302 GENERAL ADMINISTRATION

302.11 ...Pharmacies operated in nursing homes shall be operated in compliance with Arkansas laws and shall be subject to inspection by personnel from the Division.

100 DEFINITIONS

Consultant Pharmacist means a qualified licensed, registered pharmacist, who under arrangement with an institution, renders assistance in developing, implementing, evaluating, and revising where indicated, policies and procedures for providing the administrative and technical guidance of the pharmaceutical services relative to labeling, storing, handling, dispensing, and all other matters pertaining to the administration and control of drugs and medication. He/she provides such services and monitors activities within the institution with the express purpose of creating and maintaining the highest standards in medication distribution, control, and service.

330 PHARMACIST

If a facility does not employ a licensed pharmacist, it shall establish a written agreement with a licensed pharmacist to provide consultation on methods and procedures for ordering, storage, administration, disposal, and record keeping of drugs and biologicals.

517 TREATMENT AND MEDICATIONS

517.1 No medication or treatment shall be given without the written order of the physician or dentist. Drugs shall be administered in accordance with orders. Venapuncture by licensed practical nurses to obtain blood samples for lab work is permitted after the LPN has been trained by the Director of Nurses or an RN designated by the Director of Nurses. The Director of Nurses and the LPN trained shall sign a form that states that the LPN is qualified and has been trained by a Registered Nurse. The facility shall have policies and procedures for venapuncture that are available for review by nursing personnel and the Office of Long Term Care.

...517.4 Each patient shall be identified prior to administration of medication.

517.5 Each patient shall have an individual medication record.

517.6 The dose of a drug administered to a patient shall be properly recorded by the person who administered the drug. Recordation shall occur only after the medication has been administered.

517.7 Medications shall be administered by authorized personnel.
517.9 Medication setups will be prepared one pass at a time. The medication must be administered on the same shift on which they are prepared. Liquids and injectables shall not be set up more than one (1) hour in advance except where approved unit dose systems are used.

517.10 Medications shall be administered by the same person who prepared the doses for administration, except under single unit dose package distribution systems.

517.11 The attending physician shall be notified of an automatic stop order prior to the last dose so that the physician may decide if the administration of the medication is to be continued or altered.

517.12 Self-administration of medication is allowed only under the following conditions:

If the physician orders, a patient may keep at the bedside the following nonprescription medications:

- Topical agents such as Vicks Salve, Mentholatum, etc.
- Eye drops such as Murine, Visine, etc.
- Cough drops, such as Ludens, Vicks, etc.
- Sublingual vasodilating agents such as Nitroglycerine tablets, Isordil Sublingual tablets.
- Metered dose aerosols for asthmatics such as primatene or bronkaid.

Personal items such as toilet articles and cosmetic articles may be kept at the bedside.

540 PHARMACEUTICAL SERVICES

541 RESPONSIBILITY FOR PHARMACY COMPLIANCE

The administrator shall be responsible for full compliance with Federal and State laws governing procurement, control, and administration of all drugs. Full compliance is expected with the Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law 91-513, and all regulations and rulings passed down by the Federal Drug Enforcement Agency (DEA), Ark. Code Ann. § 5-64-101 et seq. and all amendments to it and these rules and regulations.

542 PHARMACY CONSULTANTS PERMIT

Each nursing home shall have a formal arrangement with a licensed pharmacist to provide supervision and consultation on methods and procedures for ordering, storing, administering, disposition, and record keeping of drugs and biologicals.
A consultant pharmacist’s permit shall be obtained yearly from the Arkansas State Board of Pharmacy and shall be displayed in a conspicuous place in the facility.

The consultant pharmacist shall visit the nursing home at least monthly to perform his consultant duties.

Before a nursing home consultant’s permit shall be issued, the pharmacist must certify to the Board of Pharmacy that he has attended a seminar or meeting explaining pharmaceutical duties and responsibilities in a nursing home as approved by the Board of Pharmacy and that he has read and understands the regulations governing pharmaceutical services in a nursing home and will abide by them.

The consultant pharmacist shall submit a written report at least monthly to the administrator of the facility. This monthly report should be a summary of the duties performed by the consultant pharmacist that month, any error or problems found in the facility, delivery of pharmaceutical services, and a detailed listing of any discrepancies and/or irregularities noted by the pharmacist during his drug regimen reviews. The pharmacist, in cooperation with the facility staff, should develop and implement policies and procedures to govern all aspects of the drug distribution system. The pharmacist may also agree to abide by and function with those policies and procedures already being used by the facility at the time of his employment.

543 PRESCRIPTIONS ON INDIVIDUAL BASIS

All drugs prescribed for each patient shall be on an individual prescription basis. Medications prescribed for one patient shall not be administered to another patient.

544 ADMINISTRATION OF MEDICATION

544.1 No medication shall be given without a written order by a Physician or dentist.

544.2 All medications shall be given by authorized nursing personnel. The administrator or his appointed assistant shall be responsible for ensuring that authorized nursing personnel administer all medications ordered by a physician or dentist.

544.3 Caution shall be observed in administering medication so that the exact dosage of the prescribed medication is given as is ordered by the doctor or dentist.

544.4 Each resident must have an individual container, bin, compartment, or drawer for the storage of his medications in the medication room except for stock medication and approved unit dose systems.

544.5 The PRN medications on current doctor’s orders can be handled in one of four ways in a facility:

• Use medication from the emergency box.

• Have it as stock medication if it is a non-legend drug.

• Have it on an individual patient basis.
• Have pharmacist maintain a policy and procedure for twenty-four (24) hour emergency service from pharmacy.

544.6 Nursing personnel cannot transfer more than one dose of medication from container to container. Loading narcotic counters, preparing take-home supply of medications, incorporating supplies, etc., by nursing personnel are not permitted.

545 EQUIPMENT FOR ADMINISTERING MEDICATIONS

There shall be calibrated medicine containers to correctly measure liquid medications.

Calibrated medicine containers include calibrated syringes when used to measure odd liquid dosages, such as 4cc, 8cc, etc. Disposable items shall not be reused. Disposable syringes and needles must be disposed of by breaking and incineration.

546 MEDICINE CARDS

In administering medications, medication cards current with the physician’s orders must be used.

Medicine cards shall be provided to include:

• Name of patient.
• Rooms or bed number.
• Medication and dosage.
• Hours to be given.

547 STOP ORDER POLICY

Medications not specifically limited as to time or number of doses when ordered by the physician shall be controlled by the facility’s policy regarding automatic stop orders.

The facility’s automatic stop order policy, at a minimum, shall cover the following categories of medications:

• C II Narcotics.
• C II Non-narcotics.
• C III, C IV, and C V medications.
• Anticoagulants.
• Antibiotics.

548 STORAGE OF DRUGS

548.1 All drugs on the premises of a nursing home, except for the emergency tray, as defined by the Arkansas State Board of Health and the Arkansas State Board of
Pharmacy, shall be properly labeled containers dispensed upon prescription by the pharmacy.

548.2 All medications shall be kept in a locked cabinet or locked room at all times.

Only the nurse responsible for administering the medication, Director of Nursing, and the Administrator shall have a key.

548.3 All controlled drugs shall be stored in a separately locked, permanently affixed substantially constructed cabinet within a locked drug room or cabinet. When mobile medication carts for unit-dose or multiple day card systems are used, the condition for security will be considered met provided that the mobile cart is in a locked room when unit contains controlled drugs and is not in actual use, and provided the controlled substances are in a separately locked compartment within the cart unless the quantity stored is minimal and a missing dose can readily be detected. A minimal quantity shall be considered to be a quantity of a twenty-four (24) hour supply or less.

548.4 All drugs for external use shall be kept in a safe place accessible only to employees and in a special area apart from other medication and prescriptions.

548.5 Medicines requiring cold storage shall be refrigerated. A locked container placed below food level in a home refrigerator is considered satisfactory storage space.

548.6 Each patient's prescription medication shall be kept in the original container and shall be clearly and adequately labeled by the pharmacist. Label shall include:

- Prescription number.
- Patient's name.
- Name and strength of medicine.
- Physician's or dentist's name.
- Date of issue.
- Name of pharmacy.
- Appropriate, accessory and cautionary labels.
- Expiration date of drug where applicable.
- The quantity of tablets or capsules dispensed.
- Directions for administration.

548.7 Labels should be affixed to the immediate container. The immediate container is that which is in direct contact with the drug at all times.

548.8 O.T.C. medications (medications not requiring a prescription for purchase) that are the private property of the patient do not have to be labeled by a pharmacist.
However, they must be identified with at least the patient’s name.

548.9 Drug rooms shall be supplied with adequate lighting so that medications can be safely prepared for administration.

548.10 Drug room shall be properly ventilated so that the temperature requirements set by the U.S.P. are met: 59 (fifty-nine) degrees to 86 (eighty-six) degrees F.

549 EMERGENCY DRUG BOX

A container which contains emergency stimulants and drugs for life saving measures must be maintained. This box should be located where it can be readily available to nursing personnel but kept in a secure place and should have a breakaway lock. There should be a list on the box of the drugs which are contained in the box. The drugs in the box should be checked periodically with the list to make sure that these drugs have been replaced after use and are not outdated. Only drugs which have been approved for this purpose by the Pharmaceutical Services Committee or Medical Director, as applicable, and/or the physician, can be placed in this box. All controlled substances assigned to the box must be kept with the other controlled substances and labeled “Emergency Box”. All controlled substances assigned to the “Emergency Box” must be entered into the bound book. The location of these controlled substances should be noted on the list of drugs. The drug list should be signed by the physician member of the committee indicating his approval. The list and contents of the box shall be reviewed annually by the appropriate committee and/or physician and so noted on the emergency drug list.

550 RECORD OF CONTROLLED DRUGS

A record shall be kept in a bound ledger book with consecutively numbered pages of all controlled drugs procured and administered. This record shall contain on each separate page:

• Name, strength, and quantity of drug received.

• Date received.

• Patient’s name.

• Prescribing physician.

• Name of pharmacy.

• Date and time of dosage given.

• Quantity of drug remaining.

• Signature of person administering the drug.

The person responsible for entering the controlled drug into the bound ledger should be the same person who signs for it in the drug ordering and receiving record. This record shall be retained by the facility as a permanent record and be readily available.

551 CONTROLLED DRUG ACCOUNTABILITY
There shall be a count of all C II controlled medications at each change of shift. All C III, IV, and V controlled medications should be counted at least once daily unless a true unit dose system is used. This count shall be made by the off-going charge nurse and the on-coming charge nurse.

If licensed personnel are not available on a shift, a non-licensed employee can co-sign as a witness with the off-going nurse, and co-sign as a witness again with the oncoming nurse. This count shall be documented. This documentation shall include the date and time of the count, a statement as to whether or not the count was correct, and if it was incorrect, an explanation of the discrepancy. This record shall be retained by the facility as a permanent record and be readily retrievable.

When loss, suspected theft, or an error in the administration of controlled drugs occurs, it must be reported to the Director of Nursing Services and an incident report filled out; also, a copy of the form for reporting theft or lost controlled substances should be mailed to the Arkansas Department of Health, Division of Drug Control.

All documentation must be retained in the facility as a permanent record.

When a dose of a controlled drug is dropped or broken, two people should make a statement in the bound ledger as to what occurred, and both must sign their names. These two people shall be licensed nursing personnel whenever possible.

552 REVIEW OF MEDICATION BY THE NURSE AND/OR PHARMACIST

There shall be for each patient a separate medication/drug regimen review sheet. This sheet is to be used to document the performance of a medication/drug regimen review by the pharmacist and/or registered nurse. This monthly review must be dated and signed by the person making the review. Any discrepancy, interaction, etc., should be entered on the review sheet.

553 REVIEW OF MEDICATIONS BY CONSULTANT PHARMACISTS

In an Intermediate Care Facility, the review of the medication/drug regimen of the skilled care patients must be done at least each month, and at least quarterly on the Intermediate and Minimum care patients. In Skilled Nursing Facilities, the review of medication/drug regimen must be done monthly on all patients.

In reviewing the medication/drug regimens of the patients, the pharmacist and registered nurse should, as a minimum, compare the doctor's orders with the medication administration record, the medication cards, cardex, actual medications, and prescription labels. Any discrepancies, interactions, irregularities, contraindications, errors, and incompatibilities will be noted on the medication/drug regimen review sheet, and if medication/drug review is being performed by the pharmacist, on the pharmacist's monthly written report to the administrator. Irregularities observed by the pharmacist that would warrant immediate action should be brought to the Director of Nursing Services' attention immediately upon their finding.

The person delegated the responsibility of correcting or following through on the errors, irregularities, and discrepancies listed on the pharmacist's monthly report should
document their actions on their report, date it, and sign it. A photocopy of the report may be used for this purpose, but both must be retained in the facility. If no irregularities or discrepancies are found during the medication/drug regimen review, the person performing the review must note on the review sheet that he has reviewed that drug regimen and found no irregularities. This notation must be dated and signed.

554 CYCLE-FILL, PHARMACY NOTIFICATION AND DISPOSITION OF UNUSED DRUGS

Schedule II, III, IV, and V drugs dispensed by prescription for a patient and no longer needed by the patient must be delivered in person or by registered mail to: Drug Control Division, Arkansas Department of Health, 4815 West Markham Street, Little Rock, Arkansas 72201 along with Arkansas Department of Health Form (PHA-DC-1) Report of Drugs Surrendered for Disposition According to Law. When unused portions of controlled drugs go with a patient who leaves the facility, the controlled drug record shall be signed by the person who assumes responsibility for the patient and the person in charge of the medication in the nursing home. This shall be done only on the written order of the physician and at the time the patient is discharged, transferred, or visits home.

Except as provided in Ark. Code Ann. § 17-92-1101 et seq. and subsection 554.4, below, all medications other than Schedule II, III, IV, and V not taken out of the home by the patient with the physician’s consent when he or she is discharged from the home shall be destroyed. See Section 554.3, below, on handling medication when a resident enters a hospital or is transferred. All discontinued medications (except controlled drugs) shall be destroyed on the premises of the facility. Destruction shall be made by the consultant pharmacist and a nurse with a record made as to the date, quantity, prescription number, patient’s name, and strength of medications destroyed. The destruction should be by means of incineration, garbage disposal, or flushing down the commode. This record shall be kept in a bound ledger with consecutively numbered pages. This record shall be retained by the facility as a permanent record and be readily retrievable.

554.1 Only oral solid medications may be cycle-filled. Provided, however, that if an oral solid medication meets one of the categories below, then that oral solid medication may not be cycle-filled.

a. PRN or “as needed” medications.

b. Controlled drugs (CII – CV).

c. Refrigerated medications.

d. Antibiotics.

e. Anti-infectives
554.2 A facility shall notify the pharmacy in writing of any change of condition that affects the medication status of a resident. For purposes of this section, change of condition includes death, discharge or transfer of a resident, as well as medical changes of condition that necessitate a change to the medication prescribed or the dosage given. The notification shall be made within twenty-four (24) hours of the change of condition. If the notification would occur after 4:30 p.m. Monday through Friday, or would occur on a weekend or holiday, the facility shall notify the pharmacy by no later than 11:00 a.m. the next business day. Documentation for drugs ordered, changed or discontinued shall be retained by the facility for a period of no less than fifteen (15) months.

554.3 When a resident is transferred or enters a hospital, a facility shall hold all medication until the return of the resident, unless otherwise directed by the authorized prescriber. All continued or re-ordered medications will be placed in active medication cycles upon the return of the resident. Except as provided in Ark. Code Ann. § 17-92-1101 et seq. and subsection 554.4, below, if the resident does not return to the facility, any medications held by the facility shall be placed with other medications or drugs for destruction or return as permitted by State Board of Pharmacy regulations.

554.4 Pursuant to Ark. Code Ann. § 17-92-1101 et seq., facilities may elect to donate designated medications to charitable clinics. If a facility elects to donate medications, facilities shall:

a. Obtain the written consent of the resident or the person who assumes responsibility for the resident through the execution of a donor form created by the Arkansas State Board of Pharmacy that states that the donor is authorized to donate the drugs and intends to voluntarily donate them to a charitable clinic pharmacy;

b. Retains the donor form along with other acquisition records in accordance with section 604.2 of these regulations;

c. Obliterate from the packaging before the nursing facility sends the drug to the charitable clinic the donor patient’s name, prescription number, and any other marks that identify the resident;

d. Ensure that the drug name, strength, and expiration date remain on the drug package label;

e. Enter into a contract, approved by the Arkansas State Board of Pharmacy, with all charitable clinics to which the facility will donate drugs;

f. Donate drugs only in their original sealed and tamper-evident packaging or, if acceptable to the charitable clinic, drugs packaged in single-unit doses or blister packs with the outside packaging opened if the single-unit dose packaging remains intact;

g. Ensure that all drugs physically transferred from the nursing facility to a charitable clinic pharmacy is performed by a person authorized by the Arkansas State Board of Pharmacy to pick up the drugs for the charitable clinic;

h. Provide all drug recall notices and information received by, or known to, the facility to all charitable clinics with which the facility has a contract to donate drugs;
i. Donate only those medications permitted under Ark. Code Ann. § 17-92-1101 et seq.; and,
j. Comply with all applicable regulations concerning donation of unused drugs to charitable clinics promulgated by the Arkansas State Board of Pharmacy.

555 PHARMACY PREPARED MEDICATION CONTAINER SYSTEMS DESIGNED FOR ADMINISTRATION WITH THE USE OF MEDICATION CARDS (UNIT DOSE SYSTEM)

All policies and procedures related to systems of this type must first be approved by OLTC before that system is put into operation.

The medication shall remain in the pharmacy-prepared container up to the point of administration to the patient.

The medication container must be properly labeled by a licensed pharmacist.

555.1 Freedom of Choice

To ensure that each patient admitted to a long term care facility is allowed freedom of choice in selecting a provider pharmacy, at the time of admission the patient or responsible party must specify in writing the pharmacy that they desire to use. The patient or responsible party must also sign the statement, or form, and the signed form should be filed with the signed Resident Rights’ statement. The patient must be allowed to change the provider pharmacy if he desires. If true unit dose system is used by the facility the patient will not be afforded the freedom of choice of pharmacy provider.