESS HOSPITALS 2021

linen. The light source should be covered by a diffuser or lens. Flexible light arms, if used, shall be mechanically controlled to prevent the lamp from contacting the bed linen. At least one night light fixture in each patient room shall be controlled at the room entrance. Lighting for coronary and intensive care bed areas shall permit staff observation of the patient while minimizing glare.

4. Operating and delivery rooms shall have general lighting in addition to special lighting units provided at surgical and obstetrical tables. General lighting and special lighting shall be on separate circuits.
5. Nursing unit corridors shall have general illumination with provisions for reducing light levels at night.
6. Light intensity for staff and patient needs should generally comply with health care guidelines set forth in the IES publication. Consideration should be given to controlling intensity and/or wavelength to prevent harm to the patient's eyes (i.e., retina damage to premature infants and cataracts due to ultraviolet light). Many procedures are available to satisfy lighting requirements, but the design should consider light quality as well as quantity for effectiveness and efficiency.
7. An examination light shall be provided for examination, treatment, and trauma rooms.
8. Light intensity of required emergency lighting shall follow IES guidelines. Egress and exit lighting shall comply with NFPA 101.

D. Receptacles.

1. Each operating and delivery room shall have at least six receptacles convenient to the head of the procedure table. Each operating room shall have at least 16 simplex or eight duplex receptacles. Where mobile X-ray, laser, or other equipment requiring special electrical configurations is used, additional receptacles distinctively marked for X-ray or laser use shall be provided.
2. Each patient room shall have duplex-grounded receptacles. There shall be one at each side of the head of each bed; one for television, if used; and one on every other wall. Receptacles may be omitted from exterior walls where construction or room configuration makes installation impractical. Nurseries shall have at least two duplex-grounded receptacles for each bassinet. Outlets for general care areas and critical care areas shall be provided for as defined by NFPA 99 and NFPA 70.
3. Duplex-grounded receptacles for general use shall be installed approximately 50 feet apart in all corridors and within 25 feet of corridor ends. Receptacles in pediatric and psychiatric unit corridors shall be of the tamper resistant type. Special receptacles marked for X-ray use shall be

installed in corridors of patient areas so that mobile equipment may be used anywhere within a patient room using a cord length of 50feet or less. If the same mobile X-ray unit is used in operating rooms and in nursing areas, receptacles for X-ray use shall permit the use of one plug in all locations. Where capacitive discharge or battery-powered X-ray units are used, special X-ray receptacles are not required.

4. Electrical receptacle cover plates or electrical receptacles supplied from the emergency systems shall be distinctively colored or marked for identification. If color is used for identification purposes, the same color shall be used throughout the facility.
5. For renal dialysis units, two duplex receptacles shall be on each side of a patient bed or lounge chair. One duplex receptacle on each side of the bed shall be connected to emergency power.

E. Equipment.

1. At inhalation anesthetizing locations, all electrical equipment and devices, receptacles, and wiring shall comply with applicable sections of NFPA 99 and NFPA 70.
2. Fixed and mobile X-ray equipment installations shall conform to articles 517 and 660 of NFPA 70.
3. The X-ray film illuminator unit or units for displaying at least two films simultaneously shall be installed in each operating room, specified emergency treatment rooms, and X-ray viewing room of the radiology department. All illuminator units within one space or room shall have lighting of uniform intensity and color value.
4. Ground-fault circuit interrupters (GFCI) shall comply with NFPA 70. When ground-fault circuit interrupters are used in critical areas, provisions shall be made to ensure the other essential equipment is not affected by activation of one interrupter.
5. In areas such as critical care units and special nurseries where a patient may be treated with an internal probe or catheter connected to the heart, the ground system shall comply with applicable sections of NFPA 99 and NFPA 70.

F. Nurse/Patient Communication Station.

1. In patient areas, each patient room shall be served by at least one

nurse/patient communication station for two-way voice communication. All primary nurse call systems shall be of the electrical/electronic nature. The signal shall activate an annunciator panel at the nurse station, a visible signal in the corridor at the patient's door, and at other areas defined by the functional program. Each bed shall be provided with a call device. Two call devices serving adjacent beds may be served on one calling station. Calls shall activate a visible signal in the corridor at the patient's door, in the clean workroom, in the soiled workroom, medication, charting, nourishment, and examination/treatment room(s) and at the nurses' station. In multi-corridor nursing units, additional visible signals shall be installed at corridor intersections. In rooms containing two or more nurse/patient communication stations, indicating lights shall be provided at each station. Nurse/patient communication stations at each calling station shall be equipped with an indicating light which remains lighted as long as the voice circuit is operating.

2. An emergency call system shall be provided at each inpatient/outpatient toilet, bath and shower room. An emergency call shall be accessible to a collapsed patient on the floor. Inclusion of a pull cord within four to six inches from the floor will satisfy this standard. The emergency call shall be designed so that a signal activated at a patient's calling station will initiate a visible and audible signal distinct from the regular nurse/patient communication station that can be turned off only at the patient calling station. The signal shall activate an annunciator panel at the nurse station, a visible signal in the corridor at the patient's door, and at other areas defined by the narrative program. Provisions for emergency calls will also be provided in outpatient and treatment areas where patients are subject to incapacitation.
3. In areas such as critical care, recovery and pre-op, where patients are under constant visual surveillance, the nurse/patient communication call may be limited to a bedside button or station that activates a signal readily seen at the control station.
4. A staff emergency assistance system for staff to summon additional assistance shall be provided in each operating, delivery, recovery, emergency examination and/or treatment area, and in critical care units, nurseries, special procedure rooms, cardiac catheterization rooms, stress-test areas, triage, outpatient surgery admission and discharge areas, and areas for psychiatric patients including seclusion and security rooms, anterooms and toilet rooms serving them, communal toilet and bathing facility rooms, and dining, activity, therapy, exam and treatment rooms. This system shall announce audibly or visually in the clean work room, in the soiled work room, medication, charting, nourishment, and examination/treatment room(s) if provided and at the administrative center of the nursing unit with back up to another staffed area from which assistance can be summoned.
5. A nurse/patient communication station is not required in psychiatric nursing units,

RULES FOR CRITICAL ACCESS HOSPITALS 2021

but if it is included, provisions shall be made for easy removal, or for covering call button outlets. In psychiatric nursing units all hardware shall have tamper-resistant fasteners.

- G. Emergency power shall be provided in accordance with NFPA 99, NFPA 101, and NFPA 110.
- H. Emergency electrical generators shall have a minimum 48hours of on-site fuel.
- I. All health care occupancies shall be provided with a fire alarm system in accordance with NFPA 101 and NFPA 72.
- J. Telecommunications and Information Systems.
 - 1. Locations for terminating telecommunications and information system devices shall be provided.
 - 2. A room shall be provided for telecommunications and information systems. Special air conditioning and voltage regulations shall be provided when recommended by the manufacturer.
- K. Annunciator alarm panels for Emergency Systems including but not limited to such as the fire alarms, medical gas and emergency generators shall be located according to the functional program and shall be located in prominent locations easily observed and accessible by staff at all times.

SECTION 73: HYPERBARIC SUITE

A. General

1. The number of treatment stations should be based upon the expected workload and may include several work shifts per day.
2. The location should offer convenient access for outpatients. Accessibility to the unit from parking and public transportation should be a consideration.

B. Treatment Areas

1. Hyperbaric chambers for multiple occupancy (Class A) should be installed in accordance with NFPA 99.
2. Hyperbaric chambers for individual patients (Class B) should be installed in accordance with NFPA 99 in a room or suite adequately sized to provide the following clearances: chamber and side wall, 5 feet; between chambers, 6 feet; and between the chamber headboard and the wall, 3 feet. A minimum passage space of 4 feet shall be provided at the foot of each chamber in addition to the required clearances for sliding patients' platforms in end-loading chambers.

C. Functional Elements. The following support spaces should be provided and may be shared with adjacent departments.

1. Patient waiting area. The area should be out of traffic, under staff control, and should have seating capacity in accordance with the functional program. When the hyperbaric suite is routinely used for outpatients and inpatients at the same time, separate waiting areas should be provided with screening for visual privacy between the waiting areas.
2. A control desk and reception area should be provided.
3. A holding area under staff control should accommodate inpatients on stretchers or beds. Stretcher patients should be out of the direct line of normal traffic. The patient holding area may be omitted for two or fewer individual hyperbaric chamber units.
4. Toilet rooms for the use of patients should be provided with direct access from the hyperbaric suite.
5. Dressing rooms for outpatients should be provided and should include a seat or bench, mirror, and provisions for hanging patients' clothing and for securing valuables. At least one dressing room should be provided to accommodate wheelchair patients.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

6. An appropriate room for individual and family consultation with referring physicians should be provided for outpatients.
 7. A clean storage space should be provided for clean supplies and linens. Handwashing stations should be provided with hands-free operable controls. When a separate storage room is provided, it may be shared with another department when conveniently located.
 8. A soiled holding room should be provided with waste receptacles and soiled linen receptacles. Storage for patients' belongings should be provided.
 9. A housekeeping room should be provided and should contain a floor receptor or service sink and storage space for housekeeping supplies and equipment; it should be located nearby.
 10. Appropriate areas should be available for male and female personnel for staff clothing change area and lounge. The areas should contain lockers, shower, toilet, and handwashing stations.
 11. A waiting room, toilet with handwashing stations, drinking fountain, public telephone, and seating accommodations for waiting periods should be available or accessible to the unit.
- D. Electrical Requirements
1. Grounding of hyperbaric chambers should be connected only to the equipment ground in accordance with NFPA 99 and NFPA 70.
 2. Additional grounds such as earth or driven grounds should not be permitted.

SECTION 74: PHYSICAL FACILITIES, HELICOPTER LANDING AREA.

Helicopter landing area (if provided) shall be documented.

- A. Safe planning for the helicopter service shall include the following:
 - 1. Plot plan showing the heliport for Department of Health files and inspection; and
 - 2. More than one approach/departure route.
- B. Service shall be as close to the emergency service at the hospital as can be accomplished safely. The Department of Health will consider that a helicopter landing area does exist upon repeated or regular use of a location.
- C. See NFPA 418 for roof top heliports.

NOTE: If there are wire obstacles, wire markers are available at no charge. They shall be picked up at the Arkansas Department of Aeronautics.

SECTION 75: PHYSICAL FACILITIES, OUTPATIENT CARE FACILITIES.

- A. General Considerations. See Section 43.A, Physical Facilities.
 - 1. This section applies to the outpatient care unit licensed under the facility as a department and under the rule of the Governing Body. An outpatient care unit can be a part of the facility or a separate freestanding facility. An outpatient unit within the main facility building shall be located so outpatients do not traverse inpatient areas.
 - 2. The general standards set forth in the following sections shall apply to each of the items below:
 - a. Outpatient psychiatric centers;
 - b. Primary care outpatient centers; and
 - c. Diagnosis and/or treatment centers.
 - 3. Each element provided in the outpatient care facility shall be described in the written functional program and meet the requirements outlined herein as a minimum.
- B. General Construction Considerations. See Section 43.A, Physical Facilities.
- C. Site Location, Inspection, Approval and Subsoil Investigation. See Section 43.D-M, Physical Facilities.
- D. Construction Documents. See Section 43.K, Physical Facilities.
- E. Codes and Standards. New/existing Outpatient Care Facilities which do not meet the criteria of the NFPA, Life Safety Code Volume 101 for healthcare and/or ambulatory healthcare occupancies may be classified as a Business Occupancy as defined in LSC 101, Chapter 26 (new)/27 (existing) with exceptions noted within these regulations.
- F. General Requirements for Outpatient Care Facilities. As needed the following elements shall be provided to satisfy the functional program.
 - 1. Functional Program. See Section 43, Physical Facilities.
 - 2. Parking. Each facility should provide adequate parking for staff and patients.
 - 3. Patient Privacy. Each facility design shall ensure patient audible and visual privacy and dignity during interview, examination, treatment and recovery.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

4. Administration and Public Areas. The following shall apply to each outpatient care facility described herein with additions and/or modification as noted for each specific type.
 - a. Entrance. Located at grade level and able to accommodate wheelchairs.
 - b. Public services shall include:
 - 1) Conveniently accessible wheelchair storage;
 - 2) A reception and information counter or desk;
 - 3) Waiting space(s). Where an organized pediatric service is part of the outpatient care facility, provisions shall be made for separating pediatric and adult patients;
 - 4) Public toilets;
 - 5) Drinking fountain; and
 - 6) Public telephones.
 - c. Interview space(s). Private interviews related to social services, credit, etc. shall be provided.
 - d. General or individual offices for business transactions, records, administrative and professional staffs shall be provided.
 - e. Clerical space or rooms for typing, clerical work, and filing, separated from public areas for confidentiality, shall be provided.
 - f. Multipurpose room(s) equipped for visual aids shall be provided for conferences, meetings and health education purposes.
 - g. Special storage for staff personal effects with locking drawers or cabinets (may be individual desks or cabinets) shall be provided. Such storage shall be near individual work stations and staff controlled.
 - h. General storage facilities for supplies and equipment shall be provided as needed for continuing operation.
 - i. In new construction and renovation where hemodialysis or hemoperfusion are routinely performed, there shall be a separate water supply and a drainage facility that do not interfere with handwashing.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

5. General purpose examination rooms. For medical, and similar examinations, rooms shall have a minimum floor area of 80square feet, excluding vestibules, toilets, and closets. Room arrangement shall permit at least two feet eight inches clearance at each side and at the foot of the examination table. A handwashing fixture and a counter or shelf space for writing shall be provided.
6. Special- purpose examination rooms. Rooms for special clinics such as eye, ear, nose, and throat examinations, if provided, shall be designed and outfitted to accommodate procedures and equipment used. A handwashing stations and a counter or shelf space for writing shall be provided.
7. Treatment Room(s). Rooms for diagnosis and/or treatment if provided, shall have a minimum floor area of 120square feet, excluding vestibule, toilet, and closets. The minimum room dimension shall be 10feet. A handwashing fixture and counter or shelf for writing shall be provided.
8. Observation room(s). Observation rooms for the isolation of suspect or disturbed patients shall have a minimum floor area of 80 square feet and shall be convenient to a nurse or control station. This is to permit close observation of patients and to minimize possibilities of patients' hiding, escape, injury, or suicide. An examination room may be modified to accommodate this function. A toilet room with lavatory should be immediately accessible.
9. Control Station. A work counter, communication system, space for supplies, and provisions for charting shall be provided.
10. Medication Distribution Station. This may be a part of the control station and shall include a work counter, sink, refrigerator, and locked storage for biologicals and medications.
11. Clean Holding. A separate room or closet for storing clean and sterile supplies shall be provided. This storage shall be in addition to that of cabinets and shelves.
12. Soiled Holding. Provisions shall be made for separate collection, storage, and disposal of soiled materials.
13. Sterilizing Facilities. A system for sterilizing equipment and supplies shall be provided, if required by the narrative program.
14. Wheelchair Storage Space. Such storage shall be out of the direct line of traffic.
15. The need for and number of required airborne infection isolation rooms shall be determined by an infection control risk assessment. When required, the airborne infection isolation room(s) shall comply with the general requirements of Section 44.C.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

16. Imaging Suite. See Section 52, Physical Facilities, Imaging Suite.
17. Laboratory. See Section 55, Physical Facilities, Laboratory Services.
18. Rehabilitation Services. See Section 76, Physical Facilities, Rehabilitation Facilities.
19. Environmental Services, Safety Services, Physical Environment. See Section 43, Physical Facilities.
20. Staff Facilities. See Section 66, Physical Facilities, Engineering Service and Equipment Areas
21. Waste Processing Services. See Section 67, Physical Facilities, Waste Processing Services.
22. Social Spaces/Group Therapy. See Rules for Hospitals and Related Institutions in Arkansas, Section, Physical Facilities for Psychiatric Hospitals – F.3 Service Areas
23. Details shall comply with the following standards:
 - a. Minimum patient corridor width shall be five feet. Staff only corridors may be 44 inches wide.
 - b. Each building shall have two exits that are remote from each other. Other details relating to exits and fire safety shall comply with NFPA 101 and the standards outlined herein.
 - c. Items such as drinking fountains, telephone booths, vending machines, etc., shall not restrict corridor traffic or reduce corridor width below the minimum. Out of traffic storage space for portable equipment shall be provided.
 - d. The minimum nominal door width for patient use shall be three feet. If the outpatient facility services hospital inpatients, the minimum nominal width of doors to rooms used by hospital inpatients transported in beds shall be three feet eight inches.
 - e. Doors, sidelights, borrowed lights, and windows glazed to within 18 inches of the floor shall be constructed with safety glass, wired glass, or similar materials. Glazing materials used for shower doors and bath enclosures shall be safety glass or plastic.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- f. Threshold and expansion joints covers shall be flush with the floor surface.
 - g. Handwashing stations shall be located and arranged to permit proper use and operation.
 - h. Provisions for hand drying shall be included at all handwashing facilities.
 - i. Radiation protection for X-ray and gamma ray installations shall be in accordance with the rules and regulations of the Arkansas Department of Health.
 - j. The minimum ceiling height shall be seven feet eight inches.
24. Finishes shall comply with the following:
- a. Cubicle curtains and draperies shall be noncombustible or flame-retardant and shall pass both the large- and small-scale tests required by NFPA 701.
 - b. The flame spread and smoke development ratings of finishes shall comply with NFPA 101, Chapter 38.
 - c. Floor materials shall be readily cleanable and appropriately wear-resistant. In all areas subject to wet cleaning, floor materials shall not be physically affected by liquid germicidal and cleaning solutions. Floors subject to traffic while wet, including showers and bath areas, shall have a nonslip surface.
 - d. Wall finishes shall be washable, and in the proximity of plumbing fixtures, shall be smooth and water resistant.
 - e. Wall bases in areas frequently subject to wet cleaning methods shall be monolithic and coved with the floor, tightly sealed to the wall, and constructed without voids.
 - f. Floor and wall areas penetrated by pipes, ducts, and conduits shall be tightly sealed to minimize entry of rodents and insects. Joints of structural elements shall be similarly sealed.
25. Provision for Disasters. See Section 42, Physical Environment.
26. Mechanical, Plumbing and Electrical.
- a. Small Outpatient Clinics that provide space and equipment serving four or fewer direct patient care workers at one time shall comply with the following minimum requirements:

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- 1) Emergency lighting shall be connected to rechargeable back-up batteries as a means of emergency illumination.
 - 2) A protected premises fire alarm system as defined in Chapter 3, NFPA 72 is required.
- b. Large Outpatient Facilities that provide space and equipment for more than four direct patient care workers at one time shall comply with the following minimum requirements:
- 1) Emergency lighting and power shall be provided in accordance with NFPA 99, NFPA 101, and NFPA 110.
 - 2) Any fire alarm system shall be as required by NFPA 101 and installed per NFPA 72.
 - 3) The installation, testing, and certification of nonflammable medical gas and air systems shall comply with the requirements of NFPA 99.
 - 4) Clinical vacuum system installed shall be in accordance with NFPA 99.
 - 5) All electrical material and equipment shall be installed, tested and certificated in accordance with NFPA 70 and NFPA 99.
 - 6) The mechanical system shall comply with Section 70, Physical Facilities, Mechanical Requirements, with the following exceptions:
 - a) Redundant space heating and water heating capability are not required, unless required by the written functional program;
 - b) Ducted return air systems are not required, unless required by the written narrative.
 - c) Stand-by fuel for space and water heating is not required.
 - 7) A nurses emergency call system shall be provided for all patient use at each patient toilet, bath, sitz bath and shower room. This system shall be accessible to a patient lying on the floor. Inclusion of a pull cord shall satisfy this standard.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- 8) Fire extinguisher(s) shall be provided and be easily accessible per NFPA requirements.

SECTION 76: PHYSICAL FACILITIES, REHABILITATION FACILITIES.

- A. General Considerations. Rehabilitation facilities may be organized under hospitals (organized departments of rehabilitation), outpatient clinics, rehabilitation centers, and other facilities designed to serve either single- or multiple-disability categories including but not limited to: cerebrovascular, head trauma, spinal cord injury, amputees, complicated fractures, arthritis, neurological degeneration, genetic, and cardiac. In general, rehabilitation hospitals shall have larger space requirements than general hospitals, have longer lengths of stay and have less institutional and more residential environments.
- B. General Construction Considerations. See Section 43.A, Physical Facilities.
- C. Site Location, Inspection, Approval and Subsoil Investigation. See Section 43.D-M, Physical Facilities.
- D. Construction Documents. See Section 43.K, Physical Facilities.
- E. Codes and Standards. See Section 43.A and O, Physical Facilities.
- F. Functional Units and Service Areas.
 - 1. Required units. Each rehabilitation facility shall contain a medical evaluation unit and shall provide the following service areas, if the services are not otherwise conveniently accessible to the facility and appropriate to program functions:
 - a. Psychological services;
 - b. Social services;
 - c. Vocational services;
 - d. Patient dining, recreation and day spaces;
 - e. Dietary;
 - f. Personal care facilities;
 - g. Space for teaching activities of daily living;
 - h. Administration Department;
 - i. Medical Records;
 - j. Engineering service and equipment areas;

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- k. Laundry Services;
 - l. Housekeeping Rooms;
 - m. Employees' facilities;
 - n. Nursing unit; 76-2
 - o. Physical therapy;
 - p. Occupational therapy; and
 - q. Speech and hearing.
2. Optional Units. The following special services areas, if required by the functional program, shall be provided as outlined in these sections. The sizes of the various departments will depend upon the services to be provided:
- a. Sterilizing facilities;
 - b. Prosthetics and orthotics;
 - c. Dental;
 - d. Radiology;
 - e. Pharmacy;
 - f. Laboratory;
 - g. Home health;
 - h. Outpatient services; and
 - i. Therapeutic pool.
- G. Evaluation Unit.
- 1. Office(s) for Personnel.
 - 2. Examination Rooms. The rooms shall have a minimum floor area of 140 square feet excluding such spaces as the vestibule, toilet, closet, and work counter (whether fixed or movable). The minimum room dimension shall be ten feet. The room shall contain a lavatory or sink equipped for handwashing, a work counter and storage facilities, and a desk, counter, or shelf space for writing.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

3. Evaluation Rooms. The room areas shall be arranged to permit appropriate evaluation of patient needs and progress and to determine specific programs of rehabilitation. Rooms shall include a desk and work area for the evaluators, writing and work space for patients, and storage for supplies. Where the facility is small and workload light, evaluation may be done in the examination room.
 4. Laboratory Facilities. Facilities shall be provided within the rehabilitation department or through contract arrangement with a nearby hospital or laboratory service for hematology, clinical chemistry, urinalysis, cytology, pathology, and bacteriology. If these facilities are provided through contract, the following minimum laboratory services shall be provided in the rehabilitation facility:
 - a. Laboratory work counter(s) with a sink, and gas and electric service;
 - b. Handwashing stations;
 - c. Storage cabinet(s) or closet(s); and
 - d. Specimen collection facilities. Urine collection rooms shall be equipped with a water closet and lavatory. Blood collection facilities shall have space for a chair and work counter.
 5. Imaging Facilities. Imaging facilities, if required by the functional program, shall be in accordance with Section 52, Physical Facilities, Imaging Suite.
- H. Psychological Service. Office(s) and work space for testing, evaluation, and counseling shall be provided.
- I. Social Service. Office space(s) for private interviewing and counseling shall be provided.
- J. Vocational Services. Office(s) and work space for vocational training, counseling, and placement shall be provided.
- K. Dining, Recreation, and Day Spaces.

The following standards shall be met for patient dining, recreation, and day spaces (areas may be in separate or adjoining spaces):

1. Inpatient and residents shall have a total of 55 square feet per bed.
2. Outpatients, if dining is part of the day care program, a total of 55 square feet per person shall be provided. If dining is not part of the program, at least 35 square feet per person shall be provided for recreation and day spaces.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

3. Storage spaces shall be provided for recreation equipment and supplies.
- L. Dietary Department. See Section 59, Physical Facilities, Dietary Facilities.
- M. Personal Care Unit for Inpatients. A separate room with appropriate fixtures and utilities shall be provided for patient grooming. The activities for daily living unit may serve this purpose.
- N. Activities for Daily Living Unit. An area for teaching daily living activities shall be provided. It shall include a bedroom, bath, kitchen, and space for training stairs. Equipment shall be functional. The bathroom shall be in addition to other toilet and bathing requirements. The daily living area shall be similar to a residential environment for the purpose of facilitating the patient's skill for daily living.
- O. Administration Department and Medical Records. See Sections 60, Physical Facilities, Administration and Public Areas.
- P. Engineering Service and Equipment Areas. See Section 66, Physical Facilities, Engineering Service and Equipment Areas.
- Q. Laundry Services. See Section 64, Physical Facilities, Linen Service.
- R. Housekeeping Rooms. See Section 65, Physical Facilities, Cleaning and Sanitizing Carts and Environmental Services.
- S. Employee Facilities. See Section 66, Physical Facilities, Engineering Service and Equipment Areas.
- T. Nursing.
 1. The nursing units for rehabilitation facilities shall follow the standards as described in Section 44, Physical Facilities, Patient Accommodations (Adult Medical, Surgical, Communicable or Pulmonary Disease), with the following exceptions:
 - a. Patient Rooms. Minimum areas exclusive of toilet rooms, closets, lockers, wardrobes, alcoves, or vestibules shall be 140 square feet in single-bed rooms and 125 square feet per bed in semi-private rooms.
 - b. Each patient shall have access to a toilet room without having to enter the general corridor area. One toilet room shall serve no more than four beds and no more than two patient rooms. The toilet room shall contain a water closet, a handwashing fixture and a tub and/or shower. The handwashing fixture may be

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- omitted from a toilet room that serves single-bed and two bed rooms if each such patient's room contains a handwashing fixture. Each toilet room shall be of sufficient size to ensure that wheelchair users and staff shall have access.
- c. Each patient shall have access to a wardrobe, closet, or locker with minimum clearance of one foot ten inches by one foot eight inches. A clothes rod and adjustable shelf shall be provided.
2. Nursing Unit Service Areas shall follow the standards described in Section 44, Physical Facilities, Patient Accommodations (Adult Medical, Surgical, Communicable or Pulmonary Disease), with the following exceptions:
- a. Patient Bathing Facilities. At least one island-type bathtub and/or gurney shower shall be provided in each nursing unit. Each tub and/or shower shall be in an individual room or privacy enclosure that provides space for the private use of bathing fixtures, for drying and dressing, and for a wheelchair and an assistant. Showers in central bathing facilities shall be at least four feet square, curb-free and designed for use by a wheelchair patient;
 - b. At least one room on each floor containing a nursing unit shall be provided for toilet training. It shall be accessible from the nursing corridor. A minimum clearance of three feet shall be provided at the front and at each side of the water closet. The room shall also contain a lavatory; and
 - c. Handrails shall be provided on both sides of corridors used by patients. A clear distance of one and one-half inches shall be provided between the handrail and the wall, and the top of the rail shall be 34 inches minimum and 36 inches maximum above the floor. Exceptions for height shall be for special care areas such as those serving children.
- U. Sterilizing Facilities. See Section 65, Physical Facilities, Cleaning and Sanitizing Carts and Environmental Services.
- V. Rehabilitation Therapy. See Section 56, Physical Facilities, Rehabilitation Therapy Department.
- W. Pharmacy Unit. See Section 58, Physical Facilities, Pharmacy.
- X. Details and Finishes. See Section 68, Physical Facilities, Details and Finishes.
- Y. Design and Construction, Including Fire-Resistant Standards. See Section 69, Physical Facilities, Construction, Including Fire Resistive Requirements.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

- Z. Waste Processing Services. See Section 67, Physical Facilities, Waste Processing Services.
- AA. Elevators. See Section 72, Physical Facilities, Electrical Standards.
- BB. Mechanical, Plumbing and Electrical Standards. See Sections 71, 72 and 75.F.22.

SECTION 77: Severability

If any provision of these Rules, or the application thereof to any person or circumstances is held invalid, such provisions or applications of these Rules that can give effect without the invalid provisions or applications will be enforced, and to this end the provisions hereto are declared to be severable.

APPENDIX

Table 1	Filter Efficiencies for Central Ventilation and Air Conditioning Systems in Health Care Facilities
Table 2	Sound Transmission Limitations in Health Care Facilities
Table 3	Temperature and Relative Humidity Requirements
Table 4	Ventilation, Medical Gas, and Air Flow Requirements in Health Care Facilities
Table 5	Final Occupancy Inspection Check List
Table 6	Dog Behavioral Screening Exam
Table 7	Dog History
Table 8	RECORD RETENTION TIME FRAMES
Table 9	REQUIRED TEMPERATURES
Table 10	Outlets for Oxygen, Vacuum (Suction), and Medical Air Systems
Table 11	VERBAL ORDERS
Table 12	THIRD PARTY REPROCESSING OF SINGLE USE ITEMS CERTIFICATION

TABLE 1

Filter Efficiencies for Central Ventilation and Air Conditioning Systems in Health Care Facilities			
Area Designation	No. Filter Beds	Filter Bed No.1 (%)	Filter Bed No.2 ¹ (%)
All areas for patient care, treatment, and diagnosis, and those areas providing direct service or clean supplies such as sterile and clean processing.	2	30	90
Protective Environment Room	2	30	99.97
Laboratories	1	80	-
Administrative, Bulk Storage, Soiled Holding Areas, Food Preparation Areas, and Laundries	1	30	-

¹ These requirements do not apply to small outpatient clinics or outpatient clinics that do not perform invasive applications or procedures.

Notes: The filtration efficiency ratings are based on average dust spot efficiency per ASHRAE 52.1 1992.

Additional roughing or prefilters should be considered to reduce maintenance required for filters with efficiencies higher than 75 percent.

TABLE 2

Sound Transmission Limitations in Health Care Facilities		
	Airborne Sound Transmission Class (STC) ¹	
	Partitions	Floors
NEW CONSTRUCTION ²		
Patients = Room to Patients = Room	45	40
Public Space to Patients = Room ³	55	40
Service Areas to Patients = Room ⁴	65	45
Patient room access corridor ⁵	45	45
Exam room to exam room	45	_____
Exam room to public space	45	_____
Toilet room to public space	45	_____
Consultation rooms/ conference rooms to public space	45	_____
Consultation rooms/ Conference rooms to patient rooms	45	_____
Staff lounges to patient rooms	45	_____
<i>Existing Construction</i> ²		
Patient room to patient room	35	40
Public space to patient room ³	40	40
Service areas to patient room ⁴	45	45

1. Sound transmission class (STC) shall be determined per ASTM Standard E90 and E413. Where partitions do not extend to the structure above, sound transmission through ceilings and composite STC performance shall be considered.
2. Treatment rooms shall be treated the same as patient rooms
3. Public space includes lobbies, dining rooms, recreation rooms, treatment rooms, and similar spaces.
4. Service areas include kitchens, elevators, elevator machine rooms, laundries, garages, maintenance rooms, boiler and mechanical equipment rooms, and similar spaces of high noise. Mechanical equipment located on the same floor or above patient rooms, offices, nurses stations, and similar occupied space shall be effectively isolated from the floor.
5. Patient room access corridors contain composite walls with doors/windows and have direct access to patient rooms.

TABLE 2-1

TABLE 3

Temperature and Relative Humidity Requirements

Area Designation	Dry Bulb Temperatures ° ¹ F	Relative Humidity (%) ₂ Minimum-Maximum
Operating Rooms, Delivery Rooms, Endoscopy, and Bronchoscopy	68-73	20-60
Newborn Intensive Care and Newborn Nursery Suite	72-78	30-60
Recovery, Intensive Care, Trauma Rooms, Procedure Rooms, and Radiological X-ray (Surgical/Critical Care and Catheterization)	70-75	30-60
Clean Work Room and ETO Sterilizer Room	75	30-60
Sterile Storage	75	70 (max)

1

Where temperature ranges are indicated, the systems shall be capable of maintaining the rooms at any point within the range. A single figure indicates a heating or cooling capacity of at least the indicated temperature. Nothing in these guidelines shall be construed as precluding the use of temperatures different than those noted when the patient’s comfort and medical conditions make different temperatures desirable.

Unoccupied areas such as storage rooms shall have temperatures appropriate for the function intended.

2

Humidification systems serving anesthetizing locations shall be designed in accordance with NFPA 99 paragraph 5-4.1.1.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

TABLE 4

Ventilation, Medical Gas, and Air Flow Requirements in Health Care Facilities¹

Area Designation	Air Movement Relationship To Adjacent Area	Minimum Air Changes Outside Air Per Hour ³	Minimum Total Air Changes Per Hour ^{4,5}	Air Recirculated By Means of Room Unit ⁷	All Air Exhausted Directly Outdoor ⁶
SURGERY AND CRITICAL CARE AREAS					
Operating/Surgical Cystoscopic Rooms ^{8,9}	Out	3	15	No	Optional
Delivery Room ⁸	Out	3	15	No	Optional
Recovery Room ⁸	-	2	6	No	Optional
Critical Care and Intensive Care	-	2	6	No	Optional
Newborn intensive care	-	2	6	No	Optional
Treatment Room ¹⁰	-	-	6	Optional	Optional
Trauma Room ¹⁰	Out	3	15	No	Optional
Anesthesia gas storage	In	-	8	Optional	Yes
Endoscopy	In	2	6	No	Optional
Bronchoscopy ⁹	In	2	12	No	Yes
ER Waiting Room	In	2	12	No	Yes ^{11,12}
Triage	In	-	12	No	Yes ¹¹
Radiology waiting rooms	In	2	12	Optional	Yes ^{11, 12}
Procedure room	Out	3	15	No	Optional
NURSING AREAS					
Patient Room	-	2	6 ¹³	Optional	Optional
Toilet Room	In	-	10	Optional	Yes
Newborn Nursery Suite	-	2	6	No	Optional
Protective environment room ^{9,14}	Out	2	12	No	Optional
Airborne Infectious Isolation, Bronchoscopy Room ^{9, 15}	In	2	12	No	Yes
Isolation alcove or anteroom ^{14,15}	In/Out	-	10	No	Yes
Labor/Delivery/Recovery (LDR)	-	2	6 ¹³	Optional	Optional
Labor/Delivery/ Recovery/ Post Partum (LDRP) -	-	2	6 ¹³	Optional	Optional
Patient Corridor	-	-	2	Optional	Optional
ANCILLARY AREAS					
Radiology X-ray (Surgical/Critical Care & Catheterization) ¹⁶	Out	3	15	No	Optional
Radiology X-ray (Diagnostic & Treatment) ¹⁶	-	-	6	Optional	Optional
Radiology Darkroom ¹⁶	In	-	10	No	Yes
Lab General ¹⁶	-	-	6	Optional	Optional
Lab Biochemistry ¹⁶	Out	-	6	No	Optional
Lab Cytology	In	-	6	No	Yes
Lab Glass Washing	In	-	10	Optional	Yes
Lab Histology	In	-	6	No	Yes
Lab Microbiology ¹⁶	In	-	6	No	Yes
Lab Nuclear Med	In	-	6	No	Yes
Lab Pathology	In	-	6	No	Yes
Lab Serology	Out	-	6	No	Optional
Lab Sterilizing	In	-	10	Optional	Yes
Autopsy ⁹	In	-	17 ¹²	No	Yes
Nonrefrigerated body holding room	In	-	10	Optional	Yes
Pharmacy	Out	-	4	Optional	Optional

TABLE 4-1

RULES FOR CRITICAL ACCESS HOSPITALS 2021

Area Designation	Air Movement Relationship To Adjacent Area	Minimum Air Changes Outside Air Per Hour ³	Minimum Total Air Changes Per Hour ^{4,5}	Air Recirculated By Means of Room Unit ⁷	All Air Exhausted Directly Outdoor ⁶
DIAGNOSTIC AND TREATMENT AREAS					
Examination Room	-	-	6	Optional	Optional
Medication Room	Out	-	4	Optional	Optional
Treatment Room	-	-	6	Optional	Optional
Physical Therapy and Hydrotherapy	In	-	6	Optional	Optional
Soiled Workroom or Soiled Holding	In	-	10	No	Yes
Clean Workroom or Clean Holding	Out	-	4	Optional	Optional
STERILIZING AND SUPPLY AREAS					
ETO Sterilizer Room	In	-	10	No	Yes
Sterilizer Equipment Room	In	-	10	Optional	Yes
Central Supply Soiled or Decontamination Room	In	-	6	No	Yes
Central Supply Clean Workroom ¹⁷	Out	-	4	No	Optional
Sterile Storage	Out	-	4	Optional	Optional
SERVICE AREAS					
Food Preparation Centers ¹⁷	-	-	10	No	Optional
Warewashing	In	-	10	No	Yes
Dietary Day Storage	In	-	2	Optional	Optional
Laundry, General	-	-	10	Optional	Yes
Soiled Linen Sorting and Storage	In	-	10	No	Yes
Clean Linen Storage	Out	-	2	Optional	Optional
Soiled Linen and Trash Chute Room	In	-	10	No	Yes
Bedpan Room	In	-	10	Optional	Yes
Bathroom	In	-	10	Optional	Optional
Janitor's Closet	In	-	10	No	Yes

Notes for Table 4

1. The ventilation rates in this table cover ventilation for comfort, as well as for asepsis and odor control in areas of acute care hospitals that directly affect patient care and are determined based on healthcare facilities being predominantly "No Smoking" facilities per Ark. Code Ann. §20-27-704 et seq.. Where smoking may be allowed, ventilation rates will need adjustment. Areas where specific ventilation rates are not given in the table shall be ventilated in accordance with ASHRAE Standard 62, Ventilation for Acceptable Indoor Air Quality; and ASHRAE Handbook-HVAC Applications. Specialized patient care areas, including organ transplant units, burn units, specialty procedure rooms, etc., shall have additional ventilation provisions for air quality control as may be appropriate. OSHA standards and/or NIOSH criteria require special ventilation requirements for employee health and safety within healthcare facilities.
2. Design of the ventilation system shall provide air movement which is generally from clean to less clean areas. If any form of variable air volume or load shedding system is used for energy conservation, it shall not compromise the corridor-to-room pressure balancing relationships or the minimum air changes required by the table. Where the air movement relationship is "In (negative) or Out (positive)", the air movement relationship shall not be reversible. Rooms with reversible airflow provision for the purpose of switching between "In" and "Out" are not acceptable.
3. To satisfy exhaust needs, replacement air from the outside is necessary. Table 4 does not attempt to describe specific amounts of outside air to be supplied to individual spaces except for certain areas such as those listed. Distribution of the outside air, added to the system to balance required exhaust, shall be as required by good engineering practice. Minimum outside air quantities shall remain constant while the system is in operation.
4. Number of air changes may be reduced when the room is unoccupied if provisions are made to ensure that the number of air changes indicated is reestablished any time the space is being utilized. Adjustments shall include provisions so that the direction of air movement shall remain the same when the number of air changes is reduced. Areas not indicated as having continuous directional control may have ventilation systems shut down when space is unoccupied

TABLE 4-2

RULES FOR CRITICAL ACCESS HOSPITALS 2021

and ventilation is not otherwise needed, if the maximum infiltration or exfiltration permitted in Note 2 is not exceeded and if adjacent pressure balancing relationships are not compromised. Air quantity calculations shall account for filter loading such that the indicated air change rates are provided up until the time of filter change-out.

5. Air change requirements indicated are minimum values. Higher values should be used when required to maintain indicated room conditions (temperature and humidity), based on the cooling load of the space (lights, equipment, people, exterior walls and windows, etc.).
6. Air from areas with contamination and/or odor problems shall be exhausted to the outside and not recirculated to other areas. Note that individual circumstances may require special consideration for air exhaust to the outside, e.g., in intensive care units in which patients with pulmonary infection are treated, and rooms for burn patients.
7. Recirculating room HVAC units refers to those local units that are used primarily for heating and cooling of air, and not disinfection of air. Because of cleaning difficulty and potential for buildup of contamination, recirculating room units shall not be used in areas marked "No." However, for airborne infection prevention and control, air may be recirculated within Individual isolation rooms if HEPA filters are used. Isolation and intensive care unit rooms may be ventilated by reheat induction units in which only the primary air supplied from a central system passes through the reheat unit. Gravity-type heating or cooling units such as radiators or convectors shall not be used in operating rooms and other special care areas.
8. National Institute for Occupational Safety and Health (NIOSH) Criteria Documents regarding Occupational Exposure to Waste Anesthetic Gases and Vapors, and Control of Occupational Exposure to Nitrous Oxide indicate a need for both local exhaust (scavenging) systems and general ventilation of the areas in which the respective gases are utilized.
9. Differential pressure shall be a minimum of 0.01" water gauge (2.5 Pa). If alarms are installed, allowances shall be made to prevent nuisance alarms of monitoring devices.
10. The term trauma room as used here is the operating room space in the emergency department or other trauma reception area that is used for emergency surgery. The first aid room and/or "emergency room" used for initial treatment of accident victims may be ventilated as noted for the "treatment room." Treatment rooms used for Bronchoscopy shall be treated as Bronchoscopy rooms. Treatment rooms used for cryosurgery procedures with nitrous oxide shall contain provisions for exhausting waste gases.
11. In a ventilation system that recirculates air, HEPA filters can be used in lieu of exhausting the air from these spaces to the outside. In this application, the return air shall be passed through the HEPA filters before it is introduced into any other spaces.
12. If it is not practical to exhaust the air from the airborne infection isolation room to the outside, the air may be returned through HEPA filters to the air-handling system exclusively serving the isolation room.
13. Total air changes per room for patient rooms, labor/delivery/recovery rooms, and labor/delivery/recovery/postpartum rooms may be reduced to 4 when supplemental heating and/or cooling systems (radiant heating and cooling, baseboard heating, etc.) are used.
14. The protective environment airflow design specifications protect the patient from common environmental airborne infectious microbes (i.e., Aspergillus spores). These special ventilation areas shall be designed to provide directed airflow from the cleanest patient care area to less clean areas. These rooms shall be protected with HEPA filters at 99.97 percent efficiency for a 0.3 micron sized particle in the supply airstream. These Interrupting filters protect patient rooms from maintenance-derived release of environmental microbes from the ventilation system components. Recirculation HEPA filters can be used to increase the equivalent room air exchanges. Constant volume airflow is required for consistent ventilation for the protected environment. If the facility determines that airborne infection isolation is necessary for protective environment patients, an anteroom shall be provided. Rooms with reversible airflow provisions for the purpose of switching between protective environment and airborne infection isolation functions are not acceptable.
15. The infectious disease isolation room described in these guidelines is to be used for isolating the airborne spread of infectious diseases, such as measles, varicella, or tuberculosis. The design of airborne infection isolation (All) rooms should include the provision for normal patient care during periods not requiring Isolation precautions. Supplemental recirculating devices may be used in the patient room, to increase the equivalent room air

RULES FOR CRITICAL ACCESS HOSPITALS 2021

exchanges; however, such recirculating devices do not provide the outside air requirements. Air may be recirculated within individual isolation rooms if HEPA filters are used. Rooms with reversible airflow provisions for the purpose of switching between protective environment and All functions are not acceptable.

16. When required, appropriate hoods and exhaust devices for the removal of noxious gases or chemical vapors shall be provided per NFPA 99.
17. Food preparation centers shall have ventilation systems whose air supply mechanisms are interfaced appropriately with exhaust hood controls or relief vents so that exfiltration or infiltration to or from exit corridors does not compromise the exit corridor restrictions of NFPA 90A, the pressure requirements of NFPA 96, or the maximum defined in the table. The number of air changes may be reduced or varied to any extent required for odor control when the space is not in use.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

TABLE 5
Final Occupancy Inspection Check List

Inspector: _____ Date: _____

Facility: _____ Job: _____

Item	Yes	No	Comments
1. Architect/Engineer=s Certification of Substantial Completion?			
2. Interior finishes development and fire spread rating information?			
3. Fire Protection Systems - Portable fire extinguishers are inspected and tagged, and shop drawing for standpipe/sprinkler systems are available?			
4. Certificate of City Building Inspector?			
5. Certification - fire alarm system, smoke detection system, sprinkler system, and any other fire suppression system has been installed, tested and meets all applicable standards?			
6. Certification - medical gas system?			
7. Certification - electrical system has been installed, tested and meets all applicable standards of the NEC, NFPA?			
8. Certification - emergency generator has been installed, tested and meets all applicable standards of the NFPA, NEC?			
9. Certification - mechanical system has been installed, tested, balanced, and approved by the engineer of record?			
10. Certification - communication system(s) has been installed, tested and meets all applicable standards of the NEC, NFPA?			
11. Are there manufacturer=s operation and maintenance manuals with equipment warranties on site for all newly installed equipment or a letter from the general contractor stating that the above items will be turned over to the owner?			
12. Have all applicable pieces of equipment installed during the construction been incorporated into the existing preventive maintenance system? Or, have new maintenance policies and procedures been written to insure that said items are maintained per the manufacturers recommendations?			
13. Are there as-built drawings on site or a letter from the general contractor stating that the as-built drawings will be turned over to the owner?			
14. Are there copies of the Architect=s and Engineer=s final punch lists with verification that all items have been repaired or remedied?			
15. Has the Architect/designer accepted testing and certification of items 5 through 10 above?			

¹In accordance with the applicable electrical system requirements of NFPA 99, grounding system effectiveness shall be determined for new and renovated equipment by voltage and impedance measurements. Receptacles shall be checked for continuity of the grounding circuit and polarity of the hot and neutral connections.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

TEST 2		
<p><u>Approaching the Dog:</u> After initial brief observation, approach the dog with hand extended at the dog's nose level, palm and fingers pointed downward. Do not rush in, but do not approach dog in a cautious or apprehensive manner. Walk up to the dog in a normal stride until your hand is within six to 12 inches of the dog's nose. Say nothing and wait for the dog to make the next move.</p>		
ACCEPTABLE	QUESTIONABLE	OTHER
Extends Head or Steps Forward to Sniff Hand	Turns Head Away or Tries to Ignore Hand	Stares At You
Seeks Attention by Nudging or Leaning into Tester	Pulls Back or Retreats	No Response
Acts Playful by Barks or Actions	Raises Hackles	
Licks Hand	with Playful Barking	
	Lips Puffed	
	Overly Exuberant	
	Bares Teeth (Don't Confuse with grin)	

TABLE 6-2

RULES FOR CRITICAL ACCESS HOSPITALS 2021

TEST 3		
<u>Handling the Dog: If the dog has not been eliminated by</u>		
		Meets You, But With Head Lowered and Eyes Averted
	Pulls Back or Retreats	
	Growls	Attempts to Lick Your Face
Becomes Playful	Lips Puffed	
Enjoys Brushing	Raises Hackles	
	Quivers or Cowers	
	Barks	
	Rolls Over on Back	
	Submissively Urinates	
	Snaps, Bites	
	Shows Whites of Eyes	
	Overly Exuberant (Jumps Up)	
	Overly Sensitive to Grooming of Certain Areas	
	Aloof	

TEST 4
<u>Interacting with the Dog:</u> See if he/she will retrieve a ball. Walk away briskly, sit on floor and call dog. Lay the dog down, then roll him/her over, rub his/her belly. Will he/she allow this subordination? Have a assistant place a novel stimulus such as a large stuffed animal or mirror close behind the dog when he/she is distracted. Does he/she have the self-confidence to investigate? How does the dog react to sudden arm movement?

TABLE 6-3

RULES FOR CRITICAL ACCESS HOSPITALS 2021

TEST 5		
<u>Sound Sensitivity</u> : While casually interacting with the dog, have an assistant make a loud noise without warning (e.g., hitting a metal pan with a spoon).		
ACCEPTABLE	QUESTIONABLE	OTHER
Notices, But Continues Previous Activity	Flees	
Notices, Investigates	Cowers	
Startles, But Recovers Quickly	Freezes	
	Trembles	
	Urinate	
	Moves As If To Attack	

TEST 6		
<u>Pain Threshold</u> : While playing with dog, briefly pinch the webbing between his/her toes or pull hair from his side to determine pain tolerance.		
Tries to Pull Away, But Shows Forgiveness	Growls	
Yelps, But is Not Aggressive	Snaps	
Trusts You, Allows Further Petting	Acts Fearful	
	Acts Distrustful	

TABLE 6-4

RULES FOR CRITICAL ACCESS HOSPITALS 2021

TEST 7
<u>Reacting to Unexpected Events (Choose One)</u> : Owner is to be present at all times. (Assess response using response categories from Test 5.)
A. Have your assistant hide around a corner, out of sight, with a noisy utility shopping cart. Walk with dog toward the intersection as the assistant rolls the cart in front of the dog as close as possible. Record the dog's reaction.
B. While the dog is playing with you and is distracted, have the assistant hide in the closet and behind the door. Lead the dog to within six feet of the hiding place and have the assistant suddenly jump out at the dog and open an umbrella. Note reactions.

TEST 8
<u>Manners</u> : Test the dog for basic obedience commands such as heel and sit-stay.

TABLE 6-5

RULES FOR CRITICAL ACCESS HOSPITALS 2021

TABLE 7

DOG HISTORY (To be completed by owner)			
Name:			
Address:			
Home Phone:			
Name of Veterinarian/Clinic:			
Address of Veterinarian			
Name of Pet:		Breed:	
Sex:	Age:	Weight:	
Comment on how dog relates to people:			
Men	Women	Children	
<input type="checkbox"/> Urinates in the house	<input type="checkbox"/> Chews	<input type="checkbox"/> Been in dog fight	
<input type="checkbox"/> Defecates in house.	<input type="checkbox"/> Jumps on people.	<input type="checkbox"/> Chases cats/birds.	
<input type="checkbox"/> Gets on furniture.	<input type="checkbox"/> Mouths people.	<input type="checkbox"/> Carsickness	
<input type="checkbox"/> Barks excessively	<input type="checkbox"/> Digs	<input type="checkbox"/> Other:	
Does the dog dislike?			
<input type="checkbox"/> Other dogs	<input type="checkbox"/> Cats	<input type="checkbox"/> Strange objects	<input type="checkbox"/> Other
<input type="checkbox"/> Tile or slippery floors.	<input type="checkbox"/> Loud noises		
Is the dog 100% house broken?		Yes	No
How does the dog indicate a need to go out?			
Volunteer/Owner Signature:			Date:

TABLE 7-1

RULES FOR CRITICAL ACCESS HOSPITALS 2021

TO BE COMPLETED BY DOG'S REGULAR VETERINARIAN	
Date of most recent exam	
DA2PP Vaccine	Rabies Vaccine
Fecal Exam:	Results: Floatation Direct Smear:
Heartworm prevention medication:	Frequency:
What does the owner state he/she does for flea prevention?	
Any major medical illness?	
Is the dog currently on any medication? If so, list:	
Date of last teeth cleaning:	
Veterinarian Signature:	Date:

TABLE 7-2

RULES FOR CRITICAL ACCESS HOSPITALS 2021

**TABLE 8
RECORD RETENTION TIME FRAMES**

DEPARTMENT	DOCUMENT	RETENTION TIME
Administrative	Governing Body	Permanent
	Medical Staff	Permanent
	Executive Committee	Permanent
	Other Hospital Committees	2 years
Medical Records	Original/Microfilm Adult/Inpatient/Outpatient Electrocardiogram Strips/ Interpretations Electroencephalogram/ Interpretations	10 years after last discharge plus 2 years past majority. Facility shall maintain information in the master patient index
	Minor/Inpatient/Outpatient Electrocardiogram Strips/ Electroencephalogram/ Original/Microfilm Fetal Monitor Strips Interpretations Interpretations	
Radiology	Films	Films
Nuclear Medicine	Films	Facility shallt maintain information in the master patient index.
Laboratory	Blood Gas Reports	2 years
	Patient Specimens	2 years
	Control Documentation	2 years
	Immunohematology	5 years
	Immunoematology Quality Control Records	5 years
	Cytology: Histopathology Quality Control Records	10 years
	Cytology: Slide Preparation	5 years
	Transfusions	5 years
	Blood Donor Samples	7 days post transfusion
	Quality Assurance	2 years

TABLE 8-1

RULES FOR CRITICAL ACCESS HOSPITALS 2021

Pathology Lab	Pathology Reports	10 years
	Reference Pathology	2 years
	Preliminary/Corrected	Exact duplicate
Histopathology	Stained Slides	10 years
	Specimen Blocks	2 years
Pharmacy	All drug records to include: official records purchase invoices Prescription records Inventory records, etc.	2 years

TABLE 8-2

RULES FOR CRITICAL ACCESS HOSPITALS 2021

TABLE 9

REQUIRED TEMPERATURES		
MEDICATIONS	Refrigerators	36-4 F
	Medication Storage Room	59-86 F
DIETARY1	Temperature of Food at Bedside	Hot Foods = 140 F
		Cold Foods = 40 F
	Temperature of Heated Food Prior to Hot Holding	160 F
	Temperature of Heated Leftovers Prior to Hot Holding	165 F
	Temperature for Thawing Potentially Hazardous Food	Tempering Units = 45 F or less
		Refrigerator = 40 F or less
	Refrigerators	40 F
	Freezers	0 F
	Single Tank Stationary Rack Dual Temperature Machine	Wash Temperature = 150 F
		Final Rinse Temperature = 180 F
	Single Tank Conveyor Machine	Wash Temperature = 160 F
		Final Rinse Temperature = 180 F
	Multi-tank Conveyor Machine	Wash Temperature = 150 F
		Final Rinse Temperature = 180 F
		Pumped Rinse Temperature = 160 F
	Single Tank Pot, Pan & Utensil Washer	Wash Temperature = 140EF
		Final Rinse Temperature = 180EF
Manual Ware washing	Wash Temperature = 110EF	
	Rinse Temperature = 120°G - 140°F	
Chemical Sanitation (Manual or Mechanical)	Sanitation Temperature = > 171°F or Immersion in 75EF water and 50 ppm of hypochlorite for at least 1 minute or other method approved by Arkansas Department of Health	

TABLE 9-1

RULES FOR CRITICAL ACCESS HOSPITALS 2021

	All Cutting Board Surfaces	Immersion in clean, hot water of > 180°F for at least 30 seconds or any other method approved.
LAUNDRY	Water	Nothing under 120 F
	Water with Chlorine Bleach	150 parts per million ppm (parts per million)
CLINICAL	Gallons per hour per bed	105°F - 120°F

Notes:

1. Provisions shall be made to provide 180°F rinse water at ware washer. (may be by a separate booster.)
2. Provisions shall be made to provide 160°F hot water at the laundry equipment when needed.
 (This may be a steam jet or separate booster heater.) However, this does not imply that all water used would be at this temperature. Water temperatures required for acceptable laundry results will vary. Lower temperatures may be adequate for most procedures in many facilities but the higher 160°F should be available when needed for special conditions.

TABLE 9-2

RULES FOR CRITICAL ACCESS HOSPITALS 2021

TABLE 10
Central Station Outlets for Oxygen, Vacuum (Suction), and Medical Air Systems in Hospitals and Related Institutions

Location	Oxygen	Vacuum	Medical Air
Patient Rooms (medical & surgical)	1/bed	1/bed	-
Examination/Treatment (medical, surgical, endoscopy & postpartum care)	1/room	1/room	-
Isolation – Infectious and protective (medical & surgical)	1/bed	1/bed	-
Security Room (medical, surgical, & postpartum)	1/bed	1/bed	-
Critical Care (general)	3/bed	3/bed	1/bed
Isolation (critical)	3/bed	3/bed	1/bed
Coronary Critical Care	3/bed	2/bed	1/bed
Pediatric Critical Care	3/bed	3/bed	1/bed
Newborn Intensive Care	3/bassinet	3/bassinet	3/bassinet
Newborn Nursery (full-term)	1 / 4 bassinets ²	1 / 4 bassinets ²	1 / 4 bassinets ²
Pediatric and Adolescent	1/bed	1/bed	1/bed
Pediatric Nursery	1/bassinet	1/bassinet	1/bassinet
Psychiatric Patient Rooms	-	-	-
Seclusion Treatment Room	-	-	-
General Operating Room	2/room	3/room	-
Cardio, Ortho, Neurological	2/room	3/room	-
Orthopedic Surgery	2/room	3/room	-
Surgical Cysto & Endo	1/room	3/room	-
Post-anesthesia Care Unit	1/bed	3/bed	1/bed
Anesthesia Workroom	1 per workstation	-	1 per workstation
Phase II Recovery ³	1/bed	3/bed	-
Postpartum Bedroom	1/bed	1/bed	1/bed
Cesarean/Delivery Room	2/room	3/room	1/room
Infant Resuscitation Station ⁴	1/bassinet	1/bassinet	1/bassinet
Labor Room	1/room	1/room	1/room
OB Recovery Room	1/bed	3/bed	1/room
Labor/Delivery/Recovery (LDR) ⁵	2/bed	2/bed	-
Labor/Delivery/Recovery (LDRP) ⁵	2/bed	2/bed	-
Initial Emergency Management	1/bed	1/bed	-
Triage Area (definitive emergency care)	1/station	1/station	-
Definitive Emergency Care Exam/Treatment Rooms	1/bed	1/bed	1/bed

TABLE 10-1

RULES FOR CRITICAL ACCESS HOSPITALS 2021

Definitive Emergency Care Holding Area	1/bed	1/bed	-
Trauma/Cardiac Room(s)	2/bed	3/bed	1/bed
Orthopedic & Cast Room	1/room	1/room	-
Cardiac Catheterization Lab	2/bed	2/bed	2/bed
Autopsy Room	-	1 per workstation	1 per workstation

Notes for Table 10:

1. For any area or room not described above, the facility clinical staff shall determine outlet requirements after consultation with the authority having jurisdiction.
2. Four bassinets may share one outlet that is accessible to each bassinet.
3. If Phase II recovery area is a separate area from the PACU, only one vacuum per bed or station shall be required
4. When infant resuscitation takes place in a room such as cesarean section/delivery or LDRP, then the infant resuscitation services shall be provided in that room in addition to the minimum service required for the mother.
5. Two outlets for mother and two for one bassinet.
6. Facilities with medical gas requirements in more than one area shall be equipped with central systems.

TABLE 10-2

TABLE 11

VERBAL ORDERS

Basic Premise:	Verbal orders may be used when there is no reasonable alternative to obtaining a written order.
State Health Rules:	Permit licensed nurses and pharmacist (for drugs only) to take verbal orders and no one else. Section 12, Medications and Section 14, Health Information Services.
Practical Application:	Health professionals other than nurses may take verbal orders pertaining directly to their profession under specified circumstances
Situation to Address:	<ol style="list-style-type: none"> 1. Doctor in the department away from nurses' station. 2. Doctor calls the department
Policy Statement Parts:	<ol style="list-style-type: none"> 1. Who are the authorized receivers? 2. Repeat order back for accuracy. 3. Identify ordering doctor. 4. Identify receiver by name and title. 5. The receiver of the order must enter the order on the medical record, and then sign first initial, last name and title.
Hospital Administration Responsibility:	<ol style="list-style-type: none"> 1. Policy must be in writing, and approved by the Medical Staff and Governing Body (including identification of receivers). 2. Policy must be made a part of applicable department manuals. 3. Inservice training provided for all personnel involved. 4. Establish an effective monitoring system.
Outpatient Department (Emergency Services is Not outpatient):	<ol style="list-style-type: none"> 1. The therapist or other authorized receivers may take a verbal or telephone order from the doctor. 2. Must document on outpatient medical record. 3. Doctor must authenticate the order on his next visit.

RATIONALE

The Division of Health Facility Services has received numerous requests for a variance in the regulations relating to who may receive doctors orders for hospital inpatients and outpatients. This office realizes the communication problems involved between every expanding service departments of hospitals and the multiplicity of diagnostic treatment, therapy, and therapeutic duties necessary for coordinating of patient care. Other certification and accrediting organizations have also realized the communication difficulty.

The reason and intent of the regulation was, and still is, to coordinate all inpatient care through nursing

RULES FOR CRITICAL ACCESS HOSPITALS 2021

service. The patients' medical record must be maintained at the nurses' station to coordinate and implement physician orders for patient care and services.

It is the intent of this policy to have both communication between departments and also assure all physician orders and services rendered to patients are promptly documented on the patients chart. In order to maintain continuity of care on an inpatient basis, it is necessary that all aspects of the patients' treatment be coordinated through the nursing service of the facility.

TABLE 12

THIRD PARTY REPROCESSING OF SINGLE USE ITEMS


The Office of Compliance Center of Devices and Radiological Health of the Food and Drug Administration (FDA) provides guidelines for third party reprocessing of devices labeled for single use provided the reprocessing firm complies fully with all FDA regulatory requirements.

The Arkansas Department of Health will recognize FDA guidelines.

RULES FOR CRITICAL ACCESS HOSPITALS 2021

CERTIFICATION

This will certify that the foregoing revisions to the Rules for Critical Access Hospitals in Arkansas were adopted by the State Board of Health of Arkansas at a regular session of said Board held in Little Rock, Arkansas, on the 1st day of August 2019.



José Romero, M.D., FAAP, FIDSA, FPIDS, FAAAS
Secretary of Health
Arkansas Board of Health



Date

QUESTIONNAIRE
FOR FILING PROPOSED RULES WITH THE
ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT/AGENCY _____
DIVISION _____
DIVISION DIRECTOR _____
CONTACT PERSON _____
ADDRESS _____
PHONE NO. _____ FAX NO. _____ E-MAIL _____
NAME OF PRESENTER AT COMMITTEE MEETING _____
PRESENTER E-MAIL _____

INSTRUCTIONS

- A. Please make copies of this form for future use.
- B. Please answer each question completely using layman terms. You may use additional sheets if necessary.
- C. If you have a method of indexing your rules, please give the proposed citation after "Short Title of this Rule" below.
- D. Rule" below.
- E. Submit two (2) copies of the Questionnaire and Financial Impact Statement attached to the front of two (2) copies of the proposed rule and required documents. Mail or deliver to:

Jessica C. Sutton
Administrative Rules Review Section
Arkansas Legislative Council
Bureau of Legislative Research
One Capitol Mall, 5th Floor
Little Rock, AR 72201

- 1. What is the short title of this rule?

- 2. What is the subject of the proposed rule?

- 3. Is this rule required to comply with a federal statute, rule, or regulation? Yes No
If yes, please provide the federal rule, regulation, and/or statute citation.

- 4. Was this rule filed under the emergency provisions of the Administrative Procedure Act?
Yes No
If yes, what is the effective date of the emergency rule? _____

When does the emergency rule expire? _____

Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act? Yes No

5. Is this a new rule? Yes No If yes, please provide a brief summary explaining the rule.

Does this repeal an existing rule? Yes No If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does.

Is this an amendment to an existing rule? Yes No If yes, please attach a mark-up showing the changes in the existing rule and a summary of the substantive changes. Note: The summary should explain what the amendment does, and the mark-up copy should be clearly labeled “mark-up.”

6. Cite the state law that grants the authority for this proposed rule? If codified, please give the Arkansas Code citation.

7. What is the purpose of this proposed rule? Why is it necessary?

8. Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b).

9. Will a public hearing be held on this proposed rule? Yes No If yes, please complete the following:

Date: _____

Time: _____

Place: _____

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)

11. What is the proposed effective date of this proposed rule? (Must provide a date.)

12. Please provide a copy of the notice required under Ark. Code Ann. § 25-15-204(a), and proof of the publication of said notice. _____

13. Please provide proof of filing the rule with the Secretary of State as required pursuant to Ark. Code Ann. § 25-15-204(e). _____

14. Please give the names of persons, groups, or organizations that you expect to comment on these rules? Please provide their position (for or against) if known.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT _____
DIVISION _____
PERSON COMPLETING THIS STATEMENT _____
TELEPHONE NO. _____ FAX NO. _____ EMAIL: _____

To comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and file two (2) copies with the Questionnaire and proposed rules.

SHORT TITLE OF THIS RULE

1. Does this proposed, amended, or repealed rule have a financial impact? Yes No

2. Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule?
Yes No

3. In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered? Yes No

If an agency is proposing a more costly rule, please state the following:

- a) How the additional benefits of the more costly rule justify its additional cost;

- b) The reason for adoption of the more costly rule;

- c) Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and

- d) Whether the reason is within the scope of the agency's statutory authority, and if so, please explain.

4. If the purpose of this rule is to implement a federal rule or regulation, please state the following:

a) What is the cost to implement the federal rule or regulation?

Current Fiscal Year

Next Fiscal Year

General Revenue _____
Federal Funds _____
Cash Funds _____
Special Revenue _____
Other (Identify) _____

General Revenue _____
Federal Funds _____
Cash Funds _____
Special Revenue _____
Other (Identify) _____

Total _____

Total _____

b) What is the additional cost of the state rule?

Current Fiscal Year

Next Fiscal Year

General Revenue _____
Federal Funds _____
Cash Funds _____
Special Revenue _____
Other (Identify) _____

General Revenue _____
Federal Funds _____
Cash Funds _____
Special Revenue _____
Other (Identify) _____

Total _____

Total _____

5. What is the total estimated cost by fiscal year to any private individual, entity and business subject to the proposed, amended, or repealed rule? Identify the entity(ies) subject to the proposed rule and explain how they are affected.

Current Fiscal Year

Next Fiscal Year

\$ _____

\$ _____

6. What is the total estimated cost by fiscal year to state, county, and municipal government to implement this rule? Is this the cost of the program or grant? Please explain how the government is affected.

Current Fiscal Year

Next Fiscal Year

\$ _____

\$ _____

7. With respect to the agency's answers to Questions #5 and #6 above, is there a new or increased cost or obligation of at least one hundred thousand dollars (\$100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined?
Yes No

If YES, the agency is required by Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously with the financial impact statement and shall include, without limitation, the following:

- (1) a statement of the rule's basis and purpose;
- (2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;
- (3) a description of the factual evidence that:
 - (a) justifies the agency's need for the proposed rule; and
 - (b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;
- (4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
- (5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
- (6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and
- (7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
 - (a) the rule is achieving the statutory objectives;
 - (b) the benefits of the rule continue to justify its costs; and
 - (c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.