REGULATION 4 —PHARMACY

04-00: GENERAL REGULATIONS REGARDING PHARMACIES

04-00-0001—EQUIPMENT SPECIFICATIONS

Minimum prescription equipment specifications as authorized by the Arkansas State Board of Pharmacy are:

(a) Graduates capable of measuring from 0.1ml to at least 120ml.
(b) Mortars and pestles--at least one (porcelain or glass)
(c) Hot and cold running water in the prescription department
(d) Spatulas
(e) Ointment slab or ointment papers
(f) Exempt narcotic record book
(g) Class III balance and weights
(h) Equipment for labeling
(i) Pharmacy library: each pharmacy shall have:
    (1) available for use by the pharmacist and use by the patient, either current drug information manuals, or computers capable of printing current drug information for the pharmacist and patient drug information and monographs for patients. (i.e.: the U.S.P.D.I. 3-book set including *Drug Information for the Healthcare Professional* {2 volumes} and *Advice for the Patient* {1 volume}; or *Drug Facts and Comparisons* and *Patient Drug Facts.*
    (2) other pharmacy reference books and periodicals necessary for effective pharmacy practice.

EXCEPTIONS: Pharmacies meeting the requirements of regulation 04-02-0100 or regulation 07-02-0001 shall be exempt from requirements of this regulation when not applicable. (10/09/80, Revised 6/25/83, 4/07/89, 6/07/90, and 8/20/97)

04-00-0002—TIME REQUIRMENTS FOR PHARMACIST ON DUTY

All drugstores or pharmacies must have on duty an Arkansas licensed pharmacist in charge a minimum of forty (40) hours per week. The said 40 hours per week must be served by a single person and cannot be met by a combination of weekly hours of two or more pharmacists with less than forty (40) hours each. The only exception shall be that the Executive Director of the Board of Pharmacy may determine that the health and welfare of the public might be in peril because of a community's limited access to pharmaceutical services if a pharmacy would be forced to close if it did not have a pharmacist to work forty (40) hours a week as the pharmacist in charge. The Executive Director may approve a pharmacist working less than forty (40) hours per week to serve as pharmacist in charge while additional pharmacists work the balance of the hours necessary for the pharmacy to operate a minimum of forty (40) hours per week. Said circumstance shall be for a limited period of time determined by the Executive Director to be reasonable for the owner to be able to employ a pharmacist to work as pharmacist in charge for a minimum of forty (40) hours per week. The Executive Director must take into consideration the ultimate health and welfare of the patients in the area in making the determination. (10/09/80, Revised 10/14/81, 6/20/91, and emergency 4/2001)

04-00-0003—VENDING MACHINES

The sale of any legend drugs or medicines by means of a coin-operated vending machine is expressly prohibited. (10/09/80)

04-00-0004—RE-USE OF DRUGS PROHIBITED

The reuse of returned portions of a prescription drug for human consumption is prohibited whether dispensed by order of a prescription or otherwise. (10/09/80)

04-00-0005—PICK UP STATIONS

No person, firm, or business establishment shall offer to the public, in any manner, their services as a "pick-up-station" or intermediary for the purpose of having prescriptions filled or delivered, whether for profit or gratuitously. Nor may the owner of any pharmacy or drug store authorize any person, firm, or business establishment to act for them in this manner—provided however, intermediary delivery stations after approval by the Board may be operated in clinics in which a practitioner is in attendance at least one day per week and located in an area where pharmaceutical services are unavailable within ten miles of the clinic provided the filled prescriptions are delivered to a designated representative of the pharmacist filling the prescription. (10/09/80, Amended 2/17/82, and 8/19/99)

04-00-0006—EMERGENCY PHARMACY SERVICES

Any pharmacy providing prescription drugs to one or more patients in a nursing home or other institution shall provide emergency prescription services for those patients and shall provide information to the nursing home or institution indicating how the pharmacists can be reached after pharmacy hours.

All pharmacies (other than hospital and institutional) who do not provide emergency drug services for non-institutionalized patients shall post a sign at least 8½ by 11" with letters of at least one (1) inch stating "This pharmacy will not provide emergency prescription drugs when the pharmacy is closed." (6/25/83)

04-01: PHARMACY PERMIT FEES

04-01-0001—PERMIT FEES

Any person, corporation or partnership operating a pharmacy in this state desiring to continue such operation must pay a renewal fee for the permit as established by law and/or regulation. If the fee is not paid on or before February 1st of any even-numbered year, a penalty as defined in regulation 01-00-0007 shall be levied for each month the pharmacy permit fee is delinquent. If the permit fee is unpaid by April 1st of any even-numbered year, the licensed pharmacy shall be expunged from the records of the State Board of Pharmacy, and the owner and/or pharmacist in charge thereof shall, within thirty days, remove all drug signs and legally dispose of all prescription legend drugs. (10/9/80, amended 6/13/85, amended 6/20/91 & 8/23/96)

04-02: REGULATIONS REGARDING RETAIL PHARMACIES

04-02-0001—APPLICATIONS FOR PHARMACY PERMITS

Pharmacies shall apply for licensure and renewal on forms provided by the Board. The permit will be issued to qualified applicants in the name of the licensed pharmacist who shall be directly responsible to the Board of Pharmacy for the operation of the prescription department. (Revised 11/15/2003)

04-02-0002—REQUIREMENTS FOR A NEW PHARMACY PERMIT

Applications for pharmacy permits, other than annual renewal of existing permits, will be reviewed by the Board of Pharmacy Staff. No pharmacy may open for business within thirty (30) days of submission of the original application. Applications for a pharmacy permit for a new pharmacy must have the name and license number of the pharmacist in charge at the time of submission and cannot be altered except by submission of an application for change of pharmacist in charge and the fee as defined in regulation 01-00-0007. The pharmacist in charge of the new pharmacy application cannot be the pharmacist in charge of another pharmacy at the time of submission of the new pharmacy application. If a post office box is used as the address for the pharmacy, the actual street address must also be included on the application. The Executive Director may require that a representative of the owner(s) and the pharmacist in charge appear before the Board of Pharmacy to finalize the application. After review by the Board of Pharmacy staff, an "Inspection Request Form" will be sent to the mailing address of the pharmacy making application. The inspection request form must be received in the Board of Pharmacy office at least one week before the facility will be ready for inspection.

Upon approval of the inspection of the physical facility by the Board of Pharmacy inspector, the Executive Director will complete the final approval of the application and the permit number will be issued.

04-02-0003—LEASED OPERATIONS—PHARMACY IS A DEPARTMENT OF ANOTHER BUSINESS

(a) In any building, firm, or place of business where the pharmacy is a leased operation, and/or in situations where the pharmacist in charge does not own a substantial part of the business and is not manager of the total operation, and/or where the pharmacy is a department in a larger business that is not a drugstore or pharmacy, the prescription department shall be completely separated from the remainder of the building by some type of partition and said department shall be arranged and constructed so that the public will not have access to any legend drugs or medicine.
(b) The prescription area or department of any pharmacy, firm or place of business must be constructed so that it may be locked to prevent unauthorized persons from entering it in the absence of a licensed pharmacist (or other authorized prescription personnel.)
(c) A copy of the signed lease must be submitted with the application of the original permit, and at such other times as the original lease is changed or renewed.

04-02-0004—NECESSARY EQUIPMENT REQUIRED

No pharmacy permit shall be issued or continued for the conduct of a pharmacy unless the premises are equipped with the necessary appliances for maintenance of proper sanitation and kept in a clean, sanitary and orderly manner.

04-02-0005—PHARMACIST IN CHARGE

(a) Pharmacists employed and in charge of pharmacies or drugstores, are required to notify the Board of Pharmacy and surrender for cancellation the permit issued in their names immediately upon the termination of such employment. It shall be the duty of the owner of such pharmacies or drugstores to immediately notify the Board upon the termination of employment of licensed pharmacists and to cause the surrender of permit as indicated. The further operation of the pharmacy or drugstore in the absence of a replacement and the issuance of a new permit is forbidden by law and each day so operated will be considered a separate offense.

(b) When a licensed pharmacist in whose name a permit has been issued leaves the employment of such pharmacy or drugstore, he will be held responsible for proper notification to the Board of Pharmacy of such termination of his services within five days in addition to providing the Board of Pharmacy with an inventory of controlled drugs as defined in regulation 04-02-0008. Failure to so notify the Board and to provide said inventory will operate to prevent his securing a permit to take charge or operate another pharmacy at a subsequent date.

(c) When the licensed pharmacist in whose name a permit has been issued to a pharmacy for any reason ceases to be actually the person who has responsible supervision over said pharmacy or drugstore the permit becomes void, and must be surrendered to the Board before a duplicate will be issued to said pharmacy. Where there is merely a change of licensed pharmacist one replacing the other as the pharmacist in charge, a duplicate permit will be issued upon proper application and payment of a fee as defined in regulation 01-00-0007.

(d) No pharmacy permit shall be issued to any drugstore or pharmacy when the licensed pharmacist in charge of the prescription department is not on duty in that pharmacy a minimum of forty (40) hours per week, except as provided in regulation 04-00-0002. A pharmacist in charge of a retail pharmacy may act as a consultant or part-time pharmacist.

(e) The pharmacist in charge is responsible for the security and accountability of all drugs, legend and/or controlled, stored in said pharmacy and is responsible for the validity and legality of all prescriptions upon which drugs are dispensed in said drugstore or pharmacy. Dispensing of drugs classified as controlled drugs under any of the schedules classifying drugs under either state or federal law governing controlled substances is the primary responsibility of the pharmacist in charge and is also the responsibility of such other pharmacist, interns or students as may have dispensed said drugs. In the event of a shortage of said drugs revealed by an accountability inventory of either federal or state agencies, the pharmacist in charge shall be held primarily responsible for such shortage and shall be subject to disciplinary action by the State Board of Pharmacy. Any other pharmacists, interns, or students causing or aiding or abetting the said unlawful shortage of said drugs shall also be subject to disciplinary action by the State Board of Pharmacy.

(f) Any pharmacist, when making his or her initial application to be licensed as pharmacist in charge, must satisfactorily complete a test on the requirements and responsibilities of a pharmacist in charge. The test shall be developed and administered by the Board of Pharmacy or its representatives.

(g) The pharmacist in charge named on any licensed pharmacy permit or pharmacist on call as designated by the pharmacist in charge, shall have immediate access to the pharmacy at all times, and if requested by Board of Pharmacy inspectors he/she shall show satisfactory proof of access. (emergency--amended 4/2001)

04-02-0006—PERMIT REQUIRED

The permit licenses the pharmacy to which it is issued and is not transferable. It is issued on the application of the owner and the licensed pharmacist in charge, on the sworn statement that it will be conducted in accordance with the provisions of law.

(a) Pharmacies or drugstores opening for business must first secure a permit and be licensed with the Board of Pharmacy before they may lawfully conduct a pharmacy or drugstore. A fee defined in regulation 01-00-0007 is charged for issuing such original permit. All pharmacies must register with the Board annually and secure an annual permit and pay a renewal fee as defined in regulation 01-00-0007.
(b) Permits must be posted in a conspicuous place. This requirement is not met when a permit is locked in a safe, placed in a desk drawer, or otherwise hidden away.
(c) No pharmacy may open for business, nor may it be inspected for the purpose of obtaining a permit, prior to the approval by the Board.

04-02-0007—CHANGE OF OWNERSHIP

(a) Upon a change of ownership of a pharmacy as set out herein, a new permit shall be secured by the new owner(s). The new owner(s) can continue operation of the pharmacy for fourteen (14) days after the effective date of the change of ownership; after the said fourteen (14) day period, the permit issued to the prior owner shall be void and same shall be surrendered to the Executive Director of the Board of Pharmacy.
(b) A change of ownership of a pharmacy occurs under, but is not limited to the following circumstances:
    (1) A change of ownership of a pharmacy, owned by a SOLE PROPRIETOR, is deemed to have occurred when:
        (A) The pharmacy is sold and the sale becomes final or the new owner assumes control of the pharmacy--whichever occurs first.
        (B) The proprietor enters into a partnership with another individual or business entity.
    (2) A change of ownership of a pharmacy, owned by a PARTNERSHIP, is deemed to have occurred when:
        (A) There is an addition or deletion of one or more partners in a partnership to which a pharmacy license has been issued.
        (B) The pharmacy is sold and the sale becomes final or the new owner assumes control of the pharmacy--whichever occurs first.
    (3) A change of ownership of a pharmacy, owned by a CORPORATION, is deemed to have occurred when:
        (A) An individual or business acquires or disposes of twenty percent (20%) or more of the corporation's outstanding shares of voting stock. (This shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over the counter market); or
        (B) The corporation merges with another business or corporation. (The corporation owning the pharmacy is required to notify the Arkansas State Board of Pharmacy if a change of ownership or merger occurs within the parent corporation of the corporation which owns the pharmacy); or
        (C) The corporation's charter expires or is forfeited; or
        (D) The pharmacy is sold and the sale becomes final or the new owner assumes control of the pharmacy--whichever occurs first.

The responsibility to ensure compliance with this regulation rests both with the pharmacist and with the pharmacy owner if they are not the same. (10/09/80, Revised 2/17/82, 6/13/85, 2/10/87, 4/07/89, 6/20/91, and 6/23/96)

04-02-0008 —INVENTORY REQUIRED

(a) When there is a change of pharmacy permit for a change of ownership of the pharmacy and the pharmacist in charge is changed, an inventory of all drugs now or hereafter classified as Schedule II, III, IV or V drugs under either federal or state statutes shall be made by the pharmacist in charge and a copy of that inventory signed by the pharmacist in charge shall be submitted with the application for change of ownership and the fee for change of ownership as defined in regulation 01-00-0007. The inventory shall be made on the day the new owner takes charge of the pharmacy.

(b) When there is a change of pharmacy permit for a change of pharmacist in charge, an inventory of all drugs now or hereafter classified as Schedule II, III, IV or V drugs under either federal or state statutes will be made by the exiting pharmacist in charge and a copy of that inventory signed by said pharmacist shall be furnished to the Arkansas State Board of Pharmacy within seven days after the pharmacist's last day to work at the pharmacy and a copy left with the Controlled Substance Records of the Pharmacy. The new pharmacist in charge as his first action in the pharmacy shall also inventory all drugs now or hereafter classified as Schedule II, III, IV or V drugs under federal or state statutes and a copy of that inventory signed by the new pharmacist in charge shall be provided to the Arkansas State Board of Pharmacy with the application to change the pharmacy permit's pharmacist in charge.

(c) It is acceptable and preferable if the inventory is made jointly by both pharmacists, signed by both pharmacists, and supplied to the Arkansas State Board of Pharmacy with the application for change of pharmacist in charge.

(d) Both copies of said inventory (exiting pharmacist and new pharmacist) must be received by the Board before a new permit will be issued. (10/09/83, Revised 6/25/80 and 6/20/96)

04-02-0009—OWNER'S RESPONSIBILITY – PHARMACIST IS LICENSED

No owner or owners of a drugstore, apothecary, pharmacy, etc., should allow any of its employees to profess to the public in any manner that they are a licensed pharmacist when they are not licensed. (10/9/80, amended (6/20/91).

04-02-0010—REGULATING THE USE OF ELECTRONIC DATA PROCESSING IN LIEU OF PRESENT RECORD KEEPING SYSTEMS IN PHARMACIES HOLDING PHARMACY PERMITS

(a) These regulations shall be construed, if possible, so as not to be in violation of, or in conflict with, any federal regulation or requirement and if any part hereof is held invalid because of such conflict such invalidity shall not affect other provisions or applications of these regulations which can be given effect without the invalid provisions and to this end, the provisions of these regulations are declared severable. In any event DEA permission to use electronic data processing record keeping systems must be obtained.

(b) The Arkansas State Board of Pharmacy must approve the system prior to implementation.

(c) Input of drug information into the system may be performed only by a pharmacist, or by a pharmacy technician under the supervision of a pharmacist. The final verification of prescription information into the computer, shall be made by the supervising pharmacist who is then totally

responsible for all aspects of the data and data entry. Any judgmental decision concerning patient utilization of drugs must be performed by a pharmacist.

(d) The original prescription order must be numbered, dated, initialed or signed by the dispensing pharmacist at the time of the first filling of the prescription order, and filed according to regulation.

(e) An electronic data processing system must be readily accessible electronically online or by hard copy, and shall be capable of printing a hard copy record. Said hard copy record, or electronic data base record, shall be available upon request by a Board of Pharmacy representative or other state or federal agencies with authority to obtain such records within 48 hours of the request. The system must be capable of furnishing the following information:

(1) Must provide online retrieval (electronic record or hard copy) of original prescription order information. This shall include, but not be limited to, the following:

(A) Original prescription order number, date filled; full name and address of patient; name, address and DEA number (if applicable) of practitioner.

(B) Trade name (or generic name and manufacturer's name), strength, dosage form and quantity of drug dispensed.

(C) Number of authorized refills or, if not refillable, it must be so indicated.

(2) Must provide online retrieval (electronic record or hard copy) of refill history of each prescription order to include, in addition to information specified in this section, but not limited to the following:

(A) Initials or code designation of dispensing pharmacist for each refill.

(B) Date refilled.

(C) Number of authorized refills remaining.

(3) Daily Prescription Record

(A) Must provide a daily prescription record, or hard copy printout of each day's prescription order activity, to include but not limited to the following:

(i) Date of record.

(ii) Prescription order number, patient's name, name of drug, quantity dispensed and dosage form of drug, practitioner's name and DEA number (if applicable), and dispensing pharmacist's designation or initials on each prescription.

(iii) If the pharmacy is using a hard copy printout, it may be replaced by monthly log containing same information. This information must be maintained at pharmacy for a period of two years.

(iv) Any electronic data processing system must ensure strict confidentiality of patient records.

(v) All required information must be entered on the records of all prescription orders filled at the pharmacy including non-refillable prescriptions and must be maintained for a period of no less than two (2) years.

(vi) Must be capable of producing a patient profile (electronic record or hard copy) indicating all drugs being taken and dates of refills for the patient.

(vii) A pharmacy shall make arrangements with supplier of data processing services or materials to assure continuing adequate and complete prescription orders and dispensing records. If for any reason the relationship with said supplier terminates, the pharmacy shall assure the continuity of records.

(viii) The pharmacist in charge of the pharmacy shall maintain a bound log book in which each individual pharmacist or individual intern involved in dispensing of

prescriptions shall sign a statement each day, attesting to the fact that the prescription information entered into the computer that day has been reviewed by him or her and is correct as shown. The log shall identify the time of day at which the pharmacist or intern started filling prescriptions and the time of day at which the pharmacist or intern stopped filling prescriptions. Said log book shall be maintained, by the pharmacist in charge or his successor, in the pharmacy for a period of two years after the date of dispensing the appropriately authorized prescription.

(4) Must be capable of providing a refill-by-refill audit trail for any specific strength and dosage form of any drug in the system to contain but not limited to the following:
   (A) Practitioner's name.
   (B) Name and address of patient.
   (C) Name of drug (must include manufacturer's name if generic name used).
   (D) Quantity dispensed on original and each refill.
   (E) Prescription order number.
   (F) Initials or code designation of dispensing pharmacist on original and each refill.
   (G) Date of original and each refill.

(5) If the pharmacy closes, it shall be the responsibility of the pharmacist in charge to assure that all prescription records are readily retrievable and can be easily accessed. The pharmacist in charge, at the date of closing, shall store said records and within fourteen (14) days of closing shall notify the Board of Pharmacy where said records are located. That pharmacist in charge shall insure that a hard copy printout or a retrievable electronic record of any prescription records shall be produced and made available to a Board of Pharmacy representative on their request and to any other person authorized by law to examine or receive copies of prescription records. The records must be kept in a readily retrievable format for a period of two years from the official closing date of the pharmacy.

(6) In event of computer breakdown (down time), the pharmacy must have an approved auxiliary record keeping system. This system must contain all necessary information to insure prompt data entry into system as soon as computer is available.

(7) If maintaining the Daily Patient Medication Record electronically, the data must be backed up at least daily (preferably continuously.) (10/09/80, Revised 6/19/97 & 10/00).

04-02-0011—CENTRAL FILL PHARMACY

A retail pharmacy with a licensed pharmacy permit may also act as a central fill pharmacy if the following requirements are met.

(a) Definitions

(1) “Central fill pharmacy” means a pharmacy which is licensed by the Arkansas State Board of Pharmacy (“ the Board”) to prepare legend and controlled substances orders for dispensing pursuant to a valid prescription transmitted to it by a licensed retail pharmacy and to return the labeled and filled prescriptions to the retail pharmacy for delivery to the ultimate user. Such central fill pharmacy shall be deemed "authorized" to fill prescriptions on behalf of a retail pharmacy only if the retail pharmacy and central fill pharmacy have a contractual relationship providing for such activities or share a common owner. Both the retail pharmacy and the central fill pharmacy involved in these activities share a corresponding responsibility regarding central fill prescriptions.

(b) Record keeping

(1) Every retail pharmacy that utilizes the services of a central fill pharmacy must keep a record of all central fill pharmacies, including name, address and DEA number that are authorized to fill prescriptions on its behalf. The retail pharmacy must also verify the registration for each central fill pharmacy authorized to fill prescriptions on its behalf at the beginning of each registration period for the central fill pharmacy. These records must be made available upon request for inspection.

(2) Every central fill pharmacy must keep a record of all retail pharmacies, including name, address and DEA number, for which it is authorized to fill prescriptions. The central fill pharmacy must also verify the registration for all retail pharmacies for which it is authorized to fill prescriptions at the beginning of each registration period for each retail pharmacy. These records must be made available upon request for inspection.

(c) Provision of prescription information of Schedule II controlled substances.

(1) Prescriptions for controlled substances listed in Schedule II may be transmitted electronically from a retail pharmacy to a central fill pharmacy including via facsimile. The retail pharmacy transmitting the prescription information must:

(A) Write the word "CENTRAL FILL" on the face of the original prescription and record the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted and, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;

(B) Ensure that all information required to be on a prescription pursuant to federal and state law is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);

(C) Maintain the original prescription for a period of two years from the date the prescription was filled;

(D) Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier), the identity of carrier and the name of the retail pharmacy employee accepting delivery.

(2) The central fill pharmacy receiving the transmitted prescription must:

(A) Keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the retail pharmacy, including the name, address, and DEA registration number of the retail pharmacy transmitting the prescription;

(B) Keep a record of the date of receipt of the transmitted prescription, the name of the pharmacist filling the prescription, and the date of filling of the prescription;

(C) Track the prescription drug order during each step in the filling process and identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist or pharmacy technician who performed any portion of the process including transmission, filling, dispensing, or delivery.

(D) Keep a record of the date the filled prescription was delivered to the retail pharmacy, the method of delivery (i.e. private, common or contract carrier) and the identity of the carrier.

(3) Central fill pharmacies shall not be authorized to prepare prescriptions for a controlled substance listed in Schedule II upon receiving an oral authorization from a retail pharmacist or an individual practitioner.

(d) Provision of prescription information for initial and refill prescriptions of legend or schedule III, IV or V controlled substances.

(1) Prescriptions for legend or controlled substances listed in Schedule III, IV or V may be transmitted electronically from a retail pharmacy to a central fill pharmacy including via facsimile. The retail pharmacy transmitting the prescription information must:

(A) Write the word "CENTRAL FILL" on the face of the original prescription and record the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted and the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;

(B) Ensure that all information required to be on a prescription pursuant to federal and state law is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);

(C) Indicate in the information transmitted the number of refills already dispensed and the number of refills remaining;

(D) Maintain the original prescription for a period of two years from the date the prescription was last refilled;

(E) Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier), the identity of the carrier and the name of the retail pharmacy employee accepting delivery.

(2) The central fill pharmacy receiving the transmitted prescription must:

(A) Keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the retail pharmacy, including the name, address, and DEA registration number of the retail pharmacy transmitting the prescription;

(B) Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and dates of filling or refilling of the prescription;

(C) Track the prescription drug order during each step in the filling process and identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist or pharmacy technician who performed any portion of the process including, transmission, filling, dispensing, or delivery

(D) Keep a record of the date the filled prescription was delivered to the retail pharmacy, the method of delivery (i.e. private, common or contract carrier) and the identity of the carrier.

(e) Carriers to transport filled prescriptions

(1) Central fill pharmacies must comply with all federal and state requirements when using private, common or contract carriers to transport filled prescriptions to a retail pharmacy for delivery to the ultimate user. When central fill pharmacies contract with private, common or contract carriers to transport filled prescriptions to a retail pharmacy, the central fill pharmacy is responsible for reporting in-transit losses upon discovery of such loss by use of a DEA Form 106.

(2) Retail pharmacies must comply with all federal and state laws when using private, common or contract carriers to retrieve filled prescriptions from a central fill pharmacy. When retail pharmacies contract with private, common or contract carriers to retrieve filled prescriptions from a central fill pharmacy, the retail pharmacy is responsible for reporting in-transit losses upon discovery of such loss by use of a DEA Form 106.

(f) Labeling

The central fill pharmacy shall:

(1) Affix to the package a label showing the retail pharmacy name and address and a unique identifier, which shall be the central fill pharmacy's DEA registration number or a Board assigned identifier, indicating that the prescription was filled at the central fill pharmacy
(2) Indicate in some manner which pharmacy filled the prescription (e.g., "Filled by ABC Pharmacy for XYZ Pharmacy").
(3) Comply with all other labeling requirements of federal and state statutes.

(g) Policies and Procedures

A policy and procedure manual as it relates to centralized filling shall be maintained at both the filling and dispensing pharmacies and be available for inspection. Each pharmacy is required to maintain only those portions of the policy and procedure manual that relate to that pharmacy's operations. The manual shall:

(1) Outline the responsibilities of each of the filling and dispensing pharmacies
(2) Include a list of the name, address, telephone numbers, and all license / registration numbers of the pharmacies involved in centralized prescription filling
(3) Include policies and procedures for:
(A) Notifying patients that their prescription may be outsourced to another pharmacy for centralized prescription filling and the name of that pharmacy
(B) Protecting the confidentiality and integrity of patient information
(C) Dispensing prescription drug orders when the filled order is not received or the patient comes in before the order is received
(D) Complying with federal and state laws and regulations
(E) Operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems
(F) Annually reviewing the written policies and procedures and documenting such review.

(11/15/2003)

04-02-0100—NUCLEAR PHARMACY

The practice of nuclear pharmacy is hereby recognized as a specialty of pharmacy practice regulated by the Arkansas State Board of Pharmacy. As such, the following rules are included to address those areas specific, or unique to, this specialty practice. These regulations are intended to supplement the regulations of other state and federal agencies.

(a) Definitions:

(1) Authentication of Product History—Identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.
(2) "Nuclear pharmacy" means a pharmacy which provides radiopharmaceutical services, and shall be licensed by the Arkansas State Board of Pharmacy.
(3) "Practice of nuclear pharmacy" means a patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other drugs.
(4) "Qualified nuclear pharmacist" means a pharmacist who holds a current license issued by the Arkansas State Board of Pharmacy, and who is certified as a nuclear pharmacist by

a certification board recognized by the Arkansas State Board of Pharmacy, or satisfies each of the following requirements:

(A) Meets minimal standards of training for status as an authorized user of radioactive material, as specified by the Arkansas Department of Health, Division of Radiation Control and Emergency Management of the Nuclear Regulatory Commission.

(B) Has successfully completed a minimum of 200 contact hours of instruction in nuclear pharmacy and the safe handling and use of radioactive materials from a College of Pharmacy approved by the Arkansas State Board of Pharmacy, or other training program recognized by the Arkansas State Board of Pharmacy, with the minimum 200 hours apportioned as follows:

(i) Radiation physics and instrumentation
(ii) Radiation protection
(iii) Mathematics pertaining to the use and measurement of radioactivity
(iv) Radiation biology
(v) Radiopharmaceutical chemistry

(C) Has attained a minimum of 500 hours of clinical/practical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in, but not limited to, the following areas:

(i) Procuring radioactive materials
(ii) Compounding radiopharmaceuticals
(iii) Performing routine quality control procedures
(iv) Dispensing radiopharmaceuticals
(v) Distributing radiopharmaceuticals
(vi) Implementing basic radiation protection procedures
(vii) Consulting and educating the nuclear medicine community, pharmacists, other health professionals, and the general public.

(D) Has submitted an affidavit of experience and training to the Board of Pharmacy.

(5) "Quality assurance procedures" means all activities necessary to assure the quality of the process used to provide radiopharmaceutical services, including authentication of product history and maintenance of all records as required by pertinent regulatory agencies.

(6) "Quality control testing" means the performance of chemical, biological and physical tests on compounded radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals.

(7) "Radiopharmaceutical" means any drug which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance but which does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term also includes any biological product which is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

(8) "Radiopharmaceutical Services" means the procurement, storage, handling, compounding, preparation, labeling, quality control testing, dispensing, distribution, transfer, record keeping, and disposal of radiochemicals, radiopharmaceuticals, and ancillary drugs, and also includes quality assurance procedures, radiological health activities, and consulting activities associated with the use of radiopharmaceuticals, health physics, and any other activities required for provision of pharmaceutical care.

(b) General requirements for pharmacies providing radiopharmaceutical services

(1) A permit to operate a nuclear pharmacy, providing radiopharmaceutical services, shall only be issued to a facility employing a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals and ancillary drugs shall be under the direct supervision of a qualified nuclear pharmacist, who shall be in personal attendance when the nuclear pharmacy is open for business. The pharmacist-in-charge shall be responsible for all operations of the nuclear pharmacy.

(2) The permit to operate a nuclear pharmacy is effective only so long as the nuclear pharmacy also holds a current Arkansas Department of Health or Nuclear Regulatory Commission license.

(3) Nuclear pharmacies shall have adequate space and equipment commensurate with the scope of services required and provided. All pharmacies handling radiopharmaceuticals shall include, but not be limited to, the following areas: radiopharmaceutical preparation/dispensing area; radioactive material shipping/receiving area; radioactive material storage area; and radioactive waste decay area. The application for a permit to operate a nuclear pharmacy shall include detailed floor plans and no material change may be made without the permission of the Board.

(4) The nuclear pharmacy professional service area shall be secured from unauthorized personnel and must be totally enclosed and lockable.

(5) Nuclear pharmacies shall maintain records of acquisition, inventory and disposition of all radioactive materials in accordance with Board and Arkansas Department of Health or Nuclear Regulatory Commission statutes and regulations.

(6) Nuclear pharmacies shall compound and dispense radiopharmaceuticals in accordance with accepted standards of radiopharmaceutical quality assurance. The Board of Pharmacy recognizes that the preparation of radiopharmaceuticals involves the compounding skills of the nuclear pharmacist to assure that the final drug product meets accepted professional standards.

(7) A radiopharmaceutical shall be dispensed only to a licensed practitioner authorized by the Arkansas Department of Health or Nuclear Regulatory Commission to possess, use, and administer such drug. A radiopharmaceutical shall be dispensed only upon receipt of a prescription or medication order from such licensed practitioner. Otherwise, a radiopharmaceutical may be transferred to a person who is authorized to possess and use such drug for non-clinical applications.

(8) A nuclear pharmacy, upon receipt of an oral prescription order for a radiopharmaceutical, shall immediately have the prescription order reduced to writing, or recorded in a data processing system, which writing or record shall contain at least the following:

(A) the name of the institution and prescriber, or prescriber's agent;
(B) the date of dispensing and the calibration time of the radiopharmaceutical;
(C) the name of the procedure;
(D) the name of the radiopharmaceutical;
(E) the dose or quantity of the radiopharmaceutical;
(F) the serial number assigned to the order for the radiopharmaceutical;
(G) any specific instructions;
(H) the initials of the person who dispensed the order.

Orders for routine diagnostic radiopharmaceuticals, which have been previously established by the nuclear pharmacist with the physician, may be taken by a pharmacy technician and entered into the computer. The nuclear pharmacist shall verify the label with the written order. However, whenever an order is for a therapeutic or blood-product radiopharmaceutical, the prescription order must be received by a nuclear pharmacist and the patient's name must be obtained and recorded prior to dispensing.

(9) The immediate outer container shield of a radiopharmaceutical to be dispensed shall be labeled with:
(A) the name and address of the pharmacy;
(B) the name of the prescriber;
(C) the date of dispensing;
(D) the serial number assigned to the order for the radiopharmaceutical;
(E) the standard radiation symbol;
(F) the words "Caution Radioactive Material";
(G) the name of the procedure;
(H) the radionuclide and chemical form;
(I) the amount of radioactivity and the calibration date and time;
(J) if a liquid, the volume;
(K) if a solid, the number of items or weight;
(L) if a gas, the number of ampoules or vials;
(M) molybdenum 99 content to USP limits; and
(N) the name of the patient or the words "Per Physician's Order" in the absence of a patient name. The requirements of this subsection shall be met when the name of the patient is readily retrievable from the physician upon demand.

When the prescription is for a therapeutic or blood-product radiopharmaceutical, the patient name shall appear on the label prior to dispensing.

(10) The immediate inner container label of a radiopharmaceutical to be dispensed shall be labeled with:
(A) the standard radiation symbol;
(B) the words "Caution Radioactive Material";
(C) the identity of the radionuclide;
(D) the chemical form;
(E) the name of the procedure; and
(F) serial number of the radiopharmaceutical.

(11) When a radiopharmaceutical is dispensed under the authority of an Investigational New Drug Application (IND), the nuclear pharmacy records shall include an investigator's protocol for the preparation of the radiopharmaceutical, a copy of the Institutional Review Board approval form (or letter), and a letter from the manufacturer (sponsor) indicating that the physician requesting the radiopharmaceutical is a qualified investigator.

(12) Each nuclear pharmacy shall have a current copy of state and applicable federal regulations governing the safe storage, handling, use, dispensing, transport, and disposal of radiopharmaceuticals.

(c) Minimum equipment

The professional area of the pharmacy shall have the following equipment:

(1) Radionuclide Dose Calibrator;

(2) Refrigerator;
(3) Single or multiple channel scintillation counter with well-type Nal(TI) or Ge(Li) detector;
(4) Radiochemical fume hood and filter system with suitable air sampling equipment;
(5) At least two GM survey meters (including one high-range meter);
(6) Microscope and hemacytometer;
(7) Supplies to perform quality assurance testing;
(8) Syringe and vial radiation shields;
(9) Lead-shielded drawing station;
(10) Decontamination supplies;
(11) Supplies to perform quality assurance testing;
(12) Lead transport shields for syringes and vials; and
(13) D.O.T. approved USA Type A, 7A approved transport containers and other labels and supplies for shipping radioactive materials. (10/14/98)

04-03 REGULATIONS REGARDING RETAIL SPECIALTY PHARMACIES

04-03-0001—SPECIALTY PHARMACY PERMITS

The Board may issue a specialty pharmacy permit for a facility to provide unique aspects of pharmaceutical care to an identified patient population as provided in regulation 04-03-0001 *et seq*. Said specialty pharmacies and the pharmacists practicing therein shall comply with applicable federal and state laws and regulations, including Arkansas Pharmacy Law, A.C.A. § 17-92-101 *et seq.,* and Board Regulations, including without limitation regulations regarding retail pharmacies 04-02-0001 *et seq*., which are not expressly superseded by the regulation applicable to the specific type of specialty pharmacy.

04-03-0002 METHADONE CLINIC SPECIALTY PHARMACY PERMIT

(a) Definitions:
  (1) "Methadone clinic pharmacy" means the place in which a licensed professional prepares methadone or buprenorphine to be administered and/or dispensed to a patient of the clinic.
  (2) "Dispensing" means the preparation of one or more doses of methadone or buprenorphine in properly labeled, patient specific containers and delivery of said drugs to the patient to consume away from the clinic; only a licensed pharmacist or physician holding a dispensing permit issued by the Arkansas State Medical Board shall dispense methadone.
  (3) "Administering" means giving a single dose of methadone or buprenorphine to a patient to consume on-site; a physician shall administer or supervise the administration of methadone and the clinic pharmacist shall retain appropriate methadone administration records.
(b) Permit
  (1) Applications for methadone clinic permits shall be submitted pursuant to regulation 04-02-0001.
  (2) Any pharmacist shall notify the Board of Pharmacy in writing and ascertain that a methadone clinic pharmacy permit has been issued to the clinic before beginning practice in that clinic.
(c) Pharmacy operations

(1) The pharmacist in charge shall provide written policies, procedures, and protocols for the operation of the pharmacy and shall obtain the approval of same by the Executive Director of the Pharmacy Board prior to operation of said pharmacy.
(2) A methadone clinic pharmacy shall stock and dispense methadone or buprenorphine only.

(d) Physical Facilities
(1) The pharmacy shall be a controlled area for the storage, safeguarding, preparation, and dispensing of methadone, a Schedule II narcotic, and buprenorphine, a Schedule III controlled substance, and shall have adequate facilities for pharmaceutical services including the procurement, storage, distribution, security and control of said drug consistent with all federal and state laws and regulations.
(2) The pharmacy shall have all equipment necessary to carry out the functions of the methadone clinic pharmacy and is otherwise exempt from regulation 04-02-0004; the equipment must be identified in the policies and procedures of each methadone clinic specialty pharmacy.

(e) Licensed pharmacist personnel requirements
(1) A methadone pharmacy shall be open to serve its patients, with a pharmacist or pharmacists on duty, a minimum of ten (10) hours per week or, if necessary, a greater period of time in order to perform pharmacy duties necessary to ensure patient safety.
(2) The pharmacy's operating hours must be approved by the Executive Director of the Arkansas State Board of Pharmacy. (Revised 11/15/2003)

04-03-0003 – STUDENT HEALTH CLINIC PHARMACY PERMIT

(a) Definitions:
(1) "Student Health Clinic Pharmacy" means a pharmacy located on a university or college campus for the purpose of filling prescriptions for students or employees or their spouses or dependents.
(2) "Board" means the Arkansas State Board of Pharmacy.

(b) Permit
(1) Applications for student health clinic pharmacy permits shall be submitted pursuant to regulation 04-02-0001.
(2) Any pharmacist shall notify the Board of Pharmacy in writing and ascertain that a student health clinic pharmacy permit has been issued to the clinic before beginning practice in that clinic.

(c) Pharmacy operations
(1) The pharmacist in charge shall provide written policies, procedures, and protocols for the operation of the pharmacy and shall obtain the approval of same by the Board prior to operation of said pharmacy.
(2) A student health clinic pharmacy may stock and dispense legend and controlled substances

(d) Physical Facilities
(1) The pharmacy shall be a controlled area for the storage, safeguarding, preparation, and dispensing of legend and controlled substances, and shall have adequate facilities for pharmaceutical services including the procurement, storage, distribution, security and control of said drugs consistent with all federal and state laws and regulations.
(2) The pharmacy shall have all equipment specified in regulation 04-00-0001.

(e) Licensed pharmacist personnel requirements

(1) The pharmacy's minimum operating hours must be approved by the Board prior to operation of said pharmacy.
(2) A pharmacist or pharmacists must be on duty during all hours of operation.
(3) The pharmacist in charge must work fifty-percent (50%) of the hours of operation. (07/15/2004)

04-04: OUT OF STATE PHARMACIES

04-04-0001—OUT OF STATE PHARMACY REGULATION

Out of State pharmacies shall comply with the following qualifications to be, and remain, licensed in Arkansas by the Board.

(a)
(1) The pharmacy holds a current license in good standing in the state(s) in which it is located.
(2) Each pharmacist dispensing drugs into Arkansas shall be licensed as a pharmacist in Arkansas or in the state where he practices if that state has standards of licensure at least equivalent to those of Arkansas.

(b) A pharmacist licensed in Arkansas shall be named in the application as the pharmacy's pharmacist in charge for the Arkansas permit and as the contact person for communications by the Board. Said Arkansas Pharmacist shall be an employee of the out of state pharmacy who is present at the pharmacy's physical location as stated on the out of state pharmacy permit. The pharmacist in charge for the Arkansas Permit need not be the same person as the pharmacist in charge of the pharmacy pursuant to the law in the state in which the pharmacy is located.
(1) That pharmacist will be responsible for receiving and maintaining publications distributed by the Board.
(2) If at anytime the pharmacist so designated as the pharmacist in charge for the Arkansas permit shall leave the employment of the pharmacy, the pharmacy shall notify the Board within ten (10) calendar days and designate another Arkansas licensed pharmacist to perform this function within thirty (30) calendar days.

(c) The out of state pharmacy shall apply for licensure and renewal on forms provided by the Board. The Board may require such information as reasonably necessary to carry out the provisions of A.C.A. §17-92-401, including, without limitation, the name, address and position of each officer and director of a corporation or of the owners if the pharmacy is not a corporation.

Provided, however, the Board may grant an exemption from licensing under A.C.A. §17-92-401 upon application by any non-resident pharmacy which confines its dispensing activity to isolated transactions. In determining whether to grant an exemption, the Board shall consider:
(1) The number of prescriptions dispensed or reasonably expected to be dispensed into Arkansas.
(2) The number of patients served or reasonably expected to be served in Arkansas.
(3) Whether the pharmacy has promoted its services in Arkansas.
(4) Whether the pharmacy has a contract(s) with any employer(s) or organization(s) to provide pharmacy services to employees or other beneficiaries in Arkansas.
(5) Medical necessity.
(6) The effect on the health and welfare of persons in Arkansas.
(7) Any other relevant matters.

(d) The pharmacy shall pay an annual license fee as defined in regulation 01-00-0007. When there is a change of Arkansas licensed pharmacist in charge, the fee for said change shall be paid as defined in regulation 01-00-0007. Final notification, to the Arkansas State Board of Pharmacy, of the new Arkansas licensed pharmacist in charge shall be on a form furnished by the Arkansas State Board of Pharmacy and accompanied by the fee for said change.
(e) The pharmacy shall maintain records of drugs dispensed to Arkansas addresses in such a manner so as to be readily retrievable upon request. These records shall be made available for inspection by the Board or by Arkansas law enforcement authorities.
(f) The pharmacy shall timely respond to any request for information from the Board or law enforcement authorities.
(g) The pharmacy shall maintain an incoming toll free telephone number for use by Arkansas customers to be answered by a pharmacist with access to patient records. This service shall be available a minimum of 40 hours a week, six days per week during normal business hours. This telephone number plus others available for use shall be printed on each container of drugs dispensed into Arkansas. The toll free number shall have sufficient extensions to provide reasonable access to incoming callers.
(h) Generic drugs shall be dispensed into Arkansas pursuant to the Arkansas Generic Substitution Act; provided, however, nothing herein shall be construed to mandate that an out of state pharmacy comply with the Arkansas Generic Substitution Act if such compliance would cause the out of state pharmacy to violate the Generic Substitution Act of the state wherein the facility of the dispensing out of state pharmacy is located.
(i) The facilities and records of the pharmacy shall be subject to inspection by the Board: provided, however, the Board may accept in lieu thereof satisfactory inspection reports by the licensing entity using similar standards of the state where the pharmacy is located.
(j) Each out of state pharmacy doing business in Arkansas by dispensing and delivering or causing to be delivered prescription drugs to Arkansas consumers shall designate a resident agent in Arkansas for service of process.
(k) Each out of state pharmacy doing business in Arkansas shall comply with Board of Pharmacy regulation 09-00-0001 (Patient Information, Drug Use Evaluation, and Patient Counseling).

Nothing herein shall be construed to mandate that an out of state pharmacy comply with Board regulation 09-00-0001 if such compliance would cause the out of state pharmacy to violate law or regulation of the state wherein the facility of the dispensing out of state pharmacy is located. (10/09/90, Revised 04/10/92, 6/23/96, 8/23/96, 10/12/99, and 11/15/2003).

04-05: REGULATIONS REGARDING HOSPITAL PHARMACIES

04-05-0001—HOSPITAL PHARMACEUTICAL SERVICES PERMIT

(a) Any pharmacist practicing in an Arkansas hospital must so notify the Board of Pharmacy and ascertain that a hospital pharmaceutical services permit has been issued. The hospital pharmaceutical services permit shall be issued in the name of the hospital showing a pharmacist in charge.
(b) Any hospital holding a retail pharmacy permit as of February 15, 1975, upon application for renewal must separate the facilities, stocks, records, etc., in compliance with A.C.A. 17-92-403--17-92-405.

All hospitals shall have adequate provisions for pharmaceutical services regarding the procurement, storage, distribution, and control of all medications. All federal and state regulations shall be complied with.

(1) Definitions

(A) "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.

"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.

(B) "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.

(C) "Qualified hospital personnel" means persons other than licensed pharmacists who perform duties in conjunction with the overall hospital pharmaceutical services for inpatients.

(D) "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.

(E) "Unit dose distribution system" means 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 medications is dispensed, delivered, or available to the patient.

"Unit dose distribution system" also means 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 Board of Pharmacy.

(2) Compounding, dispensing and distributing

(A) Compounding is the act of selecting, mixing, combining, measuring, counting, or otherwise preparing a drug or medication.

(B) Dispensing is a function restricted to licensed pharmacists which involves the issuance of:

(i) 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;

(ii) 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;

(iii) 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).

(C) 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 must be in the original labeled manufacturer's container or in a prepackaged container labeled according to federal and state statutes and regulations, by a pharmacist or under his direct and immediate supervision.

(3) Administering

An act, restricted to nursing personnel as defined in Nurses Practice Act 43 of 1971, in which a single dose of a prescribed drug or biological is given 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.

(4) 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:

(A) A pharmacy and therapeutics committee (P & T Committee), composed of a 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.

(B) The committee assists in the formation of broad professional policies regarding the evaluation, appraisal, selection, procurement, storage, distribution, use, and safety procedures, and all other matters relating to drugs in hospitals.

(C) The committee performs the following specific functions:

(i) Serves as an advisory group to the hospital medical staff and the pharmacist on matters pertaining to the choice drugs.

(ii) Develops and reviews periodically a formulary or drug list for use in the hospital;

(iii) Establishes standards concerning the use and control of investigational drugs and research in the use of recognized drugs;

(iv) Evaluates clinical data concerning new drugs or preparations requested for use in the hospital;

(v) Makes recommendations concerning drugs to be stocked on the nursing unit floors and emergency drug stocks;

(vi) Prevents unnecessary duplication in stocking drugs and drugs in combination having identical amounts of the same therapeutic ingredients.

(vii) The committee meets at least quarterly and reports to the medical staff by written report.

(5) Pharmacy operations

The hospital has a pharmacy directed by a licensed pharmacist. The pharmacy is administered in accordance with accepted professional principles.

(A) Pharmacy supervision

There is a pharmacy directed by a licensed pharmacist, defined as follows:

(i) The director of pharmacy is trained in the specialized functions of hospital pharmacy.

(ii) The director of pharmacy is responsible to the administration of the hospital and the Board of Pharmacy for developing, supervising, and coordinating all the activities of

the pharmacy department and all pharmacists providing professional services in the hospital.

(iii) 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.

(6) Physical facilities

Facilities are provided for the storage, safeguarding, preparation, and dispensing of drugs, defined as follows:

(A) Drugs are issued to floor units in accordance with approved policies and procedures.

(B) Drug cabinets on the nursing units are routinely checked by the pharmacist. All floor stocks are properly controlled.

(C) 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 should specifically relate to services rendered and functions performed by the hospital pharmacy. Equipment lists will relate to the following services and functions:

(i) Medication preparation;
(ii) Library reference facilities;
(iii) Record and office procedures;
(iv) Sterile product manufacturing;
(v) Bulk compounding (manufacturing);
(vi) Product control (assay, sterility testing, etc.);
(vii) Product development and special formulations for medical staff.

(D) Equipment and supplies necessary to the hospital pharmacy's safe, efficient and economical operation shall include but not be limited to:

(i) Graduates capable of measuring from 0.1 ml. up to at least 500 ml.
(ii) Mortars and pestles.
(iii) Hot and cold running water.
(iv) Spatulas (steel and non-metallic).
(v) Funnels.
(vi) Stirring rods.
(vii) Class A balance and appropriate weights.
(viii) Typewriter or other label printer.
(ix) Suitable apparatus for production of small-volume sterile products
(x) Suitable containers and labels.
(xi) Adequate reference library to include at least the following:

a. American Hospital Formulary Service.
b. Pharmacology text.
c. Each hospital shall have available for personal and patient use a current copy of the U.S.P.D.I. 3-book set including *Drug Information for the Healthcare Professional* (2 volumes) and *Advice for the Patient* (1 volume); or the two volume set *Drug Facts and Comparisons* (1 volume) and *Patient Drug Facts* (1 volume).

d. Text on compatibility of parenteral products.
e. Current professional journals, such as:
    1. Drug Intelligence and Clinical Pharmacy
    2. Hospital Pharmacy.
    3. Journal of ASHP.

(E) Special locked storage space is provided to meet the legal requirements for storage of controlled drugs, alcohol, and other prescribed drugs.

(7) Personnel

Personnel competent in their respective duties are provided in keeping with size and activity of the department, explained as follows:

(A) The director of pharmacy is assisted by an adequate number of additional licensed pharmacists and such other personnel as the activities of the pharmacy may require to ensure quality pharmaceutical services.

(B) The pharmacy, depending upon the size and scope of its operations, is staffed by the following categories of personnel:
    (i) Chief pharmacist (director of pharmacy)
    (ii) One or more assistant chief pharmacists (assistant director of pharmacy).
    (iii) Staff pharmacists.
    (iv) Pharmacy residents (where program has been activated).
    (v) Trained non-professional pharmacy helpers (qualified hospital personnel).
    (vi) Clerical help.

(8) 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:

(A) 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 must be kept on file in the emergency room admission book or a copy of the Emergency Room medication order must be kept by the pharmacist to be readily accessible, for control and other purposes, as required by these regulations.

(B) 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 must be observed concerning all records, labeling, and outpatient dispensing requirement.

(C) Take home prescriptions for anti-infectives issued to patients at the time of discharge from the emergency room, filled by a pharmacist, shall be quantities consistent with the medical needs of the patient.

(9) 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:

(A) 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:

(i) Maintaining adequate control over the requisitioning and dispensing of all drugs and pharmaceutical supplies, and
(ii) Charging patients for drugs and pharmaceutical supplies.

(B) A record of procurement and dispersement of all controlled drugs is maintained in such a manner that the disposition of any particular item may be readily traced.

(C) 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 within twenty-four (24) hours of the time the service is provided.

(D) 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 drugs prescribed, the name and manufacturer (or trademark) of medication dispensed.

(E) 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 and control number. The label on the medication, or the container into which the labeled medication is placed, must bear the name of the patient.

(F) The label of each outpatient's individual prescription medication container bears the name of the patient, prescribing physician, directions for use, the name and strength of the medication dispensed (unless directed otherwise by the physician).

(10) 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:

(A) The medical staff has established a written policy that all toxic or dangerous medications not specifically prescribed as to time or number of doses, will be automatically stopped after a reasonable time limit set by the staff.

(B) The classifications ordinarily thought of as toxic or dangerous drugs are controlled substances, anticoagulants, antibiotics, oxytoxics, and cortisone products.

(C) Except for controlled drugs, all deteriorated non-sterile, non-labeled or damaged medication shall be destroyed by the pharmacist.

(D) All controlled drugs (Schedule II, III, IV, and V) should be listed and a copy sent, along with the drugs to the Arkansas Department of Health by registered mail or delivered in person for disposition.

(11) 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 provisions of the Arkansas Act 436 of 1975, or are approved for use by the P & T Committee of the hospital staff, explained as follows:

(A) The pharmacist, with the advice and guidance of the P & T Committee, is responsible for specifications as to quality, quantity, and source of supply of all drugs.

(B) 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 with the cooperation of the pharmacist and the administration.

(12) Policy and procedure manual

(A) 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.

(B) The policy and procedure manual should include at a minimum the following:

(i) Provisions for procurement, storage, distribution and drug control for all aspects of pharmaceutical services in the hospital;

(ii) Specialized areas such as surgery, delivery, ICU and CCU units and emergency room stock and usage of medication shall be specifically outlined;

(iii) 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;

(iv) Detailed job descriptions and duties of each employee by job title working in the pharmacy department must be developed and made a part of these policies and procedures.

(v) The pharmacy policy and procedure manual shall be subject to review and approval by the Board of Pharmacy on request from the Board.

(13) Employee prescription medication

(A) 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.

(B) 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.

(14) 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 medical needs of the patient.

(15) Licensed pharmacist personnel requirements

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 hospitals, psychiatric hospitals, and rehabilitative facilities licensed for greater than fifty (50) beds, as determined by the institution's 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 forty (40) hours per week. The request for exemption must provide adequate written documentation to justify the services of a pharmacist for as many hours as are necessary to perform required pharmacy services, followed by an appearance before the Board for final approval of the request.

(B) The above classified hospitals, licensed for fifty (50) beds or less, as determined by the institution's license issued by the Arkansas Department of Health, shall require the services of a pharmacist for as many 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's safe and efficient operation. The pharmacist shall be on site at least five (5) 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) Recuperative centers, outpatient surgery centers, and infirmaries

(i) If the infirmary, recuperative center or outpatient surgery center has a pharmacy department, a licensed pharmacist must be employed to administer the pharmacy in accordance with all state and federal laws regarding drugs and drug control.

(ii) If the infirmary, recuperative 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.

(iii) If the infirmary, recuperative 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.

(iv) All medication for patients shall be on individual prescription basis.

(D) A pharmacist in charge, who is employed at any facility permitted by the Arkansas State Board of Pharmacy where a forty (40) hour work-week is required, may also be the pharmacist in charge at a hospital licensed for fifty (50) beds or less by the Arkansas Department of Health.

(16) Responsibility of a pharmacist in a hospital pharmacy

(A) 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.

(B) The following aspects of medication distribution and pharmaceutical service are functions involving professional evaluations of judgments and may not be performed by supportive personnel:

(i) Selection of the brand and supplier of medication.

(ii) Interpretation and certification of the medication order. This involves a number of professional responsibilities such as the determination of:

a. Accuracy and appropriateness of dose and dosage schedule.

b. Such items as possible drug interactions, medication sensitivities of the patient and chemical and therapeutic incompatibilities.

c. Accuracy of entry of medication order to patient's medication profile.

(C) Final certification of the prepared medication.

(17) Operation of pharmacy department without a pharmacist

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.

(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 could perform only those functions authorized within this regulation.

(18) 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. (Revised 6/25/83, 4/7/89, 6/15/95, and 8/2001)

04-05-0002—MECHANICAL STORAGE AND DELIVERY

Hospitals using mechanical storage and delivery machines for legend drugs must secure a hospital pharmaceutical services permit, and these machines shall be stocked only by a licensed pharmacist under this permit. Drugs may be obtained from these machines only by a physician, or registered or licensed professional nurse or student nurse, or an intern or resident physician, or a licensed pharmacist acting under the prescribed rules of safety procedures as promulgated by the individual hospital or institution using the machine. Use of these machines shall not be to circumvent adequate pharmaceutical services. (Amended 8/23/96)

04-05-0003—REGULATING THE USE OF ELECTRONIC DATA PROCESSING IN LIEU OF PRESENT RECORD KEEPING SYSTEMS IN HOSPITAL PHARMACIES HOLDING HOSPITAL PHARMACY PERMITS

(a) These regulations shall be construed, if possible, so as not to be in violation of, or in conflict with, any federal regulation or requirement. If any part hereof is held invalid because of such conflict, such invalidity shall not affect other provisions or applications of these regulations, which can be given effect without the invalid provisions of these regulations, are declared severable.

(b) The Arkansas State Board of Pharmacy must approve the system prior to implementation.

(c) Input of drug information into the system shall be performed by a pharmacist or pharmacy technician. The final verification of prescription information, entered into the computer, shall be made by the supervising pharmacist who is then totally responsible for all aspects of the data and data entry. Any judgmental decision concerning patient utilization of drugs must be performed by a pharmacist.

(d) An electronic data processing system must be readily accessible electronically online or by hard copy, and shall be capable of printing a hard copy record. The hard copy record, or electronic data base record, shall be available upon request by a Board of Pharmacy representative or other state or federal agencies with authority to obtain such records within 48 hours of the request. The system must be capable of furnishing the following information:

(1) Patient Medication Profile (accessible electronically online or by hard copy.)
Definition. The Patient Medication Profile ~~is~~ means the basic document used by the hospital pharmacist to monitor a patient's medication regimen, drug compliance, drug interactions, allergies and drug usage.

(A) The Patient Medication Profile must contain, at a minimum, the following:

(i) Patient name, patient identification number, practitioner's name, drug name, drug strength and dosage form, number of doses issued, initials, name or identification number of pharmacist approving original order into the system, and date original order was entered into the system.

(ii) The Final Patient Medication Profile must be maintained by the pharmacy

(2) Patient Daily Medication Record
The Patient Daily Medication Record is a document, whether electronic or hardcopy, which supports the Patient Medication Profile. The Patient Daily Medication Record provides a daily refill-by-refill audit trail on all drugs dispensed and supplements the base document,

the Patient Medication profile. This record is produced on a daily basis. It may be used to fill patient medication orders, for transport to the patient care area. This record must show all medications dispensed on any given day.

(A) The Patient Daily Medication Record must contain, at a minimum, the following: date of record, patient name, patient identification number, drug name, drug strength and dosage form and number of doses issued on that day.

(B) The initials of the pharmacist who checked and verified the doses dispensed must appear on the Patient Daily Medication Record if not shown on the Patient Medication Profile described in this section. Since the Patient Medication Record supports the Patient Medication Profile, some information such as practitioner's name, initials, name or identification number of pharmacist entering the original order into the system, and the date of the original order may or may not be duplicated because the information is readily retrievable from the base document.

(C) The Patient Daily Medication Record must be kept and a bound log book must be signed by all pharmacists filling orders for that day. If a printed hard copy is used, the printout may be replaced by a monthly log containing the same information. This information must be maintained at the pharmacy for a period of two (2) years.

(D) The pharmacist in charge of the hospital pharmacy will maintain a bound log book in which each individual pharmacist and intern involved in the dispensing of medications will sign the log book each day, attesting to the fact that the prescription information entered into the computer that day has been reviewed by him and is correct as shown. The log shall identify the time of day at which the pharmacist started filling and stopped filling prescriptions. The log book shall be maintained by the pharmacist in charge or his successor, in the hospital pharmacy employing such a system for a period of two (2) years after the date of dispensing the appropriately authorized prescription.

(3) Assure strict confidentiality of all patient records.

(4) If the hospital pharmacy closes, the pharmacist in charge, at the date of closing, shall store said records and within fourteen (14) days of closing shall notify the Board of Pharmacy where said records are located. A hard copy printout or electronic database of any daily log(s) shall be produced and made available to a Board of Pharmacy representative on their request and to any other person authorized by law to examine or receive copies of prescription records.

(5) If maintaining the Daily Patient Medication Report electronically, the data must be backed up at least daily (preferably continuously).

(e) Hospital pharmacies that make arrangements with outside suppliers of data processing services or materials must assure themselves of continuing, adequate and complete drug information data and issuing records. If for any reason the relationship with said supplier terminates, the pharmacy shall assure the continuity of records.

(f) In the event of computer breakdown (down time), the pharmacy must have an auxiliary record keeping system. The backup system must contain all necessary information to insure prompt data entry into the system as soon as computer is again available.

(g) Registrants holding a hospital pharmaceutical services permit, who fill outpatient prescriptions, and who wish to utilize electronic data processing equipment as a record keeping system must then comply with all the requirements of the Arkansas State Board of Pharmacy regulation 4-02-0010.

(h) The electronic data processing systems described in this regulation are acceptable as the disposition records for all drugs, except that the actual signed disposition (proof of use) records for Schedule II controlled substances must be retained separate from other records for a period of two (2) years. 10/09/80 (Revised 6/15/95, 6/19/97, & 10/11/2000)

04-06: INSTITUTIONAL PHARMACEUTICAL SERVICES PERMIT

04-06-0001—CLASS #1 INSTITUTIONAL PERMIT

(a) If a pharmacy is funded primarily by state or federal funds, and/or if prescription drugs are to be purchased, maintained or dispensed by a pharmacist in a facility that purchases drugs from Arkansas state contracts, and that facility does not meet the requirements set by the Board of Pharmacy to obtain a licensed pharmacy permit, a hospital pharmaceutical services permit, or a nursing home consultant's permit, then an exception may be made to issue an institutional pharmaceutical services permit. The institutional pharmaceutical services may be in facilities that provide extended health care to resident patients and are funded primarily by state or federal funds. The permit shall be issued in the name of the licensed pharmacist in charge.

(b) A licensed pharmacist employed or otherwise engaged to provide pharmaceutical service may have a flexible schedule of attendance in the institution, provided, however, the pharmacist must be physically present in the institution for a sufficient number of hours weekly to maintain adequate supply of medications at the service area from which medications are administered, to maintain all records, to perform other pharmaceutical services authorized by law and provide adequate control and accountability of all drugs under his responsibility.

(c) Medication for patients shall be on an individual prescription basis by order from a licensed physician and the pharmacist shall dispense drugs, properly labeled, to be used for patients being treated at the facility.

(d) Facilities are to be provided for the storage, safe-guarding, preparation, and dispensing of drugs. Equipment and supplies necessary to the facilities' safe and economical operation shall be provided. Special locked storage space is to be provided to meet all requirements for storage of controlled drugs, and other prescription drugs.

(e) All policies and procedures related to the institutional pharmaceutical services must first be approved by the Board before a permit will be issued.

(f) Special floor stock or backup to meet emergency needs such as when the pharmacy is closed, will be permitted only when specifically outlined in the policies and procedures. The policies and procedures shall include:
   (1) lists establishing quantity limits of these emergency drugs;
   (2) the method of replacement;
   (3) maintenance of records accounting for drugs used;
   (4) proper preparation and labeling by the pharmacist.

(g) With recognition of DEA's statement of policy regarding emergency kits for long-term care facilities, and recognizing DEA's definition of long term care facilities, the following requirements must be met for facilities with institutional pharmaceutical services permits to store emergency kits, containing controlled substances and/or other legend drugs, in these facilities in Arkansas.
   (1) All contents of the emergency kit will be provided by one pharmacy designated by the facility.

(2) The facility holding an institutional permit with the Board of Pharmacy must have resident patients to which the facility provides extended health care.
(3) The controlled and legend drugs must remain the property of and under the responsibility of the pharmacy, which must have an Arkansas permit.
(4) All medications must be administered only on the order of a practitioner and medications administered from the nurse's supply must be recorded as a prescription by the pharmacy prior to the pharmacy's replacement of the drug in the emergency supply.
(5) All medication records must be maintained as required by law, and out of date drugs must be properly destroyed by the pharmacy.
(6) Careful patient planning should be a cooperative effort between the pharmacy and the nursing department at the facility to make all medications available, and the emergency supply should only be used for emergency or unanticipated needs and shall not become a routine source or supply.
(7) The pharmacy is responsible to assure compliance with this regulation, and any abuse or misuse of the intent of this regulation shall be immediately reported to the Board of Pharmacy.
(8) Storage conditions for the emergency kit shall meet all state and federal requirements. The storage conditions shall be set out in the policy and procedures of the facility.

(h) Drug categories for emergency kits in facilities with institutional pharmaceutical services permits

The following is a list of categories of drugs which are acceptable in emergency kits in facilities with institutional pharmaceutical services permits in accordance with this regulation:

(1) Analgesics and controlled drugs
Schedule II injectable
Limit: one (1)
Maximum quantity: two (2)

(2) Schedule III, IV or V injectable
Limit: one (1)
Maximum quantity: ten (10)

(3) Schedule III, IV or V oral medications
Limit: two (2)
Maximum quantity: six (6)

(4) Anticonvulsants; injectable controlled drugs
Limit: one (1)
Maximum quantity: four (4)

(5) Anxiolytics; injectable controlled drugs
Limit: one (1)
Maximum quantity: four (4) (Amended 10/2001)

(a) When controlled drugs are needed for research or instruction by a licensed pharmacist, and these drugs are not to be sold or dispensed on prescriptions, an institutional pharmaceutical services permit for research or instruction (Class #2) may be issued.
(b) Total responsibility for such drugs is placed on the licensed pharmacist in whose name the permit is issued.

04-07: CHARITABLE CLINIC PERMIT

04-07-0001—ISSUANCE OF CHARITABLE CLINIC PERMIT

The Arkansas State Board of Pharmacy may provide for the issuance of a charitable clinic pharmacy permit to clinics and facilities furnishing medical care and dental care to poor and underprivileged persons, in which drugs are dispensed without charge to such persons on orders or prescriptions of practitioners authorized by law to prescribe or administer said drugs and to which the requirements of a licensed pharmacist on duty for a minimum of forty (40) hours shall not apply.

04-07-0002—PRESCRIPTIONS

All medication for patients shall be on individual prescription basis, and the pharmacist shall dispense drugs, properly labeled, and adhere to the requirements for proper storage, safeguarding, preparation and record keeping for prescription drugs.

04-07-0003—POLICIES AND PROCEDURES FOR CLINICS

All policies and procedures related to the charitable clinic pharmacy permit must first be approved by the Board staff before a permit will be issued to ensure compliance with all existing laws and regulations.

04-07-0004—CATEGORIES FOR PERMITS

The staff of the Board of Pharmacy is authorized to approve and issue charitable clinic permits for:
(a) Clinics of the Arkansas Department of Health
  (1) recognizing that medications are provided to patients in the absence of a pharmacist and that the medications dispensed in these clinics are limited to birth control medications, drugs to treat tuberculosis, and drugs to treat sexually transmitted disease treatment program.
  (2) Packaged and labeled prescription drugs shall be initialed by the pharmacist to assure accuracy and appropriateness. The prescribing practitioner or a licensed nurse may issue these pre-dispensed prescription drugs, by placing the patients name, date of issue and prescription number on the label at the time of issue to patients on order of the prescriber.
  (3) The prescription number, as placed on the label of the dispensed prescription drug, is to be placed with the prescribing practitioner's order in the patients medical record. The pharmacist shall monitor patients' medical records to assure that medication profiles and prescription orders are maintained and utilized.
  (4) Since the pharmacist is not present when the patient receives the medication, the pharmacist shall develop protocol to assure that the patient is monitored and counseled by the prescribing practitioner or nurse consistent with the requirements of Board of Pharmacy regulation 09-00-0001.
(b) Other facilities meeting the requirements of this regulation -- provided that, if a pharmacist is not present, there shall be a limited formulary negotiated by the Executive Director and

approved by the Board of Pharmacy at its next meeting. The dispensing medication distribution provisions of this section shall apply.

04-07-0005—PHARMACIST PRESENT WHEN MEDICATION PROVIDED

Other facilities meeting the requirements of this regulation and where a pharmacist is present when medications are provided to the patient shall not be restricted to a medication formulary. (Revised 04/30/93)