

ARKANSAS
STATE BOARD OF HEALTH

**RULES ~~AND REGULATIONS~~ FOR
HOSPITALS AND RELATED INSTITUTIONS**
IN ARKANSAS



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

Revision effective date: **January 1, 2020**

ARKANSAS DEPARTMENT OF HEALTH
HEALTH FACILITY SERVICES

NATHANIEL SMITH, MD, MPH
SECRETARY OF HEALTH

TABLE OF CONTENTS

SECTION 1: AUTHORITY	1.1
SECTION 2: PURPOSE	2.1
SECTION 3: DEFINITIONS	3.1-3
SECTION 4: LICENSURE AND CODES	4.1-3
SECTION 5: GOVERNING BODY	5.1-2
SECTION 6: MEDICAL STAFF	6.1-5
SECTION 7: GENERAL ADMINISTRATION	7.1-4
SECTION 8: PERSONNEL ADMINISTRATION	8.1
SECTION 9: ADMINISTRATION REPORTS	9.1
SECTION 10: PATIENT IDENTIFICATION	10.1
SECTION 11: PATIENT CARE SERVICE	11.1-4
SECTION 12: MEDICATIONS	12.1-3
SECTION 13: RESTRAINTS	13.1
SECTION 14: HEALTH INFORMATION SERVICES	14.1-7
SECTION 15: MEDICAL RECORD REQUIREMENTS FOR OUTPATIENT SERVICES, EMERGENCY ROOM, OBSERVATION SERVICES AND PSYCHIATRIC RECORDS	15.1-4
SECTION 16: PHARMACY	16.1-12
SECTION 17: FOOD AND NUTRITION SERVICES	17.1-8
SECTION 18: INFECTION CONTROL	18.1-6
SECTION 19: LABORATORY	19.1-27
SECTION 20: RADIOLOGICAL SERVICES	20.1-7
SECTION 21: PHYSICAL THERAPY	21.1-2
SECTION 22: OCCUPATIONAL THERAPY	22.1-2
SECTION 23: SPEECH PATHOLOGY/AUDIOLOGY SERVICES	23.1-2
SECTION 24: RECREATIONAL THERAPY	24.1-2
SECTION 25: PET THERAPY PROGRAM	25.1-2
SECTION 26: SPECIALIZED SERVICES: SURGICAL SERVICES	26.1-2
SECTION 27: SPECIALIZED SERVICES: POSTANESTHESIA CARE UNIT	27.1
SECTION 28: SPECIALIZED SERVICES: AMBULATORY SURGERY SERVICES	28.1
SECTION 29: SPECIALIZED SERVICES: ANESTHESIA SERVICES	29.1
SECTION 30: SPECIALIZED SERVICES: LABOR, DELIVERY, LABOR DELIVERY RECOVERY (LDR), LABOR DELIVERY RECOVERY POST PARTUM (LDRP), POST PARTUM AND MATERNAL-CHILD EDUCATION	30.1-5
SECTION 31: NURSERY SERVICES	31.1-2
SECTION 32: SPECIALIZED SERVICES: CRITICAL CARE	32.1-2
SECTION 33: SPECIALIZED SERVICES: DENTAL SERVICES	33.1
SECTION 34: SPECIALIZED SERVICES: CENTRAL STERILIZATION & SUPPLY	34.1-4

~~RULES AND REGULATIONS~~ FOR HOSPITALS AND RELATED INSTITUTIONS IN ARKANSAS 201620
07/03/19

SECTION 35: SPECIALIZED SERVICES: RESPIRATORY CARE	35.1-3
SECTION 36: SPECIALIZED SERVICE: EMERGENCY SERVICES	36.1-3
SECTION 37: SPECIALIZED SERVICE: PSYCHIATRIC SERVICES	37.1-3
SECTION 38: SPECIALIZED SERVICE: CARE OF PATIENTS WITH PULMONARY DISEASE IN GENERAL HOSPITALS	38.1
SECTION 39: AMBULATORY SURGERY CENTERS	39.1-7
SECTION 40: OUTPATIENT PSYCHIATRIC CENTERS	40.1-2
SECTION 41: REHABILITATION HOSPITALS AND UNITS	41.1-2
SECTION 42: RECUPERATION CENTERS	42.1-2
SECTION 43: PSYCHIATRIC HOSPITALS	43.1-2
SECTION 44: INFIRMARIES	44.1-4
SECTION 45: ALCOHOL/DRUG ABUSE INPATIENT TREATMENT CENTER	45.1-9
SECTION 46: PHYSICAL ENVIRONMENT	46.1-10
SECTION 47: PHYSICAL FACILITIES	47.1-18
SECTION 48: PHYSICAL FACILITIES, PATIENT ACCOMMODATIONS (ADULT) MEDICAL, SURGICAL, COMMUNICABLE OR PULMONARY DISEASE	48.1-5
SECTION 49: PHYSICAL FACILITIES, CRITICAL CARE UNIT	49.1-6
SECTION 50: PHYSICAL FACILITIES, NURSERY UNITS	50.1-3
SECTION 51: PHYSICAL FACILITIES, PEDIATRIC AND ADOLESCENT UNIT	51.1-2
SECTION 52: PHYSICAL FACILITIES, PSYCHIATRIC NURSING UNIT	52.1-3
SECTION 53: PHYSICAL FACILITIES, SURGICAL FACILITIES	53.1-7
SECTION 54: PHYSICAL FACILITIES, OBSTETRICAL FACILITIES	54.1-6
SECTION 55: PHYSICAL FACILITIES, EMERGENCY SUITE	55.1-3
SECTION 56: PHYSICAL FACILITIES, IMAGING SUITE	56.1-5
SECTION 57: PHYSICAL FACILITIES, NUCLEAR MEDICINE	57.1-5
SECTION 58: PHYSICAL FACILITIES, MOBILE, TRANSPORTABLE, AND RELOCATABLE UNITS	58.1-4
SECTION 59: PHYSICAL FACILITIES, LABORATORY SERVICES	59.1
SECTION 60: PHYSICAL FACILITIES, REHABILITATION THERAPY DEPT.	60.1-3
SECTION 61: PHYSICAL FACILITIES, MORGUE AND NECROPSY	61.1
SECTION 62: PHYSICAL FACILITIES, PHARMACY	62.1-2
SECTION 63: PHYSICAL FACILITIES, DIETARY FACILITIES	63.1-3
SECTION 64: PHYSICAL FACILITIES, ADMINISTRATION AND PUBLIC AREAS	64.1
SECTION 65: PHYSICAL FACILITIES, HEALTH INFORMATION UNIT	65.1
SECTION 66: PHYSICAL FACILITIES, CENTRAL MEDICAL AND SURGICAL SUPPLY DEPARTMENT	66.1
SECTION 67: PHYSICAL FACILITIES, CENTRAL SUPPLY AND RECEIVING	67.1
SECTION 68: PHYSICAL FACILITIES, LINEN SERVICES	68.1-2
SECTION 69: PHYSICAL FACILITIES, CLEANING AND SANITIZING CARTS,	

EMPLOYEE FACILITIES AND ENVIRONMENTAL CLOSETS	69.1
SECTION 70: PHYSICAL FACILITIES, ENGINEERING SERVICE AND EQUIPMENT AREAS	70.1
SECTION 71: PHYSICAL FACILITIES, WASTE PROCESSING SERVICES	71.1
SECTION 72: PHYSICAL FACILITIES, DETAILS AND FINISHES	72.1-6
SECTION 73: PHYSICAL FACILITIES, CONSTRUCTION, INCLUDING FIRE RESISTIVE REQUIREMENTS	73.1-3
SECTION 74: PHYSICAL FACILITIES, MECHANICAL REQUIREMENTS	74.1-7
SECTION 75: PHYSICAL FACILITIES, PLUMBING & OTHER PIPING SYSTEMS	75.1-3
SECTION 76: PHYSICAL ENVIRONMENT, ELECTRICAL STANDARDS	76.1-4
SECTION 77: HYPERBARIC SUITE	77.1-2
SECTION 78: PHYSICAL FACILITIES, HELICOPTER LANDING AREA	78.1
SECTION 79: PHYSICAL FACILITIES, FREESTANDING AMBULATORY SURGERY CENTERS	79.1-5
SECTION 80: PHYSICAL FACILITIES, OUTPATIENT CARE FACILITIES	80.1-6
SECTION 81: PHYSICAL FACILITIES, REHABILITATION FACILITIES	81.1-5
SECTION 82: PHYSICAL FACILITIES, PSYCHIATRIC HOSPITALS AND ALCOHOL/DRUG ABUSE INPATIENT TREATMENT CENTERS	82.1-3
SECTION 83: PHYSICAL FACILITIES, INFIRMARIES	83.1-2
SECTION 84: TABLES	
TABLE 1: FILTER EFFICIENCIES FOR CENTRAL VENTILATION AND AIR CONDITION IN HEALTH CARE FACILITIES	Table 1-1
TABLE 2: SOUND TRANSMISSION LIMITATIONS IN HEALTH CARE FACILITIES	Table 2-1
TABLE 3: TEMPERATURE AND RELATIVE HUMIDITY REQUIREMENTS	Table 3-1
TABLE 4: VENTILATION MEDICAL GAS & AIR FLOW REQUIREMENTS IN HEALTH CARE FACILITIES	Table 4-1-4
TABLE 5: FINAL OCCUPANCY INSPECTION CHECK LIST	Table 5-1
TABLE 6: BEHAVIORAL SCREENING EXAM	Table 6-1-3
TABLE 7: DOG HISTORY	Table 7-1
TABLE 8: RECORD RETENTION TIME FRAMES	Table 8-1
TABLE 9: REQUIRED TEMPERATURES	Table 9-1
TABLE 10: CENTRAL STATION OUTLETS OF OXYGEN VACUUM (SUCTION) & MEDICAL AIR SYSTEMS IN HOSPITALS	Table 10-1-2
TABLE 11: VERBAL ORDER	Table 11-1
TABLE 12: REUSE	Table 12-1

CERTIFICATION

SECTION 1: AUTHORITY.

The following Rules ~~and Regulations~~ for Hospitals and Related Institutions 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 Ark. Code Ann. §§20-9-201 et.seq., 20-7-123, and other laws of the State of Arkansas.

DRAFT

SECTION 2: PURPOSE.

These rules ~~and regulations~~ have been prepared for the purpose of establishing a criterion for minimum standards for licensure, operation and maintenance of hospitals and related institutions 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. Hospitals and related institutions have a strong moral responsibility for providing optimum patient care and treatment for the populations they serve.

DRAFT

SECTION 3: DEFINITIONS.

For purposes of the ~~regulations rules~~, the following definitions apply.

A. ~~Abortion complication means any harmful event or adverse outcome with respect to a patient related to an abortion that is performed on the patient and that is diagnosed or treated by a physician or at a healthcare facility including not limited to shock, uterine perforation, cervical laceration, hemorrhage, aspiration, or allergic response, infection, sepsis, death, incomplete abortion, damage to the uterus, and an infant born alive after an abortion.~~

A.B. Administrator means the person responsible for the management of any facility requiring licensure under these ~~regulations rules~~.

B.C. Alcohol/Drug Abuse Inpatient Treatment Center means a distinct unit within a hospital facility in which services are provided for the diagnosis, treatment and rehabilitation of alcohol and drug abuse.

C.D. 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.E. 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 CAH;
3. Provides staffing according to Rules and Regulations for Hospitals and Related Institutions in Arkansas; and
4. Meets Centers for 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.

NOTE: When a hospital converts to a CAH and then at a later date decides to return to a full service with no limits on bed or length of stay, the hospital shall be surveyed using the Life Safety Code under which the hospital entered into the CAH program. The hospital shall be able to show that it has continued to be licensed and complied consistently with the Life Safety Code as a CAH.

E.F. Department means the Arkansas Department of Health.

F.G. 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.H. 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.I. Infirmary 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.J. Institution means, for the purpose of these ~~regulations~~ 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.K. 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.L. 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.

~~L.M.~~ 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.N.~~ 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 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.O.~~ 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.

“Outpatient surgery center” does not include:

1. 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
2. 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.P.~~ 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.O.~~ 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.R.~~ Rehabilitation Hospital or Facility means, for the purpose of these ~~regulations~~ 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.S.~~ Shall means mandatory.

~~S.T.~~ State Health Officer means the Secretary of the State Board of Health.

~~T.U.~~ 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, surgery and general medical care 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 Ark. Code Ann. §20-9-214.
 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- rules~~ 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 Ark. Code Ann. 20-9-214.
 3. For the purpose of these ~~regulations- 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 Ark. Code Ann. 20-9-214, 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 License. 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:

RULES ~~AND REGULATIONS~~ FOR HOSPITALS AND RELATED INSTITUTIONS IN ARKANSAS 201620
06/13/19

1. Violation of any of the provisions of Ark. Code Ann. §§20-9-201 et seq.; 20-7-123 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. (Ark. Code Ann. § 20-9-215)
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 regulations-rules prescribed herein.

L. Penalties.

1. Any person, partnership, association, or corporation which establishes, conducts, manages, or operates any institution defined herein, without first obtaining a license therefore as herein provided or who violates any portion of this act or regulations-rules 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 \$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 regulations-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.

M. Codes. See Section 47, 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 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.

DRAFT

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.

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;
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

- f. Organizational performance.

DRAFT

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 shall 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 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
 2. Development by the Governing Body with advice 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.
- 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;
 - 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;
 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., Rehearsals may be 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 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 relicensure. 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 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 time frames for review of the grievance and the provision of a 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.

DRAFT

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 Prevention and 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. Annual testing of each employee for tuberculosis. Each employee, regardless of whether the employee is a reactor, non-reactor or converter shall be tested or evaluated in accordance with the applicable section of the Tuberculosis Manual of the Arkansas Department of Health; and~~
 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 ~~and regulations~~ 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 ~~regulations-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 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 submit to the Arkansas Department of Health, Division of Vital Statistics a report on each abortion complication (including live birth) 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
- (i) The date of the abortion that caused or may have caused the abortion complication;
- (ii) The type of abortion that caused or may have caused the abortion complication;
- (iii) The gestational age of the fetus at the time the abortion was performed;
- (iv) The name and type of healthcare facility in which the abortion was performed;
- (v) The date the abortion complication was diagnosed or treated;
- (vi) The name and type of any healthcare facility other than the reporting healthcare facility in which the abortion complication was diagnosed or treated;
- (vii) A description of the abortion complication;
- (viii) The patient's year of birth, race, marital status, state of residence, and county of residence;

RULES ~~AND REGULATIONS~~ FOR HOSPITALS AND RELATED INSTITUTIONS IN ARKANSAS 201620
07/03/19

(ix) 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;

(x) The number of previous live births of the patient; and

(xi) The number of previous induced abortions of the patient

E. The Facility shall report to Arkansas Department of Health, Division of Vital Statistics, when a known transfer occurs of a patient from the care of a lay midwife during the labor and delivery process.

DRAFT

SECTION 10: PATIENT IDENTIFICATION.

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

DRAFT

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 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 QA/PI program that is specific to the patient care administered. The program shall reflect nursing staff participation including reports to appropriate hospital committees.

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
 - 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 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. Licensable hospital bed means every patient care bed with the exception of bassinets and labor beds.
2. No beds shall be made up 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. 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.

DRAFT

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° and 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 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.
- 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 ~~regulations~~ 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 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 ~~regulations~~ 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. Restraint 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 time 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 65, Physical Facilities, 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 who 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 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 statutes.

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. 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, CAT 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. Postanesthesia 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 postanesthesia 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 and Regulations 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, OBSERVATION
SERVICES AND PSYCHIATRIC RECORDS.**

- 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;
 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
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.
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.
 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.

- 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).
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 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.
 4. The Committee develops and approves policies and procedures for all 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 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
 - 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);

- 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 shall be kept by the pharmacist to be readily accessible, for control and other purposes, as required by these ~~regulations~~ 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.
- 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.
- 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 Committee.
- 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 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 (1) pharmacist on the basis of forty (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 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.

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 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:
 - i. be under a current agreement; and
 - ii. 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;
 - 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.
 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 and Regulations 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 and Regulations 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 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.
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 and Regulations 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 Health Facility Services. Counter tops and other huge industrial equipment shall be washed down with concentrated solutions.
9. Clean linens, mop heads 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 regulations are referenced to the Arkansas Board of Health *Rules and Regulations 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;
 - 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:
 - i. Anthropometric measurements including height, weight, BMI, and goal weight;
 - ii. Abnormal pertinent laboratory values;
 - iii. The patient's caloric and protein needs;

- iv. nutrient intake compared to estimated needs;
 - v. Determination of abnormal intake or recent weight loss/gain prior to admission;
 - vi. An objective evaluation of the patient's compliance with a physician ordered diet prior to admission;
 - vii. Pertinent food/drug interactions;
 - viii. An evaluation of the patient's special feeding/nutrient/fluid needs;
 - ix. Patient's food preferences, dislikes, allergies or intolerances; and
 - x. 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:
- i. individualized nutrition counseling;
 - ii. discharge planning;
 - iii. comprehensive nutrition assessments to include further clinical, laboratory, social or nutrition data to assist with the ongoing evaluation;
 - iv. follow-up care to evaluate the effectiveness of the nutrition regimen; and
 - v. 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;
 - 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.

DRAFT

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 difficile infection (CDI);
 - 3) Central line associated blood stream infection (CLABSI); and
 - 4) Catheter associated urinary tract infection (CAUTI).

NOTE: The facility's system for surveillance, calculation and evaluation of the incidence of HAI within the facility shall conform to 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);
 - 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) immunosuppressed 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, immunosuppressed 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;
 - 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 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 regulations;
 - 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 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 and Regulations 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 hospital shall provide laboratory services onsite commensurate with the needs of patients that are admitted. Provision shall be made for the performance of laboratory examinations in the following categories:
 - a. Chemistry;
 - b. Hematology;
 - c. Microbiology;
 - d. Immunology;
 - e. Immunochemistry;
 - f. Urinalysis; and
 - g. Pathology.
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 hospital laboratory or from other approved laboratories, as determined by hospital policy, shall be placed in the patient's medical record.
6. Laboratory tests shall be authorized by a physician, dentist, or other person 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:
 - 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 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;
 - 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 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 years of clinical laboratory training or experience relative to the specialties being supervised;
 - d. A passing score on the Clinical Laboratory Technology Proficiency examination approved by HHS (HEW) and at least six years of clinical laboratory experience with at least two 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, troubleshooting 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 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;
 - 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 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. Immunohematology 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;
 - 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;
 - 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;
 - 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 FR 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, 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 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.

- 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.

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 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 sample of calibration material or control material each time patients are tested if the instrument does not internally verify calibration at least every 30 minutes.
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 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. Immunohematology.

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 Immunohematology and Transfusion Services and Blood Banking under the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88).
2. If the facility does not provide immunohematological 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 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;
- b. Hemolysis;
- c. Bacterial contamination; and
- d. Unit integrity.

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, crossmatched, 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;
 - 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.
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:
 - 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:
- 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;
 - 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;
 - 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 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;
 - 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.
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);
 - 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;
 - 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 years.
 12. Point of Care Testing shall be included in the hospital laboratory's Quality Assurance/Performance Improvement program.

Any tests other than those specified in P.1 above shall be subject to all of the requirements of Section 19.

DRAFT

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:
 - 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 and Regulations 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 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 and Regulations 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.
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 and Regulations for Control of Sources of Ionizing Radiation or with the specific condition of a Radioactive Material License issued pursuant to these ~~regulations~~ 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
 - 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;
 - 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 and Regulations for Hospitals and Related Institutions in Arkansas, Section 20, Radiological Services; and
 - 2) Rules and Regulations 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;
 - 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 56, 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;
 - 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 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 the Rules and Regulations 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 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.
- 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.

DRAFT

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 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 measure.
- 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.
- 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 clean up of all accidents.
- L. 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.
 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 physician's 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;
 - b. Crash cart;
 - c. Cardiac monitor
 - d. Defibrillator;
 - e. Resuscitating equipment;
 - f. Suction equipment; and

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. Refer to Health Information Services, Section 14;
 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: Postanesthesia 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. Postanesthesia 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 Postanesthesia Care Unit. See Section 27, Postanesthesia Care Unit; and
 - 9. Infection prevention and control measures.
- 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.)

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);
 - 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.

DRAFT

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 and length of gestational period; and
 - b. Baby's sex, race, date of birth, time of birth, weight, apgar score and baby identification band number.
- D. Anesthesia.
1. Only a physician, anesthesiologist or Certified Registered Nurse Anesthetist (CRNA) shall be permitted to initiate and re-inject continual epidural or caudal anesthesia and to initiate or continue general or regional anesthesia.
 2. A physician shall be immediately available 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.
 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.).

DRAFT

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

- G. 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. 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 immunosuppressed critical care patients.
- 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.

DRAFT

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.

DRAFT

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;
 - 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.
- 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 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	LOAD	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)

- 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.

DRAFT

- 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.

DRAFT

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;
 - 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:
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 semi-critical 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, and 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;
 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.
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 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 hospitals infection prevention and 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.
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.

DRAFT

SECTION 37: SPECIALIZED SERVICE: PSYCHIATRIC SERVICES.

- A. Psychiatric care units in general hospitals shall meet the construction requirements of Section 52, Psychiatric Nursing Unit, and shall in all respects comply with the requirements of Section 48, 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.
 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
 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).

DRAFT

SECTION 38: SPECIALIZED SERVICE: CARE OF PATIENTS WITH PULMONARY DISEASE IN GENERAL 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.

DRAFT

SECTION 39: AMBULATORY SURGERY CENTERS.

- A. 1. 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 unnecessary, shall be considered an ambulatory /outpatient surgery center (ASC).
- a. Ambulatory/outpatient surgery center does not include:
 - (i) 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
 - (ii) 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.
 - 2. General or intravenous anesthetics include:
 - a. Deep Sedation/Analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. (Source: 2009 American Society of Anesthesiologists *Continuum of Depth of Sedation*)
 - b. General Anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilator function is often impaired. Patient often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired. (Source: 2009 American Society of Anesthesiologists *Continuum of Depth of Sedation*)
- B. ASCs shall conform with the following sections:
- 1. Section 3, Definitions;
 - 2. Section 4, Licensure and Codes;
 - 3. Section 5, Governing Body;
 - 4. Section 6, Medical Staff;
 - 5. Section 7, General Administration;
 - 6. Section 11, Patient Care Service (Nursing);
 - 7. Section 12, Medications;
 - 8. Section 14, Health Information Services (excluding Obstetrical & Newborn Records);

9. Section 16, Pharmacy;
 10. Section 18, Infection Prevention and Control;
 11. Section 19 A, C.2 and F, Laboratory;
 12. Section 20, Radiological Services;
 13. Section 26, Specialized Services: Surgical Services;
 14. Section 27, Specialized Services: Postanesthesia Care Unit;
 15. Section 28, Specialized Services: Outpatient Surgical Services;
 16. Section 29, Specialized Services: Anesthesia Services;
 17. Section 34, Specialized Services: Central Sterilization and Supply;
 18. Section 46, Physical Environment; and
 19. Section 79, Physical Facilities, Freestanding Ambulatory Surgery Centers
- 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. There shall be Registered Nurses to staff all patient care areas. 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 assignment.
- D. Discharge criteria shall be established and approved by the Medical Staff and Governing Body.
- E. Surgical records shall include documentation stating the patient meets discharge criteria and is discharged from the facility accompanied by a responsible adult.
- F. Diagnostic and treatment services provided through contract shall be from a source approved by the Department. Such services shall be monitored by the Ambulatory Surgery Center.
- G. Surgical procedures performed in the Ambulatory Surgery Center shall be those which are:
1. Commonly performed on an inpatient basis in hospitals, but may be safely performed in an Ambulatory Surgery Center;
 2. Not of a type which are commonly performed, or which may be safely performed, in physicians' offices; and
 3. Limited to those requiring a dedicated operating room (or suite), and generally requiring a postoperative recovery room or short term (not overnight) rooms.
- H. Surgical procedures shall not be of a type that generally result in extensive blood loss; require major or prolonged invasion of body cavities; directly involve major blood vessels; or generally emergency or life threatening in nature.

- I. The Ambulatory Surgery Center shall have a written agreement with a local hospital for transfer of a patient in a medical emergency of a nature which cannot be handled in the Ambulatory Surgery Center or shall ensure that every physician performing surgeries at the ASC has admitting privileges at a local hospital.
- J. Extended Recovery Time.
 - 1. Scope/Limitations of Services.
 - a. The extended recovery time service shall be approved by the Health Facility Services prior to implementation of the service.
 - b. Ambulatory Surgery Centers shall have the capability to provide care for post- surgical patients requiring continued nursing or medical treatment, but whose condition does not warrant acute hospitalization. The extended recovery period shall not exceed 23 hours and 59 minutes. The extended recovery period shall be limited to:
 - 1) Observation;
 - 2) Control of nausea/vomiting;
 - 3) Replacement of fluids; and
 - 4) Pain management.
 - c. Patients shall be screened prior to surgery and prior to admission to the overnight area to ascertain that established admission criteria is met.
 - d. Services shall not include intensive nursing care, continuous monitoring due to the instability of vital signs, administration of IV cardiac or anti-hypertensive drugs or treatment of any unstable underlying medical condition.
 - e. If a question arises as to whether or not a patient is an appropriate candidate for extended stay, the decision shall be made by the Medical Director or Administrator.
 - 2. Admission Criteria.
 - a. Physician's order shall be obtained for transfer to extended stay;
 - b. Stable vital signs and O₂ saturation level;
 - c. Oriented to person, place and time (a return to preoperative mentation);
 - d. Presence of satisfactory airway;
 - e. Absence of significant bleeding;

RULES FOR HOSPITALS AND RELATED INSTITUTIONS IN ARKANSAS 2020
06/13/19

- f. Stabilized or resolution of any acute problem;
 - g. Movement of extremities following regional anesthetic;
 - h. Level of consciousness which permits patient to call for nurse;
 - i. Recovery will require 23 hours 59 minutes or less prior to discharge;
 - j. The surgeon and anesthesia provider (or their designee of similar training and expertise) shall be present or immediately available. "Immediately available" shall be determined by the administrative staff, Medical Staff and Governing Body; and
 - k. Patient assessment and orientation shall be recorded in the medical record.
3. Discharge Criteria.
- a. Discharge shall be done in keeping with the same criteria established for the discharge of any patient from the Ambulatory Surgery Center.
 - b. The patient shall be discharged within 23 hours and 59 minutes of his/her admission to extended recovery by the surgeon or anesthesiologist or his/her designee.
 - c. If the patient's condition is such that discharge is deemed inappropriate, arrangements shall be made for hospital transfer.
 - d. Postoperative prescription orders and instructions shall be given to the patient and responsible adult with an understanding of instructions verbally by the person(s) receiving them and a copy retained in the medical record.
4. Transfer Requirements to Acute Care Facility.
- a. Patients who require continuous monitoring due to the instability of vital signs;
 - b. Patients who require administration of IV cardiac or anti-hypertensive drugs;
 - c. Patients who require treatment of any unstable underlying medical condition;
 - d. Patients whose pain management or observation requires longer than 23 hours and 59 minutes;
 - e. Patients who have a lowered level of consciousness than their preoperative status; and
 - f. Patients who exhibit current or potential airway complications.
5. Supervision of Extended Recovery Care.
- a. Ambulatory Surgery Centers shall provide adequate supervision of extended stay area to assure quality patient care and safety.

- b. The extended stay area shall be staffed with a minimum of two caregivers at all times.
 - 1) At least one of the caregivers shall be a Registered Nurse.
 - 2) All caregivers shall be Basic Cardiac Life Support (BCLS) certified and shall be fully oriented and trained.
 - 3) At least one Registered Nurse on duty at all times shall be Advanced Cardiac Life Support (ACLS) certified.
 - 4) The anesthesiologist (or designee) and the surgeon (or designee) shall be present or immediately available. "Immediately available" shall be determined by the administrative staff, Medical Staff and Governing Body.
- 6. Emergency Procedures.
 - a. Any emergency or life-threatening situation shall be handled in a manner that provides the most appropriate and rapid care to best meet the patient needs.
 - b. Local Emergency Medical Services (EMS) shall be notified that regular hours are being extended on the days patients required extended recovery care.
 - c. Appropriate drugs, supplies and equipment shall be immediately available to the area, including a fully stocked crash cart with defibrillator and oxygen tank.
 - d. Transfer agreements to a local acute care hospital and ambulance transportation covering the Ambulatory Surgery Center shall include the extended stay area.
- 7. Medications.

The Ambulatory Surgery Center shall have provisions for obtaining prescribed drugs and biologicals to meet the needs of the population served. In addition, policies and procedures shall be developed and implemented for the handling of medications brought into the facility by patients. Should it be necessary to administer a patient's own medications, a signed physician's order shall be in the medical record identifying the medications(s) along with the route and directions for use.
- 8. Medical Records.
 - a. Ambulatory Surgery Centers shall have an expanded medical record for patients in extended stay.
 - b. The same medical record shall be utilized that was initiated upon admission for surgery.
 - c. A discharge note shall be written upon discharge from acute recovery care.
 - d. An admission note, to include a patient assessment by a Registered Nurse, shall be included when the patient is received in the extended care area.

- e. Pertinent observations, treatments and medications shall be documented in the nurses' notes.
 - f. A closing entry or discharge summary shall include information/observations regarding the patient's condition and the care provided throughout the extended care.
 - g. Patient food allergies and preferences shall be documented. Meal intake and toleration of diet shall be documented by nursing personnel in the nurses' notes.
9. Patient Nutrition.
- a. If meals are prepared onsite, the Food and Nutrition Services shall be supervised by a qualified individual on the days the facility is open. A qualified individual shall be at a minimum a certified dietary manager.
 - b. The food preparation area shall included at a minimum:
 - 1) Refrigerator/freezer;
 - 2) Microwave oven;
 - 3) Hand hygiene sink with towel and soap dispensers;
 - 4) Counter space;
 - 5) Garbage cans with cover;
 - 6) Storage area for food, food preparation equipment and tableware; and
 - 7) A three compartment sink, if disposables are not utilized at all times.
 - c. If meals are not prepared onsite, the food served to the patient shall be obtained from a food service establishment that operates in accordance with the Arkansas Department of Health Rules and Regulations Pertaining to Food Service Establishments.
 - d. Leftover foods shall not be stored for future patient use.
10. Physical Facilities.
- Extended stay may permit patient sleeping accommodations in the post-anesthesia recovery area.
11. Staffing.
- a. At least one Registered Nurse shall be on duty at all times while the center is in operation, with supportive personnel as needed.
 - b. Non-nursing personnel, i.e., aides, housekeeping, etc. shall be assigned in sufficient numbers and with sufficient training to meet the patient's needs.

12. Security Procedures.
 - a. Measures shall be employed to ensure the security of patients, families, physicians and employees while at the center after normal working hours.
 - b. The parking lot shall be well-lit.
 - c. At least two employees shall be present inside the facility when patients are present.
13. Quality Assurance/Performance Improvement/Risk Management Plan
 - a. Ambulatory Surgery Centers shall assure the same QA/PI plan is followed for extended recovery care patients as general patients.
 - b. Each extended recovery patient shall receive the same Patient Satisfaction Questionnaire as general surgical patients upon discharge from the facility.
 - c. Each extended recovery care patient shall receive a postoperative call if they are discharged to home. If they are discharged to an alternate health care facility (i.e., rehab) a discharge summary shall be obtained upon discharge from that facility.
 - d. During the first year of extended recovery services a quarterly report of the plan review shall be sent to Health Facility Services, Arkansas Department of Health.

SECTION 40: 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 80, 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.
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 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
- 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 80, Physical Facilities, Outpatient Care Facilities.

SECTION 41: 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 ~~regulations-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.
- C. Physical Environment. The Rehabilitation Facility shall comply with Section 46, Physical Environment.
- D. Physical Facilities. The Rehabilitation Facility shall comply with Section 81, Physical Facilities, Rehabilitation Facilities.

SECTION 42: 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 76, 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 Information 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 information 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 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 48, Physical Facilities, Patient Accommodations (Adult Medical, Surgical, Communicable or Pulmonary Disease) shall apply to recuperation centers with the following exceptions:

RULES FOR HOSPITALS AND RELATED INSTITUTIONS IN ARKANSAS 2020
06/13/19

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 43: PSYCHIATRIC HOSPITALS.

- A. General. Any facility used for the primary purpose of providing inpatient diagnostic care and treatment of persons having mental disorders shall be considered a psychiatric hospital and shall conform with Section 1, Authority, through Section 24, Recreational Therapy and applicable portions of Section 82, Physical Facilities, Psychiatric Hospitals and Alcohol/Drug Abuse Inpatient Treatment Centers of these ~~regulations~~ rules.
- B. Personnel. The hospital shall furnish, through the use of qualified personnel, psychological services, social work services, occupational therapy, recreational therapy and psychiatric nursing. Provisions shall be made for specialty medical requirements, i.e., neurologist, internist, etc. Each hospital or unit shall have the capability of providing or arranging emergency services 24 hours per day, seven days per week.
1. A board-certified psychiatrist shall be the Medical Director. The Medical Director shall coordinate the Psychiatric Services in conjunction with other medical, nursing, therapy, and hospital administration.
 2. The diagnosis, care and treatment for patients shall be under the direction of a psychiatrist.
 3. 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.
 4. All personnel working within an area of psychiatric patients shall be trained in psychiatric patient care.
 5. Policies and procedures shall be developed specifically for Psychiatric Services.
- C. Seclusion and Restraints.
1. Seclusion. Patients shall be placed in seclusion only on the written order of the physician. Documentation shall reflect time in seclusion, frequency of observation and frequency of re-evaluation for continued seclusion.
 2. Restraints (Mechanical).
 - a. The Medical Staff shall establish criteria for use.
 - b. If locked restraints are used a designated staff member shall have possession of the key and keep the patient under constant observation.
 - c. A schedule shall be developed for releasing the restraints.
 - d. Restraints shall be used only as a last resort for prevention of harm self-inflicted or to others.

3. Patients shall be grouped according to age (children, adolescents and adults), sex and treatment needs. Patients with communicable diseases shall be isolated.

D. Health Information Services. (See Section 14, Health Information Services.)

E. Special Precautions.

1. Special precautions shall be taken so medications and controlled substances are not accessible to patients.
2. Sharp instruments, knives, ice picks or other objects which could be used for homicidal or suicidal purposes, shall not be available to patients.

F. Patient Identification.

If the facility does not choose to follow Section 10, Patient Identification, they shall take three pictures of the patient at the time of admission. Pictures shall be attached:

1. To the medication sheet;
2. To the face sheet of the patient's medical record; and
3. In the dietary department.

G. Physical Environment. A Psychiatric hospital shall comply with Section 46, Physical Environment.

H. Clinically relevant educational programs shall be conducted on a regularly scheduled basis not less than 12 per year. There shall be evidence of s program dates, attendance, and subject matter.

I. There shall be an ongoing QA/PI program that is specific to patient care.

J. Physical Facilities. A psychiatric hospital shall comply with Section82, Physical Facilities, Psychiatric Hospitals and Alcohol/Drug Abuse Inpatient Treatment Centers.

SECTION 44: INFIRMARIES.

An infirmary shall be considered a facility established for the purpose of offering temporary medical care and/or treatment exclusively for persons residing on a designated premise, e.g., schools, reformatories, correctional institutions, etc.

- A. Compliance. Infirmaries shall comply with applicable parts of Section 10, Patient Care Service, through Section 13, Restraints. Infirmaries shall comply with all applicable parts of:
1. Section 5, Governing Body and Section 6, Medical Staff. The infirmary shall have an organized Governing Body or in its absence, a person shall be legally responsible for maintaining quality patient care, establishing policies for the infirmary and shall be legally responsible for the conduct of the infirmary;
 2. Section 6, Medical Staff. The infirmary shall be under the direction of a qualified physician who shall be responsible for the medical care and treatment rendered;
 3. Item A. of Section 11, Patient Care Service. The infirmary shall be under the supervision of a Registered Nurse on the day tour of duty. Evening and night tours shall be staffed with licensed nursing personnel. The medical record for each patient admitted to the infirmary during the day tour of duty shall document the admission and observation of patient acuity by a Registered Nurse. The admission shall be performed by the Director of Nursing or the Registered Nurse on call when such admission occurs on a weekend day;
 4. Section 14, Health Information Services and Section 15, Medical Record Requirements for Outpatient Services, Emergency Room, Observation Services and Psychiatric Records;
 5. Applicable parts of Section 19 Laboratory and Section 20, Radiological Services. The infirmary need not comply unless the services are offered in the infirmary. Where laboratory and/or radiology services are not offered in the infirmary, the infirmary shall obtain a written agreement to provide any such services, as appropriate in the scope of the infirmary setting from a source approved by the Arkansas Department of Health;
 6. Section 17, Food and Nutrition Services. Kitchen sanitation and food preparation areas shall meet the requirements for public eating establishments set forth by the Arkansas Department of Health;
 7. Section 16, Pharmacy;
 8. Section 83, Physical Facilities, Infirmaries; and
 9. Section 18, Infection Prevention and Control.
- B. Pharmacy Services. All infirmaries shall have adequate provisions for pharmaceutical services regarding the procurement, storage, distribution and control of all medications. All federal and state regulations shall be followed. (See Section 16, Pharmacy.)
- C. Administration of Pharmaceutical Services.

1. The infirmary shall provide policies and procedures for obtaining, dispensing and administering of drugs and biologicals developed with the advice of a physician or pharmacist.
 - a. Definition of Dispensing. A function restricted to licensed pharmacists which involves the issuance of:
 - 1) 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;
 - 2) 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
 - 3) 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).
 - b. Definition of Administering. An act restricted to nursing personnel as defined in The Nurse Practice Act, in which a single dose of a prescribed drug or biological is given to a patient. This activity includes the removal of the dose from a previously dispensed, properly labeled container, verifying it with the prescriber's orders, giving the individual dose to the proper patient and recording the time and dose given.
2. The infirmary shall provide for the procurement of drugs and pharmaceutical supplies as follows:
 - a. If the infirmary has a pharmacy department, a licensed pharmacist shall be employed to administer the pharmacy in accordance with all state and federal laws and regulations regarding drugs and drug control;
 - b. If the infirmary does not have a pharmacy department, the infirmary shall provide for prompt, convenient availability of prescribed drugs and biologicals from a community pharmacy;
 - c. If the infirmary does not have a pharmacy department but does maintain a supply of medications, a licensed pharmacist shall be responsible for the control of all bulk drugs and maintain records of receipt and disposition. The pharmacist shall dispense medications from the drug supply, properly labeled and available to appropriate nursing personnel; and
 - d. If a physician maintains his own stock of drugs in the infirmary, he shall dispense all drugs and maintain control as required of a pharmacist.

D. Medication Orders.

1. All medications administered to patients shall be ordered in writing by the physician. Verbal orders shall be given only to a licensed nurse or a licensed pharmacist,

immediately reduced in writing, signed by the nurse or pharmacist and countersigned by the physician within 72 hours.

2. Medications are released to patients on discharge only on the written authorization of the physician.

E. Administration of Medication.

1. All medications administered by licensed personnel shall be in accordance with the Arkansas Practice Acts.
2. Medications prescribed for one patient shall not be administered to any other patient.
3. Medication errors and adverse drug reactions shall be reported to the patient's physician and the pharmacist.
4. All medications administered shall be recorded in the medical record.

F. Labeling.

1. Medication kept as general floor stock in the facility shall be labeled with the trade name (or generic name with the name of the manufacturer), strength, lot number and expiration date.
2. The label of each patient's individual medication container shall clearly indicate the patient's full name, physician's name, prescription number, name and strength of the medication, date of issue, name, address and telephone number of issuing pharmacy.
3. Medication containers having soiled, damaged, incomplete, illegible or makeshift labels are returned to the issuing pharmacist or pharmacy for re-labeling or disposal.

G. Storage and Security of Medications.

1. All medications shall be locked to limit access to licensed personnel.
2. Each patient medication shall be kept and stored in original containers. There shall be no transferring between containers.
3. Medication cabinets shall be of sufficient size to permit storage of medication.
4. 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 to assure temperatures between 36E-46E Fahrenheit 2E-8E Centigrade. Daily documentation of temperatures shall be maintained. Refrigerated medications may be stored in a locked box inside the refrigerator.
5. Poisons and external medications shall be separated from other medications.

6. Applicable medications shall be removed from usage in the event of a drug recall or upon expiration.

H. Pharmacy Records.

1. The infirmary shall comply with all federal and state laws and regulations relating to the procurement, storage, dispensing, administering and disposal of medications.
2. A controlled substance record is maintained which lists the following information on a separate sheet for each type and strength of controlled substance: date; time administered; name of patient; dose; prescriber's name; signature of the person administering the dose; and remaining drug balance.
3. All controlled substances shall be counted by two licensed personnel at the opening and closing of each staffed shift to ensure compliance between the listed drug balances and the actual amounts in stock.
4. All pharmacy records shall be maintained for two years.
5. The pharmacy shall either maintain copies of the order or a prescription for every medication dispensed.
6. Policies and procedures shall be provided.
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. There shall be an ongoing QA/PI program that is specific to the patient care administered.

I. Physical Facilities. Infirmary shall comply with Section 83, Physical Facilities, Infirmaries.

SECTION 45: ALCOHOL/DRUG ABUSE INPATIENT TREATMENT CENTER

- A. Administrative Requirements. Policies and procedures for the alcohol/drug program shall include, but be not limited to, the following:
1. Staffing. Clinical staff shall be licensed or certified by appropriate state licensure or certification boards;
 2. Admission procedures, including a procedure for accepting emergency admissions;
 3. Patient evaluation procedures, including preliminary evaluation and establishment of an individual treatment plan;
 4. Treatment procedures and services that are consistent with accepted standards of treatment for alcohol/drug abuse illness;
 5. Procedures for referral and follow-up of patients' outside services;
 6. Procedures for involvement of family in counseling process;
 7. Provision for after-care plan;
 8. Program Quality Assurance/Performance Improvement;
 9. Provision for an education program acceptable to local school officials for patients of school age that would also include suitable recreational needs of adolescents;
 10. Provision for coordination of services with community mental health centers, substance abuse treatment programs and other appropriate facilities or programs; and
 11. 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.
- B. Medical Services. A physician licensed in the State of Arkansas shall be responsible for diagnosis and all medical care and treatment. Medical services shall be provided directly or on call 24 hours per day, seven days per week. Upon admission, there shall be written orders for the immediate care of the patient.
- C. Nursing Services. Nursing services shall be under the direct supervision of a Registered Nurse qualified by education and experience in psychiatric, mental health or chemical dependency nursing. The number of Registered Nurses, Licensed Practical Nurses and other 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.

- D. Psychiatric Services. Patients shall be provided with psychiatric services in accordance with their needs by a psychiatrist licensed in the State of Arkansas. Services to patients include evaluations, consultations, therapy and program development.
- E. Psychological Services. Patients shall be provided with psychological services in accordance with their needs by a qualified psychologist. Services to patients include evaluations, consultation, therapy and program development. A qualified psychologist is an individual licensed by the State Board of Psychological Examiners with a specialty area in clinical or counseling psychology.
- F. Social Services. Social work services are under the supervision of a qualified social worker. The director of the service or department shall be a licensed social worker in the State of Arkansas. If the director does not have a Master's Degree from an accredited School of Social Work or has not been certified by the Academy of Certified Social Workers, there shall be documented monthly supervisory consultation by such a qualified social worker.
- G. Social Work Staff. Social work staff is qualified and numerically adequate to provide the following services:
1. Psychosocial data for diagnosis and treatment planning;
 2. Direct therapeutic services to individual patients, patient groups or families;
 3. Develop community resources; and
 4. Participate in interdisciplinary conferences and meetings concerning treatment planning, including identification and utilization of other facilities and alternative forms of care and treatment.
- H. Activity Services. Activity services staff shall be sufficient in number and skills to meet the needs of patients and achieve the goals of the service. The activity service shall be supervised by a qualified Activity Director. A qualified Activity Director is an individual with a Bachelor's Degree who has at least one (1) year of experience in assessing, planning and coordinating activity services in a health care setting. In the absence of such a qualified Activity Director, this requirement may be met with a documented monthly supervisory consultation visit by a qualified Activity Therapist.
- I. Substance Abuse counselor. There shall be at least one Certified Substance Abuse Counselor on the treatment staff (as certified by the Arkansas Substance Abuse Certification Board). Substance Abuse Counselor staff is qualified and numerically adequate to provide the following services:
1. Direct counseling services to individual patients, patient groups and families;
 2. Participate in interdisciplinary conferences and meetings concerning treatment planning, including alternative forms of care and treatment;
 3. Develop treatment resources; and
 4. Participate in casework processes.