State Regulations Pertaining to Pharmacy Services

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ALABAMA

420-5-10-.16 Pharmacy Services.

(1) The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in §483.75(h) of Title 42 Code of Federal Regulations revised 10/1/93.

(a) Procedures. A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

(b) Service consultation. The facility must employ or obtain the services of a licensed pharmacist who:

1. Provides consultation on all aspects of the provision of pharmacy services in the facility;

2. Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and

3. Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

(c) Drug regimen review.

1. The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

2. The pharmacist must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon.

(d) Storage of drugs and biologicals.

1. In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls and permit only authorized personnel to have access to the keys.

2. The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse
Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

3. The facility must maintain readily traceable records of receipt and disposition of all controlled drugs.

(e) Destruction of Drugs.

1. The nursing facility develops policies and procedures for the destruction of drugs and biologicals.

2. Controlled substances and legend drugs dispensed to residents, that are unused because the medication is discontinued, or because the resident dies shall be destroyed within 30 days, except unused legend drugs may be donated to a charitable clinic pursuant to Alabama Administrative Code Chapter 420-11-11, et. seq.

3. Medications of residents transferred to a hospital may be retained until the resident is returned to the facility. Upon return of the resident to the facility, the physician's order will dictate whether or not the resident is to continue the same drug regimen as previously ordered. Medications not reordered by the physician must be destroyed.

4. Medications ordered to be used on an "as needed" basis shall be destroyed after 90 days if they have not been used during that period of time. Medications shall be destroyed upon expiration of the drug.

5. Both controlled substances and non-controlled substances may be destroyed on the premises or may be picked up by an environmental agency that provides such service. Drugs to be destroyed shall not be returned to the drugstore for destruction.

6. Records must be completed and maintained by the facility that include:

(i) Name and address of the facility;

(ii) Date of destruction/date drugs picked up;

(iii) Method used in destruction (If picked up by an environmental agency, the record/receipt must indicate the proposed date and method of destruction); and

(iv) Prescription number, name of drugstore from which the medicine was dispensed, resident’s name, name and strength of drug destroyed, amount destroyed and reason for destruction.

7. The pharmacist will verify that the list of drugs to be destroyed is accurate and with a Registered Nurse, will carry out destruction. Both will sign the destruction form indicating amounts listed are correct and have been destroyed. For destruction of controlled substances, there shall be a third witness who may be a law enforcement official, management or supervisory personnel, i.e., administrator, LPN charge nurse, etc. If medications are to be picked up and destroyed by an environmental agency, the RN should verify the list of drugs to be destroyed and should obtain a signed copy of the destruction form as a receipt.
8. If records of destruction are maintained in the resident’s medical record, they must be retained for as long as the medical record is kept. If a separate file of destruction records is to be maintained, it must be retained for a period of not less than two years.

(f) Labeling of Drugs and Biologicals.

1. All containers of medicines and drugs shall be properly and plainly labeled, including name and strength of drug, resident’s name, ordering physician, date of filling, directions for administration, prescription number, expiration date, number of tablets or capsules sent and any necessary auxiliary labels. The prescription label shall conform with any additional federal, state and local requirements.

2. Use of and labeling of generic drugs shall comply with the State Board of Pharmacy requirements.

3. When authorized substitution of a drug takes place, there will be established policies and procedures to provide accurate identification.

4. Over-the-counter (non-prescription) medicines shall be plainly labeled with the name and strength of the drug. Additional labeling information may be at the discretion of the facility as related in its policies and procedures except that manufacturer’s labeling information must be present in the absence of prescription labeling.

5. The contents of all individual prescriptions shall be kept in the original dispensed container bearing the original prescription label.

6. Procedures shall be developed to assure proper control and labeling for medications provided a resident upon leaving the facility on a temporary absence.

7. Unit dose medications shall be packaged according to an acceptable format to include product name, strength, control number, and expiration date. Procedures for utilization of the system used are developed and approved by administration, nursing and pharmacy personnel and must comply with federal and state regulations.

(g) Emergency medication kits will be kept in accordance with Chapter 680-x-2 of the Alabama State Board of Pharmacy Rules and Regulations governing institutional pharmacies.

1. Emergency kits may contain controlled substances utilizing the following conditions:

(i) The source from which a long term care facility may obtain controlled substances must be a DEA registered pharmacy or practitioner.

(ii) There shall be a maximum three day supply of any controlled substance stocked in the emergency kit.

(iii) The responsibility for proper control and accountability of the emergency kit shall rest with both the nursing facility and the DEA registrant providing the drug. The facility and the drug provider shall maintain complete and accurate records of the controlled substances.
placed in the emergency kit including receipt and disposition of the drugs as well as
destruction of unused or outdated drugs where appropriate.

(iv) Adequate security measures shall be provided for the emergency kit (if the controlled
drugs are to be maintained within the kit) or the drugs (if they are to be maintained in a
separate area) to include double locks. Access to emergency drugs shall be limited to those
with an actual need, i.e., medication nurse and/or director of nurses and the pharmacist.

(v) Controlled drugs maintained for emergency use may be used only upon the written or
telephone orders of the attending physician, who must sign a telephone order as soon as
possible after giving it.

(vi) Violations of these rules and regulations may result in the revocation, denial or
suspension of the privilege of maintaining controlled substance drugs in the emergency kit.

(h) "Stat" Medicine Cabinets.

1. Each nursing facility may maintain one "stat" medicine cabinet for the purpose of keeping
a minimum amount of stock medications that may be needed quickly or after regular duty
hours. If a facility wants more than one "stat" medicine cabinet, it must be approved by the
State Board of Health. The following rules apply to such a cabinet:

(i) There shall be a minimum number of doses of any medication in the "stat" cabinet based
upon the established needs of the facility.

(ii) There must be a list of contents, approved by the nursing facility, giving the name and
strength of the drug and the quantity of each.

(iii) There shall be records available to show amount received, name of resident and
amount used, prescribing physician, time of administration, name of individual removing
and using the medication and the balance on hand.

(iv) There shall be written procedures for utilization of the "stat" medicine cabinet with
provisions for prompt replacement of used items.

(v) The pharmacist shall inspect the "stat" medicine cabinet at least monthly replacing
outdated drugs and reconciliation of its prior usage. Information obtained shall be included
in a monthly report.

Author: Rick Harris
History: Original rules filed: July 19, 1996; effective August 23, 1996. Amended:
7 AAC 12.290. Drug regimen review

A pharmacist must review each resident’s prescribed drug regimen every 30 days for skilled nursing care residents and every 90 days for intermediate care residents, make recommendations, note the possibilities or absence of problems with the prescribed drug regimen and report potential problems and concerns to the physician.

History: Eff. 11/19/83, Register 88; am 5/28/92, Register 122 Authority: AS 18.20.010 AS 18.20.060

7 AAC 12.680. Pharmaceutical service

(a) A facility which dispenses drugs must employ a pharmacist on a regular or consultant basis. The pharmacist shall perform the following duties:

(1) procure, label, and maintain a sufficient quantity of drugs to meet patient needs at all times;

(2) inventory emergency drugs every 30 days and restock, as necessary;

(3) dispose of drugs that have been discontinued or have expired;

(4) dispose of scheduled drugs that have been discontinued or have expired which are listed in schedules I - V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 as amended, 21 U.S.C. 801 et seq.;

(5) assure that there is no more than one person on each shift who is performing the duties under 7 AAC 12.670(e), or is a physician, who has access to the pharmacy stock of drugs or controlled substances;

(6) assure that drugs, chemicals, and biologicals are properly labeled regarding their content and strength;

(7) if a consultant pharmacist, provide a written quarterly report to the administrator on the status of the pharmaceutical service; and

(8) document and evaluate medication errors to prevent reoccurrence and to ensure the accuracy and adequacy of the medication distribution system.

(b) When a pharmacist dispenses drugs by written prescription, the prescription must be an original or a carbon copy of the original and must be kept on file in the pharmacy. A pharmacist may dispense drugs based on a written order by a person authorized by law to prescribe drugs.
(c) A facility that dispenses drugs must have a pharmacy and therapeutics committee that is
(1) composed of
(A) a physician or the physician’s representative;
(B) a pharmacist or the pharmacist representative;
(C) a registered nurse or the registered nurse's representative; and
(D) an administrator or the administrator’s representative; and
(2) responsible for the
(A) development and maintenance of a formulary of drugs;
(B) development and implementation of procedures for safe and effective control, storage, dispensing, and administration of medications; those procedures must ensure that
(i) drugs and biologicals are stored in secure areas; and
(ii) drugs listed in schedules II, III, IV, and V under 21 U.S.C. 801 - 904 (Comprehensive Drug Abuse Prevention and Control Act of 1970) are kept locked within a secure area; and
(C) development and implementation of policies limiting the duration of drug therapy and for determining the stock of poison antidotes.
(d) A verbal order for a drug may be given only to a licensed nurse or pharmacist by a person lawfully authorized to prescribe medication, and must be recorded promptly in the patient’s medical record, identifying the name of the person who prescribed the order, and the signature of the person receiving the order.
(e) A standing order for a drug must specify the circumstances for drug administration, dosage, route, duration, and frequency of administration. The order must be reviewed annually and, if necessary, renewed. When a standing order is implemented for a specific patient, it must be entered into the patient’s record, dated, and signed by the person who prescribed the order within 24 hours.
(f) If the facility permits bedside storage of medications, written policies and procedures must be established for dispensing, storage, and maintenance of records for use of these medications.
(g) An investigational drug may be used only under supervision of a principal investigator who is a member of the medical staff. Basic information concerning the dosage, route of administration, strength, actions, uses, side effects, interactions and symptoms of toxicity of an investigational drug must be available at the nursing station where an investigational drug is being administered and in the pharmacy. The pharmacist shall be responsible for the proper labeling, storage, and distribution of such drugs in accordance with the written order of the investigator.
(h) A drug supplied by a facility may not be taken from the facility unless the medication has been properly labeled and prepared by the pharmacist in accordance with state and federal law for use outside of the facility.

(i) A hospice agency that does not provide inpatient care on agency premises, a freestanding birth center, and a frontier extended stay clinic are exempt from the requirements of this section.

History: Eff. 11/19/83, Register 88; am 5/28/92, Register 122; am 5/4/97, Register 142; am 12/3/2006, Register 180; am 5/24/2007, Register 182; am 9/30/2007, Register 183

Authority: AS 18.05.040 AS 47.32.010 AS 47.32.030

ARIZONA

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R9-10-911. Medication

A. An administrator shall comply with the requirements in A.R.S. Title 32, Chapter 18, and 4 A.A.C. 23;

B. An administrator shall ensure that:

1. A medication or a biological is provided to a resident at the resident’s expense including a medication or a biological used in an emergency or obtained through contract with a pharmacy licensed under A.R.S. Title 32, Chapter 18 or otherwise provided by law;

2. A medication or a biological is:

   a. Stored in a locked compartment;

   b. Maintained at temperatures recommended by the manufacturer; and

   c. Accessed only by individuals authorized according to nursing care institution policies and procedures;

3. The medication error rate at the nursing care institution, as determined by the Department during a license survey, is less than five percent;

4. A medication or a biological administered to a resident is documented as required in R9-10-913;

5. A pharmacist reviews a resident’s medications every three months and provides documentation to the resident’s attending physician and the director of nursing indicating potential medication problems such as incompatible or duplicative medications; and
6. A drug reference source, current within one year of the publication date, is available and maintained on the nursing care institution’s premises for use by a staff member, a physician, and a physician’s designee.

C. A director of nursing shall ensure that:

1. Medication policies and procedures are established, documented, and implemented that include:
   a. A system for the receipt, disposition, and reconciliation of medications, biologicals, and controlled substances;
   b. The administration, storage, and disposal of medications, biologicals, and controlled substances; and
   c. Identification of individuals who are authorized to have access to controlled substances;

2. A controlled substance is stored in a locked compartment separate from other medications;

3. A medication administration error or an adverse reaction to a medication or biological is reported to a resident’s attending physician or the attending physician’s designee and documented in the resident’s medical records;

4. An antipsychotic medication:
   a. Is only administered to a resident for a diagnosed medical condition;
   b. Unless clinically contraindicated or otherwise ordered by an attending physician or the attending physician’s designee, is gradually reduced in dosage while the resident is simultaneously provided with interventions such as behavior and environment modification in an effort to discontinue the antipsychotic medication unless a dose reduction is attempted and the resident displays behavior justifying the need for the antipsychotic medication, and the attending physician documents the necessity for the continued use and dosage; and
   c. Is documented as required in R9-10-913 and includes the resident’s response to the medication.

D. A resident may self-administer medication if the interdisciplinary team determines that the resident is capable of self-administration and the attending physician documents authorization for medication self-administration in the resident's medical records.

E. A nurse shall document a resident’s self-administration of medication as required in R9-10-913.

Historical Note

Adopted effective October 20, 1982 (Supp. 82-5). Section repealed, new Section adopted effective February 17, 1995 (Supp. 95-1). Section repealed; new Section made by final rulemaking at 9 A.A.R. 338, effective March 16, 2003 (Supp. 03-1).
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 amendments to this set 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
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 place 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.

CALIFORNIA
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s 72353. Pharmaceutical Service -General.
(a) Arrangements shall be made to assure that pharmaceutical services are available to
provide patients with prescribed drugs and biologicals.
(b) Dispensing, labeling, storage and administration of drugs and biologicals shall be in
conformance with state and federal laws.
(c) If a pharmacy is located on the premises, the pharmacy shall be licensed by the
California State Board of Pharmacy and approved by the Department. The pharmacy shall
not serve the general public unless a separate public entrance or a separate public serving
window is utilized. Pharmacies located on the licensed premises of skilled nursing facilities
shall be opened for inspection upon the request of an authorized Department
representative.
(d) The facility shall not accept money, goods or services free or below cost from any pharmacist or pharmacy as compensation or inducement for referral of business to any pharmacy.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Section 1276, Health and Safety Code; Sections 650 and 651, Business and Professions Code.

s 72355. Pharmaceutical Service - Requirements.
(a) Pharmaceutical service shall include, but is not limited to, the following:
(1) Obtaining necessary drugs including the availability of 24-hour prescription service on a prompt and timely basis as follows:
(A) Drugs ordered "Stat" that are not available in the facility emergency drug supply shall be available and administered within one hour of the time ordered during normal pharmacy hours. For those hours during which the pharmacy is closed, drugs ordered "Stat" shall be available and administered within two hours of the time ordered. Drugs ordered "Stat" which are available in the emergency drug supply shall be administered immediately.
(B) Anti-infectives and drugs used to treat severe pain, nausea, agitation, diarrhea or other severe discomfort shall be available and administered within four hours of the time ordered.
(C) Except as indicated above, all new drug orders shall be available on the same day ordered unless the drug would not normally be started until the next day.
(D) Refill of prescription drugs shall be available when needed.
(2) Dispensing of drugs and biologicals.
(3) Monitoring the drug distribution system which includes ordering, dispensing and administering of medication.
(4) Provision of consultative and other services furnished by pharmacists which assist in the development, coordination, supervision and review of the pharmaceutical services within the facility.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Section 1276, Health and Safety Code.

s 72357. Pharmaceutical Service - Labeling and Storage of Drugs.
(a) Containers which are cracked, soiled or without secure closures shall not be used. Drug labels shall be legible.

(b) All drugs obtained by prescription shall be labeled in compliance with state and federal laws governing prescription dispensing. No person other than the dispenser of the drug shall alter any prescription label.

(c) Nonlegend drugs shall be labeled in conformance with state and federal food and drug laws.

(d) Test reagents, germicides, disinfectants and other household substances shall be stored separately from drugs and shall not be accessible to patients.
(e) External use drugs in liquid, tablet, capsule or powder form shall be stored separately from drugs for internal use.

(f) Drugs shall be stored in appropriate temperatures. Drugs required to be stored at room temperature shall be stored at a temperature between 15 degrees C (59 degrees F) and 30 degrees C (86 degrees F). Drugs requiring refrigeration shall be stored in a refrigerator between 2 degrees C (36 degrees F) and 8 degrees C (46 degrees F). When drugs are stored in the same refrigerator with food, the drugs shall be kept in a closed container clearly labeled "drugs."

(g) Drugs shall be stored in an orderly manner in cabinets, drawers or carts of sufficient size to prevent crowding.

(h) Dose preparation and administration areas shall be well-lighted.

(i) Drugs shall be accessible only to personnel designated in writing by the licensee.

(j) Storage of nonlegend drugs at the bedside shall meet the following conditions:

1. The manner of storage shall prevent access by other patients. Lockable drawers or cabinets need not be used unless alternate procedures, including storage on a patient’s person or in an unlocked drawer or cabinet are ineffective.

2. The facility shall record in the patient health record the bedside medications used by the patient, based on observation by nursing personnel and/or information supplied by the patient.

3. The quantity of each drug supplied to the patient for bedside storage shall be recorded in the health record each time the drug is so supplied.

(k) Storage of legend drugs at the bedside shall meet the conditions of 72357(j) and shall in addition:

1. Be specifically ordered by the prescriber of the drugs, and

2. Be limited to sublingual or inhalation forms of emergency drugs.

(l) Drugs shall not be kept in stock after the expiration date on the label and no contaminated or deteriorated drugs shall be available for use.

(m) The drugs of each patient shall be kept and stored in their originally received containers. No drug shall be transferred between containers.

(n) Discontinued drug containers shall be marked, or otherwise identified, to indicate that the drug has been discontinued, or shall be stored in a separate location which shall be identified solely for this purpose. Discontinued drugs shall be disposed of within 90 days of the date the drug order was discontinued, unless the drug is reordered within that time.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Sections 1418.5 and 1276, Health and Safety Code.
s 72359. Pharmaceutical Service -Stop Orders.

Written policies shall be established and implemented limiting the duration of new drug orders in the absence of a prescriber's specific indication for duration of therapy. The prescriber shall be contacted for new orders prior to the termination time established by the policy. Such policies shall include all categories of drugs.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Section 1276, Health and Safety Code.

s 72361. Pharmaceutical Service -Orders for Drugs.

(a) No drugs shall be administered except upon the order of a person lawfully authorized to prescribe for and treat human illness.

(b) All drug orders shall be written, dated, and signed by the person lawfully authorized to give such an order. The name, quantity or specific duration of therapy, dosage and time or frequency of administration of the drug, and the route of administration if other than oral shall be specified. "P.R.N." order shall also include the indication for use of a drug.

(c) Verbal orders for drugs and treatments shall be received only by licensed nurses, psychiatric technicians, pharmacists, physicians, physician's assistants from their supervising physicians only, and certified respiratory therapists when the orders relate specifically to respiratory care. Such orders shall be recorded immediately in the patient's health record by the person receiving the order and shall include the date and time of the order. The order shall be signed by the prescriber within five days.

(d) The signing of orders shall be by signature or a personal computer key. Signature stamps shall not be used.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Section 1276, Health and Safety Code.


Signed orders for drugs shall be transmitted to the issuing pharmacy within 48 hours, either by written prescription of the prescriber or by an order form which produces a direct copy of the order or by an electronically reproduced facsimile.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Section 1276, Health and Safety Code.

Facilities shall maintain a record which includes, for each drug ordered by prescription, the name of the patient, the drug name, and strength, the date ordered, the date and amount received and the name of the issuing pharmacy. The records shall be kept at least one year.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Section 1276, Health and Safety Code.

**s 72367. Pharmaceutical Service - Personal Medications.**

(a) Medications brought by or with the patient on admission to the facility shall not be used unless the contents of the containers have been examined and positively identified after admission by the patient's physician or a pharmacist retained by the facility.

(b) The facility may use drugs transferred from other licensed health facilities or those drugs dispensed or obtained after admission from any licensed or governmental pharmacy and may accept the delivery of those drugs by any agent of the patient or pharmacy without the necessity of identification by a physician or pharmacist.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Section 1276, Health and Safety Code.

**s 72369. Pharmaceutical Service - Controlled Drugs.**

(a) Drugs listed in Schedules II, III and IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 shall not be accessible to other than licensed nursing, pharmacy and medical personnel designated by the licensee. Drugs listed in Schedule II of the above Act shall be stored in a locked cabinet or a locked drawer separate from noncontrolled drugs unless they are supplied on a scheduled basis as part of a unit dose medication system.

(b) Separate records of use shall be maintained on all Schedule II drugs. Such records shall be maintained accurately and shall include the name of the patient, the prescription number, the drug name, strength and dose administered, the date and time of administration and the signature of the person administering the drug. Such records shall be reconciled at least daily and shall be retained at least one year. If such drugs are supplied on a scheduled basis as part of a unit dose medication system, such records need not be maintained separately.

(c) Drug records shall be maintained for drugs listed in Schedules III and IV of the above Act in such a way that the receipt and disposition of each dose of any such drug may be readily traced. Such records need not be separate from other medication records.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Section 1276, Health and Safety Code.
s 72371. Pharmaceutical Service - Disposition of Drugs.

(a) Drugs which have been dispensed for individual patient use and are labeled in conformance with State and Federal law for outpatient use shall be furnished to patients on discharge on the orders of the discharging physician. If the physician’s discharge orders do not include provisions for drug dispositions, drugs shall be furnished to patients unless:

1. The discharging physician specifies otherwise or,

2. The patient leaves or is discharged without a physician’s order or approval or,

3. The patient is discharged to a general acute care hospital, acute psychiatric hospital, or acute care rehabilitation hospital or,

4. The drug was discontinued prior to discharge or,

5. The labeled directions for use are not substantially the same as most current orders for the drug in the patient’s health record.

(b) A record of the drugs sent with the patient shall be made in the patient’s health record.

(c) Patient’s drugs supplied by prescription which have been discontinued and those which remain in the facility after discharge of the patient shall be destroyed by the facility in the following manner:

1. Drugs listed in Schedules II, III or IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 shall be destroyed by the facility in the presence of a pharmacist and a registered nurse employed by the facility. The name of the patient, the name and strength of the drug, the prescription number, the amount destroyed, the date of destruction and the signatures of the witnesses required above shall be recorded in the patient’s health record or in a separate log. Such log shall be retained for at least three years.

2. Drugs not listed under Schedules II, III or IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 shall be destroyed by the facility in the presence of a pharmacist or licensed nurse. The name of the patient, the name and strength of the drug, the prescription number if applicable, the amount destroyed, the date of destruction and the signatures of the person named above and one other person shall be recorded in the patient’s health record or in a separate log. Such log shall be retained for at least three years.

(d) Unless otherwise prohibited under applicable federal or state laws, individual patient drugs supplied in sealed containers may be returned, if unopened, to the issuing pharmacy for disposition provided that:


2. All such drugs are identified as to lot or control number.
(3) The signatures of the receiving pharmacist and a registered nurse employed by the facility are recorded in a separate log which lists the name of the patient, the name, strength, prescription number (if applicable), the amount of the drug returned and the date of return. The log must be retained for at least three years.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Section 1276, Health and Safety Code.

HISTORY Change without regulatory effect relettering duplicate subsection (c) to (d) filed 1-11-95 pursuant to section 100, title 1, California Code of Regulations (Register 95, No. 2).

s 72373. Pharmaceutical Service -Unit Dose Medication System.

In facilities utilizing a unit dose medication system, there shall be at least a 24-hour supply of all patient medications on hand at all times, except those drugs which are to be discontinued within the 24-hour period. Drugs that are part of a unit dose medication system shall not exceed a 48-hour supply.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Section 1276, Health and Safety Code.

s 72375. Pharmaceutical Service -Staff.

(a) Facilities shall retain a consulting pharmacist who devotes a sufficient number of hours during a regularly scheduled visit, for the purpose of coordinating, supervising and reviewing the pharmaceutical service committee, or its equivalent, at least quarterly. The report shall include a log or record of time spent in the facility. There shall be a written agreement between the pharmacist and the facility which includes duties and responsibilities of both.

(b) A pharmacist shall serve on the pharmaceutical service committee and the patient care policy committee.

(c) A pharmacist shall review the drug regimen of each patient at least monthly and prepare appropriate reports. The review of the drug regimen of each patient shall include all drugs currently ordered, information concerning the patient’s condition relating to drug therapy, medication administration records, and where appropriate, physician's progress notes, nurse's notes, and laboratory test results. The pharmacists shall be responsible for reporting, in writing, irregularities in the dispensing and administration of drugs and other matters relating to the review of the drug regimen to the administrator and director of the nursing service.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Section 1276, Health and Safety Code.

s 72377. Pharmaceutical Service -Equipment and Supplies.
(a) There shall be adequate equipment and supplies necessary for the provision of pharmaceutical services within the facility including at least the following:

(1) Refrigerator with an accurate thermometer.

(2) Lockable drug cabinets, drawers, closets or rooms.

(3) Drug service trays and/or carts.

(4) Drug preparation counter area and convenient water source.

(5) Reference materials containing drug monographs on all drugs in use in the facility. Such monographs shall include information concerning generic and brand names, if applicable, available strengths and dosage forms and pharmacological data including indications and side effects.

(b) Emergency supplies as approved by patient care policy committee or pharmaceutical service committee shall be readily available to each nursing station. Emergency drug supplies shall meet the following requirements:

(1) Legend drugs shall not be stored in the emergency supply, except under the following conditions:

(A) Injectable supplies of legend drugs shall be limited to a maximum of three single doses in ampules or vials or one container of the smallest available multi-dose vial and shall be in sealed, unused containers.

(B) Sublingual or inhalation emergency drugs shall be limited to single sealed containers of the smallest available size.

(C) Not more than six emergency drugs in solid, oral dosage form or suppository dosage form for anti-infective, antidiarrheal, antinausea, or analgesic use may be stored if in sealed containers. Not more than four doses of any one drug may be so stored.

(2) The emergency drug supply shall be stored in a portable container which is sealed in such a manner that the tamper-proof seal must be broken to gain access to the drugs. The director of nursing service or charge nurse shall notify the pharmacist when drugs have been used from the emergency kit or when the seal has been broken. Drugs used from the kit shall be replaced within 72 hours and the supply resealed by the pharmacist.

(3) The contents of the supply shall be listed on the outside of the container.

(4) The supply shall be checked at least monthly by the pharmacist.

(5) Separate records of use shall be maintained for drugs administered from the supply. Such records shall include the name and dose of the drug administered, name of the patient, the date and time of administration and the signature of the person administering the dose.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Section 1276, Health and Safety Code; Section 4035, Business and Professions Code.
s 72523. Patient Care Policies and Procedures.

... (c) Each facility shall establish and implement policies and procedures, including but not limited to:

...(5) Pharmaceutical services policies and procedures.

s 72525. Required Committees.

... (c) Committee composition and function shall be as follows:

(3) Pharmaceutical service committee.

(A) A pharmaceutical service committee shall direct the pharmaceutical services in the facility.

(B) The committee shall be composed of the following: a pharmacist, the director of nursing service, the administrator and at least one physician.

(C) The committee shall meet at least quarterly.

(D) The functions of the pharmaceutical service committee shall include, but not be limited to:

1. Establishing, reviewing, monitoring and approving policies and procedures for safe procurement, storage, distribution and use of drugs and biologicals.

2. Reviewing and taking appropriate action on the pharmacist's quarterly report.

3. Recommending measures for improvement of services and the selection of pharmaceutical reference materials.

Note: Authority cited: Sections 208(a) and 1275, Health and Safety Code. Reference: Sections 1276, 1315, 1316 and 1316.5, Health and Safety Code.

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COLORADO

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Part 6. MEDICAL CARE SERVICES

6.1 PHYSICIAN CARE.

...6.1.7 The facility shall take all necessary steps to assure that all drugs and therapies ordered by the physician are supported by diagnoses indicating the use of those drugs and therapies.
Part 7. NURSING SERVICES

7.4 WRITTEN PROCEDURES.

7.4.1 Procedures shall include the requirement that medications be administered in compliance with applicable Colorado law.

7.10 MEDICATION ADMINISTRATION. Medications shall be identified as provided in Subsection 16.3.2. Staff shall verify identification of the medication when the medication is prepared as well as when it is administered.

7.10.1 Medications and treatments shall be given only as ordered by a physician.

7.10.2 Medication shall be administered in a form that can be most easily tolerated by the resident. Staff shall not mask the medication or alter its form, through crushing or dissolving or other means, if to do so would be hazardous and not without first informing the resident or responsible party.

7.10.3 Medications that are prepared but unused shall be disposed of in accordance with state law and the facility's written procedures.

7.10.4 All administered medications shall be recorded in the resident's health record, indicating the name, strength, dosage, and mode of administration of the medication, the date and time of administration, and the signature of the person administering the medication.

7.10.5 To encourage independence and prepare residents for discharge, the facility shall permit self-administration of medications in appropriate cases upon the order of the attending physician and under the guidance of a registered or a licensed practical nurse.

7.10.6 If facility policy permits medications to be kept at the bedside, the pharmaceutical advisory committee shall approve such types of medications. The facility shall assure that each such medication is ordered by the physician to be kept at the bedside, it is used properly, use is documented, and it is stored in a secure manner that protects all residents.

7.10.7 Drug reactions and significant medication errors shall be reported within thirty minutes to the resident's physician. A call to the office or answering service does not meet the facility's responsibility to provide emergency care. The resident's condition shall be monitored for 72 hours and observations documented in the health record.

7.10.8 If a resident is administered psychoactive medications, he or she shall be evaluated for symptoms of tardive dyskinesia at least every three months.

Part 16 - Pharmaceutical Services

16.1 ORGANIZATION. The pharmaceutical services of the facility shall be organized and maintained exclusively for the benefit of the facility's residents.
16.1.1 The pharmaceutical service shall be supervised by a consultant pharmacist licensed to practice pharmacy in the State of Colorado.

16.1.2 All compounding and dispensing shall be from a pharmacy licensed by the Colorado Board of Pharmacy in accordance with all pharmacy laws and regulations.

16.2 ADVISORY COMMITTEE. The facility shall establish a pharmaceutical advisory committee, including a registered nurse, the consulting pharmacist and the medical advisor, to assist in the formulation of broad professional policies and procedures relating to pharmaceutical service in the facility.

16.3 DRUG REQUISITION AND STORAGE POLICIES. The facility shall designate in written policies approved by the governing body the person authorized to requisition, receive, control, and manage drugs.

16.3.1 Resident drugs shall be obtained from a licensed pharmacy or an individual prescription basis for each resident.

16.3.2 Unless the facility uses a unit dose system, each resident drug shall be stored in individual, originally received containers or "blister" or "bubble" cards that are clearly and legibly labeled with the name, strength, dosage, frequency and mode of administration, date of issue and expiration of the drug; physician’s name; name, address, and telephone number of the dispensing pharmacy; and the full name of the resident for whom the drug is prescribed.

16.3.3 The facility shall protect each resident’s drugs from use by other residents, visitors, and staff.

16.4 CONSULTING PHARMACIST. The facility shall contract in writing with a licensed pharmacist to be responsible for all pharmaceutical matters in the facility. The contract shall set forth the fees to be paid for services and the pharmacist’s responsibilities, including at least the following:

(1) Legal compounding;

(2) Prompt dispensing of properly labeled individual resident prescriptions;

(3) Inventory control; establishment of necessary records;

(4) Periodic inspection of all pharmaceutical supplies and drugs on all resident care units;

(5) Provision of an emergency medical kit, which remains the property of a licensed pharmacy approved by the pharmaceutical advisory committee and the Colorado State Board of Pharmacy;

(6) Regularly scheduled visits and consultations and at least annual in-service training to staff;

(7) Inspection of prescriptions and all drugs for proper labeling, proper storage, and drug deterioration or expiration of shelf life;
(8) Determination of proper procurement and maintenance of all prescriptions and other drugs;

(9) Development of proper accounting procedures for controlled substances and legend drugs;

(10) Evaluation of the implementation of policies of the pharmaceutical advisory committee; and

(11) Quarterly reports to the Pharmacy Advisory Committee on the status of pharmacy services.

16.5 CONTROLLED SUBSTANCES. Only practitioners authorized under the laws of the State of Colorado and properly registered with the federal government shall prescribe controlled substances. The facility shall comply with all federal and state laws and regulations relating to procurement, storage, administration, and disposal of scheduled drugs. Unless the facility uses a unit dose system, it shall maintain a record on a separate sheet for each resident receiving a scheduled drug, which contains the name of the drug, strength, date, time administered, resident name, dose, physician's name, signature of person administering, and the quantity of the drug remaining.

16.6 DISPOSITION OF MEDICATIONS [Eff. 07/30/2006]

16.6.1 If controlled substances (Schedules 2 through 5) are being held by a facility on behalf of a resident and the controlled substances are no longer needed, the facility shall conduct on-site destruction of the controlled substances as follows:

(1) The facility shall properly inventory the destruction and keep the inventory copy on file for at least two years.

(2) At least the administrator or designee, the supervisory nurse, and the consulting pharmacist shall witness each destruction and sign the destruction inventory.

(3) The destruction shall be performed in a manner that renders the controlled substances totally irretrievable.

16.6.2 Except as provided herein, all prescriptions and other drugs (except controlled substances) remaining upon death or discharge shall be destroyed by the administrator, a registered nurse, and a pharmacist who shall record the quantity of the drugs destroyed. In accordance with state law, including Section 12-22-133, C.R.S. (2005), the facility may return unused medications to a pharmacist for redispensing if those medications were donated to the facility by the resident or the resident's next of kin. For purposes of this paragraph, unused medications means prescription medications that are not controlled substances. If a facility accepts donated medications for redispensing by a pharmacist, it shall implement a written policy that addresses inventory control and prevents the diversion of such
16.7 MEDICATION RELEASE. The facility staff shall release medications to a resident only upon written physician authorization.

16.8 RESIDENT DRUG PROFILE RECORD. The dispensing pharmacist shall maintain drug profile records on each resident for whom he or she dispenses medications.

**CONNECTIONT**

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**19-13-D8t. Chronic and convalescent nursing homes and rest homes with nursing supervision**

(d) General Conditions.

...(6) All medications shall be administered only by licensed nursing personnel, qualified physician assistants or other health care practitioners with statutory authority to administer medications and/or in accordance with Section 19-13-D8v.

(n) Medical and professional services.

...(6) No medication or treatments shall be given without the order of a physician or a health care practitioner with the statutory authority to prescribe medications or treatments. If orders are given verbally or by telephone, they shall be recorded by an on duty licensed nurse or on duty health care practitioner with the statutory authority to accept verbal or telephone orders with the physician’s name, and shall be signed by the physician on the next visit.

**19-13-D8v. Pharmaceutical services in chronic and convalescent nursing homes and rest homes with nursing supervision**

(b) Pharmaceutical services.

(1) Each facility shall assure the availability of pharmaceutical services to meet the needs of the patients. All such pharmaceutical services shall be provided in accordance with all applicable federal and state laws and regulations. Drug distribution and dispensing functions shall be conducted through:

(A) a community pharmacy; or
(B) an institutional pharmacy.

(2) The pharmaceutical services obtained by each facility shall be provided under the supervision of a pharmacist as follows:

(A) If the facility operates an institutional pharmacy, the facility shall employ a pharmacist who shall supervise the provision of pharmaceutical services at least thirty-five (35) hours per week.

(B) When pharmaceutical services are obtained through a community pharmacy, the facility shall have a written agreement with a pharmacist to serve as a consultant on pharmaceutical services, as follows:

(i) The consultant pharmacist shall visit the facility at least monthly, to review the pharmaceutical services provided, make recommendations for improvements thereto and monitor the service to assure the ongoing provision of accurate, efficient and appropriate services.

(ii) Signed dated reports of the pharmacist's monthly reviews, findings and recommendations shall be forwarded to the facility's Administrator, Medical Director and Director of Nursing and kept on file in the facility for a minimum of three (3) years.

(C) Whether pharmaceutical services are obtained through a community pharmacy or an institutional pharmacy, the facility shall ensure that a pharmacist is responsible for the following functions:

(i) compounding, packaging, labeling, dispensing and distributing all drugs to be administered to patients;

(ii) monitoring patient drug therapy for potential drug interactions and incompatibilities at least monthly with documentation of same; and

(iii) inspecting all areas within the facility where drugs (including emergency supplies) are stored at least monthly to assure that all drugs are properly labeled, stored and controlled.

(3) Proper space and equipment shall be provided within the facility for the storage, safeguarding, preparation, dispensing and administration of drugs.

(A) Any storage or medication administration area shall serve clean functions only and shall be well illuminated and ventilated. When any mobile medication cart is not being used in the administration of medicines to patients it shall be stored in a locked room that meets this requirement.

(B) All medication cabinets (stationary or mobile) shall be closed and locked when not in current use unless they are stationary cabinets located in a locked room that serves exclusively for storage of drugs and supplies and equipment used in the administration of drugs.

(C) Controlled substances shall be stored and handled in accordance with provisions set forth in Chapter 420b of the Connecticut General Statutes and regulations thereunder.
(D) When there is an institutional pharmacy:

(i) The premises shall be kept clean, lighted and ventilated, and the equipment and facilities necessary for compounding, manufacturing and dispensing drugs shall be maintained in good operational condition.

(ii) Adequate space shall be provided to allow specialized pharmacy functions such as sterile IV admixture to be performed in discrete areas.

(4) Each facility shall develop, implement and enforce written policies and procedures for control and accountability, distribution, and assurance of quality of all drugs and biologicals, which shall include the following specifics:

(A) Records shall be maintained for all transactions involved in the provision of pharmaceutical services as required by law and as necessary to maintain control of, and accountability for, all drugs and pharmaceutical supplies.

(B) Drugs shall be distributed in the facility in accordance with the following requirements:

(i) All medications shall be dispensed to patients on an individual basis except for predetermined floor stock medication.

(ii) Floor stock shall be limited to emergency drugs, contingency supplies of legend drugs for initiating therapy when the pharmacy is closed, and routinely used non-legend drugs. Floor stock may include controlled substances in facilities that operate an institutional pharmacy.

(iii) Emergency drugs shall be readily available in a designated location.

(C) Drugs and biologicals shall be stored under proper conditions of security, segregation and environmental control at all storage locations.

(i) Drugs shall be accessible only to legally authorized persons and shall be kept in locked storage at any time such a legally authorized person is not in immediate attendance.

(ii) All drugs requiring refrigeration shall be stored separately in a refrigerator that is locked or in a locked room and that is used exclusively for medications and medication adjuncts.

(iii) The inside temperature of a refrigerator in which drugs are stored shall be maintained within a thirty-six degree (36°) to forty-six degree (46°) Fahrenheit range.

(D) All drugs shall be kept in containers that have been labeled by a pharmacist or in their original containers labeled by their manufacturer and shall not be transferred from the containers in which they were obtained except for preparation of a dose for administration. Drugs to be dispensed to patients on leaves of absence or at the time of discharge from the facility shall be packaged in accordance with the provisions of the Federal Poison Prevention Act and any other applicable Federal or State Law.

(E) Drugs and biologicals shall be properly labeled as follows:
(i) Floor stock containers shall be labeled at least with the following information: name and strength of drug; manufacturer's lot number or internal control number; and, expiration date.

(ii) The label for containers of medication dispensed from an institutional pharmacy for inpatient use shall include at least the following information: name of the patient; name of prescribing practitioner; name, strength and quantity of drug dispensed; expiration date.

(iii) The label for containers of medication obtained from a community pharmacy for inpatient use shall include at least the following information: name, address and telephone number of the dispensing pharmacy; name of the patient; name of the prescribing practitioner; name, strength and quantity of drug dispensed, date of dispensing the medication; expiration date. Specific directions for use must be included in the labeling of prescriptions containing controlled substances.

(iv) The label for containers of medication dispensed to patients for inpatient self care use, or during leaves of absence or at discharge from the facility shall include at least the following information: name, address and telephone number of the dispensing pharmacy; name of the patient; name of the prescribing practitioner; specific directions for use; name, strength and quantity of the drug dispensed; date of dispensing.

(v) In cases where a multiple dose package is too small to accommodate a standard prescription label, the standard label may be placed on an outer container into which the multiple dose package is placed. A reference label containing the name of the patient, prescription serial number and the name and strength of the drug shall be attached to the actual multiple dose package. Injectables intended for single dose that are ordered in a multiple quantity may be banded together for dispensing and one (1) label placed on the outside of the banded package.

(vi) In lieu of explicitly stated expiration dating on the prescription container label, a system established by facility policy may be used for controlling the expiration dating of time-dated drugs.

(F) Drugs on the premises of the facility which are outdated, visibly deteriorated, unlabeled, inadequately labeled, discontinued, or obsolete shall be disposed of in accordance with the following requirements:

(i) Controlled substances shall be disposed of in accordance with Section 21a-262-3 of the regulations of Connecticut State Agencies.

(ii) Non-controlled substances shall be destroyed on the premises by a licensed nurse or pharmacist in the presence of another staff person, in a safe manner so as to render the drugs non-recoverable. The facility shall maintain a record of any such destructions which shall include as a minimum the following information: date, strength, form and quantity of drugs destroyed; and the signatures of the persons destroying the drugs and witnessing the destruction.

(iii) Records for the destruction of drugs shall be kept on file for three (3) years.
(G) Current pharmaceutical reference material shall be kept on the premises in order to provide the professional staff with complete information concerning drugs.

(H) The following additional requirements shall apply to any unit dose drug distribution system:

(i) Each single unit or unit dose of a drug shall be packaged in a manner that protects the drug from contamination or deterioration and prevents release of the drug until the time the package is opened deliberately.

(ii) A clear, legible label shall be printed on or affixed securely to each package of a single unit or unit dose of a drug. Each drug label shall include the name; strength; for each unit dose package, the dosage amount of the drug; the lot or control number; and the expiration date for any time-dated drugs.

(iii) Packages of single unit or unit doses of drugs shall be placed, transported and kept in individual compartments.

(iv) Each individual drug compartment shall be labeled with the full name of the patient, and the patient's room number or bed number.

(I) The facility shall implement a drug recall procedure which can be readily implemented.

(5) Each facility shall develop and follow current written policies and procedures for the safe prescribing and administration of drugs.

(A) Medication orders shall be explicit as to drug, dose, route, frequency, and if P.R.N., reason for use.

(i) Medications not specifically limited as to time or number of doses shall be stopped in accordance with the following time frame: controlled substances shall be stopped within three (3) days; antibiotics and other antiinfectives (topical and systemic), anti-coagulants, antiemetics, corticosteroids (topical and systemic), cough and cold preparations, and psychotherapeutic agents shall be stopped within ten (10) days.

(ii) Orders for all other drugs shall remain in effect until the time of the next scheduled visit of the physician.

(iii) A staff member shall notify the practitioner of the impending stop order prior to the time the drug would be automatically stopped in accordance with the preceding policy.

(B) Patients shall be permitted to self-administer medications on a specific written order from the physician. Self-administered medication shall be monitored and controlled in accordance with procedures established in the facility.

(C) Medication errors and apparent adverse drug reactions shall be recorded in the patient's medical record, reported to the attending physician, director of nursing, and consultant pharmacist, as appropriate, and described in a full incident report in accordance with Section 19-13-D8t (g) of the Regulations of Connecticut State Agencies.
(6) A pharmacy and therapeutics committee shall oversee the pharmaceutical services provided to each facility, make recommendations for improvement thereto, and monitor the service to ensure its accuracy and adequacy.

(A) The committee shall be composed of at least one pharmacist, the facility’s director of nursing, the facility’s administrator, and a physician.

(B) The committee shall meet, at least quarterly, and document its activities, findings and recommendations.

(C) Specific functions of the committee shall, as a minimum, include the following:

(i) Developing procedures for the distribution and control of drugs and biologicals in the facility in accordance with these regulations;

(ii) Reviewing adverse drug reactions that occur in the facility and reporting clinically significant incidents to the Federal Food and Drug Administration; and

(iii) Reviewing medication errors that occur in the facility and recommending appropriate action to minimize the recurrence of such incidents.

(Effective March 30, 1994)

6.7 Pharmacy Services

6.7.1 Each nursing facility shall have a consultant pharmacist who shall be responsible for the general supervision of the nursing facility’s pharmaceutical services.

6.7.2 For a resident admitted or readmitted from the hospital with orders for nine or more medications (excluding over-the-counter medications), the facility shall complete an on-site or off-site pharmacy review within 10 days of admission or readmission.

6.8 Medications

6.8.1 Medication Administration

6.8.1.1 All medications (prescription and over-the-counter) shall be administered to residents in accordance with orders which are signed and dated by the ordering physician or prescriber. Each medication shall have a documented supporting diagnosis. Verbal or telephone orders shall be written by the nurse receiving the order and then signed by the ordering physician or prescriber within 10 days.

6.8.1.2 Standing orders may be established for over-the-counter medications that have been approved by the resident’s attending physician.
6.8.1.3 Standing orders shall be initiated by licensed nurses, but shall not be used for more than 72 hours without approval by the physician.

6.8.1.4 When any standing order is initiated, it shall be written as a complete order on the MAR for the specified time period and charted when administered.

6.8.1.5 Medications shall be given only to the individual resident for whom the prescription or order was issued, and shall be given in accordance with the prescriber’s instructions.

6.8.1.6 An individual resident may self-administer medications upon the written order of the physician, following determination by the interdisciplinary team that this practice is safe. The facility shall establish policies and procedures pertaining to the security of self-administered medication.

6.8.1.7 The facility's policies and procedures shall not prohibit or restrict a resident from receiving medications from the pharmacy of the resident’s choice. However, the resident and/or his representative shall be informed of any ramifications of ordering medications from other than the facility’s pharmacy, such as cost differences, responsibility for delivery of medication to the facility and length of ordering time.

6.8.1.8 Only licensed nurses shall administer medications and then record the administration on the resident’s Medication Administration Record (MAR) immediately after administration to that resident.

6.8.1.9 The facility shall ensure that licensed nurses administering medications count controlled substances at the beginning and end of each shift. The on-coming medication nurse shall conduct, verify, and document the controlled substance count in the presence of the off-going medication nurse.

6.8.1.10 Any medications removed but not administered to the resident shall not be returned to the original container. In circumstances such as refusal of drugs by the resident, the drugs shall be discarded and the refusal recorded on the resident’s Medication Administration Record (MAR). If the medication is a controlled substance, the signature of the administering nurse is required on the record of the controlled substance count.

6.8.1.11 Each nursing home shall have available a current edition of at least one drug reference text for the nursing staff.

6.8.1.12 Medication shall be released to residents on discharge or transfer only by the written authorization of the resident’s physician. A resident who leaves the nursing facility on a short leave may be issued a quantity of medication to meet his/her needs, with the approval of the resident’s physician.

6.8.1.13 The barrel, plunger, needle and contents of disposable hypodermic syringes shall be properly discarded in accordance with OSHA regulations immediately after use.

6.8.1.14 The administrator or designee shall notify the Office of Controlled Substances in the Division of Professional Regulation and the Division of Long Term Care Residents Protection of any unexplained loss of controlled substances, syringes, needles, or prescription pads within 8 hours of discovery of such loss or theft.
6.8.2 Medication Storage and Stocks

6.8.2.1 Stock supplies of drugs available without a prescription (over-the-counter drugs such as antacids, aspirin, laxatives) may be kept in the facility. These over-the-counter drugs shall be labeled "house stock".

6.8.2.2 All medications shall be stored in a locked cabinet. The key to the cabinet shall be kept in the control of the licensed nurse responsible for the administration of medications.

6.8.2.3 Prescription medications for emergency or interim use may be stocked by the facility subject to Board of Pharmacy regulations.

6.8.3 Medication Labeling

6.8.3.1 Medications shall be labeled in accordance with 24 Delaware Code, §2522 and the regulations of the Board of Pharmacy.

6.8.3.2 Medications dispensed using a unit dose system shall be pharmacy-prepared or manufacturer-prepared in individually packaged and sealed doses that are identifiable and properly labeled. The label shall include, at a minimum, the brand and/or generic name of the medication, strength, and lot number and expiration date.

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DISTRICT OF COLUMBIA

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3224 SUPERVISION OF PHARMACEUTICAL SERVICES

3224.1 Each facility shall establish methods and written procedures for dispensing and administering drugs and biologicals.

3224.2 The pharmaceutical services shall be under the supervision of a licensed pharmacist for developing, coordinating and supervising pharmaceutical services.

3224.3 The supervising pharmacist shall do the following:

(a) Review the drug regimen of each resident at least monthly and report any irregularities to the Medical Director, Administrator, and Director of Nursing Services;

(b) Submit a written report to the Administrator on the status of the pharmaceutical services and staff performance, at least quarterly;
(c) Provide a minimum of two (2) in-service sessions per year to all nursing employees, including one (1) session that includes indications, contraindications and possible side effects of commonly used medications;

(d) Establish a system of records of receipt and disposition of all controlled substances in sufficient detail to enable an accurate reconciliation; and

(e) Determine that drug records are in order and that an account of all controlled substances is maintained and periodically reconciled.

3224.4 If the facility has an on-site pharmacy, it shall be administered by the supervising licensed pharmacist.

3224.5 If the facility does not have a pharmacy, it shall arrange for prompt and convenient methods to obtain prescribed medications and biologicals twenty-four (24) hours a day from a provider pharmacy and shall contract with a consultant pharmacist who shall supervise pharmaceutical services.

3224.6 Any arrangement by a facility to obtain prescribed medications and biologicals from a provider pharmacy shall be pursuant to a written agreement between the facility and the provider pharmacist; any arrangement by the facility to employ a consultant pharmacist shall be pursuant to a written agreement between the facility and the consultant pharmacist.

3224.7 If the facility does not have a pharmacy but maintains a supply of medications, the consulting or supervisory pharmacist shall do the following:

(a) Control all bulk medications and maintain records of receipt and disposition;

(b) Dispense medication, properly label them, and make them available to appropriate licensed nursing employees;

(c) Provide for emergency withdrawal of medications from the medication supply; and

(d) Be a member of the Infection Control Committee and be available for resident care meetings.


3225. PHYSICIAN ORDERS FOR MEDICATIONS

3225.1 A medication may only be administered to a resident if it has been ordered in writing by a physician, except as provided by subsection 3225.2.

3225.2 Medication may be ordered by telephone if:

(a) The order is given by a physician or licensed advanced registered nurse;
(b) The order is reduced to writing immediately in the resident's medical record by the person taking the order; and

(c) The order is taken by a licensed registered or practical nurse and countersigned by the physician within ten (10) days.

3225.3 Physician orders may be transmitted by facsimile if the facility establishes adequate safeguards to ensure secure transmittal.

3225.4 Each medication order shall state:

(a) The name and strength of the medication;

(b) The dosage;

(c) The duration;

(d) The form of the drug;

(e) The frequency and time of administration; and

(f) The route of administration.

3225.5 The attending physician shall record on the resident’s medical record each condition for which the medication has been ordered.

3225.6 Each allergy shall be documented in the resident’s medical record.

3225.7 Each resident’s attending physician shall be notified of any stop order policies and contacted promptly by the licensed nurse for renewal of each medication order to provide continuity of the resident’s therapeutic regimen.

3226 ADMINISTRATION OF MEDICATION

3226.1 Unless administered under a self-administer order, all medication shall be prepared and administered only by a licensed physician or by a licensed nurse.

3226.2 Each dose of medication shall be properly and promptly recorded and initialed in the resident’s medical record by the person who administers it.

3226.3 Each item necessary for the proper preparation and administration of medication shall be available at each nursing station.

3226.4 All medication shall be prepared immediately preceding administration and each person who prepares the medication shall administer the medication.
3226.5 The medication for self-administration shall be securely stored and accessible only to the appropriate resident and staff.

3226.6 Medication shall be released to a resident upon discharge only on the authorization of his or her physician.

3226.7 Current medication reference text and sources of information such as text on pharmacology, dosages, the “Physician’s Desk Reference” or the “American Society of Hospital Pharmacists Formally” shall be available at each nursing station.

3226.8 No medication shall be administered to a resident more than sixty (60) minutes before or after the time stated in the prescription order by his or her physician.

3226.9 The facility shall document medication errors and error rates, and shall maintain the documentation for a period of three years from the date of the error.

3227 LABELING AND STORAGE OF MEDICATION

3227.1 Medication shall be stored in accordance with this section.

3227.2 Each medication area, including each cabinet or cart shall be well lighted and large enough to permit storage without crowding and shall be clean and orderly.

3227.3 Proper storage temperature shall be maintained for each medication according to the manufacturer’s direction.

3227.4 Medication that is dispensed by a pharmacy within the facility for use within the facility shall be labeled to identify the generic chemical or brand name, strength, lot number and expiration date.

3227.5 Each label shall be securely affixed to the outside of each medication container.

3227.6 Each medication of each resident shall be kept in its original container.

3227.7 Each medication that requires refrigeration shall be kept in a pharmaceutical refrigerator or in a separate locked compartment within a refrigerator at each nursing station. 3227.8 Each refrigerator that is used for storage of medications shall operate at a temperature between thirty-six degrees (34°C) and forty-six degrees (48°F) Fahrenheit; each refrigerator shall be equipped with a thermometer that is easily readable, accurate and in proper working condition.

3227.9 Each medication that is labeled poisonous shall be kept separate from other medications in a locked cabinet.

3227.10 Each medication container that has a soiled, damaged, illegible or otherwise incomplete label on it shall be returned to the pharmacy for relabeling or shall be destroyed.

3227.11 No employee other than a pharmacist shall package, repackage, return to a container or label in whole or in part any medication, or alter in any way a medication label.
3227.12 Each expired medication shall be removed from usage.

3227.13 Each medication that is no longer in use shall be destroyed or returned to the in-house pharmacy.

3227.14 Destruction of controlled substances shall be witnessed by two (2) licensed nurses and a signed and dated notation shall be made in the resident’s medical record.

3227.15 Each unopened, sealed medication may be returned to the issuing pharmacy.

3227.16 No medication container shall be reused.

3227.17 A separate double locked cabinet, permanently affixed compartment box or drawer within a locked cabinet shall provide for the storage of each substance that is controlled by the D.C. Uniform Controlled Substance Act, effective August 5, 1981, D.C. Law 4-29, D.C. Code § 33-501 et seq., and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and missing doses can be readily detected.

3227.18 Each facility shall comply with all applicable District and federal laws, regulations, standards, administrative guidelines, and rules that regulate the procurement, handling, storage, administering, and recording of medication.

3227.19 The facility shall label drugs and biologicals in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and their expiration date.

**FLORIDA**

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59A-4.112 Pharmacy Services.

(1) The facility shall adopt procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals, to meet the needs of each resident.

(2) The facility shall employ, or obtain, the services of a state licensed consultant pharmacist. A consultant pharmacist is a pharmacist who is licensed by the Department of Business and Professional Regulation and registered as a consultant pharmacist by the Board of Pharmacy in accordance with Rule 64B16-26.300, F.A.C., and who provides consultation on all aspects of the provision of pharmacy services in the facility.
(3) The consultant pharmacist shall establish a system to accurately record the receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation.

(4) The pharmacist shall determine that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

(5) Drugs and biologicals used in the facility shall be labeled in accordance with currently accepted professional principles, Chapter 499, F.S., and Chapter 64B16, F.A.C.

(6) Drugs and non-prescription medications requiring refrigeration shall be stored in a refrigerator. When stored in a general-use refrigerator, they shall be stored in a separate, covered, waterproof, and labeled receptacle.

(7) All controlled substances shall be disposed of in accordance with state and federal laws. All non-controlled substances may be destroyed in accordance with the facility’s policies and procedures. Records of the disposition of all substances shall be maintained in sufficient detail to enable an accurate reconciliation.

(8) Non-controlled substances, in unit dose containers, may be returned to the dispensing pharmacy.

(9) If ordered by the resident’s physician, the resident may, upon discharge, take all current prescription drugs with him. An inventory of the drugs released shall be completed, shall be dated, and signed by both the person releasing the drugs and the person receiving the drugs, and shall be placed in the resident’s record.

(10) The facility shall maintain an Emergency Medication Kit, the contents of which shall be determined in consultation with the Medical Director, Director of Nursing and Pharmacist, and it shall be in accordance with facility policies and procedures. The kit shall be readily available and shall be kept sealed. All items in the kit shall be properly labeled. The facility shall maintain an accurate log of receipt and disposition of each item in the Emergency Medication Kit. An inventory of the contents of the Emergency Medication Kit shall be attached to the outside of the kit. If the seal is broken, the kit must be resealed the next business day after use.
400.23 Specific Authority 400.23 FS. Law Implemented 400.022, 400.102, 400.141, 400.23 FS.
History–New 4-1-82, Amended 4-1-84, 7-10-91, Formerly 10D-29.112, Amended 4-18-94.

400.141 Administration and management of nursing home facilities.

(1) Every licensed facility shall comply with all applicable standards and rules of the agency and shall:

... (d) Provide for resident use of a community pharmacy as specified in s. 400.022(1)(q). Any other law to the contrary notwithstanding, a registered pharmacist licensed in Florida, that is under contract with a facility licensed under this chapter or chapter 429, shall repack a nursing facility resident’s bulk prescription medication which has been packaged by another pharmacist licensed in any state in the United States into a unit dose system compatible with the system used by the nursing facility, if the pharmacist is requested to offer such service. In order to be eligible for the repackaging, a resident or the resident’s spouse must receive prescription medication benefits provided through a former employer as part of his or her retirement benefits, a qualified pension plan as specified in s. 4972 of the Internal Revenue Code, a federal retirement program as specified under 5 C.F.R. s. 831, or a long-term care policy as defined in s. 627.9404(1). A pharmacist who correctly repackages and relabels the medication and the nursing facility which correctly administers such repackaged medication under this paragraph may not be held liable in any civil or administrative action arising from the repackaging. In order to be eligible for the repackaging, a nursing facility resident for whom the medication is to be repackaged shall sign an informed consent form provided by the facility which includes an explanation of the repackaging process and which notifies the resident of the immunities from liability provided in this paragraph. A pharmacist who repackages and relabels prescription medications, as authorized under this paragraph, may charge a reasonable fee for costs resulting from the implementation of this provision.

GEORGIA

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290-5-8-.08 Pharmacy Management and Administration.

Each home shall provide pharmaceutical services in full compliance with State and Federal laws and regulations.

290-5-8-.10 Medical, Dental and Nursing Care.

...(6) All medications, administered to patients must be ordered in writing by the patient’s
physician or oral orders may be given to a licensed nurse, immediately reduced to writing, signed by the nurse and countersigned by the physician as soon as practical. Medications not specifically limited as to time or number of doses, when ordered, must be automatically stopped in accordance with written policy approved by the organized professional staff.

(a) The patient’s attending physician shall be notified of stop order policies and contacted promptly for renewal of such orders so that continuity of the patient’s therapeutic regimen is not interrupted.

(7) All medications must be administered by medical or nursing personnel in accordance with the Medical and Nurse Practice Acts of the State of Georgia. Each dose administered shall be properly recorded in the clinical records:

(a) The nurses’ station shall have readily available items necessary for the proper administration of medication;

(b) In administering medications, medication cards or other State approved systems must be used and checked against the physician’s orders;

(c) Legend drugs prescribed for one patient shall not be administered to any other patient unless ordered by a physician;

(d) Self-administration of medications by patients should be discouraged except for emergency drugs on special order of the patient’s physician or in a predischarge program under the supervision of a licensed nurse;

(e) Medication errors and drug reactions shall be immediately reported to the patient’s physician and an entry thereof made in the patient’s clinical records as well as on an incident report;

(f) Up-to-date medication reference texts and sources of information shall be available.

HAWAI'I

§11-94-27 Pharmaceutical services.

(a) The facility shall employ a licensed pharmacist, or shall have a formal contractual arrangement with a licensed pharmacist to provide consultation on methods and procedures for ordering, storage, administration, disposal, recordkeeping of drugs and biologicals, and provision for emergency services.

(b) There shall be a current pharmacy policy manual developed and approved by the pharmacist, physician, and licensed nursing staff which:
(1) Includes policies and procedures and defines the functions and responsibilities relating to pharmacy services.

(2) Is revised as necessary to keep abreast of current developments in overall drug usage.

(3) Governs the safe administration and handling of all drugs.

(4) Includes policies regarding self-administration of drugs.

(5) Includes a formulary appropriate to the facility.

(c) Medications administered to a patient shall be ordered either in writing or verbally by a physician so authorized by facility policy.

(1) Physician's verbal orders for prescription drugs shall be given only to a licensed nurse, pharmacist, or another physician.

(2) All verbal or telephone orders for medication shall be recorded and signed by the person receiving them and shall be countersigned by the attending physician within seventy-two hours.

(3) All orders shall be reviewed by the physician at the time of visit to the patient.

(d) Each drug shall be rechecked and identified immediately prior to administration.

(e) Medications shall not be used for any patient other than the one for whom they were issued.

(f) Only appropriately licensed and trained staff shall be allowed to administer drugs and shall be responsible for proper recording of the medication including the route of administration. Medication errors and drug reactions shall be recorded in the patient's chart and reported immediately to the physician who ordered the drug and an incident report shall be prepared. All incident reports shall be kept available for inspection by the director.

(g) Drugs shall be stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security.

(1) All drugs shall be kept under lock and key except when authorized personnel are in attendance.

(2) All security requirements of federal and state laws shall be satisfied as they refer to storerooms and pharmacies.

(3) Poisons, drugs used externally, and drugs taken internally shall be stored in locked, well-marked separate cabinets, at all locations.

(4) Medications that are stored in a refrigerator containing things other than drugs shall be kept apart and in a locked container.

(5) If there is a drug storeroom separate from the pharmacy, there shall be a perpetual inventory of receipts and issues of all drugs by the storerooms.
(6) Discontinued and outdated drugs, and containers with worn, illegible, or missing labels, shall be returned to the pharmacy or drug room for proper disposition.

(7) There shall be automatic stop orders on all drugs.

(8) There shall be a drug recall procedure that can be readily implemented.

(h) A pharmacist shall:

(1) Review and document monthly the record of each skilled nursing facility patient receiving medications, to determine potential adverse reactions, interactions, and contraindications. A registered nurse shall carry out this function for intermediate care facility patients.

(2) When appropriateness of drugs or dosage of such as ordered are questioned, the physician shall be consulted and a record of this consultation shall be available to the administrator.


IDAHO

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200. NURSING SERVICES.

04. Medication Administration. Medications shall be provided to patients/residents by licensed nursing staff in accordance with established written procedures which shall include at least the following: (1-1-88)

a. Administered in accordance with physician’s dentist’s or nurse practitioner’s written orders; (1-1-88)

b. The patient/resident is identified prior to administering the medication; (1-1-88)

c. Medications are administered as soon as possible after preparation; (1-1-88)

d. Medications are administered only if properly identified; (1-1-88)

e. Medications are administered by the person preparing the medication for delivery to the patient (exception: Unit dose); (1-1-88)

f. Patients/residents are observed for reactions to medications and if a reaction occurs, it is immediately reported to the charge nurse and attending physician; (1-1-88)
g. Each patient’s/resident’s medication is properly recorded on his individual medication record by the person administering the medication. The record shall include: (1-1-88)
   i. Method of administration; (1-1-88)
   ii. Name and dosage of the medication; (1-1-88)
   iii. Date and time of administration; (1-1-88)
   iv. Site of injections; (1-1-88)
   v. Name or initial (which has elsewhere been identified) of person administering the medication; (1-1-88)
   vi. Medications omitted; (1-1-88)
   vii. Medication errors (which shall be reported to the charge nurse and attending physician. (1-1-88)

201. PHARMACY SERVICES.

01. Pharmacy Service. Each SNF and ICF shall have a written agreement with a pharmacist licensed by the state of Idaho to direct, supervise and be responsible for pharmacy service in the facility. He shall be responsible for: (1-1-88)
   a. Reviewing the medication profile for each individual patient at least every thirty (30) days. The attending physician shall be advised of drug therapy duplication, incompatibilities or contraindications. (1-1-88)
   b. Reviewing all medications in the facility for expiration dates and shall be responsible for the removal of discontinued or expired drugs from use as indicated at least every ninety (90) days. (1-1-88)
   c. Reviewing the facility for proper storage of medications and dangerous chemicals at least every thirty (30) days and notifying the administrator of the facility of any nonconformance. (1-1-88)
   d. Reviewing the narcotic and dangerous drug records at least every thirty (30) days and certifying to the administrator that this inventory is correct. (1-1-88)
   e. Participating in the formulation of pharmacy service policies and procedures in conjunction with the administrator, director of nursing service, and the physician(s) responsible for the medical direction of the facility. (1-1-88)
   f. Coordinating services when more than one (1) supplier of medications is utilized by the facility. (1-1-88)
   g. Providing the administrator, on a quarterly basis, a written report of services and activities given by him at the facility and shall include any recommendations. (1-1-88)
02. Care of General Medications. The care and handling of medications shall be conducted in the following manner: (1-1-88)

a. Medications shall be administered to patients of the SNF or ICF only on the order of a person authorized by law in Idaho to prescribe medications. This order shall be recorded on the patient’s/resident’s medical record, dated and signed by the ordering physician, dentist or nurse practitioner. (1-1-88)

b. All telephone and verbal orders shall be taken by licensed nurses, pharmacists and physicians only, and shall be recorded on the patient’s/resident’s clinical record, dated and signed by the person taking the order. Telephone and verbal orders shall be countersigned by the ordering physician, dentist or nurse practitioner within seven (7) days. (1-1-88)

c. No person other than licensed nursing personnel and physicians shall administer medications. This does not include execution of duties of inhalation therapists as ordered by the attending physician. (1-1-88)

d. Nursing service personnel shall not package or repackage, bottle or label any medication, in whole or in part. (1-1-88)

e. Prescription medication shall be administered only to the patient whose name appears on the prescription legend. (1-1-88)

f. All medications shall be labeled with the original prescription legend including the name and address of the pharmacy, patient’s/resident’s name, physician’s name, prescription number, original date and refill date, dosage unit, number of dosage units, and instructions for use and drug name. (Exception: See Unit Dose System.) (1-1-88)

g. No alteration or replacement of original prescription legend shall be allowed. (1-1-88)

h. Prescription renewal or refill shall be made only under physician’s, dentist’s or nurse practitioner’s authorization. (1-1-88)

i. No medication shall be in the possession of the patient/resident unless specifically ordered by the physician on the patient’s/resident’s medical record, and in no case shall exceed two (2) units of dosage. All such medications shall be individually packaged by the pharmacist in units of dose, labeled with the patient’s/resident’s name, unit of dose, and date of distribution. The charge nurse shall maintain an inventory of these drugs on the patient’s/resident’s medical record. (1-1-88)

j. Medication containers which are poorly labeled or bear worn labels shall not be used. (1-1-88)

k. Drugs dispensed shall meet the standards established by the United States Pharmacopeia, the National Formulary, New Drugs, the Idaho Board of Pharmacy, and the U.S. Food and Drug Administration. (1-1-88)

l. All medications in the facility shall be maintained in a locked cabinet located at, or convenient to, the nurses’ station. Such cabinet shall be of adequate size, and locked when not in use. The key for the lock of this cabinet shall be carried only by licensed nursing personnel and/or the pharmacist. (1-1-88)
m. An adequate lighting system shall be provided in the drug storage area. (1-1-88)

n. Poisons and toxic chemicals shall be stored in separate locked areas apart from medications. (1-1-88)

o. External-use-only medications shall be stored only in a separate, locked area apart from internal use medications. (1-1-88)

p. All bleaches, detergents, and disinfectants shall be kept in locked utility storage, separate and apart from medicines, drugs, and food. (1-1-88)

q. Biologics and other medications requiring cold storage shall be refrigerated. A covered container in a home refrigerator is considered satisfactory storage space if the temperature is maintained at thirty-six degrees Fahrenheit (36F) to forty-five degrees Fahrenheit (45F). The temperature shall be monitored daily. (1-1-88)

r. An up-to-date medication reference index and sources of information such as the American Hospital Formulary Service of the American Society of Hospital Pharmacists, or other suitable and acceptable references, shall be provided in each unit. (1-1-88)

s. Hypodermic syringes and needles (except sterile disposables) shall be autoclaved before each use. (1-1-88)

t. Equipment for the administration of medications shall be thoroughly cleaned and suitably stored after each use. (1-1-88)

03. Care of Schedule II Drugs. Schedule II drugs shall be maintained as follows (see alternate method - "Unit Dose Pharmacy"): (1-1-88)

a. A separate schedule II drug inventory sheet shall be maintained for each patient/resident listing the patient’s/resident’s name, date the medication was received from the pharmacist, medication dose unit and number of dose units received. (1-1-88)

b. On a monthly basis or upon refill of the prescription, the charge nurse shall inventory the remaining number of dose units against the units administered to the patient/resident from the patient’s/resident’s chart medication record and certify by the nurse’s signature that the inventory is correct. (1-1-88)

c. The pharmacist shall review this inventory and certification at least every thirty (30) days. (1-1-88)

d. The schedule II drug record shall be maintained as a permanent record in the patient’s/resident’s chart. (1-1-88)

e. Schedule II drugs shall be stored in a separate, locked section of the medication storage area or cabinet. (Alternate allowed under Unit Dose Pharmacy and emergency drug kit provisions.) (1-1-88)

f. All schedule II drugs which are discontinued or which are left over after the discharge or death of a patient/resident shall be handled or returned according to applicable regulations
of the Idaho Board of Pharmacy. It shall be noted in the patient's/resident's medical record when schedule II drugs are returned. (1-1-88)

g. If there is a loss or wastage of unused portions of a prescribed schedule II drug, a notation to that effect shall be made in the nursing notes and signed by the person responsible and attested to by the Director of Nursing Services. (1-1-88)

04. Record of Medications. (7-1-93)

a. An accurate and complete record of all medication given, both prescription and nonprescription, shall be recorded in the patient's/resident's chart. The record shall also include the time given, the medication given, date, dosage, method of administration, and the name and professional designation (R.N., L.P.N.) of the person preparing and administering the medication. The first and last name initials may be used if identified fully elsewhere in the medical record. (1-1-88)

b. Entries shall be made on the patient's/resident's medication record whenever medications are started or discontinued. (1-1-88)

c. Reasons for administration of a PRN medication and the patient's/resident's response to the medication shall be documented in the nurse's notes. (1-1-88)

05. Unit Dose Pharmacy. A unit dose pharmacy system may be provided in a SNF or ICF as the drug distribution system under the following rules and regulations. (1-1-88)

a. All patients/residents of the facility shall be served by the unit dose system. (1-1-88)

b. All medications distributed to the patients/residents shall be under the unit dose system, if they are prepared and available in unit dose. (1-1-88)

c. The unit dose system shall be on a signed, written agreement basis between the facility and the pharmacist. If the facility employs a pharmacist to operate its own in-house pharmacy, a signed, written agreement is not necessary. (1-1-88)

d. All medications shall be packaged by individual unit dose, and labeled with drug (proprietary and/or generic) name, unit of dose, and lot identification number or date packaged, and such other rules that may be promulgated by the Board of Pharmacy. The pharmacist shall maintain a log identifying the drug lot number by date packaged. (1-1-88)

e. The pharmacist (or the facility) shall provide suitable drug-distribution cabinets which can be locked, or in lieu of a locked cabinet, medications shall be stored in a room which can be locked. Safe, orderly transport of the drug distribution cabinets shall be assured by the pharmacist. (1-1-88)

f. A direct copy of all medication orders from the patient's/resident's chart shall be supplied to the pharmacist in a timely manner so that he can maintain each individual patient's/resident's medication profile in the pharmacy from which he fills each patient's/resident's twenty-four (24) hour medication orders. (1-1-88)
g. The pharmacist shall be responsible to see that each individual patient’s/resident’s medication drawer is filled from the drug distribution cabinet each twenty-four (24) hours from the patient’s/resident’s medication profile; shall record individual doses not administered from returned sets of drawers; shall indicate the reason the medication was not administered; and shall record medications supplied for the next twenty-four (24) hour period. (1-1-88)

h. Designated nursing staff shall check each patient’s/resident’s medication drawer contents against his medication profile prior to distribution to the patient/resident. (1-1-88)

i. The unit dose system is an alternate to packaging and labeling requirements and does not preclude the facility from meeting all other requirements of Section 201. (12-31-91)

06. Customized Medication Packaging. The packaging of medications commonly referred to as "blister paks,” “punch cards” and “bingo cards” may be utilized by the facility provided that measures of accountability, safety and sanitation are employed. Customized packaging is not to be interpreted to mean a unit dose system. All other requirements of Section 201 shall apply except for alternate packaging systems. (12-31-91)

07. Emergency Medication Supply. (1-1-88)

a. Certain emergency medications shall be available within the facility for occasional use where the pharmacy source is not immediately available. (1-1-88)

b. All medications included in the emergency supply shall be listed in an emergency medication formulary for the facility and reviewed and approved by the physician(s) responsible for the medical direction of the facility, director of nurses, and the administrator. (1-1-88)

c. All medication supplies of this category shall be stored apart from other prescription drugs in a separate, locked and convenient location near the nursing station. Control and access to these medications shall be limited to the nurse in charge of each shift and the pharmacist. (1-1-88)

d. Medications shall be withdrawn and administered to patients/residents from this supply on direct physician, dentist or nurse practitioner order and shall be signed by the physician, dentist or nurse practitioner on the patient’s/resident’s medical record no later than seven (7) days from the withdrawal, and a copy of the order forwarded to the pharmacist. The pharmacist shall be responsible for replacing drugs which have been withdrawn. (1-1-88)

e. All medication inventories contained within this emergency medication supply are the property and responsibility of the pharmacist, and he shall be responsible for maintenance of records for these medications. (1-1-88)
Section 300.830 Consultation Services

... g) The facility shall arrange for a consultant pharmacist as set forth in Section 300.1610.

Section 300.1610 Medication Policies and Procedures

a) Development of Medication Policies

1) Every facility shall adopt written policies and procedures for properly and promptly obtaining, dispensing, administering, returning, and disposing of drugs and medications. These policies and procedures shall be consistent with the Act and this Part and shall be followed by the facility. These policies and procedures shall be in compliance with all applicable federal, State and local laws.

2) Medication policies and procedures shall be developed with the advice of a pharmaceutical advisory committee that includes at least one licensed pharmacist, one physician, the administrator and the director of nursing. This committee shall meet at least quarterly.

b) For the purpose of this Subpart, "licensed prescriber" means a physician; a dentist; a podiatrist; an optometrist certified to use therapeutic ocular pharmaceutical agents; a physician assistant to whom prescriptive authority has been delegated by a supervising physician; or an advanced practice nurse practicing under a valid collaborative agreement.

c) All legend medications maintained in the facility shall be on individual prescription or from the licensed prescriber's personal office supply, and shall be labeled as set forth in Section 300.1640. A licensed prescriber who dispenses medication from his or her personal office supply shall comply with Sections 33 and 54.5 of the Medical Practice Act of 1987 [225 ILCS 60/33 and 54.5]; or Section 51 of the Illinois Dental Practice Act [225 ILCS 25/51]; or the Podiatric Medical Practice Act of 1987 [225 ILCS 100]; or Section 15.1 of the Illinois Optometric Practice Act of 1987 [225 ILCS 80/15.1]; or Section 15-20 of the Nursing and Advanced Practice Nursing Act [225 ILCS 65/15-20]; or Section 7.5 of the Physician Assistant Practice Act of 1987 [225 ILCS 95/7.5].

d) All medications administered shall be recorded as set forth in Section 300.1810. Medications shall not be recorded as having been administered prior to their actual administration to the resident.

e) The staff pharmacist or consultant pharmacist shall participate in the planned in-service education program of the facility on topics related to pharmaceutical service.

f) A pharmacist shall obtain a Division III license to operate an on-premises pharmacy in accordance with the Pharmacy Practice Act of 1987 [225 ILCS 85] and the rules of the Department of Professional Regulation (68 Ill. Adm. Code 1330).
g) No facility shall maintain a stock supply of controlled drugs or legend drugs, except for those in the emergency medication kits and convenience boxes, as described in this Section.

h) A facility may stock drugs that are regularly available without prescription. These shall be administered to a resident only upon the order of a licensed prescriber (see Section 300.1620). Administration shall be from the original containers, and shall be recorded in the resident's clinical record.

i) A facility may keep convenience boxes containing medications to be used for initial doses.

1) The contents and number of convenience boxes shall be determined by the pharmaceutical advisory committee. The contents shall be listed on the outside of each box.

2) Each convenience box shall be the property of and under the control of the pharmacy that supplies the contents of the box, and it shall be kept in a locked medicine room or cabinet.

3) No Schedule II controlled substances shall be kept in convenience boxes.

j) The contents and number of emergency medication kits shall be approved by the facility's pharmaceutical advisory committee, and shall be available for immediate use at all times in locations determined by the pharmaceutical advisory committee.

1) Each emergency medication kit shall be sealed after it has been checked and refilled.

2) Emergency medication kits shall also contain all of the equipment needed to administer the medications.

3) The contents of emergency medication kits shall be labeled on the outside of each kit. The kits shall be checked and refilled by the pharmacy after use and as otherwise needed. The pharmaceutical advisory committee shall review the list of substances kept in emergency medication kits at least quarterly. Written documentation of this review shall be maintained.

k) The following requirements shall be met when controlled substances are kept as part of the emergency medication kits:

1) If an emergency medication kit is not stored in a locked room or cabinet, or if the kit contains controlled substances that require refrigeration, then the controlled substances portion of the kit shall be stored separately in a locked cabinet or room (or locked refrigerator or a locked container within a refrigerator, as appropriate) and labeled with a list of the substances and a statement that they are part of the emergency medication kit. The label of the emergency medication kit shall list the substances and the specific location where they are stored.

2) Controlled substances for emergency medication kits shall be obtained from a federal Drug Enforcement Administration registered hospital, pharmacy, or licensed prescriber.
3) Only the director of nursing, registered nurse on duty, licensed practical nurse on duty, consultant pharmacist or licensed prescriber shall have access to controlled substances stored in emergency medication kits.

4) No more than ten different controlled substances shall be kept as part of an emergency medication kit, and there shall be no more than three single doses of any one controlled substance.

5) Controlled substances in emergency medication kits may be administered only by persons licensed to administer medications, in compliance with 21 CFR 1306.11 and 1306.21 and the Illinois Controlled Substances Act [720 ILCS 570].

6) A proof-of-use sheet shall be stored with each controlled substance. Entries shall be made on the proof-of-use sheet by the nursing staff or licensed prescriber when any controlled substance from the kit is used. The consultant pharmacist shall receive and file for two years a copy of all completed proof-of-use sheets.

7) Whenever the controlled substance portion of an emergency medication kit is opened, the consultant pharmacist shall be notified within 24 hours. During any period when this kit is opened, a shift count shall be done on all controlled substances until the kit is closed or locked, or the controlled substance is replaced. Shift counts are not mandatory when the kit is sealed. Forms for shift counts shall be kept with the controlled substances portion of the emergency medication kit.

8) The consultant pharmacist shall check the controlled substances portions of emergency medication kits at least monthly and so document on the outside of each kit.

9) Failure to comply with any provision of this Section or with any applicable provision of State or federal statutes or State regulations pertaining to controlled substances shall result in loss of the privilege of having or placing controlled substances in emergency medication kits until the facility can demonstrate that it is in compliance with such regulations. This is in addition to the usual methods of corrective action available to the Department, such as fines and other penalties.

1) Oxygen may be administered in a facility. The oxygen supply shall be stored and handled in accordance with the National Fire Protection Association Standard No. 99: Standard for Health Care Facilities (2002, no later amendments or editions included) for nonflammable medical gas systems. The facility shall comply with directions for use of oxygen systems as established by the manufacturer and the applicable provisions of the NFPA Life Safety Code (see Section 300.340) and NFPA 99.

1) Facilities shall store medical grade products separately from industrial grade products. The storage area for medical grade products shall be well defined with one area for receiving full medical gas vessels and another for storing empty vessels.

2) All personnel who will be handling medical gases shall be trained to recognize the various medical gas labels. Personnel shall be trained to examine all labels carefully.
3) If the facility's supplier uses 360-degree wrap-around labels to designate medical oxygen, personnel shall be specifically trained to make sure each vessel they connect to the oxygen system bears such a label.

4) All facility personnel responsible for changing or installing medical gas vessels shall be trained to connect medical gas vessels properly. Personnel shall understand how vessels are connected to the oxygen supply system and shall be alerted to the serious consequences of changing connections.

5) If a medical gas vessel fitting does not seem to connect to the oxygen system fitting, the supplier shall be contacted immediately. The vessel shall be returned to the supplier to determine the fitting or connection problem.

6) Once a medical gas vessel has been connected to the oxygen supply system, but prior to introducing the product into the system, a trained facility staff member shall ensure that the correct vessel has been connected properly.

(Source: Amended at 27 Ill. Reg. 5862, effective April 01, 2003)

Section 300.1620 Compliance with Licensed Prescriber’s Orders

a) All medications shall be given only upon the written, facsimile or electronic order of a licensed prescriber. The facsimile or electronic order of a licensed prescriber shall be authenticated by the licensed prescriber within 10 calendar days, in accordance with Section 300.1810. All such orders shall have the handwritten signature (or unique identifier) of the licensed prescriber. (Rubber stamp signatures are not acceptable.) These medications shall be administered as ordered-by the licensed prescriber and at the designated time.

b) Telephone orders may be taken by a registered nurse, licensed practical nurse or licensed pharmacist. All such orders shall be immediately written on the resident’s clinical record or a telephone order form and signed by the nurse or pharmacist taking the order. These orders shall be countersigned by the licensed prescriber within 10 calendar days.

c) Review of medication orders: The staff pharmacist or consultant pharmacist shall review the medical record, including licensed prescribers’ orders and laboratory test results, at least monthly and, based on their clinical experience and judgment, and Section 300.Appendix F, determine if there are irregularities that may cause potential adverse reactions, allergies, contraindications, medication errors, or ineffectiveness. This review shall be done at the facility and shall be documented in the clinical record. Any irregularities noted shall be reported to the attending physician, the advisory physician, the director of nursing and the administrator, and shall be acted upon.

d) A medication order not specifically limiting the time or number of doses shall be automatically stopped in accordance with written policies approved by the pharmaceutical advisory committee.
e) The resident’s licensed prescriber shall be notified of medications about to be stopped so that the licensed prescriber may promptly renew such orders to avoid interruption of the resident’s therapeutic regimen.

f) The licensed prescriber shall approve the release of any medications to the resident, or person responsible for the resident’s care, at the time of discharge or when the resident is going to be temporarily out of the facility at medication time. Disposition of the medications shall be noted in the resident’s clinical record.

(Source: Amended at 27 Ill. Reg. 5862, effective April 01, 2003)

Section 300.1630 ADMINISTRATION of Medication

a) All medications shall be administered only by personnel who are licensed to administer medications, in accordance with their respective licensing requirements. Licensed practical nurses shall have successfully completed a course in pharmacology or have at least one year’s full-time supervised experience in administering medications in a health care setting if their duties include administering medications to residents.

1) Medications shall be administered as soon as possible after doses are prepared at the facility and shall be administered by the same person who prepared the doses for administration, except under single unit dose packaged distribution systems.

2) Each dose administered shall be properly recorded in the clinical record by the person who administered the dose. (See Section 300.1810.)

3) Self-administration of medication shall be permitted only upon the written order of the licensed prescriber.

b) The facility shall have medication records that shall be used and checked against the licensed prescriber’s orders to assure proper administration of medicine to each resident. Medication records shall include or be accompanied by recent photographs or other means of easy, accurate resident identification. Medication records shall contain the resident’s name, diagnoses, known allergies, current medications, dosages, directions for use, and, if available, a history of prescription and non-prescription medications taken by the resident during the 30 days prior to admission to the facility.

c) Medications prescribed for one resident shall not be administered to another resident.

d) If, for any reason, a licensed prescriber’s medication order cannot be followed, the licensed prescriber shall be notified as soon as is reasonable, depending upon the situation, and a notation made in the resident’s record.

e) Medication errors and drug reactions shall be immediately reported to the resident’s physician, licensed prescriber if other than a physician, the consulting pharmacist and the dispensing pharmacist (if the consulting pharmacist and dispensing pharmacist are not associated with the same pharmacy). An entry shall be made in the resident’s clinical record, and the error or reaction shall also be described in an incident report.
f) Nurses’ stations shall be equipped as per Sections 300.2860 or 300.3060 and shall have all necessary items readily available for the proper administration of medications.

g) Current medication references shall be available, such as the current edition of "Drug Facts and Comparisons", "Hospital Formulary", "USP-DI (United States Pharmacopeia-Drug Information)", "Physician's Desk Reference" or other suitable references.

(Source: Amended at 27 Ill. Reg. 5862, effective April 01, 2003)

Section 300.1640  Labeling and Storage of Medications

a) All medications for all residents shall be properly labeled and stored at, or near, the nurses’ station, in a locked cabinet, a locked medication room, or one or more locked mobile medication carts of satisfactory design for such storage. (See subsections (f) and (g) of this Section.)

1) These cabinets, rooms, and carts shall be well lighted and of sufficient size to permit storage without crowding.

2) All mobile medication carts shall be under the visual control of the responsible nurse at all times when not stored safely and securely.

b) All medications for external use shall be kept in a separate area in the medicine cabinet, medicine room, or mobile medication cart.

c) All poisonous substances and other hazardous compounds shall be kept in a separate locked container away from medications.

d) Biologicals or medications requiring refrigeration shall be kept in a separate, securely fastened locked box within a refrigerator or a locked refrigerator, at or near the nurses’ station or in a refrigerator within a locked medication room.

e) The key or access code to the medicine cabinet, medicine room, or mobile medication cart shall be the responsibility of, and in the possession of, the persons authorized to handle and administer medications, at all times.

(f) The label of each individual multi-dose medication container filled by a pharmacist shall clearly indicate the resident's full name; licensed prescriber's name; prescription number, name, strength and quantity of drug; date this container was last filled; the initials of the pharmacist filling the prescription; the name and address of the pharmacy; and any necessary special instructions. If the individual multi-dose medication container is dispensed by a licensed prescriber from his or her own supply, the label shall clearly indicate all of the preceding information and the source of supply; it shall exclude identification of the pharmacy, pharmacist and prescription number.

g) Each single unit or unit dose package shall bear the proprietary or nonproprietary name of the drug, strength of dose and total contents delivered, lot or control number, and expiration date, if applicable. The names of the resident and the licensed prescriber do not have to be on the label of the package, but they must be identified with the package in such
a manner as to assure that the drug is administered to the right resident. Appropriate
accessory and cautionary statements and any necessary special instruction shall be
included, as applicable. Hardware for storing and delivering the medications shall be
labeled with the identity of the dispensing pharmacy. The pharmacist shall provide
written verification of the date the medications were dispensed and the initials (or unique
identifier) of the pharmacist who reviewed and verified the medications. The pharmacist
need not store such verification at the facility but shall readily make it available to the
Department upon request. The lot or control number need not appear on unit dose
packages if the dispensing pharmacy has a system for identifying those doses recalled by
the manufacturer/distributor or if the dispensing pharmacy will recall and destroy all
dispensed doses of a recalled medication, irrespective of a manufacturer's/distributor's
specifically recalled lot.

h) Medication in containers having soiled, damaged, incomplete, illegible, or makeshift
labels shall be returned to the issuing pharmacist, pharmacy, or dispensing licensed
prescriber for relabeling or disposal. Medications whose directions for use have changed
since the medication was originally dispensed and labeled may be retained for use at the
facility, in accordance with the licensed prescriber's current medication order. Medications
in containers having no labels shall be destroyed in accordance with federal and State laws.

i) The medications of each resident shall be kept and stored in their originally received
containers. Medications shall not be transferred between containers, except that a licensed
nurse, acting as the agent of the resident, may remove previously dispensed medication
from original containers and place it in other containers to be sent with a resident when the
resident will be out of the facility at the time of scheduled administration of medication.
When medication is sent out of the facility with the resident, it shall be labeled by the nurse
with the name of the resident, name and strength of the medication, instructions for
administration and any other appropriate information.

(Source: Amended at 27 Ill. Reg. 5862, effective April 01, 2003)

Section 300.1650 Control of Medications

a) The facility shall comply with all federal and State laws and State regulations relating to
the procurement, storage, dispensing, administration, and disposal of medications.

b) All Schedule II controlled substances shall be stored so that two separate locks, using two
different keys, must be unlocked to obtain these substances. This may be accomplished by
several methods, such as locked cabinets within locked medicine rooms; separately locked,
securely fastened boxes (or drawers) within a locked medicine cabinet; locked portable
medication carts that are stored in locked medicine rooms when not in use; or portable
medication carts containing a separate locked area within the locked medication cart, when
such cart is made immobile.

c) All medications having an expiration date that has passed, and all medications of
residents who have been discharged or who have died shall be disposed of in accordance
with the written policies and procedures established by the facility in accordance with
Section 300.1610. Medications shall be transferred with a resident, upon the order of the
resident’s physician, when a resident transfers to another facility. All discontinued medications, with the exception of those products regulated and defined as controlled substances under Section 802 of the federal Controlled Substances Act (21 USC 802), shall be returned to the dispensing pharmacy. Medications for any resident who has been temporarily transferred to a hospital shall be kept in the facility. Medications may be given to a discharged resident only upon the order of the licensed prescriber.

d) Inventory Controls

1) For all Schedule II controlled substances, a controlled substances record shall be maintained that lists on separate sheets, for each type and strength of Schedule II controlled substance, the following information: date, time administered, name of resident, dose, licensed prescriber’s name, signature of person administering dose, and number of doses remaining.

2) The pharmaceutical advisory committee may also require that other medications shall be subject to such inventory records.

(Source: Amended at 27 Ill. Reg. 5862, effective April 01, 2003)

410 IAC 16.2-3.1-14 Personnel

... (j) Medication shall be administered by licensed nursing personnel or qualified medication aides. If medication aides handle or administer drugs or perform treatments requiring medications, the facility shall ensure that the persons have been properly qualified in medication administration by a state-approved course. Injectable medications shall be given only by licensed personnel.

410 IAC 16.2-3.1-25 Pharmacy services

Authority: IC 16-28-1-7; IC 16-28-1-12 Affected: IC 16-28-5-1; IC 25-26-13

Sec. 25. (a) The facility must provide routine and emergency drugs and biologicals to its residents or obtain them under an agreement.

(b) The administration of drugs and treatments, including alcoholic beverages, nutrition concentrates, and therapeutic supplements, shall be as ordered by the attending physician and shall be supervised by a licensed nurse as follows:

(1) Medication shall be administered by licensed nursing personnel or qualified medication aides. When other than licensed personnel administer drugs, the facility shall ensure that
the person has been properly qualified in medication administration by a state approved course.

(2) The resident shall be observed for effects of medications. Documentation of any undesirable effects shall be contained in the clinical record. The physician shall be notified immediately if undesirable effects occur, and such notification shall be documented in the clinical record.

(3) The individual administering the medication shall document the administration indicating the time, name of drug or treatment, and dosage (if applicable), with name or initials.

(4) Medication shall be administered by the person who has set up the doses, except under a single unit dose package system.

(5) Setting up of doses for more than one (1) scheduled administration is not permitted.

(6) Injectable medications shall be given only by licensed personnel.

(7) No medication shall be used for any resident other than the resident for whom it was prescribed.

(8) Per required need (PRN) medications may be administered only upon authorization of a licensed nurse or physician. All contacts with a nurse or physician not on the premises for authorization to administer PRNs shall be documented in the nursing notes indicating the time and date of the contact.

(9) Any error in medication administration shall be noted in the resident's record. The physician shall be notified of any error in medication administration when there are any actual or potential detrimental effects to the resident. The facility must ensure that it is free of medication error rates of five percent (5%) or greater and that residents are free of any medication errors that jeopardize their health, safety, or welfare.

(c) The facility may permit qualified medication aides and student nurses to administer drugs under the general supervision of a licensed nurse following successful completion of the state qualifying test for medication aides.

(d) Student nurses may administer medications when under the direct supervision of the instructor and the activity is part of the student's educational programs.

(e) The facility must employ or obtain the services of a licensed pharmacist who is required to do the following:

(1) Provide consultation and written reports on all aspects of the provision of pharmacy services in the facility.

(2) Establish a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation.

(3) Determine that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.
(f) If a facility operates its own duly licensed pharmacy, it shall comply with IC 25-26-13.

(g) The facility shall only utilize a pharmacy that:

1. complies with the facility policy regarding receiving, packaging, and labeling of pharmaceutical products unless contrary to state and federal laws and rules on pharmacy practices;
2. provides prescribed drugs, including the availability of a twenty-four (24) hour prescription service on a prompt and timely basis; and
3. refills prescription drugs, when needed, in order to prevent interruption of drug regimens.

(h) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

(i) The pharmacist must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon.

(j) Over-the-counter medications, prescription drugs, and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.

(k) Labeling of prescription drugs shall include the following:

1. Resident’s full name.
2. Physician’s name.
3. Prescription number.
4. Name and strength of drug.
5. Directions for use.
6. Date of issue and expiration date (when applicable).
7. Name and address of the pharmacy that filled the prescription. If a facility is supplied medication in a unit dose packaging, reasonable variations that comply with the acceptable pharmaceutical procedures are permitted.

(l) Over-the-counter medications must be identified with the following:

1. Resident name.
2. Physician name.
3. Expiration date.
4. Name of drug.
(5) Strength.

(m) In accordance with state and federal law, the facility must store all drugs and biologicals in locked compartments under proper temperature controls and permit only authorized personnel to have access to the keys.

(n) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems, in which the quantity stored is minimal and a missing dose can be readily detected.

(o) Discontinued, outdated, or deteriorated medication shall not be maintained or used in the facility. Medications shall be disposed of in compliance with federal, state, and local laws.

(p) All unused portions of any properly labeled medications, including controlled substances, shall be released to the discharged resident, along with instructions for their use, upon written order of the physician.

(q) Unopened and unexposed medication may be returned to the issuing pharmacy for credit to the appropriate party.

(r) Unused portions of medications not released with the resident or returned for credit shall be destroyed on the premises within seven (7) days by the consultant pharmacist or licensed nurse with a witness.

(s) Disposition of any released, returned, or destroyed medication shall be written in the resident's clinical record and shall include the following information:

(1) The name of the resident.

(2) The name and strength of the drug.

(3) The prescription number.

(4) The reason for disposal.

(5) The amount disposed of.

(6) The method of disposition.

(7) The date of disposal.

(8) The signatures of the persons conducting the disposal of the drug.

(t) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (a), (b), (c), (f), (g), (i), (j), (k), (l), (m), (n), or (o) is a deficiency;

(2) subsection (d), (e), (h), (p), (r), or (s) is a noncompliance; and
481-58.21(135C) Drugs, storage, and handling.

58.21(1) Drug storage for residents who are unable to take their own medications and require supervision shall meet the following requirements:

a. A cabinet with a lock, convenient to nursing service, shall be provided and used for storage of all drugs, solutions, and prescriptions; (III)

b. The drug storage cabinet shall be kept locked when not in use; (III)

c. The medication cabinet key shall be in the possession of the person directly responsible for issuing medications; (II, III)

d. Double-locked storage of Schedule II drugs shall not be required under single unit package drug distribution systems in which the quantity stored does not exceed a three-day supply and a missing dose can be readily detected. (II)

58.21(2) Drugs for external use shall be stored separately from drugs for internal use. (III)

58.21(3) Medications requiring refrigeration shall be kept in a refrigerator and separated from food and other items. A method for locking these medications shall be provided. (III)

58.21(4) All potent, poisonous, or caustic materials shall be stored separately from drugs. They shall be plainly labeled and stored in a specific, well-illuminated cabinet, closet, or storeroom and made accessible only to authorized persons. (I, II)

58.21(5) All flammable materials shall be specially stored and handled in accordance with applicable local and state fire regulations. (II) 58.21(6) A properly trained person shall be charged with the responsibility of administering non-parenteral medications.

a. The individual shall have knowledge of the purpose of the drugs, their dangers, and contraindications.

b. This person shall be a licensed nurse or physician or shall have successfully completed a department-approved medication aide course or passed a department-approved medication aide challenge examination administered by an area community college.

c. Prior to taking a department-approved medication aide course, the individual shall:
(1) Successfully complete an approved nurse aide course, nurse aide training and testing program or nurse aide competency examination.

(2) Be employed in the same facility for at least six consecutive months prior to the start of the medication aide course. This requirement is not subject to waiver.

(3) Have a letter of recommendation for admission to the medication aide course from the employing facility.

d. A person who is a nursing student or a graduate nurse may take the challenge examination in place of taking a medication aide course. This individual shall do all of the following before taking the medication aide challenge examination:

(1) Complete a clinical or nursing theory course within six months before taking the challenge examination;

(2) Successfully complete a nursing program pharmacology course within one year before taking the challenge examination;

(3) Provide to the community college a written statement from the nursing program’s pharmacology or clinical instructor indicating the individual is competent in medication administration.

(4) Successfully complete a department-approved nurse aide competency evaluation.

e. A person who has written documentation of certification as a medication aide in another state may become a medication aide in Iowa by successfully completing a department-approved nurse aide competency examination and a medication aide challenge examination.

The requirements of paragraph "c" of this subrule do not apply to this individual.

58.21(7) Unless the unit dose system is used, the person assigned the responsibility of medication administration must complete the procedure by personally preparing the dose, observing the actual act of swallowing the oral medication, and charting the medication. (II) In facilities where the unit dose system is used, the person assigned the responsibility must complete the procedure by observing the actual act of swallowing the medication and charting the medication. Medications shall be prepared on the same shift of the same day that they are administered, (II) unless the unit dose system is used.

58.21(8) An accurate written record of medications administered shall be made by the individual administering the medication. (III)

58.21(9) Records shall be kept of all Schedule II drug medications received and dispensed in accordance with the controlled drug and substance Act. (III)

58.21(10) Any unusual resident reaction shall be reported to the physician at once. (II)

58.21(11) A policy shall be established by the facility in conjunction with a licensed pharmacist to govern the distribution of prescribed medications to residents who are on leave from the facility. (III)
a. Medication may be issued to residents who will be on leave from a facility for less than 24 hours. Notwithstanding the prohibition against paper envelopes in 58.21(14)“a,” non-child-resistant containers may be used. Each container may hold only one medication. A label on each container shall indicate the date, the resident’s name, the facility, the medication, its strength, dose, and time of administration.

b. Medication for residents on leave from a facility longer than 24 hours shall be obtained in accordance with requirements established by the Iowa board of pharmacy examiners.

c. Medication distributed as above may be issued only by a nurse responsible for administering medication. (I, II, III)

58.21(12) Emergency medication tray. A nursing facility shall provide an emergency medication tray. (III) There shall be compliance with the following requirements:

a. Prescription drugs as well as nonprescription items in the tray must be prescribed or approved by the physician, in consultation with the pharmacist, who provides emergency service to the facility;

(III)

b. The tray shall be stored in an accessible place; (III)

c. The tray shall contain a list of its contents and quantities of each item on the outside cover and within the box; (III)

d. The tray shall be closed with a seal which may be broken when drugs are required in an emergency or for inspection; (III)

e. Any item removed from the tray will be replaced within 48 hours; (III)

f. A permanent record shall be kept of each time the tray is utilized; (III)

g. The tray shall be inspected by a pharmacist at least once every three months to determine the stability of items in the tray. (III)

58.21(13) Drug handling.

a. Bulk supplies of prescription drugs shall not be kept in a nursing facility unless a licensed pharmacy is established in the facility under the direct supervision and control of a pharmacist. (III)

b. Inspection of drug storage condition shall be made by the health service supervisor and a registered pharmacist not less than once every three months. The inspection shall be verified by a report signed by the nurse and pharmacist and filed with the administrator.

The report shall include, but not be limited to, certifying absence of the following: expired drugs, deteriorated drugs, improper labeling, drugs for which there is no current physician’s order, and drugs improperly stored. (III)
c. If the facility permits licensed nurses to dilute or reconstitute drugs at the nursing station, distinctive supplementary labels shall be available for the purpose. The notation on the label shall be so made as to be indelible. (III)

d. Dilution and reconstitution of drugs and their labeling shall be done by the pharmacist whenever possible. If not possible, the following shall be carried out only by the licensed nurse:

(1) Specific directions for dilution or reconstitution and expiration date should accompany the drug; (III)

(2) A distinctive supplementary label shall be affixed to the drug container when diluted or reconstituted by the nurse for other than immediate use. (III) The label shall bear the following: resident’s name, dosage and strength per unit/volume, nurse’s name, expiration date, and date and time of dilution. (III)

58.21(14) Drug safeguards.

a. All prescribed medications shall be clearly labeled indicating the resident’s full name, physician’s name, prescription number, name and strength of drug, dosage, directions for use, date of issue, and name and address and telephone number of pharmacy or physician issuing the drug. Where unit dose is used, prescribed medications shall, as a minimum, indicate the resident’s full name, physician’s name, name and strength of drug, and directions for use. Standard containers shall be utilized for dispensing drugs. Paper envelopes shall not be considered standard containers. (III)

b. Medication containers having soiled, damaged, illegible or makeshift labels shall be returned to the issuing pharmacist, pharmacy, or physician for relabeling or disposal. (III)

c. There shall be no medications or any solution in unlabeled containers. (II, III)

d. The medications of each resident shall be kept or stored in the originally received containers. (II, III)

e. Labels on containers shall be clearly legible and firmly affixed. No label shall be superimposed on another label of a drug container. (II, III)

f. When a resident is discharged or leaves the facility, the unused prescription shall be sent with the resident or with a legal representative only upon the written order of a physician. (III)

g. Unused prescription drugs prescribed for residents who are deceased shall be destroyed by a qualified nurse with a witness and notation made on the resident’s record, or, if a unit dose system is used, such drugs shall be returned to the supplying pharmacist. (III)

h. Prescriptions shall be refilled only with the permission of the attending physician. (II, III)

i. No medications prescribed for one resident may be administered to or allowed in the possession of another resident. (II)
j. Instructions shall be requested of the Iowa board of pharmacy examiners concerning disposal of unused Schedule II drugs prescribed for residents who have died or for whom the Schedule II drug was discontinued. (III)

k. There shall be a formal routine for the proper disposal of discontinued medications within a reasonable but specified time. These medications shall not be retained with the resident’s current medications. Discontinued drugs shall be destroyed by the responsible nurse with a witness and a notation made to that effect or returned to the pharmacist for destruction or resident credit. Drugs listed under the Schedule II drugs shall be disposed of in accordance with the provisions of the Iowa board of pharmacy examiners. (II, III)

l. All medication orders which do not specifically indicate the number of doses to be administered or the length of time the drug is to be administered shall be stopped automatically after a given time period. The automatic stop order may vary for different types of drugs. The physician, in consultation with the pharmacist serving the home, shall institute policies and provide procedures for review and endorsement of stop orders on drugs. This policy shall be conveniently located for personnel administering medications. (II, III)

m. No resident shall be allowed to keep possession of any medications unless the attending physician has certified in writing on the resident’s medical record that the resident is mentally and physically capable of doing so. (II)

n. Residents who have been certified in writing by the physician as capable of taking their own medications may retain these medications in their bedroom, but locked storage must be provided. (II)

o. No medications or prescription drugs shall be administered to a resident without a written order signed by the attending physician. (II)

p. A qualified nurse shall:

(1) Establish a medication schedule system which identifies the time and dosage of each medication prescribed for each resident. (II, III)

(2) Establish a medication record containing the information specified above needed to monitor each resident’s drug regimen. (II, III)

q. Telephone orders shall be taken by a qualified nurse. Orders shall be written into the resident’s record and signed by the person receiving the order. Telephone orders shall be submitted to the physician for signature within 48 hours. (III)

r. A pharmacy operating in connection with a nursing facility shall comply with the provisions of the pharmacy law requiring registration of pharmacies and the regulations of the Iowa board of pharmacy examiners. (III)

s. In a nursing facility with a pharmacy or drug supply, service shall be under the personal supervision of a pharmacist licensed to practice in the state of Iowa. (III)

58.21(15) Drug administration.
a. Injectable medications shall not be administered by anyone other than a qualified nurse or physician. In the case of a resident who has been certified by the resident’s physician as capable of taking the resident’s own insulin, the resident may inject the resident’s own insulin. (II)

b. An individual inventory record shall be maintained for each Schedule II drug prescribed for each resident. (II)

c. The health service supervisor shall be responsible for the supervision and direction of all personnel administering medications. (II)

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39-936. Statement on admission; qualified personnel; education and training of unlicensed personnel; examination and fees; state registry established; refresher course required; supplier of medication; limitations on involuntary transfer or discharge of resident; effect of reliance upon spiritual means or prayer for healing by resident.

... (f) No adult care home shall require as a condition of admission to or as a condition to continued residence in the adult care home that a person change from a supplier of medication needs of their choice to a supplier of medication selected by the adult care home. Nothing in this subsection (f) shall be construed to abrogate or affect any agreements entered into prior to the effective date of this act between the adult care home and any person seeking admission to or resident of the adult care home.

28-39-156. Pharmacy services.

The nursing facility shall provide pharmaceutical services including policies and procedures that assure the accurate acquisition, receipt, and administration of all drugs and biologicals to meet the needs of each resident.

(a) Supervision by a licensed pharmacist.

(1) A pharmacist shall develop, coordinate, and supervise all pharmacy services.

(2) The pharmacist shall perform a monthly review of the methods, procedures, storage, administration, disposal, and record-keeping of drugs and biologicals.

(3) The pharmacist shall prepare a written report which includes recommendations for the administrator after each monthly review.

(b) Ordering and labeling.
(1) All drugs and biologicals shall be ordered pursuant to a written order issued by a licensed physician.

(2) The dispensing pharmacist shall label each prescription container in accordance with K.A.R. 68-7-14.

(3) Over-the-counter drugs. The facility shall ensure that any over-the-counter drug delivered to the facility is in the original, unbroken manufacturer's package. The pharmacist or licensed nurse shall place the full name of the resident on the package. If over-the-counter drugs are removed from the original manufacturer's package other than for administration, the pharmacist shall label the drug as required for prescription drugs.

(4) Physicians, advanced registered nurse practitioners, and physician assistants shall give verbal orders for drugs only to a licensed nurse, pharmacist or another physician. The licensed nurse, physician, or pharmacist shall immediately record the verbal order in the resident's clinical record. The physician shall counter-sign all verbal orders within seven working days after receipt of the verbal order.

c) Automatic stop orders. Drugs not specifically limited as to time or number of doses when ordered shall be controlled by automatic stop orders in accordance with written policies of the facility. A licensed nurse shall notify the physician of an automatic stop order before the administration of the last dose so that the physician may decide if additional drug is to be ordered.

(d) Storage.

(1) The licensed pharmacist shall ensure that all drugs and biologicals are stored according to state and federal laws.

(2) The nursing facility shall store all drugs and biologicals in a locked medication room or a locked medication cart located at the nurses' station. Only the administrator and persons authorized to administer medications shall have keys to the medication room or the medication cart.

(3) The nursing facility shall store drugs and biologicals under sanitary conditions.

(4) The temperature of the medication room shall not exceed 85°F. The nursing facility shall store drugs and biologicals at the temperatures recommended by the manufacturer.

(e) The nursing facility shall develop and implement policies and procedures to assure that residents who self-administer drugs do so safely and accurately.

(f) Accountability and disposition. The nursing facility shall control and dispose of drugs and biologicals in a manner that ensures the safety of the resident.

(1) The nursing facility shall maintain records of receipt and disposition of all controlled substances in order that there can be an accurate reconciliation.
(2) The licensed pharmacist shall determine whether the records of drug and biological administration are in order and that an accurate account of all controlled substances was maintained and reconciled.

(3) The licensed pharmacist shall identify any deteriorated, outdated, or discontinued drugs and biologicals and any drugs or biologicals that are unused remaining from a discharged or deceased resident during the monthly pharmacy services review. The licensed pharmacist shall destroy, if appropriate, any deteriorated, outdated, unused, or discontinued drugs and biologicals at the nursing facility and in the presence of one witness who is a licensed nurse employed by the facility. A record shall be on file in the facility which contains the date, drug name, quantity of drugs and biologicals destroyed, and signatures of the pharmacist and licensed nurse.

(4) The nursing facility shall return to the dispensing pharmacy any drugs and biologicals which have been recalled and shall maintain documentation of this action in the facility.

(5) Staff members who have authority to administer drugs may provide drugs to residents or a responsible party during short-term absences from the facility.

(A) A staff member who has the authority to administer drugs may transfer drugs to a suitable container.

(B) The staff member preparing the drugs shall provide written instructions for the administration of the drugs to the resident or responsible party.

(6) The staff member preparing the drugs shall document the drugs provided and the instructions given in the resident's clinical record.

(7) The nursing facility may send drugs with a resident at the time of discharge, if so ordered by the physician.

(g) Drug regimen review.

(1) The licensed pharmacist shall review the drug regimen of each resident at least monthly.

(2) The licensed pharmacist shall document in the resident's clinical record that the drug regimen review has been performed.

(3) The licensed pharmacist shall report any irregularities to the attending physician, the director of nursing, and the medical director. The pharmacist or a licensed nurse shall act upon any responses by the physician to the report.

(4) The pharmacist shall document the drug regimen review in the resident's clinical record or on a drug regimen report form. A copy of the drug regimen review shall be available to the department.

(5) Any deviation between drugs ordered and drugs given shall be reported to the quality assessment and assurance committee.

(h) Emergency drug kits. A nursing facility may have an emergency drug kit available for use when needed.
(1) The medical director, director of nursing, and licensed pharmacist shall determine the contents of the emergency drug kit. The contents of the kit shall be periodically reviewed and drugs added and deleted as appropriate. Written documentation of these determinations shall be available in the facility.

(2) Policies and procedures shall be available for the use of the emergency drug kit.

(3) The facility shall have a system in place which ensures that drugs used from the emergency drug kit are replaced in a timely manner.

(4) The emergency drug kit shall be in compliance with K.A.R. 68-7-10 (d).

(Authorized by and implementing K.S.A. 39-932; effective Nov. 1, 1993; amended Feb. 21, 1997.)


(a) Each medication aide candidate shall be either a nurse aide who has been issued a certificate by the licensing agency or a qualified mental retardation professional as defined in 42 C.F.R. 483.430(a), revised October 1, 2001 and hereby adopted by reference, and shall meet the following requirements.

(1) Has completed a course in medication administration approved by the licensing agency; and

(2) has passed a state test as approved by the licensing agency.

(b) Each person who has met one of the following requirements shall be eligible to enroll in a medication aide course.

(1) Is a nurse aide who has a Kansas nurse aide certificate and who has been screened and tested for reading comprehension at an eighth-grade level; or

(2) is a qualified mental retardation professional employed by an intermediate care facility for the mentally retarded.

(c) A qualified mental retardation professional who is not a nurse aide, who has completed a course in medication administration as approved by the licensing agency, and who has passed the state test shall be allowed to administer medications only to residents in an intermediate care facility for the mentally retarded.

(d) Each medication aide course shall meet the following requirements:

(A) Consist of a minimum of 75 total hours, which shall include a minimum of 25 hours of clinical instruction;

(B) be prepared and administered in accordance with the guidelines prescribed by the licensing agency and follow the content outlined in the “Kansas medication aide curriculum,” dated April 1, 2003, and the “Kansas medication aide sponsor and instructor
manual,” pages 1 through 17, dated November 13, 2003, which are hereby adopted by reference and

(C) be sponsored by one of the following:

(i) A postsecondary school under the jurisdiction of the state board of regents;

(ii) a state-operated institution for the mentally retarded; or

(iii) a professional health care association approved by the licensing agency.

(2) No correspondence course shall be approved as a medication aide course.

(3) Distance-learning and computer-based educational offerings shall be required to meet the requirements specified in this subsection.

(e) Each medication aide course instructor shall meet the following requirements:

(1) Each person who intends to be a course instructor shall submit an instructor approval application form to the licensing agency at least three weeks before offering an initial course and shall be required to receive approval as an instructor before the first day of an initial course.

(2) Each instructor shall be a registered nurse with a current Kansas license and two years of clinical experience as a registered nurse. Any Kansas-licensed pharmacist actively working in the pharmacy field may conduct part of the training under the supervision of an approved instructor.

(f) Each course sponsor and course instructor shall be responsible for ensuring that the following requirements are met:

(1) Only persons who meet the qualifications specified in subsection (b) of this regulation shall be eligible to take the course.

(2) Each trainee shall be screened and tested for comprehension of the written English language at an eighth-grade reading level before enrolling in the course.

(3) The course shall be prepared and administered in accordance with the guidelines and follow the content in the “Kansas medication aide curriculum,” and the “Kansas medication aide sponsor and instructor manual,” as adopted in subsection (d) of this regulation.

(4) The clinical instruction and skills performance involving the administering of medications shall be under the direct supervision of the course instructor.

(5) During the clinical instruction and skills performance, the course instructor shall perform no other duties than the provision of direct supervision to the trainees.

(g) Any course instructor or course sponsor who does not fulfill the requirements of this regulation may be subject to withdrawal of approval to serve as a course instructor or a course sponsor.
Any person whose education or training has been deemed equivalent to the medication aide course by an approved sponsor as specified in paragraph (d)(1)(C) may apply to take the state test to become certified as a medication aide. Before requesting a determination of equivalency for a person’s education or training, that person shall be a Kansas-certified nurse aide and shall meet one of the following conditions:

1. The person is currently credentialed to administer medications in another state. The licensing agency or the designated agent shall evaluate that state’s credentialed training for equivalency in content and skills level to the requirements for certification as a medication aide in Kansas.

2. The person is currently enrolled in an accredited practical nursing or professional nursing program and has completed a course of study in pharmacology with a grade of C or better.

3. The person is currently licensed in Kansas or another state, or has been licensed within 24 months from the date of application, as a licensed mental health technician, and there are no pending or current disciplinary actions against the individual’s license.

4. The person has been licensed in Kansas or another state, within 24 months from the date of application, as a licensed practical nurse whose license is inactive or a registered nurse whose license is inactive, and there are no pending or current disciplinary actions against the individual’s license.

(Authorized by K.S.A. 75-5625; implementing K.S.A. 65-1124; effective Dec. 29, 2003.)


(a) The state test shall be administered by the licensing agency or the designated agent and in accordance with guidelines prescribed by the licensing agency as outlined in the “test administration manual for proctors of the medication aide tests,” dated October 17, 2002, which is hereby adopted by reference.

1. Each person who has completed the medication aide course as specified in K.A.R. 28-39-169a shall have a maximum of two attempts to pass the state test within 12 months after the first day of the course. If the person does not pass the test within this 12-month period, the course shall be retaken. Each time the person successfully completes the course, the personal shall have two attempts to pass the state test within 12 months after the first day of the course. The number of times a person may retake the course shall be unlimited.

2. Each person who is a Kansas-certified nurse aide and whose training has been deemed equivalent to the Kansas medication aide course shall have a maximum of one attempt to pass the test within 12 months after the date the equivalency is approved. If the person
does not pass the test within this 12-month period, the person shall be required to take the medication aide course.

(3) There shall be three different forms of the state test. The different forms of the test shall be used on an alternating basis. Each of the three forms shall be comprised of 85 multiple-choice questions. The passing scores for the three forms of the test shall be as follows:

(A) A score of 57 or higher shall constitute a passing score for form 1 of the state test.

(B) A score of 61 or higher shall constitute a passing score for form 2 of the state test.

(C) A score of 63 or higher shall constitute a passing score for form 3 of the state test.

(4) Only persons who have met the requirements specified in K.A.R. 28-39-169a(a)(1) and (h) shall be eligible to take the state test.

(5) Each person whose second language is English shall be allowed to use a bilingual dictionary while taking the state test. Limited English proficiency shall not constitute a disability with regard to accommodation. An extended testing period of up to two additional hours may be offered to persons with limited English proficiency.

(b) Each person shall be issued a medication aide certificate by the licensing agency and shall be listed on a public nurse aide registry upon successful completion of the requirements specified in K.A.R. 28-39-169a(a) and (h).

(c) The course instructor shall submit to the licensing agency a course roster of names, an application form, and a nonrefundable application fee of $20.00 for each medication aide who has completed the course and passed the state test.

(d) A replacement medication aide certificate for a medication aide whose certification is current shall be issued by the licensing agency upon the receipt and processing of a certificate replacement form and a nonrefundable fee of $20.00.

(Authorized by K.S.A. 65-1,121 and K.S.A. 75-5625; implementing K.S.A. 65-1, 121 and 65-1124; effective Dec. 29, 2003.)


(a) Each person who has a certificate of completion for a medication aide training course as specified in K.A.R. 28-39-169a and who wishes to maintain the certificate shall complete, every two years, a program of 10 hours of continuing education approved by the licensing agency.

(b) The continuing education requirement shall include one or more of the following topics:

(1) Classes of drugs and new drugs;

(2) new uses of drugs;
methods of administering drugs;

alternative treatments, including herbal drugs and their potential interaction with traditional drugs;

(5) safety in the administration of drugs; or

(6) documentation.

c) Each program of continuing education shall be sponsored by one of the following:

(1) A postsecondary school under the jurisdiction of the state board of regents;

(2) an adult care home;

(3) a long-term care unit of a hospital;

(4) a state-operated institution for the mentally retarded; or

(5) a professional health care association approved by the licensing agency.

d) Each course instructor shall be a registered nurse with a current Kansas license and two years of clinical experience as a registered nurse or a licensed practical nurse. Any Kansas-licensed pharmacist actively working in the pharmacy field may be selected to conduct part of the training under the supervision of the instructor.

e) Each person who intends to be a course instructor shall submit an instructor approval application form to the licensing agency at least three weeks before offering an initial course and shall be required to receive approval as an instructor before the first day of an initial course.

(f) Each sponsor and course instructor of continuing education shall be responsible for ensuring that the following requirements are met:

(1) The course shall be prepared and administered as prescribed by regulation and the “Kansas medication aide sponsor and instructor manual,” as adopted in K.A.R. 28-39-169a.

(2) A course approval application form shall be submitted to the licensing agency at least three weeks before offering a course, and course approval shall be required to be received before beginning the course.

(3) A course roster of names, a renewal application form, and a nonrefundable renewal application fee of $20.00 for each medication aide who has completed the course shall be submitted to the licensing agency.

(4) If clinical instruction in administering medications is included in the program, each student administering medications shall be under the direct supervision of the
registered nurse instructor.

(g) Any sponsor or instructor who does not fulfill the requirements specified in subsections (d), (e), and (f) of this regulation may be subject to withdrawal of approval to serve as a course instructor or a course sponsor.

(h) College credits or vocational training may be approved by the licensing agency as substantially equivalent to medication aide continuing education. The instructor or nursing program coordinator shall submit a department-approved form attesting that the course content is substantially equivalent to the topics listed in paragraphs (b)(1) through (6) of this regulation.

(i) Each certified medication aide shall be responsible for notifying the licensing agency of any change in the aide’s address or name.

(j) No correspondence course shall be approved for a medication aide continuing education course.

(k) Distance-learning educational offerings and computer-based educational offerings shall meet the requirements specified in subsections (b), (c), (d), (e), (f), and (g) of this regulation.

(l) Each medication aide certificate shall be renewed upon the department’s receipt from the course instructor of the following:

(1) Verification of the applicant’s completion of 10 hours of approved continuing education;

(2) a renewal application form; and

(3) a nonrefundable renewal application fee of $20.00.

(m) Each medication aide certificate or renewed certificate shall be valid for two years from the date of issue.

(n) Each applicant for renewal of certification shall have completed the required number of hours of documented and approved continuing education during each certification period immediately proceeding renewal of the certificate. Approved continuing education hours completed in excess of the requirement shall not be carried over to a subsequent renewal period.

(o) Each medication aide certificate that has been expired for three or fewer years shall be reinstated upon the department’s receipt of the following:

(1) Verification of the applicant’s completion of 10 hours of approved continuing education. This continuing education shall have been completed within the three-year period following expiration of the certification;
(2) a renewal application form; and

(3) a nonrefundable renewal application fee of $20.00.

(p) Each lapsed certificate renewed within the three-year period specified in subsection

(o) shall be valid for two years from the date of issuance.

(q) Each person whose medication aide certification has been expired for more than three years shall be required to retake the 75-hour medication aide course.

(Authorized by K.S.A. 65-1,121 and K.S.A. 75-5625; implementing K.S.A. 65-1,121 and 65-1124; effective Dec. 29, 2003.)

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Section 14. Pharmacy Services [nursing facilities].

The facility shall provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in Section 15(6)(a) and (b) of this administrative regulation.

(1) Procedures.

(a) A facility shall provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

(b) Administration of medications. All medications shall be administered by licensed medical or nursing personnel in accordance with the Medical Practice Act (KRS 311.530 to 311.620) and Nurse Practice Act (KRS Chapter 314) or by personnel who have completed a state approved training program from a state approved provider. The administration of oral and topical medicines by certified medicine technicians shall be under the supervision of licensed medical or nursing personnel. Intramuscular injections shall be administered by a licensed or registered nurse, or a physician. If intravenous injections are necessary they shall be administered by a licensed physician, registered nurse, or properly trained licensed practical nurse. Each dose administered shall be recorded in the medical record.

(2) Service consultation. The facility shall employ or obtain the services of a pharmacist licensed pursuant to KRS Chapter 315 who:

(a) Provides consultation on all aspects of the provision of pharmacy services in the facility;
(b) Establishes a system of records of receipt and disposition of all drugs in sufficient detail to enable an accurate reconciliation; and

c) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

(3) Drug regimen review.

(a) The drug regimen of each resident shall be reviewed at least once a month by a licensed pharmacist.

(b) The pharmacist shall report any irregularities to the attending physician or the director of nursing, or both, and these reports shall be acted upon.

(4) Labeling of drugs and biologicals. The facility shall label drugs and biologicals in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date.

(5) Storage of drugs and biologicals. In accordance with state and federal laws, the facility shall store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.

(6) The facility shall provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

Subchapter A. Physician Services

§9807. Standing Orders

A. Physician's standing orders are permissible but shall be individualized, taking into consideration such things as drug allergies, sex-specific orders, and the pertinent physical condition of the resident.

B. Over-the-counter drugs are to be utilized on a physician's standing orders. Controlled or prescription drugs except those commonly used in routine situations, should not be on standing orders and must be an individual order reduced to writing on the physician's order sheet as either a routine or pro re nata (prn) order. Each order shall include the following:

1. name of the medication;
2. strength of the medication;
3. specific dose of the medication (not a dose range);
4. route of administration;
5. reason for administration;
6. time interval between doses for administering the medication;
7. maximum dosage or number of times to be administered in a specific time frame; and
8. when to notify the attending physician if the medication is not effective.

C. Standing orders shall be signed and dated by the attending physician initially and at least annually thereafter.

D. A copy of the standing orders shall be maintained in the resident's active clinical record.


HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 24:56 (January 1998).

Subchapter D. Pharmaceutical Services §9825. General Requirements

A. The nursing home shall provide emergency drugs and biologicals to its residents from an emergency kit licensed by the Louisiana State Board of Pharmacy and shall provide routine and emergency drugs and biologicals, ordered by a licensed practitioner, from a licensed pharmacy. Whether drugs and biologicals are obtained from the emergency kit(s) or from a community or institutional pharmacy permitted by the Louisiana State Board of Pharmacy, the nursing home is responsible for ensuring the timely availability of such drugs and biologicals for its residents and that pharmaceutical services are provided in accordance with accepted professional standards and all appropriate federal, state, and local laws and regulations.

B. The most current edition of drug reference materials shall be available.


HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 24:58 (January 1998).

§9827. Consultant

A. If the nursing home does not employ a licensed pharmacist, it shall have a designated consultant pharmacist that provides services in accordance with accepted pharmacy
principles and standards. The minimum consultation time shall not be less than one hour per quarter, which shall not include drug regimen review activities.

B. There shall be documentation to support that the consultation time was given.


HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 24:59 (January 1998).

§9829. Labeling

A. All drug and biological containers shall be properly labeled by a licensed pharmacist following the guidelines established by the Louisiana State Board of Pharmacy.

B. The label on prepackaged (unit dose) containers shall follow the established guidelines of the Louisiana State Board of Pharmacy.

C. Over-the-counter (nonprescription) medications and biologicals, may be purchased in bulk packaging and shall be plainly labeled with the medication name and strength and any additional information in accordance with the nursing home's policies and procedures. Over-the-counter medications specifically purchased for a resident shall be labeled as previously stipulated to include the resident's name. The manufacturer's labeling information shall be present in the absence of prescription labeling.

D. The nursing home shall develop procedures to assure proper labeling for medications provided a resident for a temporary absence.

E. The nursing home shall have a procedure for the proper identification and labeling of medication brought into the nursing home from an outside source.


HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 24:59 (January 1998).

§9831. Storage

A. All drugs and biologicals shall be stored in a locked area/cabinet and kept at proper temperatures and lighting. The medicine room or medication preparation area shall have an operable sink with hot and cold water, paper towels, and a soap dispenser.

B. Access to drug storage areas shall be limited to licensed nursing personnel, the licensed nursing home administrator, and the consultant pharmacist as authorized in the nursing home's policy and procedure manual. Any unlicensed, unauthorized individual (e.g., housekeepers, maintenance personnel, etc.) needing access to drug storage areas shall be under the direct visual supervision of licensed authorized personnel.
C. Medication requiring refrigeration shall be kept separate from foods, in separate containers, within a refrigerator and stored at a temperature range of 36 to 46 F.

1. Laboratory solutions or materials awaiting laboratory pickup shall not be stored in refrigerators with food and/or medication.

2. Medication for "external use only" shall be stored separate from other medication and food.

D. Separately locked, permanently affixed compartments shall be provided for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse.

E. Medications of each resident shall be kept and stored in their originally received containers, and transferring between containers is forbidden.


HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 24:59 (January 1998).

§9833. Disposition

A. Prescription and Over-The-Counter (OTC) medications and biologicals are to be disposed of in the following manner:

1. If medication(s) and/or biological are discontinued, or the resident is discharged to the hospital, the nursing home will retain the medication(s) for up to 60 days and then destroy as described in §9833.C.2. These must be stored in an appropriately secured storage area approved by the DON and consultant pharmacist. If the resident is deceased, the medication will be disposed of as described in §9833.C.2, unless a written order of the attending physician specifies otherwise. If the resident is transferred to another facility, the medication will accompany the resident to the receiving facility, on the written order of the attending physician.

2. Controlled drugs shall not be released or sent with a resident upon transfer or discharge, except on the written order of the attending physician.

B. If the resident/legal representative receives the medications or biologicals, upon written order of the physician, documentation containing the name and the amount of the medication or biological to be received shall be completed and signed by the resident or legal representative and a facility representative acknowledging their receipt. This document shall be placed in the resident’s clinical record.

C. Expired medication(s) shall not be available for resident or staff use. These shall be destroyed on-site by nursing home personnel no later than 90 days from their expiration/discontinuation date utilizing the following methods:

1. Controlled drugs shall be destroyed on-site by a licensed pharmacist after receiving DEA authorization to do so on a continuing basis, and witnessed by a state or local law enforcement officer.
enforcement officer or other licensed nursing home individual, such as RN, LPN or MD. All controlled substances to be destroyed shall be inventoried and listed on a DEA Form 41, a copy of which shall be maintained on the premises, and a copy mailed to the Louisiana State Board of Pharmacy.

These drugs shall also be listed on the resident’s individual accumulative drug destruction record.

2. For noncontrolled drugs, there shall be documentation of the resident’s name; name, strength, and quantity of the drug destroyed; prescription number; method and date of destruction; signatures of at least two individuals (which shall be either licensed nurses who are employees of the nursing home, or the consultant pharmacist) witnessing the destruction. Medications of residents transferred to a hospital may be retained until the resident’s return. Upon the resident’s return, the physician’s order shall dictate whether or not the resident is to continue the same drug regimen as previously ordered. Medications not reordered by the physician shall be destroyed, using the procedures outlined above.


HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 24:59 (January 1998).

§9835. Administration

A. Drugs and biologicals shall not be administered to residents unless ordered by a practitioner (e.g., physician, dentist, or Doctor of Osteopathy) duly licensed to prescribe drugs. Such orders shall be in writing over the practitioner’s signature. Drugs and biologicals shall be administered only by medical personnel or licensed nurses authorized to administer drugs and biologicals under their practice act.

B. Drugs and biologicals shall be administered as soon as possible after doses are prepared, not to exceed two hours. They shall be administered by the same person who prepared the doses for administration, except under unit dose package distribution systems.

C. An individual resident may self-administer drugs if permissible by the nursing home’s policy and procedure, and if an interdisciplinary team has determined that this practice is safe. The team shall also determine who will be responsible for storage and documentation of the administration of drugs. The resident’s care plan shall reflect approval to self-administer medications.


§9837. Drug Regimen Review

The drug regimen of each resident shall be reviewed as often as dictated by the resident’s condition. Irregularities shall be reported, in writing, to the resident’s attending physician and director of nursing, and these reports shall be acted upon.

§9839. Emergency Medication Kit

A. If an emergency medication kit is used in the nursing home, a permit shall be obtained and maintained in accordance with the Louisiana State Board of Pharmacy.

B. A separate permit is required for each emergency medication kit.


§9841. Medication Record Keeping

A. General Records

1. Each resident shall have a Medication Administration Record (MAR) on which the dose of each drug or biological administered shall be properly recorded by the person administering the drug or biological to include:
   a. name, strength, and dosage of the medication;
   b. method of administration including site, if applicable;
   c. time of administration defined as one hour before to one hour after the ordered time of administration; and
   d. the initials of persons administering the medication along with a legend of the initials.

2. Medication errors and drug reactions shall be reported immediately to the resident’s attending physician by a licensed nurse, and an entry made in the resident’s record.

3. Medications not specifically prescribed as to time or number of doses shall automatically be stopped after a reasonable time that is predetermined by the nursing home’s written policy and procedures. The attending physician shall be notified of an automatic stop order prior to the last dose so that he/she may decide if the administration of the medication is to be continued or altered.

B. Controlled Drugs

1. The nursing home shall establish a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate accounting of all controlled drugs received, administered, and destroyed or otherwise disposed. Only licensed medical personnel shall be allowed to receive and sign for delivery of controlled drugs.
2. Control records of schedule II drugs shall be maintained. The individual resident records shall list each type and strength of drug and the following information:

a. date;
b. time administered;
c. name of resident;
d. dose;
e. physician's name;
f. signature of person administering the dose; and
g. the balance on hand.

C. Noncontrolled Drugs. Records of noncontrolled medication destruction shall be maintained in the resident's clinical record and shall include the following:

1. resident's name;
2. name, strength, and quantity of the medication;
3. prescription number;
4. method and date of destruction;
5. signatures of at least two individuals (which shall be either licensed nurses, who are employees of the nursing home, or the consultant pharmacist) witnessing the destruction.


HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 24:60 (January 1998).

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9.B.4. Administration of Medication by a Certified Nursing Assistant/Medications

A certified nursing assistant/medications may administer medications only when this function is assigned by a registered professional nurse and there is a licensed nurse on duty.

17.A. Pharmaceutical Services
Pharmaceutical services shall be conducted in accordance with currently accepted professional standards of practice and in accordance with all applicable laws and regulations.

Facilities shall develop policies and procedures for the prescribing (including standing orders), obtaining, dispensing, administering, controlling, storing, and disposing of all drugs and biologicals with the advice of a staff pharmacist or a consultant pharmacist and approved by the professional policy group.

17.B. Definitions

17.B.1. Adverse Drug Reaction - is any undesired or unintended effect of a medication, to include:
   a. Hypersensitivity or allergic reactions: a reaction due to a patient's immune response,
   b. Idiosyncrasy: a susceptibility or sensitivity peculiar to a rare phenotype (extreme sensitivity to low doses),
   c. Toxicity: a "poisoning" due to overdosage or accumulation,
   d. Side Effect: an undesired pharmacologic effect which is predictable.

17.B.2. Psychoactive Drugs or Agents - As defined in medical literature, are medications subdivided into five (5) therapeutic classes:
   a. Long-lasting Benzodiazepine drugs;
   b. Benzodiazepine or other anxiolytic sedative drugs;
   c. Drugs for sleep induction;
   d. Antipsychotic drugs;
   e. Antidepressant drugs.

17.B.3. Unnecessary Drug - is any drug that is used in excessive doses, for excessive periods of time, without adequate monitoring, without an appropriate diagnosis or reason for the drug, used in the presence of adverse reactions which indicate that the drug should be reduced or discontinued entirely, and any combination of the above reasons.

17.C. Supervision of Drugs and Biologicals

17.C.1. Each facility shall have a State licensed Pharmacist as a consultant.

17.C.2. Responsibilities of the Pharmacist Consultant:
   a. Assists with the development of written policies and procedures for pharmaceutical services.
b. Reviews medication storage areas for, but not limited to, labeling, storage, ventilation, humidity and temperature control, expired medications, security, sanitation and completeness of emergency medications box. (See Chapter 17.I.4.)

c. Determines that drug records are in order and that an account of controlled drugs is maintained and reconciled.

d. Monitors adherence to stop order and standing order policies.

e. Evaluates staff performance in carrying out pharmaceutical policies and procedures.

f. Reviews the drug regimen of each resident monthly and as needed, including monitoring for unnecessary drugs.

g. Provides the professional staff with in-service education and on-going communication regarding drugs and biologicals, including information on drug incompatibilities, new drugs, drug sensitivities, and drug interactions.

h. Participates in resident care conference as appropriate.

i. Participates in the Professional Policy Committee and Quality Assurance Committee meetings to review and make recommendations relating to pharmaceutical services.

17.C.3. Reports of the Pharmacist Consultant shall contain:

a. Documentation in the resident’s record that review of the medication regimen has been performed and that issues and irregularities identified have been reported to the Director of Nursing and the attending physician.

b. A description of all activities, findings and recommendations contained in a report submitted to the Director of Nursing and the Administrator.

17.D. Handling of Drugs and Biologicals

17.D.1. All medications shall be kept in their original containers unless transfer of the medication is done to another storage container by or under the supervision of a pharmacist or a physician. All pharmaceutical containers having soiled, damaged, incomplete, illegible or makeshift labels shall be returned to the issuing pharmacy for relabeling or shall be destroyed in accordance with 17.D.8. of this section.

17.D.2. Each resident’s medication container shall be clearly labeled in accordance with State and Federal law and shall include:

a. Prescription number;

b. Resident's full name;

c. The name, strength and dosage form of the drug;

d. Current directions for use;

e. Name of prescribing physician;
f. Name, address and telephone number of the pharmacy issuing the drug;

g. Date of issue (latest refill);

h. Expiration date, not to exceed one (1) year from the date of repackaging or dispensing or
the manufacturer's original date, whichever is earlier;

i. Appropriate accessory and cautionary instructions.

17.D.3. There shall be a physical barrier between medications marked "for external use
only" and any medication to be taken internally. There shall also be a physical barrier
separating eye medications, ear medications and topical medications.

17.D.4. The telephone number of the Poison Control Center shall be conspicuously posted
near the telephone at each nurses station.

17.D.5. All drugs and biologicals shall be stored in locked rooms or compartments,
separate from food and laboratory specimens, and under proper temperature control in
accordance with United States Pharmacopeia standards:

a. Refrigeration: 36-46 degrees Fahrenheit

b. Cool 46-59 degrees Fahrenheit

c. Controlled Room Temperature 59-86 degrees Fahrenheit

17.D.6. Medications which have an expiration date that has been exceeded shall be
removed from use and properly disposed of, according to requirements (17.D.8.).

17.D.7. All prescribed medicines are the property of the resident. Upon discharge of a living
resident from a licensed facility, the prescribed medicine, including controlled drugs or
substances may be released with the resident, but only upon written authorization of the
resident's physician. Each drug release will be documented in the resident's record.
Subsequent to discharge, unclaimed medications shall be retained no longer than ninety
(90) days.

17.D.8. Disposition of Medications

a. All prescribed medications, other than Schedule II controlled substances, shall be
destroyed by the Director of Nursing Service or a designee, and shall be witnessed by a
licensed member of the nursing staff.

b. The destruction shall be conducted in such a manner as to prevent any persons from
being able to use administer, sell or give away the medication.

c. Individual unit doses, other than Schedule II through V controlled substances must be
returned to the pharmacist and any credit or rebate made to person(s) who originally paid
for the medication.

d. Amounts destroyed or returned to the pharmacy shall be recorded on the resident's
record with the signature of two (2) witnesses.
e. Following the death of the resident, medications shall be removed from circulation within seventy-two (72) hours.

f. Schedule II controlled substances shall be disposed of as outlined in Section 17.F.2. of this Chapter.

17.D.9. Licensed facilities may stock in bulk supply those items and drugs regularly available at a pharmacy without prescription.

17.D.10. Reporting of Tampered With or Stolen Drugs

The Department and the Attorney General shall be notified verbally within seventy-two (72) hours when there is suspicion that a medication has been tampered with or stolen. A written report shall also be submitted by the facility to both agencies.

17.D.11. A record shall be maintained, in which the following information shall be available for all prescription medications received in the facility:

a. Name of resident for whom received;

b. Name of pharmacy;

c. Prescription number;

d. Name of drug and strength;

e. Amount of medication received;

f. Date received;

g. Signature of licensed person receiving the medication.

17.D.12. All resident Schedule II controlled substances received in the facility shall be listed as received in a bound book from which no pages shall be removed

17.D.13. A separate emergency supply inventory, which is the property of the provider pharmacy, shall also be maintained with the following record requirements:

Receiving:

a. Date received

b. Name of the nurse receiving

c. Name, strength and dosage form of the medication

d. Amount received

Utilization:

a. Date used

b. Nurse administering
c. Patient's name

d. Amount used

e. Amount remaining

These records shall be duplicated and kept as a permanent part of the facility records. The originals remain the property of the pharmacy, as does the medication.

17.D.14. A medication supply shall not be maintained by a resident, unless requested by the resident and specifically authorized by the resident's physician and the multidisciplinary team.

17.E. Administration

17.E.1. Medications shall be administered as prescribed and according to a clearly defined procedural system and reconciled with the physician's orders on a regular basis.

17.E.2. Orders for Medication

a. All medications administered to residents shall be ordered in writing by the resident's physician or authorized designee. Oral orders for medications shall be accepted only by a licensed nurse or pharmacist, immediately reduced to writing, signed by the person accepting the order and countersigned by the attending physician within five (5) business days.

b. Medications not specifically limited as to time or number of doses, when ordered, shall be automatically stopped in accordance with written stop order policy approved by the physician or physicians responsible for advising the facility on its written policies. The resident's physician shall be notified prior to any discontinuance of medication.

c. Orders concerning medications and treatments shall be in writing, signed and dated by a physician and shall be in effect for the time specified by the physician, but not to exceed a period of sixty (60) days. A grace period of ten (10) days may be allowed for the resident whose condition during this period of time did not require a physician's visit.

d. Orders for Schedule II controlled substances shall be in effect for no longer than one (1) week, unless there are specific written orders to the contrary, but in no case shall the order be in effect for a period of more than thirty (30) days without a reorder.

17.E.3. Personnel Administering Medication

a. All medications shall be administered by medical and nursing personnel in accordance with the Nurse Practice Act of Maine and applicable law.

b. All medications shall be administered by licensed medical or nursing personnel, Certified Nursing Assistant/Medications, or other individuals authorized by law who have been issued a certificate indicating completion of an advanced training program including the administration of oral medications as approved by the Maine State Board of Nursing.
c. Medications which are prescribed to be given as needed must only be administered after an evaluation of the resident by a licensed nurse or physician.

d. Medications shall be administered as soon as possible after doses are prepared by the same person who prepared the medication for administration.

17.E.4. Medication Identification

The facility must have an organized system for drug administration that identifies each drug up to the point of administration.

17.E.5. Resident Identification

There shall be provision for assuring proper identification of residents by all personnel administering medications.

17.E.6. Self-Administration of Medications

An individual may self-administer medications if the multidisciplinary team has determined that the practice is safe, and with the written permission of the resident’s attending physician.

17.F. Control of Narcotics, Barbiturates and Other Controlled Substances

17.F.1. Policies and Procedures

a. All facilities shall comply with State and Federal regulations governing narcotics and those drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970, and any amendments thereto.

b. For purposes of this section, narcotics, barbiturates and other controlled substances shall include any substance listed under the Federal Uniform Controlled Substance Act, Sections 1 through 5.

c. All Schedule II controlled substances, including the emergency supply, received in the facility shall be recorded in a bound drug book as specified in this Chapter. Whenever a container of Schedule II controlled substances has been used up, as evidenced by the record required in this Chapter, it shall be noted in the bound drug order book by signature and date that the supply is depleted.

d. For all substances listed in Schedule II as above, there shall be an individual narcotic sheet on which shall be recorded the name of the resident receiving the substance, prescription number, the name, date, strength, dosage, and method of administration, the name of the prescribing physician, the signature of the nurse administering it and the balance on hand. This record shall be filed in the individual resident’s record upon completion.

e. The emergency supply inventory shall name the resident for whom the controlled substance was issued, the name of the physician, and the date issued, signed by the nurse issuing the medication and the nurse receiving the medication.
f. The count of Schedule II controlled substances, to include the emergency supply, shall be recorded and signed at the change of each shift by two people qualified to administer medications, one of whom shall be a licensed nurse.

g. All Schedule II controlled substances, including the emergency supply, shall be stored under double lock, in a locked box attached to the wall or shelf or locked cabinet within the medication cabinet or cart, or an approved double locked cabinet attached to the wall.

h. Policies shall be developed relative to the accounting of controlled substances other than Schedule II.

17.F.2. Handling of Unused Schedule II Controlled Substances

a. The Director of Nursing Services, or a designee, shall list all such unused substances, tape the cap or cover with tamper evident seals and keep the same in a secure, double-locked area, apart from all other drugs. The drugs shall be accessible only to the Director of Nursing or designee.

b. A current inventory of these substances shall be maintained and recorded in a monthly inventory recorded by the Director of Nursing and one other licensed nurse. These inventories must be maintained for a period of at least five (5) years or as required under Federal/State statutes.

c. Prior to the destruction of these substances by the authorized person, the inventory shall be verified by that person. Notation shall be made of the destruction, date and signed by all authorized individuals.

d. Disposal of such substances shall occur by incineration or by flushing into the sewage system and shall be made in the presence of a representative from the Department, a Maine licensed pharmacist, a member of the Board of Pharmacy who is a licensed pharmacist, or Federal Drug Enforcement Agency agent. At least one party must be a disinterested party. For the purposes of this section, a disinterested party shall be considered to be either a nurse who was not the last nurse to inventory the discarded item or a pharmacist who is not affiliated with the provider who dispensed the drug.

e. For Schedule II controlled substances, notation of such destruction shall be made on the inventory list required in 17.F.2.b. For Schedule II substances, notation of such destruction shall also be made on the residents individual Schedule II controlled drug sheet, signed and dated by the person who disposed of the drug and the authorized person witnessing the disposition. For Schedule II substances, notation of such destruction shall be made in the bound book required in Chapter 17.F.1.c.

17.G. Recording of Medications

17.G.1. Records of Administration

A record shall be kept of all drugs and medications administered, including name of drug, dose form, dosage, and time given. This shall be promptly recorded on the record of medications and treatment, initialed by the administering individual, with the full name of the individual written somewhere on such record. The need for and response to
medications administered which were prescribed to be given as needed shall be documented on the medication or clinical record.

17.G.2. Record of Time Started, Given or Discontinued

Entries shall be made on the medication records to indicate whenever medications are started, given, or discontinued.

17.H. Reporting of Medication Errors and Adverse Reactions

17.H.1. Reports to Physician

Medication errors and adverse reactions shall be immediately reported to the resident's physician. Medication errors include omissions, as well as errors of commission. Adverse reactions shall also be reported to the pharmacist consultant and pharmacy.

17.H.2. Clinical Records

An entry of the error and/or adverse reaction shall be made in the resident clinical record.

17.H.3. Incident Reports

There shall be an incident report made out for each medication error and/or adverse reaction. These reports shall be kept together on the premises of the facility, reviewed by the Quality Assurance Committee and be made available for review by representatives of the Department.

17.I. Equipment and Supplies

17.I.1. Medicine Cabinet

A cabinet or medication cart shall be provided for individual prescriptions. The cabinet/cart shall be of sufficient size, properly lighted, and located where easily accessible and locked when not in use. The medicine cabinet/cart shall be equipped with separate cubicles, plainly labeled, or provided with other physical separation for the storage of each resident's prescriptions.

17.I.2. Medicine Measuring Devices

Appropriate measuring devices for the accurate measure of liquid medications shall be provided. If not disposable, these medicine containers shall be returned to the institution’s dishwashing unit for processing after each use.

17.I.3. Cabinets for Cleaning Supplies and Poisons

There shall be a separate secure cabinet apart from medicine, drugs, and food, for the storage of all bleaches, detergents, disinfectants, insecticide, and poisons. These shall be clearly labeled.

17.I.4. Emergency Medication Box
There shall be readily available in a secure area, an emergency medication box approved by the facility's group of professional personnel. All medication shall be in single dose form, if available, and any drug removed from the kit shall be replaced within 24 hours and have a drug prescription to cover replacement of same within 5-7 days. An adequate inventory level shall be maintained to assure that a supply is available.

17.I.5. Reference Material

There shall be, readily available to all staff, current (within two [2] years) medication reference material and up-to-date information for all medications in use in the facility.

17.I.6. First Aid Kit

There shall be a first aid kit which is OSHA approved and equipped as facility policy dictates, readily available at each nurses station.

10.07.02.15 Pharmaceutical Services.

A. Facility Responsible for Pharmacy Services. The facility shall provide appropriate methods and procedures for administering drugs and biologicals. The facility shall be responsible for providing drugs and biologicals for its patients. Pharmaceutical services shall be provided in accordance with accepted professional principles and appropriate federal, State, and local laws. Any regulation in this chapter shall govern if higher.

B. Composition of Pharmaceutical Services Committee.

(1) A pharmaceutical services committee (or its equivalent) shall develop written policies and procedures for safe and effective drug therapy, distribution, control, and use. The composition of the committee shall include at least:

(a) The pharmacist;
(b) The director of nursing services;
(c) The consultant dietitian;
(d) One physician;
(e) The administrator.

(2) All members of the committee are not required to be present at all meetings. The participation of members at a specific meeting shall be controlled by the agenda items to be discussed.
(3) Policies and procedures developed by the pharmaceutical services committee may not prohibit or restrict a resident from receiving medications from the pharmacy of the resident’s choice except that, when the cost of any medication obtained from the pharmacy selected by the resident exceeds the cost of the same or equivalent medication available through a pharmacy that the facility has contracted with to provide pharmaceutical services, the resident shall be responsible for the excess amount. The committee may not require the pharmacy to provide drugs by way of a specific drug distribution system such as unit dose or utilization of a particular packaging system.

C. Duties of Pharmaceutical Services Committee. Unless the Department decides that semiannual meetings are appropriate, the committee shall meet at least quarterly to:

(1) Establish policies and procedures which shall include, at least, statements which assure that:

(a) Medications, legend and non-legend, administered to patients shall be ordered in writing by the patient’s physician.

(b) Medications shall be administered by appropriately licensed personnel in accordance with laws and regulations governing these acts or by certified graduates of a State-approved medication aide course.

(c) The person who prepares medications shall give and record them.

(d) Medicine may not be returned to the container. If the patient refuses the drug or a mistake occurs, the drug shall be discarded and an annotation entered on the patient’s chart. For unit dose policy see § E of this Regulation.

(e) Nurses may not package, repackage, bottle, or label in whole or in part any medication, or alter in any way by tampering or defacing any labeled medication.

(f) Medications not specifically limited as to time or number of doses, when ordered, shall be automatically stopped in accordance with the written policy originated by the committee.

(g) Before invoking stop order policies, the patient's attending physician shall be contacted for instructions so that continuity of the patient’s therapeutic regimen is not interrupted.

(h) Medications shall be accurately and plainly labeled. Except for those over-the-counter medications which the Department may list as suitable for purchasing in bulk and dispensing as needed, the labels for all medications shall bear at least:

(i) The patient's full name;

(ii) The name of the drug;

(iii) Potency;

(iv) Original filling date and date refilled, if applicable;

(v) Name of prescribing physician;
(vi) Expiration date of medication (month, year);
(vii) Appropriate special handling instructions regarding special storage;
(viii) Name and address of dispensing pharmacy;
(ix) Serial number;
(x) Number of tablets or capsules;
(xi) Accessory federal labels.

(i) Medications shall be stored in a locked medication storage area provided at, or convenient to, the nurses' station, which:

(i) Is well lighted;
(ii) is located where personnel preparing drugs for administration will not be interrupted;
(iii) Is sufficiently spacious to allow storage of external medications separately from internal medications;
(iv) Is kept in a clean, orderly and uncluttered manner; and
(v) Contains a refrigerator if medications are to be maintained in it.

(j) Poisons and medications marked "for external use only" shall be kept separate from general medications and Schedule II drugs.

(k) Schedule II drugs shall be kept in separately locked, securely fixed boxes or drawers in the storage area, under two locks. The lock on the door of a medication room shall be counted as one of the two locks.

(l) Facilities which administer Schedule II Drugs shall maintain a drug record in which is recorded:

(i) The name of the patient, the date, time, kind, dosage, and method of administration of all Schedule II Drugs;
(ii) The name of the physician who prescribed the medication;
(iii) The name of the nurse or medicine aide who administered the medication.

(m) Each facility, whether or not operating a licensed pharmacy, shall maintain a record and signed Schedule II count at each change of shift.

(n) Two members of the nursing home staff (administrator or nurse) may destroy controlled dangerous substances in Schedules II--V on the premises of the nursing home. In addition to any other required records, a record of the disposal shall be maintained in the facility. A copy of the record of disposal shall be forwarded to the Division of Drug Control.

(o) All medications written on prescription for patients who have left the institution shall be destroyed in the presence of an authorized representative of the Department or two
witnesses, authorized by the facility, who shall sign a notation on the patient's chart. Any adulterated, deteriorated, or out-dated medications shall be destroyed in the presence of an authorized representative of the Department or two witnesses, authorized by the facility, who shall sign an appropriate record of the action.

(p) Medications shall be released to patients on a discharge only basis with the written authorization of the patient's physician. With the approval of the patient's physician, the pharmacy shall issue a quantity of medication to meet the needs of a patient on short-term leave of absence.

(2) Establish the contents of sealed, emergency drug kits. A sealed kit shall be kept readily available in each nurses' station. A list of contents, with expiration dates, shall be attached to the kit. The kits shall be of durable construction and easily cleaned.

(3) Oversee the pharmaceutical service to the facility to ensure accuracy and adequacy.

(4) Make recommendations for improvements.

(5) Document actions and recommendations.

D. The pharmacist, or his agent, shall be responsible for delivering medications to the facility. Members of the patient's family or the sponsor for the patient may not deliver medications to the patient or to the facility.

E. Pharmacist Supervises Services. If the facility does not employ a licensed pharmacist, it shall arrange for, by written contract, a licensed pharmacist to provide consultation on the administering of the pharmacy services in accordance with the policies and procedures established by the pharmaceutical services committee. The pharmaceutical services shall be under the general supervision of a qualified pharmacist who shall:

(1) Be responsible, with the advice of the pharmaceutical services committee, to develop, coordinate, and supervise the pharmaceutical services and provide in-service at least twice yearly.

(2) Visit the facility frequently enough to assure that policies and procedures established by the pharmaceutical services committee are enforced.

(3) If a patient desires to designate a particular pharmacy to provide his drugs, he shall inform the pharmacist that he must conform with the facility's written policies concerning the provision of drugs. If the pharmacist agrees to comply with the facility's policies, the patient may request that the consenting pharmacist perform the service. If the pharmacist fails to comply with the policies, a representative of the facility shall discuss with the patient the policy infractions. If after being informed of the infractions the pharmacist then refuses to cooperate, the patient shall select another pharmacist who will agree to comply with the facility's policies. Providers of drugs, pharmacists, shall have access to a copy of the written patient care policies.

(4) Arrange for pharmacies which provide medications for patients in the facility to agree, in a written agreement with the facility, to maintain at the pharmacy a patient profile record system for each patient in the facility for whom prescriptions are dispensed.
(5) At least monthly, review at the facility the individual patient records, performing a drug regimen review, and document the findings in the patient’s medical record.

(6) Bring to the attention of the attending physician any potential drug problems found during the drug regimen review.

(7) At least quarterly, submit a report to the pharmaceutical services committee on the status of the facility’s pharmaceutical service and staff performance.

E. Unit Dose System. A facility, before installing a unit dose system which has not been approved by the Division of Licensing and Certification, shall obtain this approval before installing the system. Prior approval is not required for a system which has been approved unless the facility plans to make substantial changes in the system. Departmental approval of the unit dose system indicates compliance with these regulations.

10.07.02.43 Medicine Aide—Scope of Responsibility.

A. Upon successful completion of the Department of Health and Mental Hygiene approved Medicine Aide Course, and when applicable, the continuing education course, the medicine aide may perform all medication administration functions except for those prohibited in § B of this regulation. These functions, including the following delegated nursing functions may only be performed by the aide under the direct supervision of a registered nurse or licensed practical nurse:

(1) Prepare, administer and chart oral, topical and suppositorial drugs;

(2) Perform pulse and blood pressure measurements;

(3) Administer PRN medicines under the following directive:

(a) For non-legend PRN drugs, the medicine aide administers under the supervision of a registered nurse or licensed practical nurse,

(b) For legend drugs, the medicine aide shall inform the charge nurse, who shall first make a bedside assessment, and a written documentation of that assessment, before giving permission to a medicine aide to administer that medication;

(4) Sign and have access to the controlled schedule drug cabinet; and

(5) Administer drugs only with a written order.

B. The medicine aide shall be prohibited from performing the following duties:

(1) Transcribing doctors’ original orders to medicine charts or Kardexes;

(2) Administering any parenteral medications;

(3) Administering any substances by nasogastric or gastrostomy tubes; and

(4) Receiving instructions for or being placed in charge level responsibilities.
C. On or after October 1, 1990, a medicine aide shall meet all applicable requirements of Regulations .39—.42, in addition to the requirements of this regulation.

10.07.02.44 Medicine Aide Course Requirements.

A. Successful course completion will be recognized by the Department when:

(1) Before admission to the program, the applicant meets the following requirements:

(a) Possesses at least 1 year of full-time experience or its equivalent as a nursing assistant in a comprehensive care facility or extended care facility in Maryland;

(b) Evidences experience in basic patient care procedures; and

(c) Is currently employed as a geriatric nursing assistant in a comprehensive care facility or extended care facility.

(2) The curriculum satisfies the following model requirements:

(a) Is 60 hours in duration and gives equal weight to the theoretical and supervised clinical experience components;

(b) Includes each of the following pertinent subjects:

(i) Responsibilities and limitations of the medicine aide,

(ii) Drug standards, references and resources,

(iii) Legislation concerning drug utilization,

(iv) Characteristics of the elderly client (or exceptional) client-mentally retarded, multiple handicap:

(aa) Sources and purpose of drugs,

(bb) Dosage forms and methods of administration,

(cc) Drug life,

(dd) The medication order,

(ee) The administration of non-parenteral medications,

(ff) Procedures and techniques for administering drugs,

(gg) Drug classification, related health problems, and patient care responsibilities,

(hh) Drug solutions and their measurements, and

(ii) Monitoring for side effects of drugs and drug interactions.
B. As evidence of successful completion, the applicant shall possess a certificate issued to the applicant by the community college. Certificates issued by the community college shall remain valid proof of certification until June 30th of the second year following the date of issuance.

C. Certification beyond the initial two-year period is predicated upon the satisfactory completion of an 8-hour continuing education course designed as follows:

(1) A three-hour core content identifying:

(a) Current State regulations related to the role of the medicine aide;

(b) Uses, actions, related precautions, and possible interactions of current medications used in the care of the geriatric patient;

(c) New care procedures; and

(d) Resources available to the medicine aide which clarify and expand the knowledge of the medicine aide.

(2) Three hours on topics selected from the following:

(a) Documentation;

(b) Nutrition;

(c) The physiological system of the geriatric patient;

(d) Deinstitutionalization of the mentally retarded and psychiatric patient; or

(e) Other aspects of pharmacology.

(3) Two hours of assessment testing administered at the completion of the continuing education course.

(4) Each renewed certification shall be valid for a period of 2 years, until June 30th of the second year, following the satisfactory completion of the continuing education course.

D. An individual who has received a certificate evidencing completion of a program which the Department approved before the adoption of these regulations shall be deemed to meet the training requirements of this regulation.
(G) **Nursing and Supportive Routines and Practices.**

...(2) No medication, treatment or therapeutic diet shall be administered to a patient or resident except on written or oral order of a physician or physician assistant or nurse practitioner.

150.008: **Pharmaceutical Services and Medications**

(A) All facilities shall maintain current written policies and procedures regarding the procurement, storage, dispensing, administration and recording of drugs and medications.

(1) Policies and procedures shall be developed with the advice of a committee of professional personnel including a physician or physician-physician assistant team or physician-nurse practitioner team, a pharmacist and a nurse.

(2) Provision shall be made for the prompt and convenient acquisition of prescribed drugs from licensed community, institutional or hospital pharmacies. Facilities shall make no exclusive arrangements for the supply or purchase of drugs; and patients or residents, their next of kin or sponsor may arrange for the purchase of prescribed medications from pharmacies of their own choice provided medications are dispensed and labeled as specified in 105 CMR 150.000.

(3) No drug or medication that has been removed from the market by the Food and Drug Administration shall be stocked or administered in any facility.

(4) Facilities shall comply with all Federal and State laws and regulations relating to the procurement, storage, dispensing, administration, recording and disposal of drugs.

(B) There shall be a current written order by a physician, physician assistant, or nurse practitioner in the Doctor's Order Book for all medication or drugs administered to patients or residents.

(1) Verbal or telephone orders shall be given only to a licensed nurse (or responsible person in facilities that provide only Level IV care), shall be immediately recorded in writing and signed by the same nurse or responsible person. All verbal or telephone orders shall be countersigned by a physician, physician assistant, or nurse practitioner within 48 hours except for cathartics, aspirin and buffered aspirin.

(2) A licensed nurse and the attending physician together shall review each patient's or resident's medications in conjunction with the routinely scheduled comprehensive review of the patient's or resident's condition. Such services shall be scheduled at least as often as follows:

   Level I or II, every 30 days.

   Level II every 90 days,

   In a Level IV facility, at the time of a resident's review by his/her physician, as outlined under 105 CMR 150.005(G)(3), both the physician and the nurse shall review the resident's
medications. Any concerns regarding medication side effects or needs for adjustment shall be discussed by the attending physician and the facility nurse to develop and implement an appropriate adjustment in the resident's plan of care.

If the resident also has an identified psychiatrist and the medication change involves psychiatric medication, the resident's psychiatrist should be consulted. If the resident is a Community Support Resident, any change in psychiatric medication and the rationale for that change must be communicated to the social worker so that an appropriate adjustment in the Mental Health Treatment Plan may be made. In addition, the resident must consent (if she/he is competent to consent) or the resident's guardian (if the resident is not competent to consent) to any medication change as required under 105 CMR 150.011(E)(5)(d)10.

(3) Orders for medications and treatments shall be in effect for the specific number of days indicated by the physician, physician assistant or nurse practitioner.

(a) Orders shall not exceed the facility's stop order policies where applicable.

(b) Orders shall not exceed the limits of 72 hours for narcotics and 14 days for stimulants, depressants, antibiotics and anticoagulants unless specified in writing by the attending physician or physician-physician assistant team or physician-nurse practitioner team.

(c) Medications not specifically limited to time or number of doses by the physician, nurse practitioner, or physician assistant shall automatically be stopped in accordance with the facility's stop order policies or, in the absence of such policies, at the end of 30 days. The physician, physician assistant, or nurse practitioner shall be contacted for renewal of orders or other instructions.

(4) Medication may be released to patients or residents on discharge only in the written authorization of a physician, physician assistant or nurse practitioner. Otherwise they shall be held for disposal (105 CMR 150.008(D)(13)).

(5) If medications for a patient are ordered by a physician assistant or nurse practitioner, all initial orders for medication or significant changes in medications and all orders for Schedule II drugs must be reviewed by the supervising physician as specified in 105 CMR 700.000 et seq.

(6) If medications for a patient are ordered by a physician assistant or nurse practitioner, there shall be a review of medications by the physician assistant or nurse practitioner and the supervising physician as specified in the written guidelines established pursuant to 105 CMR 100.003(C)(3) or more frequently if clinically indicated. At a minimum, there shall be an onsite medication review at the long term care facility by the supervising physician at least once every 90 days.

(C) Supervision and administration of medication shall be as follows:

(1) Every medication administered in a facility shall be administered by a physician, physician assistant, nurse practitioner, registered nurse, or licensed practical nurse, except as provided in CMR 150.008(C)(2).
In a Level IV facility or unit and a CSF, the following medications may be administered by a responsible person who has documented evidence of having satisfactorily completed a training course approved by the Department on the topic of dispensing medications, or may be self-administered if so authorized by a physician or psychiatrist's order:

(a) Any oral medication, which is not included in the schedules of controlled substances established under the Federal Comprehensive Drug Abuse Prevention and Control Act.

(b) Any of the following medications contained in federal schedules of controlled substances: chlorodiazepoxide, diazepam, oxazepam, chorazepete, flurazepam, clonazepam, chloral hydrate, phenobarbital when used in the treatment of seizure disorders, trazolam, lorazepam, alprazolam, temazepam, prazepam, propoxyphene hydrochloride, and propoxyphene napsylate.

(c) The administration of all other controlled substances must be approved by the Department through a written waiver request pursuant to 105 CMR 153.030(B).

(3) Notwithstanding a physician's order, a licensee shall not permit self-administration by any resident where, in his/her judgment, this practice would endanger another resident or other residents.

(a) All medication which is to be self-administered shall be kept in the resident's room in a locked cabinet or in a locked drawer.

(b) In the case of a resident with a history of mental illness, a self-administration order must be supported by written finding by the physician that the resident has the ability to manage the medication on this basis.

(c) Every self-administration order shall be reconsidered as part of the periodic review of medications under 105 CMR 150.0008(B)(2).

(4) All medications shall be accurately recorded and accounted for at all times, and each dose of medication administered shall be properly recorded in the clinical record with a signature of the administering nurse or responsible person.

(5) Medications prescribed for a specified patient or resident shall not be administered to any other patient or resident.

(6) Individual medication cards shall be provided for each medication for each patient. Cards shall be used when administering medications and checked against the physician's orders. Adequate medicine trays shall be provided.

(7) Medication errors and drug reactions shall be reported to the patient's or resident's physician and recorded in the clinical record.

(8) A current medication reference book shall be provided in the facility at each nurse's or attendant's station.

(D) Labeling, Storage and Supervision of Medications.
(1) All facilities shall provide a locked medicine cabinet or closet of a type approved by the Department within the nurses’ or attendants’ station for the proper storage of all patients’ or residents’ drugs except those approved for self-administration. Such cabinets or closets shall be used exclusively for the storage of medications and equipment required for the administration of medications.

(2) The locked medicine cabinet or closet shall be located within or close to the nurses’ or attendants’ station in a place that is removed from areas frequented by patients, residents or visitors.

(3) The medicine cabinet or closet shall be well-lighted, locked at all times with a suitable lock, and maintained in a clean and sanitary manner. It shall be sufficient in size to permit storage without crowding and shall have running water accessible.

(4) There shall be a separately locked, securely fastened compartment within the locked medicine cabinet or closet for the proper storage of prescribed controlled substances under the federal Comprehensive Drug Abuse Prevention and Control Act.

(5) Medication requiring refrigeration shall be properly refrigerated and kept in a separate, locked box within a refrigerator at or near the nurses’ or attendants’ station.

(6) Poisons and medications for "external use only," including rubbing alcohol, shall be kept in a locked cabinet or compartment separate and apart from internal medications.

(7) Medications shall not be stored in patient’s or resident’s rooms except drugs approved for self-administration.

(8) A current medication reference book shall be provided in the facility at each nurse’s or attendant’s station.

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(6) Poisons and medications for "external use only," including rubbing alcohol, shall be kept in a locked cabinet or compartment separate and apart from internal medications.

(7) Medications shall not be stored in patient’s or resident’s rooms except drugs approved for self-administration.

(8) The custody of all keys to the medicine cabinets or closets shall at all times be assigned to a licensed nurse (or a responsible person in facilities that provide only Level IV care).

(9) The label affixed to each individual medication container shall clearly indicate the patient’s or resident’s full name, physician’s name or physician assistant’s name and his supervising physician’s name or nurse practitioner’s name and his supervising physician’s name, prescription number, name and strength of drug, quantity, dose, frequency and method of administration, date of issue, expiration date of all time-date drugs, and name, address and telephone number of pharmacy issuing the drug.

(10) Prescription labels shall not be defaced, and medication containers with soiled, damaged, incomplete, illegible, or make shift labels shall be returned to the issuing pharmacy for relabeling or disposal. Containers without labels shall be destroyed as directed by the Department.

(11) Medications for each patient or resident shall be kept and stored in the containers in which they were originally received; transfer to other containers is forbidden.

(12) Medications having a specific expiration date shall be removed from usage and destroyed at expiration. All medications no longer in use shall be disposed of or destroyed at as directed by the Department.

(13) Following a patient’s or resident’s death, transfer or discharge, all drugs prescribed for that individual, if not transferred with him, shall be disposed of as directed by the Department.

(E) An emergency medication kit shall be provided in all facilities.

(1) The contents of the kit shall be approved by the Department. In accordance with Federal law, narcotics shall be excluded.

(2) The emergency medication kit shall be kept in a separate, sealed container, which shall be stored in a suitable place when not in use. Exception: Drugs requiring refrigeration shall be kept in a separate sealed container under proper refrigeration (150 CMR 150.008(D)(5)).
(3) Each emergency medication kit shall be prepared, packaged and sealed by a pharmacist and shall contain a list of contents of the outside cover and within the box.

(4) The medications contained in the emergency medication kit shall be used only upon the orders of a physician or physician assistant or nurse practitioner.

(5) After a kit has been opened, it shall be inspected, re-stocked and resealed by the pharmacist within 48 hours prior to further use.

(F) Facilities shall be permitted to stock those drugs and medical supplies that are approved as stock items or medicine chest items by the Department.

(G) Records.

(1) When drugs are transferred with a patient or resident, an accurate record shall be made at the time of discharge including the following: date, name and new address of patient or resident; name of drug, strength, quantity, pharmacy and physician's name or physician assistant's name and his supervising physician's name or nurse practitioner's name and his supervising physician's name.

(2) An individual narcotic and sedative record shall be maintained for each narcotic, sedative, amphetamine, barbiturate or other dangerous drug prescribed for each patient or resident. This record shall be kept in a bound book with numbered pages in a manner approve by the Department and shall include:

(a) Patient's or resident's name.

(b) Name of physician prescribing the medication or the name of the physician assistant or nurse practitioner prescribing the medication and the name of his supervising physician.

(c) Name of medication, quantity prescribed, strength or dosage prescribed, the amount of medication received and the balance on hand.

(d) Date received, prescription number and name of pharmacy that dispensed medication,

(e) Date, time, dosage and method of administration and signature of nurse who administered the medication.

(3) A recorded, dated count of controlled substances under the federal Comprehensive Drug Abuse Prevention and Control Act shall be checked by a nurse or responsible person going off duty on each shift in the presence of a nurse or responsible person reporting on duty and both shall sign the count in the Narcotic and Sedative Book with their legal signatures.

(4) All facilities shall maintain a Pharmacy Record Book which is bound with numbered pages and maintained in a form approved by the Department. All deliveries of prescribed medications shall be entered into this book, and entries shall include:

(a) Patient’s or resident’s name.
(b) Name of physician prescribing the medication or the name of the physician assistant or nurse practitioner prescribing the medication and the name of his supervising physician.

(c) Name of pharmacy dispensing medication.

(d) Name of medication, prescription number, quantity ordered, quantity received.

(e) Date and time received and signature of individual who receives the medication.

(5) Change of Ownership (See 105 CMR 150.002(G)(4).)

PART 9. PHARMACEUTICAL SERVICES

R 325.20901 Medication kits.

Rule 901.

(1) A medication kit for medical emergency use, which is accessed only on the direct order of a physician and which is maintained in a locked cabinet, shall be accessible only to the licensed nurse in charge.

(2) The emergency kit shall be obtained only on the order of a licensed physician and shall be prepared and sealed by a pharmacist.

(3) The kit shall contain a list of its contents and expiration date on the outside surface of the lid, and a complete record of usage and disposal shall be available.

History: 1981 AACS; 1983 AACS.

R 325.20902 Medications; dispensing and storage.

Rule 902.

(1) A legend drug shall not be dispensed except by a pharmacist according to established pharmacy policies and procedures. It shall be contained in properly labeled individual containers, kept in a locked cabinet, and shall be accessible only to the nurse in charge. Labeling and relabeling of all drugs shall only be done by a pharmacist.

(2) A controlled substance shall be kept in a separate locked box within the locked medication cabinet, except that under a unit dose system, a single dose or limited number of doses shall be stored separately for each patient as indicated in subrule (1) of this rule.
(3) A medication requiring refrigeration shall be kept in a separate locked box within a refrigerator. Drugs and biologics requiring refrigeration shall be stored at a temperature recommended by the manufacturer.

(4) A medication for external use only shall be kept in a locked cabinet separate from other medications.

History: 1981 AACS.

R 325.20903 Medications; administration.

Rule 903.

(1) Medications shall be administered only by medical or nursing personnel in accordance with the written or verbal order of the attending physician.

(2) A dose of medication administered shall be properly recorded in the patient's clinical record and, when applicable, in special records for controlled substances as required by law. Abbreviations used in recording medication orders and administration shall be standardized in the home according to a written source document.

(3) A medication shall be listed on an approved medication card or its equivalent and shall be checked against the physician's orders before being administered.

(4) A medication prescribed for a patient shall not be administered to another patient.

(5) A medication prescribed for a patient shall be administered promptly after the appropriate dose is prepared for administration.

(6) Self-administration of medication by a patient shall not be permitted, except when special circumstances exist and when supported by a physician's written order and justification.

(7) An unused portion of a previously prepared medication dose not administered to a patient shall not be returned to its original container, but shall be disposed of appropriately.

History: 1981 AACS.

R 325.20904 Medications; errors; reactions.

Rule 904. Medication error or drug reaction shall be immediately reported to the charge nurse, physician, and the pharmacist as soon as possible and shall be recorded in the patient's clinical record as well as on an incident report form which shall be forwarded to the administrator and kept on file. Corrective action shall be initiated promptly by the physician, administrator, director of nursing, or pharmacist as appropriate.

History: 1981 AACS.
R 325.20905 Stop orders and policies.

Rule 905. An automatic stop order and policy governing the use of drugs shall be formulated and shall be made a part of the written patient care policy implemented and in effect in the home.

History: 1981 AACS.

R 325.20906 Medications; disposal and release.

Rule 906.

(1) A medication no longer in use or outdated shall be disposed of immediately and in accordance with federal or state laws and regulations.

(2) A medication shall not be released or sent with a patient upon discharge, except on the written order of the physician.

History: 1981 AACS.

MINNESOTA

4658.1300 MEDICATIONS AND PHARMACY SERVICES; DEFINITIONS.

Subpart 1. Controlled substances. "Controlled substances" has the meaning given in Minnesota Statutes, section 152.01, subdivision 4.

Subp. 2. Schedule II drugs. "Schedule II drugs" means drugs with a high potential for abuse that have established medical uses as defined in Minnesota Statutes, section 152.02, subdivision 3.

Subp. 3. Pharmacy services. "Pharmacy services" means services to ensure the accurate acquiring, receiving, and administering of all drugs to meet the needs of each resident.

Subp. 4. Drug regimen. "Drug regimen" means all prescribed and over-the-counter medications a resident is taking.

STAT AUTH: MS s 144A.04; 144A.08; 256B.431

HIST: 20 SR 303

Current as of 01/19/05
4658.1305 PHARMACIST SERVICE CONSULTATION.

A nursing home must employ or obtain the services of a pharmacist currently licensed by the Board of Pharmacy who:

A. provides consultation on all aspects of the provision of pharmacy services in the nursing home;

B. establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and

C. determines that drug records are accurately maintained and that an account of all controlled drugs is maintained.

STAT AUTH: MS s 144A.04; 144A.08; 256B.431

HIST: 20 SR 303

Current as of 01/19/05

4658.1310 DRUG REGIMEN REVIEW.

A. The drug regimen of each resident must be reviewed at least monthly by a pharmacist currently licensed by the Board of Pharmacy. This review must be done in accordance with Appendix N of the State Operations Manual, Surveyor Procedures for Pharmaceutical Service Requirements in Long-Term Care, published by the Department of Health and Human Services, Health Care Financing Administration, April 1992. This standard is incorporated by reference. It is available through the Minitex interlibrary loan system. It is not subject to frequent change.

B. The pharmacist must report any irregularities to the director of nursing services and the attending physician, and these reports must be acted upon by the time of the next physician visit, or sooner, if indicated by the pharmacist. For purposes of this part, "acted upon" means the acceptance or rejection of the report and the signing or initialing by the director of nursing services and the attending physician.

C. If the attending physician does not concur with the pharmacist's recommendation, or does not provide adequate justification, and the pharmacist believes the resident's quality of life is being adversely affected, the pharmacist must refer the matter to the medical director for review if the medical director is not the attending physician. If the medical director determines that the attending physician does not have adequate justification for the order and if the attending physician does not change the order, the matter must be referred for review to the quality assessment and assurance committee required by part 4658.0070. If the attending physician is the medical director, the consulting pharmacist must refer the matter directly to the quality assessment and assurance committee.

STAT AUTH: MS s 144A.04; 144A.08; 256B.431

HIST: 20 SR 303
4658.1315 UNNECESSARY DRUG USAGE.

Subpart 1. General. A resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:

A. in excessive dose, including duplicate drug therapy;

B. for excessive duration;

C. without adequate indications for its use; or

D. in the presence of adverse consequences which indicate the dose should be reduced or discontinued.

In addition to the drug regimen review required in part 4658.1310, the nursing home must comply with provisions in the Interpretive Guidelines for Code of Federal Regulations, title 42, section 483.25(1)(1) found in Appendix P of the State Operations Manual, Guidance to Surveyors for Long-Term Care Facilities, published by the Department of Health and Human Services, Health Care Financing Administration, April 1992. This standard is incorporated by reference. It is available through the Minitex interlibrary loan system and the State Law Library. It is not subject to frequent change.

Subp. 2. Monitoring. A nursing home must monitor each resident's drug regimen for unnecessary drug usage, based on the nursing home's policies and procedures, and the pharmacist must report any irregularity to the resident's attending physician. If the attending physician does not concur with the nursing home's recommendation, or does not provide adequate justification, and the pharmacist believes the resident's quality of life is being adversely affected, the pharmacist must refer the matter to the medical director for review if the medical director is not the attending physician. If the medical director determines that the attending physician does not have adequate justification for the order and if the attending physician does not change the order, the matter must be referred for review to the Quality Assurance and Assessment (QAA) committee required by part 4658.0070. If the attending physician is the medical director, the consulting pharmacist shall refer the matter directly to the QAA.

STAT AUTH: MS s 144A.04; 144A.08; 256B.431

HIST: 20 SR 303

Current as of 01/19/05

4658.1320 MEDICATION ERRORS.

A nursing home must ensure that:
A. Its medication error rate is less than five percent as described in the Interpretive Guidelines for Code of Federal Regulations, title 42, section 483.25(m), found in Appendix P of the State Operations Manual, Guidance to Surveyors for Long-Term Care Facilities, which is incorporated by reference in part 4658.1315. For purposes of this part, a medication error means:

(1) a discrepancy between what was prescribed and what medications are actually administered to residents in the nursing home; or

(2) the administration of expired medications.

B. It is free of any significant medication error. A significant medication error is:

(1) an error which causes the resident discomfort or jeopardizes the resident’s health or safety; or

(2) medication from a category that usually requires the medication in the resident’s blood to be titrated to a specific blood level and a single medication error could alter that level and precipitate a reoccurrence of symptoms or toxicity.

C. All medications are administered as prescribed. An incident report or medication error report must be filed for any medication error that occurs. Any significant medication errors or resident reactions must be reported to the physician or the physician's designee and the resident or the resident's legal guardian or designated representative and an explanation must be made in the resident’s clinical record.

STAT AUTH: MS s 144A.04; 144A.08; 256B.431

HIST: 20 SR 303

Current as of 01/19/05

4658.1325 ADMINISTRATION OF MEDICATIONS.

Subpart 1. Pharmacy services. A nursing home must arrange for the provision of pharmacy services.

Subp. 2. Staff designated to administer medications. A nurse or unlicensed nursing personnel, as described in part 4658.1360, must be designated as responsible for the administration of medications during each work period.

Subp. 3. List of staff to administer medications. A list of staff authorized to administer medications must be available at each nursing station.

Subp. 4. Self-administration. A resident may self-administer medications if the comprehensive resident assessment and comprehensive plan of care as required in parts 4658.0400 and 4658.0405 indicate this practice is safe and there is a written order from the attending physician.
Subp. 5. Medications administered by injection. Medications for injection may be given only by a physician, physician’s assistant, registered nurse, nurse practitioner, or licensed practical nurse, or may be self-administered by a resident in accordance with subpart 4.

Subp. 6. Medications added to food. Adding medication to a resident’s food must be prescribed by the resident’s physician and the resident, or the resident’s legal guardian or designated representative, must consent to having medication added to food. This subpart does not apply to adding medication to food if the sole purpose is for resident ease in swallowing.

Subp. 7. Administration requirements. The administration of medications must include the complete procedure of checking the resident’s record, transferring individual doses of the medication from the resident’s prescription container, and distributing the medication to the resident.

Subp. 8. Documentation of administration. The name, date, time, quantity of dosage, and method of administration of all medications, and the signature of the nurse or authorized person who administered and observed the same must be recorded in the resident’s clinical record. Documentation of the administration must take place following the administration of the medication. If administration of the medication was not completed as prescribed, the documentation must include the reason the administration was not completed, and the follow-up that was provided, such as notification of a registered nurse or the resident’s attending physician.

STAT AUTH: MS s 144A.04; 144A.08; 256B.431
HIST: 20 SR 303
Current as of 01/19/05

4658.1330 WRITTEN AUTHORIZATION FOR ADMINISTERING DRUGS.

All medications, including those brought into a nursing home by a resident, must be administered only in accordance with a written order signed by a health care practitioner licensed to prescribe in Minnesota except that order may be given by telephone provided that the order is done according to part 4658.0455.

STAT AUTH: MS s 144A.04; 144A.08; 256B.431
HIST: 20 SR 303
Current as of 01/19/05

4658.1335 STOCK MEDICATIONS.

Subpart 1. Stock supply medications. Only medications obtainable without prescription may be retained in general stock supply and must be kept in the original labeled container.
Subp. 2. Emergency medication supply. A nursing home may have an emergency medication supply which must be approved by the QAA committee. The contents, maintenance, and use of the emergency medication supply must comply with part 6800.6700.

Subp. 3. Prohibitions. No prescription drug supply for one resident may be used or saved for the use of another resident in the nursing home.

STAT AUTH: MS s 144A.04; 144A.08; 256B.431
HIST: 20 SR 303
Current as of 01/19/05

4658.1340 MEDICINE CABINET AND PREPARATION AREA.

Subpart 1. Storage of drugs. A nursing home must store all drugs in locked compartments under proper temperature controls, and permit only authorized nursing personnel to have access to the keys.

Subp. 2. Storage of Schedule II drugs. A nursing home must provide separately locked compartments, permanently affixed to the physical plant or medication cart for storage of controlled drugs listed in Minnesota Statutes, section 152.02, subdivision 3.

STAT AUTH: MS s 144A.04; 144A.08; 256B.431
HIST: 20 SR 303
Current as of 01/19/05

4658.1345 LABELING OF DRUGS.

Drugs used in the nursing home must be labeled in accordance with part 6800.6300.

STAT AUTH: MS s 144A.04; 144A.08; 256B.431
HIST: 20 SR 303
Current as of 01/19/05

4658.1350 DISPOSITION OF MEDICATIONS.

Subpart 1. Drugs given to discharged residents. Current medications, except controlled substances listed in Minnesota Statutes, section 152.02, subdivision 3, belonging to a resident must be given to the resident, or the resident’s legal guardian or designated representative, when discharged or transferred and must be recorded on the clinical record.

Subp. 2. Destruction of medications.
A. Unused portions of controlled substances remaining in the nursing home after death or discharge of a resident for whom they were prescribed, or any controlled substance discontinued permanently must be destroyed in a manner recommended by the Board of Pharmacy or the consultant pharmacist. The board or the pharmacist must furnish the necessary instructions and forms, a copy of which must be kept on file in the nursing home for two years.

B. Unused portions of other prescription drugs remaining in the nursing home after the death or discharge of the resident for whom they were prescribed or any prescriptions discontinued permanently, must be destroyed according to part 6800.6500, subpart 3, or must be returned to the pharmacy according to part 6800.2700, subpart 2. A notation of the destruction listing the date, quantity, name of medication, prescription number, signature of the person destroying the drugs, and signature of the witness to the destruction must be recorded on the clinical record.

Subp. 3. Loss or spillage. When a loss or spillage of a prescribed Schedule II drug occurs, an explanatory notation must be made in a Schedule II record. The notation must be signed by the person responsible for the loss or spillage and by one witness who must also observe the destruction of any remaining contaminated drug by flushing into the sewer system or wiping up the spill.

Subp. 4. Returned to pharmacy. Drugs and prescribed medications used in nursing homes may be returned to the dispensing pharmacy according to part 6800.2700, subpart 2.

STAT AUTH: MS s 144A.04; 144A.08; 256B.431
HIST: 20 SR 303
Current as of 01/19/05

4658.1355 MEDICATION REFERENCE BOOK.

A nursing home must maintain at least one current medication reference book. For the purposes of this part, "current" means material published within the previous two years.

STAT AUTH: MS s 144A.04; 144A.08; 256B.431
HIST: 20 SR 303
Current as of 01/19/05

4658.1360 ADMINISTRATION OF MEDICATIONS BY UNLICENSED PERSONNEL.

Subpart 1. Authorization. The director of nursing services may delegate medication administration to unlicensed personnel according to Minnesota Statutes, sections 148.171, subdivision 15, and 148.262, subdivision 7.
Subp. 2. Training. Unlicensed nursing personnel who administer medications in a nursing home must:

A. have completed a nursing assistant training program approved by the department; and

B. have completed a standardized medication administration training program for unlicensed personnel in nursing homes which is offered through a Minnesota postsecondary educational institution that includes, at a minimum, instruction on the following:

(1) the complete procedure of checking the resident’s medication record;

(2) preparation of the medication for administration;

(3) administration of the medication to the resident;

(4) assisting residents with self-administration as necessary;

(5) documentation after administration of the date, time, dosage, and method of administration of all medications, or the reason for not administering the medication as ordered, and the signature of the nurse or authorized person who administered and observed the same; and

(6) the type of information regarding medication administration reportable to a nurse.

Subp. 3. Documentation of training course. A nursing home must keep written documentation verifying completion of the required course by all unlicensed nursing personnel administering medications.

Subp. 4. Medication administration. A person who completes the required training course, and has been delegated the responsibility, may administer medication, whether oral, suppository, eye drops, ear drops, inhalant, or topical, if:

A. the medications are regularly scheduled; and

B. in the case of pro re nata (PRN) medications, the administration of the medication is authorized by a nurse or reported to a nurse within a time period that is specified by nursing home policy prior to the administration.

STAT AUTH: MS s 144A.04; 144A.08; 256B.431

HIST: 20 SR 303; L 1999 c 172 s 18

Current as of 01/19/05
123 PHARMACY SERVICES

123.01 General. The facility shall provide routine drugs, emergency drugs and biologicals to its residents or obtain them by agreement.

123.02 Policies and procedures. Each facility shall have policies and procedures to assure the following:

1. Accurate acquiring;
2. Receiving;
3. Dispensing;
4. Storage; and
5. Administration of all drugs and biologicals.

123.03 Consultation. Each facility shall obtain the services of a licensed pharmacist who will be responsible for:

1. Establishing a system of records of receipt and disposition of all controlled drugs and to determine that drug records are in order and that an account of all controlled drugs are maintained and reconciled;
2. Provide drugs regimen review in the facility on each resident every thirty (30) days by a licensed pharmacist;
3. Report any irregularities to the attending physician or nurse practitioner and the director or nursing; and
4. Records must reflect that the consultation pharmacist monthly report is acted upon.

123.04 Labeling of drugs. Each facility shall follow the Mississippi State Board of Pharmacy labeling requirements.

123.05 Disposal of drugs.

1. Unused portions of medicine may be given to a discharged resident or the responsible party upon orders of the prescribing physician or nurse practitioner.

2. Drugs and pharmaceuticals discontinued by the written orders of an attending physician or nurse practitioner or left in the facility on discharge or death of the resident will be disposed of according to the Mississippi State Board of Pharmacy disposal requirements.
123.06 Poisonous Substances. All poisonous substances such as insecticides, caustic cleaning agents, rodenticide, and other such agents must be plainly labeled and kept in locked cabinet or closet. No substances of this type shall be kept in the following areas: kitchen, dining area, food storage room or pantry, medicine cabinet or drug room, resident's bedroom or toilet, public rooms, or spaces.
19 CSR 30-84.020 Certified Medication Technician Training Program

PURPOSE: Individuals who administer medications in intermediate care and skilled nursing facilities are required by rule to have successfully completed a medication administration training program approved by the Department of Health and Senior Services. This rule sets forth the requirements for the approval of a medication technician training program designating the required course curriculum content, outlining the qualifications required of students and instructors, designating approved training facilities, outlining the testing and certification requirements, and establishing an update course.

[PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.]

(1) Definitions. For the purpose of this rule the following definitions shall apply.

(A) Cooperating agency—an intermediate care facility (ICF) or skilled nursing facility (SNF) licensed by the Department of Health and Senior Services (the department) which has entered into a written agreement with the educational training agency to provide the setting for the clinical portion of the course.

(B) Course—the sixty (60) hours of classroom training, eight (8) hours of clinical practice, and a two (2)-part final examination of the department-approved certified medication technician course curriculum.

(C) Educational training agency—an area vocational-technical school, an area career center, a comprehensive high school, a community college, or an approved four (4) year institution of higher learning that is approved by the department to conduct the Certified Medication Technician (CMT) Course. A long-term care facility cannot be a training agency.

(2) The CMT course shall be prescribed by the department in order to prepare individuals for employment as certified medication technicians in intermediate care facilities and skilled nursing facilities (ICF/SNF). The program shall be designed to teach skills in medication administration of nonparenteral medications, which will qualify students to perform this procedure to assist licensed practical nurses (LPNs) or registered nurses (RNs) in medication therapy. All aspects of the CMT course included in this rule shall be met in order for a program to be approved.
(3) If the CMT course is to be conducted in an ICF/SNF, the facility must enter into an agreement with an educational training agency which is responsible to:

(A) Provide administration of the Test of Adult Basic Education (TABE) and review of the student’s qualifications;

(B) Arrange for a department-approved instructor;

(C) Arrange for administration of the final examination; and

(D) Certify the students through a department-approved certifying agency which is any one of the long-term care associations or any other department-approved agency authorized to issue certificates.

(4) The objective of the CMT Training Program shall be to ensure that the medication technician will be able to do the following:

(A) Prepare, administer, and document administration of medications by all routes except those administered by the parenteral route;

(B) Observe, report, and document responses of residents to medications administered;

(C) Identify responsibilities associated with acquisition, storage, and security of medications;

(D) Identify appropriate medication reference materials;

(E) Observe, report, and document responses of residents to medications;

(F) Identify lines of authority and areas of responsibility; and

(G) Identify what constitutes a medication error.

(5) The course shall consist of at least sixty (60) classroom hours of instruction taught by a department-approved CMT instructor or examiner (instructor/examiner). The course shall include an additional minimum eight (8) hours of clinical practice conducted in a licensed ICF or SNF under the direct supervision of the CMT instructor/examiner or under the direct supervision of an RN employed by the cooperating agency and designated by the educational training agency in section (9) of this rule. The instructor/examiner or the RN employed by the cooperating agency may require the student to complete more than the minimum eight (8) hours of clinical practice based on each student’s mastery of course content. A final written examination and a minimum two (2)-hour final practicum examination must be conducted in an ICF/SNF.

(A) For all courses beginning on or after the effective date of this rule, the student manual and course developed by the Department of Elementary and Secondary Education and the Missouri Center for Career Education at University of Central Missouri as outlined in the manual entitled Certified Medication Technician, (Revised 2008), incorporated by reference in this rule and available by Internet at: www.cmttest.org shall be considered the approved course curriculum. This rule does not incorporate any subsequent amendments or additions.
(B) For all courses beginning on or after the effective date of this rule, the approved course curriculum instructor’s guide shall be the companion Instructor’s Guide, (Revised 2008), incorporated by reference in this rule, and accessed by Internet: www.cmttest.org. This rule does not incorporate any subsequent amendments or additions.

(C) Students and instructors shall each have a copy of the approved course curriculum manual.

(D) The curriculum content shall include procedures and instructions in the following areas:

1. Basic review of body systems and medication effects on each;
2. Medical terminology;
3. Infection control;
4. Medication classifications;
5. Medication dosages, measurements, and forms;
6. Acquisition, storage, and security;
7. Problems of observations in medication therapy; and
8. Administration by oral, rectal, vaginal, otic, ophthalmic, nasal, skin, topical, transdermal patches, and oral metered dose inhaler.

(E) A student shall not be allowed to independently administer medications until successfully completing the CMT course. The CMT Course Evaluation Record may be used as authorization to independently administer medications for up to sixty (60) days. After this period the student must be listed on the Missouri CNA Registry as an active CMT.

(6) Student Qualifications.

(A) Any individual employable in an ICF/SNF who will be involved in direct resident care shall be eligible to enroll as a student in the course if the following criteria are also met:

1. High school diploma or General Education Development (GED) Certificate;
2. A minimum score of 8.9 on both Vocabulary and Comprehension tests and a minimum score of 7.0 on Mathematics Concepts and Application tests on the D level of the TABE. The tests shall be administered by the educational training agency;
3. Six (6) months of employment as a CNA who is listed as active on the Missouri CNA Registry;
4. For an individual currently employed in a long-term care facility, a letter of recommendation submitted to the educational training agency by the administrator or director of nursing of the facility, or for an individual not currently employed in a long-term care facility, a letter of recommendation submitted to the educational training agency by a previous long-term care facility employer;

5. The individual is not listed on the department’s Employee Disqualification List (EDL) and does not have a Federal Indicator on the Missouri CNA Registry or any other state’s CNA Registry that the educational training agency has checked based on a belief that information on the individual may be included;

6. The individual has not been convicted of or entered a plea of guilty or nolo contendere to a crime in this state or any other state, which if committed in Missouri would be a Class A or Class B felony violation of Chapters 565, 566, or 569, RSMo, or any violation of subsection 3 of section 198.070, or section 568.020, RSMo, unless a good cause waiver has been granted by the department under the provisions of 19 CSR 3082.060; and

7. The individual meets the employment requirements listed in 19 CSR 30-85.042(32).

(B) Students who drop the CMT course due to illness or incapacity may reenroll within six (6) months of the date the student withdrew from the course and make up the missed course material upon presenting proof of prior attendance and materials covered if allowed by the educational training agency’s policy.

(C) Individuals seeking to challenge the CMT examination shall be listed as active on the Missouri CNA Registry and shall meet the criteria in paragraph (6)(A)6. of this rule. If not listed as active on the Missouri CNA Registry, the individual shall first apply to challenge and successfully pass the CNA written and practicum examination. The following individuals may qualify to challenge the final written and practicum CMT examination:

1. A student enrolled in a professional nursing school or in a practical nursing program who has completed a medication administration course and who has a letter of endorsement from the school or program director;

2. An individual who successfully completed a professional or practical nursing program in the last five (5) years but who failed the professional (RN) or practical (LPN) state licensure examination;

3. An individual who provides evidence of successful completion of a department-approved CMT course while working as an aide at a facility operated by the Missouri Department of Mental Health who is listed as a CNA on the Missouri CNA Registry.

(D) An individual who provides evidence of successful completion of a Missouri Department of Mental Health (DMH) approved CMT course while working at a facility operated by the DMH but who is not listed as a CNA on the department’s Missouri CNA Registry may
challenge the CMT examination. The CMT challenge may only be made after first completing the orientation module of the department’s approved Nurse Assistant Training Program and successfully challenging the final CNA examination so that the individual’s name appears on the department’s Missouri CNA Registry.

(E) An individual who has successfully completed a department-approved medication technician course in another state, who is currently listed as a CMT in good standing in that state, and who submits a letter of recommendation to the department’s Health Education Unit from an administrator or director of nursing of a facility in which the individual worked as a medication technician.

(7) Obtaining Approval to Challenge the CMT Examination.

(A) An individual wanting to challenge the written and practicum final examination shall submit a request in writing to the department’s Health Education Unit enclosing documentation required by this rule. If approved to challenge the examination, a letter so stating will be sent from the department to be presented to the educational training agency. The educational training agency shall review and maintain a copy of the letter in the agency’s file prior to scheduling the individual for testing. Challenge approval letters shall be valid for one hundred twenty (120) days from the date of the department’s approval.

(B) An individual who has successfully completed a professional or practical nursing program and who has not yet taken or received the results of the state licensure examination may request a qualifying letter from the department’s Health Education Unit allowing the individual to administer medication in a long-term care facility. The qualifying letter allows the individual to administer medications according to this regulation in lieu of a certificate or the individual being listed on the Missouri CNA Registry as an active CMT. However, if more than ninety (90) days have lapsed since graduation or since taking the Missouri State Board Examination with no successful results confirmed, the individual shall request department approval to challenge the final examination for certification as a medication technician.

(C) An individual shall not administer medications without the instructor present until the individual has successfully completed the challenge examination and holds an authorized signed CMT Course Evaluation Record. An authorized signed CMT Course Evaluation Record is good for up to sixty (60) calendar days from the examination date pending receipt of the certificate or of listing on the Missouri CNA Registry as an active CMT.

(8) CMT Course Examiner Qualification Requirements.

(A) In order to qualify as an instructor, examiner, or both, the individual:

1. Shall be currently licensed to practice as an RN in Missouri or shall have a temporary permit from the Missouri State Board of Nursing. The instructor/examiner shall not be the subject of current disciplinary action, such as probation, suspension, or revocation of license;
2. Shall hold a current Certified Medication Technician teaching certificate from the Department of Elementary and Secondary Education, Division of Career Education;

3. Shall complete an instructor/examiner program workshop and be listed as a qualified CMT instructor/examiner on the department’s Instructor/Examiner Registry;

4. Shall sign an agreement with the department to protect and keep secure the final examination and the PIN used to electronically access the Instructor Guide/Test Bank;

5. May be an employee of the ICF/SNF in which training is conducted, but the ICF/SNF must have a cooperative agreement with an educational training agency;

6. Shall teach the course or facilitate the challenge examination only as permitted by the educational training agency; and

7. May be assisted by pharmacists as guest instructors in the areas of medication systems, regulations governing medications, medication actions, adverse reactions, medication interactions, and medication errors.

(B) CMT Instructor/Examiner Disqualification Criteria.

1. An individual shall not be approved to be an instructor/examiner if he or she has ever been found to have knowingly acted or omitted any duty in a manner which would materially and adversely affect the health, safety, welfare, or property of a resident.

2. An individual who has been approved to be an instructor/examiner shall have that status revoked if, after an investigation by the department, it is found that the individual:

A. Knowingly acted or omitted any duty in a manner which materially and adversely affected the health, safety, welfare, or property of a resident;

B. Defrauded an educational agency or student by taking payment and not completing a course or following through with certification documentation required by 19 CSR 30-84.020;

C. Failed to teach, examine, or clinically supervise in accordance with 19 CSR 30-84.020;

D. Falsified information on the CMT Course Evaluation Record or any other required documentation;

E. Failed to keep secure the automated PIN access system;

F. Failed to keep secure the CMT web-based, department-approved Instructor Guide/Test Bank;

G. Copied test questions or answer keys; or

H. Prepared students directly from the exam or utilized unfair or subjective testing techniques.
(C) When an individual is no longer qualified to be an instructor/examiner, the department shall:

1. Notify the individual that he or she is no longer eligible to be an instructor/examiner;

2. Notify all certifying agencies that the individual is no longer considered an approved instructor or examiner; and

3. Remove the individual’s name from the department’s Instructor/Examiner Registry.

(D) To be reinstated as an approved instructor/examiner the individual shall submit a request in writing to the department’s Health Education Unit stating the reasons why reinstatement is warranted. If the individual has not attended the Train-the-Trainer Program Workshop within two (2) years of the date of request, the individual shall retake the Train-the-Trainer Program Workshop. The Section for Long-Term Care administrator or designee shall respond in writing to the request.

(9) Educational Training Agencies.

(A) The following entities are eligible to apply to the department’s Health Education Unit to be an approved educational training agency: vocational-technical schools, comprehensive high schools, community colleges or approved four (4)-year institutions of higher learning.

(B) All classrooms shall contain sufficient space, equipment and teaching aids to meet the course objectives.

(C) A school requesting approval to teach the CMT Training Course or facilitate challenging the examination shall file an application with the department’s Health Education Unit giving the names of the instructors and listing the equipment and classroom space that will be used and shall provide a copy of an agreement with the cooperating agency where the course, clinical practice, or final practicum examination of the program will be conducted and provide the names of the RNs supervising the clinical observation. Educational training agencies shall be approved for a two (2)-year period and shall submit a new application thirty (30) days prior to the expiration date.

(D) The cooperating agency in which clinical practice and the final practicum examination are conducted shall allow students, instructors and examiners access to the medication room, supervised access to residents and access to the medication documentation area.

(E) There shall be a signed written agreement between the educational training agency and each cooperating agency which specifies the rules, responsibilities, and liabilities of each party.

(F) The educational training agency is responsible for sending the department’s Health Education Unit a copy of the most current signed agreement with the cooperating agency where any portion of the course or the entire course will be conducted. The department shall review all signed agreements of cooperation. On-site inspections of the cooperating agency or the educational training agency may be made by the department if problems occur or complaints are received. If requirements are not met, the status as an educational training agency may be revoked by the department.
(G) The classroom portion of the course may be taught in an ICF/SNF if there is an approved educational training agency as a sponsor.

(10) Certified Medication Technician Course Testing.

(A) Prior to the student’s enrollment, the TABE shall be administered by qualified examiners designated by the educational training agency. See paragraph (6)(A)2. of this rule.

(B) To be eligible for the final course examination, students shall have achieved a score of at least eighty percent (80%) on each written examination in the course curriculum.

(C) Courses beginning on or after the effective date of this rule require the instructor/examiner to administer the department-approved written final examination accessed through the department’s website at www.cmttest.org using a secure PIN system. The final examination shall include fifty (50) multiple choice questions based on course objectives. A score of at least eighty percent (80%) is required for passing.

(D) The practicum examination shall include preparing and administering all nonparenteral routes and documenting administration of medications administered to residents. The practicum examination shall be conducted under the direct supervision of the department-approved instructor/examiner and the individual responsible for medication administered in the ICF/SNF. Testing on medications not available in the ICF/SNF shall be done in a simulated classroom situation.

(E) The final examination may be retaken one (1) time within ninety (90) days of the first fail date without repeating the course.

(F) A challenge examination may be taken one (1) time. If failed, the entire course shall be taken.

(G) The instructor/examiner shall complete the CMT Course Evaluation Record, which includes competencies, scores, and other identifying information.

(11) Records and Certification.

(A) Records.

1. The educational training agency shall maintain records for at least two (2) years for those individuals who have completed the CMT Course and shall submit to a department-approved certifying agency within thirty (30) calendar days from the examination date the following: the student’s legal name, Social Security number, class beginning date and completion date, whether certified by a challenge or full course, and other identifying information from the CMT Course Evaluation Record.

2. The educational training agency shall provide a copy of the CMT Course Evaluation Record to the certified medication technician.
3. The educational training agency may release a transcript with written permission from the student in accordance with the provisions of the Family Education Rights and Privacy Act, 20 U.S.C. section 1232g.

(B) Certification.

1. The educational training agency shall maintain the records of individuals who have been enrolled in the CMT course and shall submit to a department-approved certifying agency, the legal name, date of birth, Social Security number, certificate number, certification date, educational training agency and cooperating agency for all individuals who successfully complete the course and final examination within thirty (30) calendar days from the examination date. Upon receipt of the successful completion of the course, a department-approved certifying agency shall issue a certificate of completion to the student through the educational training agency. Any final examination documentation over sixty (60) days old shall be invalid.

1. Each week the certifying agency shall provide the department's Health Education Unit with names and other identifying information of those receiving certificates.

2. The department shall maintain a list of certifying agencies approved to issue certificates for the CMT Training Program. In order for a certifying agency to be approved by the department, the agency shall enter into an annually renewable agreement of cooperation with the department.

(12) Requirements for Hiring an Individual as a CMT.

(A) The department shall maintain a CNA Registry, which will list the names of CMTs and other relevant and identifying information.

(B) Any individual seeking employment in an ICF/SNF as a CMT must be employable as a CNA and be listed with active status as a CNA and CMT on the department’s CNA Registry.

(C) When employing an individual as a CMT, the facility shall contact the department’s website at www.dhss.mo.gov/cnaregistry in order to verify current certification status of the individual. Current registry status must be verified even though the individual presents a CMT certificate.


PURPOSE: Individuals who administer medications in residential care facilities I and II are required by 13 CSR 15-15.042(49) to be either a physician, a licensed nurse, a certified medication technician or a level I medication aide. This rule sets forth the requirements for approval of a Level I Medication Aide Training Program designating the required course curriculum content, outlining the qualifications required of students and instructors, designating approved training facilities and outlining the testing and certification requirements.

[PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.]

(1) The Level I Medication Aide Training Program shall be administered by the Department of Health and Senior Services (the department) in order to prepare individuals for employment as level I medication aides in residential care facilities (RCFs) and assisted living facilities (ALFs). The program shall be designed to teach skills in medication administration of nonparenteral medications in order to qualify students to perform this procedure only in RCFs and ALFs in Missouri.

(2) All aspects of the level I Medication Aide Training Program included in this rule shall be met in order for a program to be considered approved.

(3) The objective of the level I Medication Aide Training Program shall be to ensure that the medication aide will be able to—define the role of a level I medication aide; prepare, administer and chart medications by nonparenteral routes; observe, report and record unusual responses to medications; identify responsibilities associated with control and storage of medications; and utilize appropriate drug reference materials.

(4) The course shall be an independent self-study course with a minimum of sixteen (16) hours of integrated formal instruction and practice sessions supervised by an approved instructor which shall include a final written and practicum examination.

(5) The curriculum content shall include procedures and instructions in the following areas: basic human needs and relationships; drug classifications and their implications; assessing drug reactions; techniques of drug administration; medication storage and control; drug reference resources; and infection control.

(6) The course developed by the Missouri Department of Elementary and Secondary Education and the Department of Health and Senior Services as outlined in the manual entitled Level I Medication Aide (50-6064-S and 50-6064-I) 1993 edition, produced by the Instructional Materials Laboratory, University of Missouri-Columbia, incorporated by reference in this rule and available through the Department of Health and Senior Services, PO Box 570, Jefferson City, MO 65102-0570, shall be considered the approved course curriculum. This rule does not incorporate any subsequent amendments or additions to the
materials incorporated by reference. Students and instructors each shall have a copy of this manual.

(7) A student shall not administer medications without the instructor present until s/he successfully completes the course and obtains a certificate.

(8) Student Qualifications.

(A) Any individual employable by an RCF or ALF to be involved in direct resident care shall be eligible to enroll as a student in the course. Employable shall mean an individual who is at least eighteen (18) years of age; not listed on the department’s Employee Disqualification List (EDL) and has not been convicted of, or entered a plea of guilty or nolo contendere to a crime in this state or any other state, which if committed in Missouri would be a class A or B felony violation of Chapters 565, 566, and 569, RSMo, any violation of section 568.020, RSMo or any violation of section 198.070.3, RSMo, unless a good cause waiver has been granted by the department pursuant to the provisions of 19 CSR 30-82.060.

(B) The following individuals may qualify as level I medication aides by successfully challenging the final examination: Individuals either enrolled in or who have been enrolled in a professional nursing school or in a practical nursing program who have completed the medication administration or pharmacology course and who have letters of endorsement from the directors of their respective programs.

(9) Those persons wanting to challenge the final examination shall submit a request in writing to the department’s Section of Long Term Care director enclosing applicable documentation. If approved to challenge the examination, a letter so stating will be sent from the division to present to an approved instructor so that arrangements can be made for testing.

(10) Instructor Qualifications.

(A) An instructor shall be currently licensed to practice as either a registered nurse or practical nurse in Missouri or shall hold a current temporary permit from the Missouri State Board of Nursing. The licensee shall not be subject to current disciplinary action such as censure probation, suspension or revocation. If the individual is a licensed practical nurse, the following additional requirements shall be met:

1. Shall be a graduate of an accredited program which has pharmacology in the curriculum.

2. This additional requirement shall not be waived.

(B) In order to be qualified as an instructor, the individual shall have had one (1) year’s experience working in a long-term care (LTC) facility licensed by the department or the Department of Mental Health within the past five (5) years; or shall be currently employed in an LTC facility licensed by the department or the Department of Mental Health and shall have been employed by that facility for at least six (6) months; or shall be an instructor in a Health Occupations Education program; and shall have attended a “Train the Trainer”
workshop to implement the Level I Medication Aide Program conducted by a Missouri registered nurse presenter approved by the department.

(C) Upon completion of the workshop and receipt of all credentials validating qualifications, the presenter shall issue a certificate indicating that an instructor is approved to teach the level I medication aide course and shall submit the names of the approved instructors to the approved LTC association.

(D) A person who has been approved as an instructor shall have that status revoked if, after an investigation by the division, it is found that the instructor:

1. Accepted money from a student and did not follow through with the class or upon successful completion of the class did not follow through with certification;

2. Falsified information on the final score sheet or any other required documentation; or

   Administered the final examination incorrectly and not in accordance with section (12) of this rule.

(E) Once an instructor's status is revoked only the director of the division or his/her designee may reinstate the individual after the individual requests reinstatement documenting new circumstances. If the instructor's status is revoked or reinstated, the division shall immediately notify all certifying agencies of the action.

(11) Sponsoring Agencies.

(A) The following entities are eligible to apply to the department to be an approved training agency: an area vocational-technical school, a comprehensive high school, a community college, an approved four (4) year institution of higher learning or an RCF or ALF licensed by the department or an LTC association.

(B) The sponsoring agency is responsible for obtaining an approved instructor, determining the number of manuals needed for a given program, ordering the manuals for the students and presenting a class schedule for approval by an approved LTC association. The required information will include: the name of the approved instructor; the instructor's Social Security number, current address and telephone number; the number of students enrolled; the name, address, telephone number, Social Security number and age of each student; the name and address of the facility that employs the student, if applicable; the date and location of each class to be held; and the date and location of the final examination. The LTC association which approved the course shall be notified in advance if there are any changes in dates or locations.

(C) Classrooms used for training shall contain sufficient space, equipment and teaching aids to meet the course objectives as determined by an approved LTC association.
(D) If the instructor is not directly employed by the agency, there shall be a signed written agreement between the sponsoring agency and the instructor which shall specify the role, responsibilities and liabilities of each party.

(12) Testing.

(A) The final examination shall consist of a written and a practicum examination administered by the instructor.

1. The written examination shall include twenty-five (25) questions based on the course objectives.

2. The practicum examination shall be done in an LTC facility which shall include the preparation and administration by nonparenteral routes and recording of medications administered to residents under the direct supervision of the instructor and the person responsible for medication administration in the long-term care facility. Testing on medications not available in the LTC facility shall be done in a simulated classroom situation.

(B) A score of eighty percent (80%) is required for passing the final written examination and one hundred percent (100%) accuracy in the performance of the steps of procedure in the practicum examination.

(C) The final examination, if not successfully passed, may be retaken within ninety (90) days one (1) time without repeating the course, however, those challenging the final examination must complete the course if the examination is not passed in the challenge process.

(D) The instructor shall complete final records and shall submit these and all test booklets to the sponsoring agency.

(13) Records and Certification.

(A) Records.

1. The sponsoring agency shall maintain records of all individuals who have been enrolled in the Level I Medication Aide Program and shall submit to the LTC association which approved the course all test booklets, a copy of the score sheets and a complete class roster.

2. A copy of the final record shall be provided to any individual enrolled in the course.

3. A final record may be released only with written permission from the student in accordance with the provisions of the Privacy Act (PL 90-247).

(B) Certification.
1. The LTC association which approved the course shall award a Level I medication aide certificate to any individual successfully completing the course upon receiving the required final records and test booklets from the sponsoring agency.

2. The LTC association which approved the course shall submit to the department the names of all individuals receiving certificates.

(14) The department shall maintain a list of LTC associations approved to handle the Level I Medication Aide Training Program. In order for an LTC association to be approved by the department the association shall enter into an agreement of cooperation with the department which shall be renewable annually and shall effectively carry out the following responsibilities:

(A) Maintain a roster of approved instructors;

(B) Approve sponsoring agencies, class schedules and classroom space;

(C) Distribute final examinations, review test booklets, score sheets and class rosters;

(D) Award certificates to individuals who successfully complete the course, provide the department with the names of those receiving certificates; and

(E) Maintain records.

(15) Maintaining Certification.

(A) If the department, upon completion of an investigation, finds that the Level I medication aide has stolen or diverted drugs from a resident or facility or has had his/her name added to the employee disqualification list, the division shall delete such person’s name from the department’s Level I medication aide listing. Such deletion shall render the medication aide’s certificate invalid.


19 CSR 30-85.042 Administration and Resident Care Requirements for New and Existing Intermediate Care and Skilled Nursing Facilities

...(14) A pharmacist currently licensed in Missouri shall assist in the development of written policies and procedures regarding pharmaceutical services in the facility.
(46) No medication, treatment or diet shall be given without a written order from a person lawfully authorized to prescribe such and the order shall be followed. No restraint shall be applied except as provided in 13 CSR 1518.010, Resident Rights. I/II

(47) There shall be a safe and effective system of medication distribution, administration, control and use. I/II

(48) Verbal and telephone orders for medication or treatment shall be given only to those individuals licensed or certified to accept orders. Orders shall be immediately reduced to writing and signed by that individual. If a telephone order is given to a certified medication technician, an initial dose of medication or treatment shall not be given until the order has been reviewed by telephone or in person by a licensed nurse or pharmacist. The review shall be documented by the reviewer co-signing the telephone order. II

(49) Medications shall be administered only by a licensed physician, a licensed nurse or a medication technician who has successfully completed the state-approved course for medication administration. II

(50) Injectable medication, other than insulin, shall be administered only by a licensed physician or a licensed nurse. Insulin injections may be administered by a certified medication technician who has successfully completed the state-approved course for insulin administration. II

(51) Self-administration of medication is permitted only if approved in writing by the resident’s physician and it is in accordance with the facility’s policy and procedures. II

(52) All medication errors and adverse reactions shall be reported immediately to the nursing supervisor and the resident’s physician and, if there was a dispensing error, to the issuing pharmacist. II/III

(53) At least monthly a pharmacist or a registered nurse shall review the drug regimen of each resident. Irregularities shall be reported in writing to the resident’s physician, the administrator and the director of nurses. There must be written documentation which indicates how the reports were acted upon. II/III

(54) All prescription medications shall be supplied as individual prescriptions. All medications, including over-the-counter medications, shall be packaged and labeled in accordance with applicable professional pharmacy standards and state and federal drug laws and regulations. The United States Pharmacopoeia (USP) labeling shall include accessory and cautionary instructions as well as the expiration date, when applicable, and the name of the medication as specified in the physician’s order. Over-the-counter medications for individual residents shall be labeled with at least the resident’s name. II/III

(55) If the resident brings medications to the facility, they shall not be used unless the contents have been examined, identified and documented by a pharmacist or a physician. II/III

(56) Facilities shall store all external and internal medications at appropriate temperatures in a safe, clean place and in an orderly manner apart from foodstuffs and dangerous chemicals. A facility shall secure all medications, including those refrigerated, behind at
least one (1) locked door or cabinet. Facilities shall store containers of discontinued medication separately from current medications. II/III

(57) Facilities shall store Schedule II medications, including those in the emergency drug supply, under double lock separately from noncontrolled medication. Schedule II medications may be stored and handled with other noncontrolled medication if the facility has a single unit dose drug distribution system in which the quantity stored is minimal and a missing dose can be readily detected. II

(58) Upon discharge or transfer, a resident may be given medications with a written order from the physician. Instructions for the use of those medications will be provided to the resident or the resident’s designee. III

(59) All non-unit doses and all controlled substances which have been discontinued must be destroyed on the premises within thirty (30) days. Outdated, contaminated or deteriorated medications and non-unit dose medications of deceased residents shall be destroyed within thirty (30) days. Unit dose medications returnable to the pharmacy shall be returned within thirty (30) days. II/III

(60) Medications shall be destroyed in the facility by a pharmacist and a licensed nurse or by two (2) licensed nurses. III

(61) Facilities shall maintain records of medication destroyed in the facility. Records shall include: the resident’s name; the date; the name, strength and quantity of the medication; the prescription number; and the signatures of the participating parties. III

(62) The facility shall maintain records of medication released to the family or resident upon discharge or to the pharmacy. Records shall include: the resident’s name; the date; the name, strength and quantity of the medication; the prescription number; and the signature of the persons releasing and receiving the medication. III

(63) The facility must establish a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation. The system must enable the facility to determine that drug records are in order and that an account of all controlled drugs is maintained and reconciled. II/III

(64) Facilities shall make available to all nursing staff up-to-date reference material on all medications in use in the facility. III

(65) The facility shall develop policies to identify any emergency stock supply of prescription medications to be kept in the facility for resident use only. This emergency drug supply must be checked at least monthly by a pharmacist to ensure its safety for use and compliance with facility policy. A facility shall have the emergency drug supply readily available to medical personnel and use of medications in the emergency drug supply shall assure accountability. III
37.106.606 MINIMUM STANDARDS FOR A SKILLED AND SKILLED/INTERMEDIATE CARE FACILITY: DRUG SERVICES

(1) Medication shall be released to a patient at discharge only on the written authorization of his licensed physician.

(2) Self-administration of medication by a patient is not permitted except on order of his licensed physician.

(3) Any deviation from the prescribed drug dosage, route or frequency of administration and unexpected drug reactions shall be reported immediately to the patient's licensed physician with an entry made on the patient's medical record and on an incident report.

(4) A current medication reference book must be provided at each nurses station. (History: Sec. 50-5-103 and 50-5-404, MCA; IMP, Sec. 50-5-103, 50-5-204 and 50-5404, MCA; NEW, 1980 MAR p. 1587, Eff. 6/13/80; TRANS, from DHES, 2002 MAR p. 185.) Rules 07 through 39 reserved

37.106.1121 MEDICAL ASSISTANCE FACILITIES: PHARMACEUTICAL SERVICES

(1) A medical assistance facility must have pharmaceutical services that meet the needs of the patients and comply with the following standards:

(a) The facility must have either a pharmacy directed by a registered pharmacist or a drug storage area under the supervision of a consulting pharmacist who must develop, supervise, and coordinate all the pharmacy services activities.

(b) The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

(c) When a pharmacist is not available, drugs and biologicals may be removed from the pharmacy or storage area only by personnel designated in writing in medical staff and pharmaceutical services policies, in accordance with federal and state law.

(d) All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed in a manner consistent with federal and state law.

(e) Drugs and biologicals must be kept in a locked storage area.

(f) Outdated, mislabeled, or otherwise unusable drugs and biologicals must be removed from the facility and destroyed; and
(g) Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending practitioner. (History: Sec. 50-5-103, MCA; IMP, Sec. 50-5-101, 50-5-103 and 50-5-204, MCA; NEW, 1989 MAR p. 663, Eff. 4/28/89; TRANS, from DHES, 2002 MAR p. 185.)

37.40.110 SERVICES FURNISHED

(1) Medications given by intravenous or intramuscular injections usually require skilled services. The frequency of injections would be particularly significant in determining whether the patient needs continuous skilled nursing care.

Injections which can usually be self-administered – for example, the well-regulated diabetic who receives a daily insulin injection – do not require skilled services. Oral medications which require immediate changes in dosages because of sudden undesirable side effects or reactions should be administered to the patient and observed by licensed nurses, e.g., anticoagulants, quinidine. This is a skilled service. Where a prolonged regimen of oral drug therapy is instituted, the need for continued presence of skilled nursing personnel can be presumed only during the period in which the routine is being established and changes in dosage cannot be anticipated or accomplished by unskilled personnel, e.g., digitalis.

(a) Administration of eye drops and topical ointments (including those required following cataract surgery) is not a skilled service. In Montana, institutional patients must receive all medications from licensed nurses; this fact, however, would not make the administration of oral medication a skilled service where the same type of medications are frequently prescribed for home use without skilled personnel being present.

(2) Levine tube and gastrostomy feedings must be properly prepared and administered. Supervision and observation by licensed nurses are required, thus making this procedure a skilled service.

12-006.04B Training: The facility must provide initial and ongoing training designed to meet the needs of the resident population. Training must be provided by a person qualified by education, experience, and knowledge in the area of the service being provided. The training must include the following:

...12-006.04B2b Medication Aides: When medication aides are utilized by the facility, there must be ongoing training to ensure competencies are met as provided in 172 NAC 95.
12-006.10 Administration of Medication: The facility must establish and implement policies and procedures to ensure residents receive medications only as legally prescribed by a medical practitioner in accordance with the five rights and prevailing professional standards.

12-006.10A Methods of Administration of Medication: When the facility is responsible for the administration of medication, it must be accomplished by the following methods:

12-006.10A1 Self-Administration: The facility must allow residents of the facility to self-administer medication, with or without supervision, when resident assessment determines resident is capable of doing so.

12-006.10A2 Licensed Health Care Professional: When the facility utilizes licensed health care professionals for whom medication administration is included in the scope of practice, the facility must ensure the medications are properly administered in accordance with prevailing professional standards.

12-006.10A3 Provision of Medication by a Person Other Than a Licensed Health Care Professional: When the facility utilizes persons other than a Licensed Health Care Professional in the provision of medications, the facility must follow 172 NAC 95 and 96. Each facility must establish and implement policies and procedures:

1. To ensure that medication aides who provide medications are trained and have demonstrated the minimum competency standards specified in 172 NAC 95-004;

2. To ensure that competency assessments and/or courses for medication aides have been completed in accordance with the provisions of 172 NAC 96-005;

3. That specify how direction and monitoring will occur when the facility allows medication aides to perform the routine/acceptable activities authorized by 172 NAC 95-005 and as follows:
   a. Provide routine medication; and
   b. Provide medications by the following routes:
      (1) Oral, which includes any medication given by mouth, including sublingual (placing under the tongue) and buccal (placing between the cheek and gum) routes and oral sprays;
      (2) Inhalation, which includes inhalers and nebulizers, including oxygen given by inhalation;
      (3) Topical application of sprays, creams, ointments, and lotions and transdermal patches; and
      (4) Instillation by drops, ointments, and sprays into the eyes, ears, and nose;

4. That specify how direction and monitoring will occur when the facility allows medication aides to perform the additional activities authorized by 172 NAC 95-007, which include but are not limited to:
a. Provision of PRN medications;

b. Provision of medications by additional routes including but not limited to gastrostomy tube, rectal, and vaginal; and/or;

c. Participation in monitoring;

5. That specify how competency determinations will be made for medication aides to perform routine and additional activities pertaining to medication provision;

6. That specify how written direction will be provided for medication aides to perform the additional activities authorized by 172 NAC 95-009;

7. That specify how records of medication provision by medication aides will be recorded and maintained; and

8. That specify how medication errors made by medication aides and adverse reactions to medications will be reported. The reporting must be:

a. Made to the identified person responsible for direction and monitoring;

b. Made immediately upon discovery; and

c. Documented in the resident’s medical record.

12-006.10A4 When the facility is not responsible for the administration/provision of medications, the facility must maintain overall responsibility for the supervision, safety and welfare of the resident.

12-006.10B Medication Record: Each resident must have an individual medication administration record, which must include:

1. The name of the facility;

2. The name of the resident;

3. The room and bed number of the resident;

4. Resident identification number;

5. The name of the medication prescribed;

6. The strength of the individual dose;

7. Directions for administration of the medication;

8. Name of physician; and


12-006.10B1 Medication Documentation: The dose administered to the resident must be properly documented on the medication record by the person who administered the drug,
after the drug is administered. For oral medications, the actual act of swallowing must be observed.

12-006.10B1a If the resident refuses the medication, the refusal must be documented as refused on the medication record.

12-006.10C Medications must be administered by the same person who prepared the dose, except under single unit dose package distribution systems.

12-006.10D Medication Errors: The facility must ensure that it is free of medication error rates of 5% or greater, and residents are free of any significant medication errors.

12-006.10D1 The facility must have a method of recording, reporting, and reviewing medication administration errors. All medication administration errors must be reported to the prescribing medical practitioner in accordance with standards of care.

12-006.10E The facility must have policies and procedures for reporting any adverse reaction to a medication as in accordance with standards of care, to the resident's medical practitioner and for documenting such event in the resident's medical record.

12-006.12 Pharmacotherapy Services: The facility must provide routine and emergency drugs, devices and biologicals to its residents, or obtain them under an agreement. The storage, control, handling, administration, and provision of drugs, devices, and biologicals must be in accordance with state laws and regulations relating to same, and to the practice of pharmacy and medicine and surgery.

12-006.12A Procedures: The facility must develop and implement appropriate policies and procedures for accurate acquiring, receiving, and administering of all medications to meet the needs of each resident.

12-006.12B Pharmacotherapy Services Supervision: The facility must employ or obtain the services of a Nebraska-licensed pharmacist to provide for the development, coordination, and supervision of all pharmaceutical services. The pharmacist is responsible for:

1. Consultation on all aspects of the provision of pharmacotherapy services in the facility;

2. Ensuring that the pharmacotherapy service has procedures for control and accountability of all medications throughout the facility;

3. Ensuring that medication records are in order and that an account of all Schedule II and III controlled substances is maintained and reconciled;

4. Maintaining records of receipt and disposition of all controlled substances in sufficient detail to enable an accurate reconciliation; and

5. Reviewing the drug regimen of each resident at least monthly and reporting any irregularities to the primary medical practitioner and Director of Nursing Services in accordance with standards of care. The drug regimen review must include a signed and dated statement that:
a. No potential problems were found;

b. A problem was found but it was deemed not significant; or

c. A significant problem was found. The statement must include a description of the situation and the information that was communicated to the individual with the authority to correct it, usually the medical practitioner.

12-006.12C Controlled Substances and Prescription Drugs: The facility must comply with all state laws and regulations related to the procurement, storage, administration and destruction of drugs, devices, and biologicals and of those medications subject to the Nebraska Uniform Controlled Substance Act.

12-006.12C1 The possession of a controlled substance or prescription drug is prohibited except as may be ordered by a medical practitioner by prescription for a resident.

12-006.12D Bulk Supply: Any duly licensed facility may purchase bulk quantities of non-prescription drugs, devices, and biologicals e.g., aspirin, milk of magnesia, and certain cough syrups, and may administer these medications to individual residents in the facility only on the order of a medical practitioner.

12-006.12E Drug Accountability and Disposition: The facility must establish and implement procedures for storing and disposing of drugs, devices and biologicals in accordance with State and local laws.

12-006.12E1 Drug Storage: The facility must have all drugs, devices, and biologicals stored in locked areas and stored in accordance with the manufacturer’s or pharmacist’s instructions for temperature, light, humidity, or other storage instructions. Only authorized personnel who are designated by the facility responsible for administration or provision of medications must have access to the medications.

12-006.12E1a Controlled Substance Storage: The facility must provide separately locked, permanently affixed compartments for storage of controlled medications listed in Schedule II of Neb. Rev. Stat. § 28-405, and other medications subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

12-006.12E1b Controlled Substance Count: A shift count of all controlled substances in Schedules II and III must be completed by two persons with each initialing the separate medication control sheet for each medication when the count is completed. The individual medication administration record can serve as a record of the receipt and disposition of all other Controlled Substances.

12-006.12E2 Compounding and Dispensing: Only the pharmacist, or a pharmacy intern under the direct supervision of the pharmacist, may compound or dispense drugs, devices or biologicals or make label changes.

12-006.12E3 The facility must ensure drugs, devices and biologicals are stored in the container in which they are received from the pharmacy.
12-006.12E4 Discontinued, Outdated, Deteriorated Drugs, Devices and Biologicals: The facility must ensure no discontinued, outdated, or deteriorated drugs, devices and biologicals are available for use in the facility.

12-006.12E5 Separate Storage Requirement: Drugs, devices and biologicals for external use, as well as poisons, must be stored separately from all other medications.

12-006.12E6 Emergency Box Drug: Authorized personnel of the facility may administer medications to residents of the institution from the contents of emergency boxes located within such facility if such drugs and boxes meet all of the requirements as set out in the Emergency Box Drug Act.

12-006.12E7 Medication Integrity and Labeling: The facility must ensure all medications used in the facility are labeled in accordance with currently accepted professional standards of care, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.

12-006.12E8 Disposition of Prescription Medications: The facility must ensure the proper disposal of all prescription medications.

12-006.12E8a Discharged Resident Medications: The facility may send prescribed medication with a resident upon discharge only with the order of a medical practitioner and all medication containers must be properly labeled by the dispensing pharmacy.

12-006.12E8b Discontinued Medications: When any prescription medication is discontinued permanently or the resident has expired, the facility must either:

1. Return the medication to the dispensing pharmacy for credit in accordance with Neb. Rev. Stat. § 71-2421; or

2. Properly dispose of any residue. The disposal must be performed by a pharmacist assisted by a licensed nurse employed by the facility according to the following terms:

a. The disposal must take place on the site of the facility; and

b. Medication name, strength and quantity disposed of must be recorded in the resident's medical record, dated and signed by the pharmacist.

12-006.12E8c Shared Medication Usage: The facility must ensure that no medications are saved for use by other residents.
(a) In excessive doses, including duplicate drug therapy;
(b) For an excessive duration;
(c) Without monitoring the patient properly;
(d) Without adequate indications for the use of the drug; or
(e) If there are any adverse reactions which indicate that the dosage should be reduced or discontinued.

2. Based on the comprehensive assessment of a patient conducted pursuant to NAC 449.74433, a facility for skilled nursing shall ensure that a patient who:
   (a) Has not used an antipsychotic drug is not given such a drug unless it is required to treat a condition of the patient that has been diagnosed and documented in the medical record of the patient.
   (b) Uses an antipsychotic drug receives gradual reductions in the dosage, in conjunction with behavioral intervention, in an attempt to discontinue the use of the drug, unless the medical condition of the patient requires otherwise.

3. A facility for skilled nursing shall ensure that patients are not subjected to significant errors in their medication and that the rate of error in the administration of medication is less than 5 percent.

4. A facility for skilled nursing shall not prohibit a patient from administering medication to himself if the interdisciplinary team responsible for the care of the patient determines that this practice is safe.

(Added to NAC by Bd. of Health by R051-99, eff. 9-27-99)

NAC 449.74531 Pharmaceutical services. (NRS 449.037)

1. A facility for skilled nursing shall provide such pharmaceutical services, including, without limitation, acquiring, receiving, dispensing and administering drugs and biologicals, as are required to meet the needs of the patients in the facility. The facility shall provide such drugs and biologicals as are needed or obtain them from qualified outside sources pursuant to NAC 449.74521.

2. A facility for skilled nursing shall employ or otherwise obtain the services of a registered pharmacist. The registered pharmacist shall:
   (a) Provide consultations on all matters relating to the pharmaceutical services provided by the facility;
   (b) Establish a system of records for the receipt and disposition of all controlled substances in the facility in sufficient detail to ensure an accurate reconciliation; and
(c) Ensure that those records are in order and that an account of all controlled substances in the facility is maintained and periodically reconciled.

3. The regimen of drugs for each patient in the facility must be reviewed at least once each month by a registered pharmacist. The pharmacist shall report any irregularities he discovers to the patient’s attending physician and the chief administrative nurse of the facility. The physician and chief administrative nurse shall take such actions as they deem necessary in response to the report.

4. Drugs and biologicals used by a facility must be:

(a) Labeled in accordance with state and federal law and accepted professional standards. Each label must include the appropriate accessory and cautionary instructions and the expiration date, if applicable.

(b) Stored in accordance with state and federal law in locked compartments with proper controls for the temperature. Only authorized personnel may have access to the keys to unlock the compartments. Substances listed as schedule II controlled substances pursuant to chapter 453 of NRS and other drugs that have the potential for abuse must be stored separately in a locked compartment that is immovable, unless the facility uses a system to distribute the substances or drugs in single-unit packages, the quantity stored is minimal and a dosage that is missing can be readily detected.

(Added to NAC by Bd. of Health by R051-99, eff. 9-27-99)

NEW HAMPSHIRE

He-P 803.16 Medication Services.

(a) All medications shall be administered in accordance with the orders of the licensed practitioner.

(b) Medications, treatments and diets ordered by the licensed practitioner shall be made available to the resident within 24 hours of the order, or in accordance with the licensed practitioner's direction.

(c) The licensee shall have a written policy and system in place instructing how to:

(1) Obtain any medication ordered for immediate use at the nursing home;

(2) Reorder medications for use at the nursing home; and
(3) Receive and record new medication orders.

(d) For each prescription medication being taken by a resident, the licensee shall maintain one of the following:

(1) The original written order in the resident’s record, signed by a licensed practitioner or other professional with prescriptive powers; or

(2) A copy of the original written order in the resident’s record, signed by a licensed practitioner or other professional with prescriptive powers.

(e) Each medication order shall legibly display the following information unless it is an emergency medication as allowed by (aa) below:

(1) The resident’s name;

(2) The medication name, strength, and prescribed dose and route, if different then by mouth;

(3) The frequency of administration;

(4) The indications for usage for all medications that are used PRN; and

(5) The dated signature of the ordering practitioner.

(f) Pharmaceutical samples shall be used in accordance with the licensed practitioner’s written order and labeled with the resident’s name by the licensed practitioner, the administrator, or authorized personnel.

(g) The label of all medication containers maintained in the nursing home shall match the current written orders of the licensed practitioner and include the expiration date of the medication unless authorized by (aa) below.

(h) Except as allowed by (f) above and (i) below, only a pharmacist shall make changes to prescription medication container labels.

(i) When the licensed practitioner changes the dose of a medication and personnel of the nursing home are unable to obtain a new prescription label:

(1) The original container shall be clearly and distinctly marked, for example, with a colored sticker that does not cover the pharmacy label, in a manner consistent with the nursing home’s written procedure, indicating that there has been a change in the medication order;

(2) Personnel shall cross out the previous order on the daily medication record, indicating that the dose has been changed, and write the new order in the next space available on the medication record; and

(3) The change in dosage, without a change in prescription label as described in (1) and (2) above, shall be allowed for a maximum of 90 days from the date of the new medication order or until the medications in the marked container are exhausted or, in the case of PRN medications, until the expiration date on the container, whichever occurs first.
(j) Any change or discontinuation of medications taken at the nursing home shall be pursuant to a written order from a licensed practitioner or other professional with prescriptive powers.

(k) The licensee shall require that all telephone orders for medications, treatments, and diets are immediately transcribed and signed by the individual receiving the order.

(l) The transcribed order in (k) above shall be counter-signed by the authorized provider within 30 days of receipt.

(m) The licensee shall obtain written approval from the resident’s licensed practitioner for all over-the-counter medications.

(n) The medication storage area shall be:

(1) Locked and accessible only to authorized personnel;

(2) Clean and organized with adequate lighting to ensure correct identification of each resident’s medication(s); and

(3) Equipped to maintain medication at the proper temperature.

(o) All medication at the nursing home shall be kept in the original containers and properly closed after each use.

(p) Topical liquids, ointments, patches, creams, or powder forms of products shall be stored in such a manner that cross contamination with oral, optic, ophthalmic and parenteral products shall not occur.

(q) If controlled substances, as defined by RSA 318-B, are stored in a central storage area in the nursing home, they shall be kept in a separately locked compartment within the locked medication storage area accessible only to authorized personnel.

(r) The licensee shall develop and implement written policies and procedures regarding a system for maintaining counts of controlled drugs.

(s) All contaminated, expired or discontinued medication shall be destroyed within 90 days of the expiration date, the end date of a licensed practitioner’s orders or the date the medication becomes contaminated, whichever occurs first.

(t) Controlled drugs shall be destroyed only in accordance with state law.

(u) Medication(s) may be returned to pharmacies for credit only as allowed by the law.

(v) If a resident is going to be absent from the nursing home at the time medication is scheduled to be taken and the resident is not capable of self-administering, the medication shall be given to the person responsible for the resident while the resident is away from the nursing home.

(w) Upon discharge or transfer, the licensee may make the resident’s current medications available to the resident and the guardian or agent, if any.
(x) A written order from a licensed practitioner shall be required annually for any resident who is authorized to carry emergency medications, including but not limited to nitroglycerine and inhalers.

(y) The licensee shall maintain a written record for each medication taken by the resident at the nursing home that contains the following information:

1. Any allergies or allergic reactions to medications;
2. The medication name, strength, dose, frequency and route of administration;
3. The date and the time the medication was taken;
4. The signature, identifiable initials and job title of the person who administers, supervises or assists the resident taking medication;
5. For PRN medications, the reason the resident required the medication and the effect of the PRN medication; and
6. Documented reason for any medication refusal or omission.

(z) Non-prescription stock medications shall only be accessed and administered by the licensed nurse or medication nurse assistant on duty.

(aa) A nursing home shall use emergency drug kits only in accordance with board of pharmacy rule Ph 705.03 under circumstances where the nursing home:

1. Has a director of nursing who is a registered nurse (RN) licensed in accordance with RSA 326-B; and
2. Has a contractual agreement with a medical director who is licensed in accordance with RSA 329 and a consultant pharmacist who is licensed in accordance with RSA 318. (ab) The licensee shall develop and implement a system for reporting within 24 hours any observed adverse reactions to medication and side effects, or medication errors such as incorrect medications.

(ac) The written documentation of the report in (ab) above shall be maintained in the resident’s record.
(a) A facility shall have a consultant pharmacist and either a provider pharmacist or, if the facility has an in-house pharmacy, a director of pharmaceutical services.

(b) A New Jersey licensed pharmacist shall serve as director of pharmaceutical services or as consultant pharmacist. The pharmacist shall comply with Federal and State statutes, rules, regulations and currently accepted standards of practice.

(c) The facility shall have an interdisciplinary pharmacy and therapeutics committee, appointed by and reporting to the administrator and consisting of at least the administrator, a representative of the nursing staff, and the consultant pharmacist, with oversight as needed by the medical director. The committee may include a licensed pharmacist representing the provider pharmacy. The committee shall hold meetings as needed but at least quarterly and records, including the dates of meetings, attendance, activities, findings, and recommendations, shall be maintained.

(d) The facility shall appoint a consultant pharmacist who is not also the director of pharmaceutical services or pharmacist provider and does not have an affiliation with either the director of pharmaceutical services or the pharmacist provider.

(e) If the facility keeps emergency injectable or oral controlled substances, a current Drug Enforcement Administration registration and Controlled Dangerous Substance registration for that location shall be available. (See N.J.S.A. 24.21-10 for registration requirements; registration application procedures are specified at N.J.A.C. 8:65-1.4.)

8:39-29.2 Mandatory drug administration policies and procedures

(a) The pharmacy and therapeutics committee shall establish and enforce procedures for documenting drug administrations in accordance with law.

(b) The facility shall have a system to accurately identify recipients before any drug is administered.

(c) Self-administration of drugs shall be permitted by qualified residents only as specified by the policy of the pharmacy and therapeutics committee and the assessment of the interdisciplinary team. Self-administration procedures shall include, at a minimum, the following:

1. The written order of the prescriber;

2. Storage of medications in the resident’s room, based on resident assessments;

3. Specifications for labeling, including directions for use;

4. Methods for documentation in the medical record, based on resident assessment;

5. Training of residents in self-administration by the nursing staff or the consultant pharmacist; and

6. Policies for individual assessment of residents’ ability to self-administer medications.
(d) Medications shall be accurately administered and documented by properly authorized individuals, as per prescribed orders and stop order policies.

8:39-29.3 Mandatory pharmacy reporting policies and procedures

(a) The consultant pharmacist shall conduct a drug regimen review and enter appropriate comments into the medical record of every resident receiving medication, at least monthly, on a pharmacist consultation sheet or another portion of the medical record in accordance with N.J.A.C. 13.39. The drug regimen review shall be performed in accordance with Federal and State Statutes, rules and regulations, and currently accepted standards of practice for rational drug therapy.

1. The consultant pharmacist shall report any irregularities promptly to the attending physician or advanced practice nurse and to the director of nurses and these reports shall be acted upon. These reports shall include, but are not limited to, problems and recommendations about drug therapy which may be affected by biologicals, laboratory tests, special dietary requirements and foods used or administered concomitantly with other medication to the same recipient. Also, these reports are required to include monitoring for potential adverse effects, allergies, drug interactions, contraindications, rationale, and drug evaluation.

2. Drug product defects and adverse drug reactions shall be reported in accordance with the ASHSP-USP-FDA (American Society of Health System Pharmacists, United States Pharmacopoeia, Food and Drug Administration) Drug Product Defect Reporting System and the USP Adverse Drug Reaction Reporting System.

3. All known drug allergies shall be documented in the resident’s medical record including the medication administration records and physician or advanced practice nurse order sheets and on the outside front cover and communicated to the provider or dispensing pharmacy.

4. Drugs that are not specifically limited as to duration of use or number of doses shall be controlled by automatic stop orders. The resident’s attending physician or advanced practice nurse shall be notified of the automatic stop order prior to the last dose so that he or she may decide whether to continue use of the drug.

5. If medication is withheld, the reason for withholding the medication shall be documented in the resident’s medical record.

6. Medication errors and adverse drug reactions shall be reported immediately to the director of nursing or the alternate to the director of nursing, and a description of the error or adverse drug reaction shall be entered into the medical record before the end of the employee shift. If the resident has erroneously received medication, the resident’s physician or advanced practice nurse shall be notified immediately. If a medication error originated in the pharmacy, the pharmacy shall be notified immediately. The Department shall be notified of an adverse drug reaction that results in death.
8:39-29.4 Mandatory pharmacy control policies and procedures

(a) The label of each resident's individual medication container or package shall be labeled in accordance with the New Jersey State Board of Pharmacy regulations at N.J.A.C. 13:39-5.9, permanently affixed, and contain the following information:

1. The resident's full name;
2. The prescriber's name;
3. The prescription number;
4. The name and strength of drug;
5. The quantity dispensed;
6. The lot number;
7. The date of issue;
8. The expiration date;
9. The manufacturer's name if generic;
10. Cautionary and/or accessory labels.
   i. If a generic substitute is used, the drug shall be labeled according to the Drug Utilization Review Council Formulary, N.J.S.A. 24:6E-1 et seq. and N.J.A.C. 8:71.
   ii. Required information appearing on individually packaged drugs or within an alternate medication delivery system need not be repeated on the label; and
11. The name, address, and telephone number of the pharmacy.

(b) If a unit dose distribution system is used ("unit dose drug distribution" means a system in which drugs are delivered to the resident areas in single unit packaging), the following requirements shall be met:

1. Each resident shall have his or her own medication tray labeled with the resident's name and location in the facility;

2. Each medication shall be individually wrapped and labeled with the generic or trade (brand) name and strength of the drug, lot number or reference code, expiration date, dose, and manufacturer's name, and shall be ready for administration to the resident;

3. Cautionary instructions shall appear on the resident's record of medication, and the system shall include provisions for noting additional information, including, but not limited to, special times or routes of administration and storage conditions; and

4. Delivery and exchange of resident medication trays shall occur promptly, and, if a 24-hour unit-dose system is used, then at least one exchange of resident medication trays shall occur every 24 hours, including weekends and holidays.
(c) Both over-the-counter and prescription medications may be kept as stock. A limited amount of prescription medications may be kept as stock for the administration of stat (emergency) doses, lost doses, or doses not sent by the provider pharmacy. These medications shall be approved by the pharmacy and therapeutics committee, monitored for accountability, and labeled to include drug name, drug strength, manufacturers’ name, lot number, expiration date, recommended dosage for over-the-counter medications, and applicable cautionary and/or accessory labels.

(d) The consultant pharmacist shall:

1. Make monthly inspection of all areas in the facility where medications are dispensed, administered, or stored;

2. Periodically, as determined by the quality assurance program, observe a medication pass and review the crediting system; and

3. Document any problems and propose solutions to these problems.

(e) The contents of emergency kits shall have been approved by the pharmacy and therapeutics committee. Emergency kits shall be stored securely at each nursing unit, but not kept under lock and key, checked after each use, and checked at least monthly by the consultant pharmacist. Emergency kits shall not be accessible to residents but shall be accessible to staff in a timely manner.

(f) All medications repackaged by the pharmacy shall be labeled with an expiration date, name and strength of drug, lot number, date of issue, manufacturer’s name if generic, and cautionary and/or accessory labels, in accordance with N.J.A.C. 13:39-5.9, United States Pharmacopoeia (U.S.P.) requirements and applicable FDA regulations.

(g) The pharmacy and therapeutics committee shall establish and enforce procedures for removal of discontinued, unused, expired, recalled, deteriorated, and unlabeled drugs and intravenous solutions and for removal of containers of medications with worn, illegible, damaged, incomplete, or missing labels.

(h) All medications shall be stored in accordance with manufacturers’ and United States Pharmacopoeia (U.S.P.) requirements and all medications shall be kept in locked storage areas.

(i) All medication destruction in the facility shall be witnessed by at least two persons, each of whom shall be either the pharmacist consultant, a registered professional nurse or a licensed practical nurse. A record of each instance of drug destruction shall be maintained.

(j) Where allowable by law, the facility shall generate a crediting mechanism for medications dispensed in a unit-of-use drug distribution system, or other system that allows for the re-use of medications. The crediting system shall be monitored by the provider pharmacist and a facility representative.

(k) The pharmacy and therapeutics committee shall establish and enforce procedures for the inventory of controlled substances in accordance with law.
(l) Based on prescriber’s orders for medications, drug tests, diet and treatments, the facility shall implement written methods and procedures for obtaining prescribed prescription medications and biologicals from a pharmacy that has a permit from the New Jersey State Board of Pharmacy, in accordance with N.J.A.C. 13:39-4. The telephone number of the pharmacy and procedures for obtaining drugs shall be posted at each nursing unit.

(m) If the facility utilizes drugs marked “sample”, the pharmacy and therapeutics committee shall develop a mechanism for the control and limitation of these drugs, in accordance with N.J.A.C. 13:35-6.6.

(n) The facility shall develop and implement a system whereby instructions for use are provided whenever medications are released to residents. Instructions shall be written in a manner intended to promote proper storage, secure handling, and safe administration of medications released to residents. Documentation of released medications shall be entered into the resident’s medical record.

8:39-29.5 Mandatory pharmacy staff qualifications

If the facility maintains a pharmacy in-house, the pharmacy shall be licensed by the New Jersey State Board of Pharmacy, and shall possess a current Drug Enforcement Administration registration and a Controlled Dangerous Substance registration from the New Jersey State Department of Law and Public Safety.

8:39-29.6 Mandatory resident pharmacy services

(a) The facility shall provide pharmaceutical services, either directly or by contract with a provider pharmacy, 24 hours a day, seven days a week.

(b) If a resident obtains medications from a pharmacy that is not the facility provider pharmacy, the following conditions shall be met:

1. The pharmacy provider shall comply with all labeling requirements specified at N.J.A.C. 8:39-29.4(a); and

2. The facility shall establish a plan for obtaining the resident’s drugs on an emergency basis.

(c) A resident may obtain medications from a pharmacy that is not the facility provider pharmacy unless:

1. The resident is expressly informed during the admission process and within the admission agreement that this service is not permitted in the facility; or

2. For existing residents, the facility submits documentation to the Department, prior to denying the request, demonstrating a significant risk to the health and safety of residents as a result of this practice.
8:39-29.7 Mandatory pharmacy supplies and equipment

(a) Medication containers and carts shall be handled properly to prevent damage, injury and harm.

(b) Needles and syringes shall be stored, used, and disposed of in accordance with New Jersey State law, and a record shall be maintained of the purchase, storage, and disposal of needles and syringes.

(c) Controlled substances shall be stored, and records shall be maintained, in accordance with the Controlled Dangerous Substances Acts and all other Federal and State laws and regulations concerning procurement, storage, dispensation, administration, and disposition.

(d) Pharmaceutical reference materials and other information sources about drugs, including investigational drugs, if used, shall be approved by the pharmacy and therapeutics committee and shall be current.

8:39-29.8 Mandatory pharmacy quality assurance

The pharmacy and therapeutics committee shall review reports of medication errors and suspected adverse drug reactions and shall summarize these reports yearly.

8:39-30.1 Advisory pharmacy staffing amounts and availability

The consultant pharmacist or a licensed pharmacist representing the provider pharmacy provides or arranges for quarterly meetings open to residents, families, and interested others to discuss medication issues.

8:39-30.2 Advisory pharmacy resident services

The consultant pharmacist reviews drug records within 48 hours of admission via a facsimile service. All dated and signed comments and recommendations made by the consultant pharmacist shall be added to the resident’s medical record and shall be distributed to the attending physician or advanced practice nurse and director of nurses for review and action.

8:39-30.3 Advisory provider formulary criteria

The provider pharmacy through the Pharmacy and Therapeutics Committee, may establish a formulary which is not in contradiction to the Drug Utilization Review Council Formulary, N.J.S.A. 24:6E-1 et seq., and N.J.A.C. 8:71. The formulary policies must be approved by the Pharmacy and Therapeutics Committee and every prescriber with prescriptive authority in
the facility. The Pharmacy and Therapeutics Committee establishes policies for the prescribing of non-formulary agents. The formulary is developed to avoid negative outcomes.

8:39-30.4 Advisory consultant pharmacist certification

The consultant pharmacist holds current certification by the Joint Board of Certification of Consultant Pharmacists.

NEW MEXICO

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7.9.2.44 TREATMENT AND ORDERS:

...B. STOP ORDERS: Medications shall be in accordance with the stop order policy required by Subsection E of 7.9.2.57 NMAC of these regulations.

(1) Notice to physicians or dentists: Each resident’s attending physician or dentist shall be notified of stop order policies and contacted promptly for renewal of orders which are subject to automatic termination.

C. RELEASE OF MEDICATIONS TO RESIDENTS: Medications shall be released to residents who are on leave or have been discharged only on order of the physician.

D. ADMINISTRATION OF MEDICATIONS:

(1) Personnel who may administer medications: In a nursing home, medications may be administered only by a nurse or other licensed medical professional whose, licensed scope of practice permits administration of medication.

(2) Responsibility for administration: Policies and procedures designed to provide safe and accurate administration of medications shall be developed by the facility and shall be followed by personnel assigned to prepare and administer medication except when a single unit dose package distribution system is used. Person administering medication will immediately record in the resident’s clinical records.

(3) Omitted doses: If, for any reason, a medication is not administered as ordered the omission shall be noted in the resident’s medication record with explanation of the omission.

(4) Self-administration: Self-administration of medications by residents shall be permitted on order of the resident's physician.
(5) Errors and reactions: Medication errors and suspected or apparent drug reactions shall be reported to the nurse in charge or on call as soon as discovered and any entry made in the resident's clinical record. The nurse shall take appropriate action, including notifying the physician.

(6) Day care: The handling and administration of medications for day care clients shall comply with the requirements of this subsection. [7-1-60, 5-2-89; 7.9.2.44 NMAC - Rn, 7 NMAC 9.2.44, 8-31-00]

7.9.2.57 PHARMACEUTICAL SERVICES:

A. DEFINITIONS: As used in this section:

(1) Medication: has the same meaning as the term "drug".

(2) Prescription medication: has the same meaning as the term "prescription drug".

B. SERVICES: Each facility shall provide for obtaining medications for the residents from licensed pharmacies.

C. SUPERVISION:

(1) Medication Consultant: Each facility shall retain a registered pharmacist who shall visit the facility at least monthly to review the drug regimen of each resident and medication practices.

(2) The pharmacist shall submit a written report of findings at least monthly to the facility's administrator.

D. EMERGENCY MEDICATION KIT:

(1) A facility may have one or more emergency medication kits available to each charge nurse. All emergency kits shall be under the control of a pharmacist.

(2) The emergency kit shall be sealed and stored in a locked area. The facility shall have a policy and procedures for access by staff to the emergency kit in case of need.

E. REQUIREMENTS FOR ALL MEDICATION SYSTEMS:

(1) Obtaining new medications: When medications are needed which are not stocked, a licensed nurse shall telephone an order to the pharmacist who shall fill the order.

(2) Storing and labeling medications: All medications shall be handled in accordance with the following provisions:

(a) The storage and labeling of medications shall be based on currently acceptable professional practices.

(b) The consulting pharmacist shall be responsible to develop policies and procedures governing all aspects of storage and labeling of medications.
(c) The consulting pharmacist shall be responsible for assuring the facility meets all requirements for storage and labeling as required by New Mexico Board of Pharmacy.

(3) Destruction of medications:

(a) Time limit: Unless otherwise ordered by a physician, a resident's medication not returned to the pharmacy for credit shall be removed to a locked storage area when discontinued by a physician's order. Such discontinued medications will be destroyed within thirty (30) days of the physician's discontinuance of use.

(b) Procedure: Records shall be kept of all medication returned for credit and/or disposal.

(c) Remaining controlled substances: Any controlled substances remaining after the discontinuance of physician's orders or the discharge or death of the resident shall be inventoried on the appropriate U.S. drug enforcement agency form and one copy shall be kept on file in the facility.

(4) Control of medication:

(a) Receipt of medications: The administrator or a physician, nurse, or pharmacist, may be an agent of the resident for the receipt of medications.

(b) Signatures: When the medication is received by the facility, the person completing the control record shall sign the record indicating the amount received.

(c) Discontinuance of medications: The consulting pharmacist shall assist the facility to develop policies for the automatic discontinuance of medications.

(5) Proof-of-use record:

(a) For schedule II drugs, a proof-of-use record shall be maintained which lists, on separate proof-of-use sheets for each type and strength of schedule II drug, the date and time administered, resident's name, physician's name, dose, signature of the person administering dose, and balance.

(b) Proof-of-use records shall be audited daily by the registered nurse or licensed practical nurse.

(6) Resident control and use of medications:

(a) Residents may have medications in their possession or stored at their bedside on the order of a physician.

(b) Medications which, if ingested or brought into contact with the nasal or eye mucosa, would produce toxic or irritant effects shall be stored and used only in accordance with the health, safety, and welfare of all residents.

[7-1-60, 7-1-64, 5-2-89; 7.9.2.57 NMAC – Rn, 7 NMAC 9.2.57, 8-31-00]
Effective Date: 10/11/2005

Title: Section 415.18 - Pharmacy services

415.18 Pharmacy Services. (a) The facility shall provide pharmaceutical services and develop and implement policies and procedures that assure the accurate acquisition, receipt, dispensing and administering of all drugs and biologicals required to meet the needs of each resident. The facility shall provide routine and emergency drugs and biologicals directly to its residents, or obtain them under a contract as described in section 400.4 of Part 400 of this Subchapter. The facility shall be licensed under Article 33 of the Public Health Law and Part 80 of this Title.

(b) Service consultation. The facility shall employ or obtain the services of a registered pharmacist who:

(1) provides consultation on all aspects of the provision of pharmacy services in the facility;
(2) establishes a system of records of receipt and disposition of all controlled drugs; and
(3) determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled consistent with the requirements of Article 33 of the Public Health Law and Part 80 of this Title.

(c) Drug regimen review. (1) The drug regimen of each resident shall be reviewed at least once a month by a registered pharmacist.

(2) The pharmacist shall report any irregularities to the attending physician and the director of nursing, and these reports shall be acted upon promptly. The findings and corrective actions shall be regularly reviewed by the quality assessment and assurance committee established pursuant to section 415.27 of this Part.

(3) Psychotropic drugs may be administered only on the orders of a physician and only as part of a plan of care, developed in accordance with sections 415.4, 415.11 and 415.12 of this Part, designed to eliminate or modify the symptoms for which the drugs are prescribed.

(d) Labeling of drugs and biologicals. The facility shall label drugs and biologicals in accordance with currently accepted standards of practice and include the appropriate accessory and cautionary instructions and the expiration date. Labeling of all medications shall be accordance with Article 137 of the State Education Law and 8 NYCRR Part 29. Facilities which use a unit dose drug distribution system shall develop and implement an appropriate method of providing accessory and cautionary instructions.

(e) Storage of drugs and biologicals. (1) The facility shall store all drugs and biologicals in locked compartments under proper temperature controls, and permit access only to authorized personnel.

(2) The facility shall provide separately locked, permanently affixed, compartments for storage of controlled drugs and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected. Storage of controlled substances shall be in accordance with Article 33 of the Public Health Law and Part 80 of this Title.

(3) Poisons and medications for "external use only" shall be kept in a locked cabinet and separate from other medications; and
(4) medications whose shelf life has expired or which are otherwise no longer in use shall be disposed of or destroyed in accordance with State and Federal laws and regulations.

(f) Return of unused medications. (1) When services are provided by a cooperating vendor pharmacy, the facility shall establish policies and procedures which permit either the staff registered pharmacist or consultant registered pharmacist to return to the vendor pharmacy from which it was purchased any unused medications or drug products, provided such medication is sealed in unopened, individually packaged, units and within the recommended period of shelf life for the purpose of redispensing and which are in accord with the following provisions:

(i) Drug products which may be returned are limited to:
(a) oral and parenteral medication in single-dose hermetically sealed containers; and
(b) parenteral medication in multiple-dose hermetically sealed containers from which no doses have been withdrawn.

(ii) The drug products returned show no obvious sign of deterioration.

(iii) Drug products packaged in manufacturer’s unit-dose packages may be returned for redispensing provided that they are redispensed in time for use before the expiration date, if any, indicated on the package.

(iv) Drug products repackaged by the pharmacy into unit-dose or multiple-dose “blister packs” may be returned for redispensing provided that:
(a) the date on which the drug product was repackaged, its lot number and expiration date are indicated clearly on the package;
(b) not more than 90 days have elapsed from the date of the repackaging;
(c) a repackaging log is maintained by the pharmacy in the case of drug products repackaged in advance of immediate needs.

(v) “Blister packs”.

(a) Partially used “blister packs” may be redispensed only as returned.
(b) Partially used “blister packs” may not be emptied and repackaged.
(c) Additional units of medication may not be added to partially used “blister packs”.

(vi) No drug product dispensed in bulk in a dispensing container may be returned.

(vii) No medication or drug product defined as a controlled substance in section 3306 of the Public Health Law may be returned.

(2) The vendor pharmacy to which such drug products are returned shall reimburse or credit the nursing home or purchaser of such drug products for the unused medication that is restocked and redispensed and shall not otherwise charge any individual resident or the State, if a resident is a recipient or beneficiary of a State-funded program, for unused medication or drug products returned for reimbursement or credit.

(g) Emergency medications. The facility shall ensure the provision of (an) emergency medication kit(s) as follows:
(1) The contents of each kit shall be approved by the medical director, pharmacist and director of nursing.

(2) Limited supplies of controlled substances for use in emergency situations may be stocked in sealed emergency medication kits.
(i) Each such kit may contain up to a 24 hour supply of a maximum of ten different controlled substances in unit dose packaging, three of which may be injectable drugs.
(ii) Controlled substances contained in emergency medication kits may be administered by authorized personnel pursuant to an order of an authorized practitioner to meet the
immediate need of a resident. Personnel authorized to administer controlled substances shall include registered professional nurses, licensed practical nurses or other practitioners, licensed/registered under Title VIII of the Education Law and authorized to administer controlled substances.

(iii) The facility shall maintain all records of controlled substances furnished or transferred from the pharmacy and the disposition of all controlled substances in emergency kits, as required by article 33 of the Public Health Law and corresponding regulations.

(3) For medications other than controlled substances the medication contents of each kit shall be limited to injectables except that the kit may also include:

(i) sublingual nitroglycerin; and

(ii) up to five noninjectable, prepackaged medications, not to exceed a 24-hour supply. The total number of noninjectables may not exceed 25 medications for the entire facility;

(4) Each kit shall be kept and secured within or near the nurses' station.

(h) Medications for leaves. Medication shall be released to discharged residents or to a resident going on temporary leave. The medication supply in the facility may be used to supply the medications needed for a temporary leave of absence.

(i) Verbal orders. All medications administered to residents shall be ordered in writing by a legally authorized practitioner unless unusual circumstances justify a verbal order, in which case the verbal order shall be given to a licensed nurse, or to a licensed pharmacist, immediately reduced to writing, authenticated by the nurse or registered pharmacist and countersigned by the prescriber within 48 hours. In the event a verbal order is not signed by the prescriber or a legally designated alternate practitioner within 48 hours, the order shall be terminated and the facility shall ensure that the resident's medication needs are promptly evaluated by the medical director or another legally authorized prescribing practitioner.

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**NORTH CAROLINA**

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**10A NCAC 13D .2306  MEDICATION ADMINISTRATION**

(a) The facility shall ensure that medications are administered in accordance with standards of professional practice and applicable occupational licensure regulations.

(b) The facility shall ensure that each patient's drug regimen is free from drugs used in excessive dose or duplicative therapy, for excessive duration or without adequate indications for the prescription of the drug. Drugs shall not be used without adequate monitoring or in the presence of adverse conditions that indicate the drugs' usage should be modified or discontinued.

(c) Antipsychotic therapy shall not be initiated on any patient unless necessary to treat a clinically diagnosed and clinically documented condition. When antipsychotic therapy is
prescribed, unless clinically contraindicated, gradual dose reductions and behavioral interventions shall be employed in an effort to discontinue these drugs.

(d) The facility shall ensure that procedures aimed at minimizing medication error rates include, but are not limited to, the following:

(1) All medications or drugs and treatments shall be administered and discontinued in accordance with signed medical orders which are recorded in the patient’s medical record. Such orders shall be complete and include drug name, strength, quantity to be administered, route of administration, frequency and, if ordered on an as-needed basis, a clearly stated indication for use.

(2) The requirements for self-administration of medication shall include, but not be limited to, the following:

(A) determination by the interdisciplinary team that this practice is safe;

(B) administration ordered by the physician or other person legally authorized to prescribe medications;

(C) specific instructions for administration printed on the medication label; and

(D) administration of medication monitored by the licensed nursing staff and consultant pharmacist.

(3) The administration of one patient’s medications to another patient is prohibited except in the case of an emergency. In the event of such emergency, steps shall be taken to ensure that the borrowed medications are replaced promptly and so documented.

(4) Omission of medications and the reason for omission shall be indicated in the patient’s medical record.

(5) Medication administration records shall provide time of administration, identification of the drug and strength of drug, quantity of drug administered, route of administration, frequency, documentation sufficient to determine the staff who administered the drugs. Medication administration records shall indicate documentation of injection sites and topical medication sites requiring rotation, including, but not limited to, transdermal medication.

(6) The pharmacy shall receive an exact copy of each physician’s order for medications and treatments.

(7) Automatic stop orders for medications and treatments shall be established and implemented.

(8) The facility shall maintain an accountability of controlled substances as defined by the North Carolina Controlled Substances Act, G.S. 90, Article 5.

History Note: Authority G.S. 131E-104; Eff. January 1, 1996.
SECTION .2600 - PHARMACEUTICAL SERVICES

10A NCAC 13D .2601 AVAILABILITY OF PHARMACEUTICAL SERVICES

(a) The facility shall provide pharmaceutical services under the supervision of a pharmacist, including procedures that ensure the accurate acquiring, receiving and administering of all drugs and biologicals.

(b) The facility shall be responsible for obtaining drugs, therapeutic nutrients and related products prescribed or ordered by a physician for patients in the facility.

(c) To ensure that drug therapy is rational, safe and effective, a pharmaceutical care assessment shall be conducted in the facility at least every 31 days for each patient. All new admissions shall receive a pharmaceutical care assessment at the time of the pharmacist’s next visit or within 31 days, whichever comes first. This assessment shall include at least:

1. A review of the patient’s diagnoses, history and physical, discharge summary, diet, vital signs, current physician’s orders, laboratory values, progress notes, interdisciplinary care plans and medication administration records; and

2. The pharmacist’s progress notes in the patient’s medical record which reflect the results of this assessment and, if necessary, recommendations for change based on desired drug outcomes.


10A NCAC 13D .2602 PHARMACY PERSONNEL

(a) If the pharmacist is an employee of the facility and performs vending or clinical services, an up-to-date job description and personnel file shall be maintained.

(b) If pharmaceutical vending or clinical services are contracted, there shall be a current written agreement for each service which includes a statement of responsibilities for each party.

(c) The facility shall keep, or be able to make available, a copy of the current license of the pharmacists.

History Note: Authority G.S. 131E-104; 131E-117; Eff. January 1, 1996.

10A NCAC 13D .2603 ADMINISTRATIVE RESPONSIBILITIES

(a) The pharmacist shall report any potential drug therapy irregularities or discrepancies in drug accountability and administration with recommendations for change to the director
of nursing and the attending physician. Recommendations shall be communicated to the
health care professionals in the facility who have the authority to effect a change. These
reports shall be submitted monthly following the pharmacist’s pharmaceutical care
assessments.

(b) The administrator shall ensure documentation of action taken relative to the
pharmacist’s reports.

History Note: Authority G.S. 131E-104; 131E-117; Eff. January 1, 1996.

10A NCAC 13D .2604       DRUG PROCUREMENT

(a) The facility shall not possess a stock of prescription legend drugs for general or common
use except as permitted by the North Carolina Board of Pharmacy and as follows:

(1) for all intravenous and irrigation solutions in single unit quantities exceeding 49 ml.
and related equipment for the use and administration of such;

(2) diagnostic agents;

(3) vaccines;

(4) drugs designated for inclusion in an emergency kit approved by the facility's
Quality Assurance Committee;

(5) water for injection; and

(6) normal saline for injection.

(b) Patient Drugs:

(1) The contents of all prescriptions shall be kept in the original container bearing the
original label as described in Subparagraph (b)(2) of this Rule.

(2) Except in a 72-hour or less unit dose system, each individual patient’s prescription or
legend drugs shall be labeled with the following information:

(A) the name of the patient for whom the drug is intended;

(B) the most recent date of issue;

(C) the name of the prescriber;

(D) the name and concentration of the drug, quantity dispensed, and prescription serial
number;

(E) a statement of generic equivalency which shall be indicated if a brand other than the
brand prescribed is dispensed;

(F) the expiration date, unless dispensed in a single unit or unit dose package;
auxiliary statements as required of the drug;

the name, address and telephone number of the dispensing pharmacy; and

the name of the dispensing pharmacist.

(c) Non-legend drugs shall be kept in the original container as received from the supplier and shall be labeled as described in Subparagraph (b)(2) of this Rule or with at least:

(1) the name and concentration of the drug, and quantity packaged;

(2) the name of the manufacturer, lot number and expiration date.

History Note: Authority G.S. 131E-104; 131E-117; Eff. January 1, 1996.

10A NCAC 13D .2605 DRUG STORAGE AND DISPOSITION

(a) The pharmacist and director of nursing shall ensure that drug storage areas are clean, secure, well lighted and well ventilated; that room temperature is maintained between 59 degrees F. and 86 degrees F.; and that the following conditions are met:

(1) All drugs shall be maintained under locked security except when under the immediate or direct physical supervision of a nurse or pharmacist.

(2) Drugs requiring refrigeration shall be stored in a refrigerator containing a thermometer and capable of maintaining a temperature range of 2 degrees C. to 8 degrees C. (36 degrees F. to 46 degrees F.) Drugs shall not be stored in a refrigerator containing non-drugs and non-drug related items, except when stored in a separate container.

(3) Drugs intended for topical use, except for ophthalmic, otic and transdermal medications, shall be stored in a designated area separate from the drugs intended for oral and injectable use.

(4) Drugs that are outdated, discontinued or deteriorated shall be removed from the facility within five days.

(b) Upon discontinuation of a drug or upon discharge of a patient, the remainder of the drug supply shall be disposed of promptly. If it is reasonably expected that the patient shall return to the facility and that the drug therapy will be resumed, the remaining drug supply may be held for not more than 30 calendar days after the date of discharge or discontinuation.

(c) The disposition of drugs shall be in accordance with written policies and procedures established by the Quality Assurance Committee.

(d) Destruction of controlled substances shall be in compliance with North Carolina Controlled Substance Act and Regulations (10A NCAC 26E) which is hereby incorporated by reference including subsequent amendments. Copies of the rules may be obtained from the
10A NCAC 13D .2606 PHARMACEUTICAL RECORDS

(a) The pharmacist shall ensure that accurate records of the receipt, use and disposition of drugs are maintained and readily available.

(b) The director of nursing and pharmacist shall ensure accountability of controlled substances as defined by the North Carolina Controlled Substances Act and Regulations (10A NCAC 26EG) which is hereby incorporated by reference including subsequent amendments. Copies of the rules may be obtained from the Drug Regulatory Branch, Division of Mental Health, Developmental Disabilities and Substance Abuse Services, 3016 Mail Service Center, Raleigh, NC 27699-3016 at a cost of thirteen dollars ($13.00).


10A NCAC 13D .2607 EMERGENCY DRUGS

(a) The facility shall maintain a supply of emergency drugs in compliance with 21 NCAC 46 .1403 which is hereby incorporated by reference including subsequent amendments. Copies of the rule may be obtained from the North Carolina Board of Pharmacy, P.O. Box 459, Carrboro Plaza, Highway 54 Bypass, Carrboro, North Carolina 27510 at a cost of eight dollars and forty eight cents ($8.48).

(b) Emergency drugs shall be stored in a portable container sealed with an easily breakable closure which cannot be resealed or reused and shall be readily accessible for use.

(c) Emergency drug kits shall be stored in a secure area out of site of patients and the general public. If stored ina locked area the kits shall be immediately accessible to all licensed nursing personnel.

(d) All emergency drugs and quantity to be maintained shall be approved by the Quality Assurance Committee.

(e) If emergency drug items require refrigerated storage, they shall be stored in a separate sealed container within the medication refrigerator. The container shall be labeled to indicate the emergency status of the enclosed drug and sealed as indicated in Paragraph (b) of this Rule.

(f) An accurate inventory of emergency drugs and supplies shall be maintained with each emergency drug kit.
(g) The pharmacist shall personally examine the refrigerated and non-refrigerated emergency drug supply at least every 90 days and make any necessary changes at that time.

(h) The facility shall have written policies and procedures which are enforced to ensure that in the event the sealed emergency drug container is opened and contents utilized, immediate steps are taken to replace the items used.

(i) The availability of a controlled substance in an emergency kit shall be in compliance with the North Carolina Controlled Substances Act and Regulations (10A NCAC 26E) which is hereby incorporated by reference including subsequent amendments. Copies of the rules may be obtained from the Drug Regulatory Branch, Division of Mental Health, Developmental Disabilities and Substance Abuse Services, 3016 Mail Service Center, Raleigh, NC 27699-3016 at a cost of thirteen dollars ($13.00).


NORTH DAKOTA

33-07-03.2-18. Pharmaceutical services.

The facility shall provide pharmaceutical services to meet resident needs.

1. The facility shall obtain the services of a licensed pharmacist who shall develop policies and procedures for the provision of pharmaceutical services within the facility consistent with chapter 61-03-02, state laws, and federal laws. These policies and procedures must be approved by medical staff or medical director and governing body and must include provisions for:

a. The procurement, storage, dispensing, labeling, administration, and disposal of drugs and biologicals.

b. Allowing the resident to be totally responsible for the resident's own medication based on request of the resident, assessment of the functional capability of the resident by facility nursing staff, documentation of the assessment and resultant recommendations, and
specific approval and order of the licensed health care practitioner. The facility must provide a secure storage area for medications self-administered by the resident.

2. The pharmacist shall review each resident’s medications monthly and report any discrepancies to the nurse executive or the resident’s licensed health care practitioner.

3. All medications administered to a resident must be ordered in writing by a licensed health care practitioner. Telephone and verbal orders may be given to qualified licensed personnel and must be immediately reduced in writing, signed, and dated by the individual receiving the order, and countersigned or initialed by the licensed health care practitioner.

History: Effective July 1, 1996.

General Authority: NDCC 23-01-03, 28-32-02

Law Implemented: NDCC 23-16-01, 28-32-02

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**OHIO**

Downloaded January 2011

**3701-17-17 Medicines and drugs.**

(A) The nursing home shall provide or obtain routine and emergency medicines, drugs and biologicals for its resident except if prohibited by state or federal law. The nursing home shall permit residents to use and continue to obtain medicines, drugs and biologicals dispensed to them from a pharmacy of choice provided the medicines, drugs and biologicals meet the standards of this rule.

(1) Each nursing home shall provide pharmacy services by employing a pharmacist on either a full-time, part-time, or consultant basis or by contracting with a pharmacy service. The pharmacist or pharmacy service shall be responsible for maintaining supervision and control of the stocking and dispensing of drugs and biologicals in the home in accordance with state pharmacy rules.

(2) The nursing home, in conjunction with the pharmacist or pharmacy service, shall:

(a) Maintain an emergency and contingency drug supply for use in the absence of the pharmacist; and

(b) Ensure that the contingency drug supply is maintained in accordance with state pharmacy rules.

(B) Medicines and drugs shall be given only to the individual resident for whom they are prescribed, shall be given in accordance with the directions on the prescription or the physician’s orders, and shall be recorded on the resident’s medication administration record.
Every container of medicine and drugs prescribed for a resident shall be properly and clearly labeled in accordance with applicable state regulations as to the following:

1. Date dispensed.
2. Name of resident.
3. Directions for use.
4. Name of the prescriber.
5. Name of the drug, strength, and prescription number if there is one.

Containers too small to bear a complete prescription label shall be labeled with at least the prescription number and the name of the resident, unless application of this label would impair the functioning of the product, and shall be dispensed in a container bearing a complete prescription label.

The nursing home shall ensure that all medications and drugs are stored under proper temperature controls and secured against unauthorized access. All medicines and drugs, including those requiring refrigeration, shall be kept in locked storage areas and separate from materials that may contaminate the medicines and drugs such as poisonous substances. Where a pharmacist is not present twenty-four hours-a-day, keys to locked contingency drug supplies shall be made available to a health care professional licensed under Chapter 4723. or 4731. of the Revised Code and authorized by such chapters to administer drugs.

Each nursing home shall ensure that the following requirements regarding individual resident's drugs are met:

1. Appropriate drugs for an individual resident shall, upon order of a prescriber, be sent with or arranged for the resident upon temporary absence other than for hospital leave.
2. At the order of a prescriber, a resident's drugs shall be sent with or arranged for the resident upon transfer and discharge. Drugs not so ordered by the prescriber upon transfer or discharge shall be returned to the pharmacy or disposed of in accordance with any applicable state or federal laws, rules and regulations.
3. Upon death of a resident all drugs shall be returned to the pharmacy, or disposed of in accordance with any applicable state or federal laws, rules, and regulations. This paragraph does not preclude a nursing home from charging a resident for medications and drugs provided to the resident upon discharge for which the resident has not already paid.

Controlled substances shall be ordered, dispensed, administered, and disposed of in accordance with state and federal laws and regulations.

The nursing home shall ensure that the pharmaceutical needs of each resident are met and that the drug regimen of each resident is reviewed and documented at least once a month by a pharmacist.
(I) The nursing home shall coordinate the ordering of medicines, drugs and biologicals for hospice patients with the appropriate hospice care program.

R.C. 119.032 review dates: 05/19/2006 and 05/01/2011

CERTIFIED ELECTRONICALLY__________ Certification 05/19/2006____ Date Promulgated
Under: 119.03 Statutory Authority: 3721.04 Rule Amplifies: 3721.011, 3721.04, 3721.10,
3721.14 Prior Effective Dates: 5/2/1966, 12/21/92, 10/20/2001

OKLAHOMA

Downloaded January 2011

310:675-7-11.1. Medication records

(a) The facility shall maintain written policies and procedures for safe and effective acquisition, storage, distribution, control, and use of medications and controlled drugs.

(b) The facility shall establish a policy for providing information about administering prescribed medications to residents who are on leave from the facility.

(c) The facility shall maintain records of consultation and services provided by the consultant registered pharmacist at the facility.

(d) The facility shall maintain a system to account for controlled medications prescribed for each resident, and an individual inventory record on all Schedule II medications.

(e) The facility shall maintain a medication regimen review record on each resident.

[Source: Added at 9 Ok Reg 3163, eff7-192 (emergency); Added at 100k Reg 163, eff 6-1-93]

310:675-9-9.1. Medication services

(a) Storage.
1. Medications shall be stored in a medication room, a locked cabinet, or a locked medication cart, that is convenient to the nursing station and used exclusively for medication storage.

2. The medication storage area temperature shall be maintained between 60° F. (15.5° C.) to 80° F.(26.6° C.)

3. The medication room, the medication storage cabinet, and medication cart shall be locked when not in use.

4. The key to the medication storage areas shall be in the possession of the person responsible for administering medications.

5. Scheduled medications shall be in a locked box within the locked medication area or cart.

6. Medications for external use shall be stored separately from medications for internal use.

7. Medications requiring refrigeration shall be kept within a temperature range of 36° F. (2.2° C.) to 48° F. (8.8° C.) and separated from food and other items. There shall be a method for locking these medications.

8. The medication areas shall have a work counter; the counter and cabinet shall be well lighted, clean and organized.

9. Running water shall be in close proximity to the medication area.

10. Powdered over-the-counter medication for topical use may be kept in the resident's room for administration by a nurse aide if:

   A. The facility submits its policies and procedures for safe and appropriate storage and application of the powder to the Department and receives written approval from the Department prior to implementation; and

   B. Each aide who applies the over-the-counter topical medication is trained in accordance with the established policies and procedures of the facility.

b. Emergency medications. Emergency medication, policies and equipment shall include but not be limited to:

   1. An electric suction machine with necessary aseptic aspirator tips.

   2. An emergency tray or cart with the following items labeled and accessible to licensed personnel only: resuscitation bag; tongue depressors; and assorted airways; sterile hypodermic syringes in 2 cc, 5 cc, and 20 cc or larger sizes and appropriate needles. The content shall be limited to emergency medications and contain no scheduled medications. Only two single dose vials of the following medications may be on the tray or cart: 50% Dextrose, respiratory stimulant, a cardiac stimulant, injectable lasix, injectable dilantin and injectable benadryl.
(3) A certified medication aide shall not administer injectable medications from any emergency tray or cart, but shall have access to resuscitation bags, tongue depressors, and assorted sizes of airways.

(c) Medication accountability.

(1) Medications shall be administered only on a physician's order.

(2) The person responsible for administering medications shall personally prepare the dose, observe the swallowing of oral medication, and record the medication. Medications shall be prepared within one hour of administration.

(3) An accurate written record of medications administered shall be maintained. The medication record shall include:

(A) The identity and signature of the person administering the medication.

(B) The medication administered within one hour of the scheduled time.

(C) Medications administered as the resident's condition may require (p.r.n.) are recorded immediately, including the date, time, dose, medication, and administration method.

(D) Adverse reactions or results.

(E) Injection sites.

(F) An individual inventory record shall be maintained for each Schedule II medication prescribed for a resident.

(G) Medication error incident reports.

(4) A resident's adverse reactions shall be reported at once to the attending physician.

(d) Medication labels and handling.

(1) All prescribed medications shall be clearly labeled indicating the resident's full name, physician's name, prescription number, name and strength of medication, dosage, directions for use, date of issue and expiration, and name, address and telephone number of pharmacy or physician issuing the medication, and the quantity. If a unit dose system is used, medications shall indicate, at least, the resident's full name, physician's name and strength of medication, and directions for use.

(2) When over-the-counter medications are prescribed and obtained in the original manufacturers container, the package directions shall be considered part of the label. The resident's name shall be on the package.

(3) Each resident's medications shall be kept or stored in the originally received containers. Paper envelopes shall not be considered containers.

(4) Medication containers having soiled, damaged, illegible or makeshift labels shall be relabeled by the issuing pharmacy or physician. Labels on containers shall be clearly legible
and firmly affixed. No label shall be superimposed on another label on a medication container except for over-the-counter medication containers.

(5) No person shall change labels on medication containers. If the attending physician orders a change of directions, there shall be a procedure to mark the container indicating a label change is needed at the next prescription refill.

(6) A pharmacist shall dilute, reconstitute and label medications, whenever possible. If not possible, a registered nurse may reconstitute, dilute and label medications. A distinctive, indelible, supplementary label shall be affixed to the medication container when diluted or reconstituted for other than immediate use. A licensed practical nurse may reconstitute oral medications only. The label shall include the following: resident’s name, dosage and strength per unit/volume, nurse’s initials, expiration date, and date and time of dilution or reconstitution.

(7) When a resident is discharged, or is on therapeutic leave, the unused medication shall be sent with the resident, or with the resident's representative, unless there is a written physician’s order to the contrary, or the medication has been discontinued, or unless the resident or the resident's representative donates unused prescription medications for dispensation to medically indigent persons in accordance with the Utilization of Unused Prescription Medications Act. The clinical record shall document the quantity of medication sent, and returned or donated, and the signature of the person receiving or transferring the medications.

(8) All medication orders shall be automatically stopped after a given time period, unless the order indicates the number of doses to be administered, or the length of time the medication is to be administered. The automatic stop order may vary for different types of medications. The facility shall develop policies and procedures, in consultation with the medical director and pharmacist, to review automatic stop orders on medications. The policy shall be available to personnel administering medications.

(9) No resident shall be allowed to keep any medications unless the attending physician or interdisciplinary team has indicated on the resident's clinical record that the resident is mentally and physically capable of self-administering medications.

(10) A resident who has been determined by the physician or interdisciplinary team as capable of self-administering medication may retain the medications in a safe location in the resident's room. The facility shall develop policies for accountability. Scheduled medications shall not be authorized for self-administration, except when delivered by a patient controlled analgesia pump.

(11) A physician’s telephone orders shall be conveyed to, recorded in the clinical record, and initialed by the licensed nurse receiving the orders.

(12) Medications shall be administered only by a physician, registered nurse, a licensed practical nurse, or a certified medication aide. The only injectables which a certified medication aide may administer are insulin and vitamin B-12 and then only when specifically trained to do so.
(13) A pharmacy, operating in connection with a facility, shall comply with the State pharmacy law and the rules of the Oklahoma State Board of Pharmacy.

(14) Powdered over-the-counter medication for topical use may be administered by a trained nurse aide when designated in writing by the attending physician and delegated by a licensed nurse. The licensed nurse shall ensure that the aide demonstrates competency in reporting skin changes, storage, application and documentation policies and procedures. The licensed nurse or the attending physician shall document in the resident's record a skin assessment at least twice each week and more often if required by the facility's approved policy.

(e) Medication destruction.

(1) Medications prescribed for residents who have died and medications which have been discontinued shall be destroyed by the director of nursing and the consultant pharmacist, except that the facility may transfer unused prescription drugs to city-county health department pharmacies or county pharmacies in compliance with the Utilization of Unused Prescription Medications Act and all rules promulgated thereunder. Medications shall not be returned to the family or resident representatives. The destruction and the method used shall be noted on the clinical record.

(2) Medications prescribed for one resident may not be administered to, or allowed in the possession of, another resident.

(3) There shall be policies and procedures for the destruction of discontinued or other unused medications within a reasonable time. The policy shall provide that medications pending destruction shall not be retained with the resident's current medications. The destruction of medication shall be carried out in the facility jointly by the director of nursing and the licensed pharmacist who shall sign a record of destruction that is retained in the facility.

(f) Medication regimen review. The facility shall ensure that each resident's medications are reviewed monthly, by a registered nurse or a licensed pharmacist. The reviewer shall notify the physician and director of nursing, in writing, when irregularities are evident.

(g) Consultant pharmacist. The facility shall have a consultant licensed pharmacist to assist with the medication regimen review and medication destruction. The consultant pharmacist shall discuss policies and procedures for the administration, storage, and destruction of medications with the administrator, director of nursing and other appropriate staff.

(h) Emergency pharmacist. The facility shall have a contract, or letter of agreement, with a licensed pharmacist or a hospital pharmacy, that agrees to serve as the emergency pharmacist. This licensed pharmacist shall practice in a licensed pharmacy within a ten-mile radius of the facility, and shall be available twenty-four hours a day. If a licensed pharmacist is not available within a ten mile radius, the Department may approve a licensed pharmacist beyond the ten mile radius.

(i) Bulk nonprescription drugs. A facility may maintain nonprescription drugs for dispensing from a common or bulk supply if all of the following are accomplished.
(1) Policy of facility. The facility must have and follow a written policy and procedure to assure safety in dispensing and documentation of medications given to each resident.

(2) Acquisition. The facility shall maintain records which document the name of the medication acquired, the acquisition date, the amount and the strength received for all medications maintained in bulk.

(3) Dispensing. Only licensed nurses, physicians, pharmacists or certified medication aides (CMA) may dispense for administration these medications and only upon the written order for as needed (p.r.n.) or nonscheduled dosage regimens dosing from a physician as documented in the clinical record of the resident.

(4) Storage. Bulk medications shall be stored in the medication area and not in resident rooms.

(5) Records. The facility shall maintain records of all bulk medications which are dispensed on an individual signed medication administration record (MAR).

(6) Labeling. The original labels shall be maintained on the container as it comes from the manufacturer or on the unit-of-use (blister packs) package.

(7) Package size. The maximum size of packaging shall be established by the facility in its policy and procedures and shall insure that each resident receives the correct dosage; provided however, that no liquid medications shall be acquired nor maintained in a package size which exceeds 16 fluid ounces.

(8) Allowed nonprescription drugs. Facilities may have only oral analgesics, antacids, and laxatives for bulk dispensing. No other categories of medication may be maintained as bulk medications.

[Source: Added at 9 Ok Reg 3163, eff 7-1-92 (emergency); Added at 10 Ok Reg 1639, eff 6-1-93; Amended at 11 Ok Reg 907, eff 12-17-93 (emergency); Amended at 11 Ok Reg 2645, eff 6-25-94; Amended at Ok Reg 2521, eff 6-25-99; Amended at 18 Ok Reg 2533, eff 6-25-01; Amended at 19 Ok Reg 524, eff 1-3-02 (emergency); Amended at 19 Ok Reg 2099, eff 6-27-02]

310:675-13-5. Nursing service

(f) Certified medication aide

(1) Each medication aide shall be a certified nurse aide who has passed a Department approved medication administration program.

(2) A graduate nurse or a graduate practical nurse, who has not yet been licensed, may administer medications if the nurse has passed an approved competency test for medication administration.
A certified medication aide may administer physician ordered medications and treatments under the direction of a licensed nurse.

The facility shall have a licensed nurse or physician on-call to handle medical emergencies. The charge person shall notify the designated person when a medical emergency arises.

A certified medication aide shall complete eight hours of continuing education a year that is approved by the Department.

OREGON

411-086-0100 Nursing Services: Staffing

...(6) CERTIFIED MEDICATION AIDES. The licensee shall ensure that all nursing assistants administering non-injectable medications are certified as nursing assistants and as medication aides. Documentation of these two certifications must be maintained in the facility.

Stat. Auth.: ORS 410.070, 410.090, 441.055, 441.073 & 441.615 Stats. Implemented: ORS 410.070, 410.090, 441.055, 441.073 & 441.615 Hist.: SSD 19-1990, f. 8-29-90, cert. ef. 10-1-90; SSD 8-1993, f. & cert. ef. 10-1-93; SPD 23-2004, f. 7-30-04, cert, ef, 8-1-04; SPD 1-2008(Temp), f. 2-8-08, cert. ef. 3-1-08 thru 8-28-08; SPD 10-2008, f. & cert. ef. 8-28-08

411-086-0260 Pharmaceutical Services

(Effective 10/01/1990)

(1) CONSULTING PHARMACIST. Each facility shall have a consulting pharmacist who shall ensure compliance with ORS Chapter 689, the administrative rules adopted pursuant thereto, facility policy (OAR 411-085-0210) and this rule.

(2) PHARMACEUTICAL SERVICES REVIEW. The Quality Assessment and Assurance Committee shall:

(a) Develop written policies and procedures for safe and effective drug therapy, distribution and use;

(b) Oversee pharmaceutical services in the facility, monitor the service to ensure accuracy and adequacy, and make recommendations for improvement; and
(c) Meet at least quarterly and document its activities, findings and recommendations.

(3) DRUG SUPPLY, STORAGE & LABELING.

(a) Drug Room. Facilities without a pharmacy shall have a drug room as defined in ORS Chapter 689, supervised by the consulting pharmacist. Drug rooms shall contain only prescribed (legend and non-legend) drugs, non-prescription (non-legend) stock drug supply and the emergency medication kit authorized pursuant to this rule. Locked carts or locked cupboards shall be used to prevent pilferage.

(b) Labels.

(A) All medications purchased or designated for specific residents shall be labeled as prescribed for such resident.

(B) If facility policy allows medications accompanying the resident on admission to be used, the medication must be identified as to the resident and medication and shall be authorized for use only on the written order of the attending physician.

(c) Storage. Except as provided in subsection (4)(b) of this rule, all medications shall be stored in the facility pharmacy, a drug room, or in a locked medication cart.

(d) Stock Supply.

(A) Except as provided in section (6) of this rule, a stock supply of prescription (legend) drugs may be maintained only within a licensed pharmacy.

(B) A stock supply of nonprescription drugs may be maintained in a drug room or locked medication cart, but there must be a doctor's order for administering such drugs. A stock supply of nonprescription drugs means those non-legend medications supplied in the manufacturer's original package or repackaged by a registered pharmacist and labeled in accordance with ORS Chapter 689.

(e) Resident Discharge. Medication to accompany the resident upon discharge must be on the written order of the physician.

(f) References. References regarding use, dosage, contraindications, drug interactions, and adverse reactions shall be available on drug products used in the facility.

(4) DRUG ADMINISTRATION.

(a) Medications prescribed to one resident shall not be administered to another.

(b) Self administration. Facilities shall have written policies and procedures allowing self-administration of medication.

(A) All bedside medications, except nitroglycerine, shall be stored in closed, locked cupboards or drawers.

(B) The consulting pharmacist shall specify maximum quantities of medications to be stored at bedside to ensure prevention of poisoning by confused or suicidal residents.
(c) Stop Order Policy. An automatic stop order policy shall be adopted and enforced. This policy shall provide guidance when medications ordered are not specifically limited as to time or number of doses. The policy shall be developed by the Quality Assessment and Assurance Committee.

(5) MEDICATION REVIEW. Medications shall be reviewed monthly by the consulting pharmacist and reordered by the physician as necessary, but no less often than quarterly. The pharmacist shall alert the DNS when drugs designated "less-than effective" ("DESI" drugs) by the Federal Food and Drug Administration have been ordered and what alternative medications may be available. The DNS shall notify the physician.

(6) EMERGENCY MEDICATION KIT.

(a) An emergency medication kit shall be prepared and authorized by a registered pharmacist for use in the facility in accordance with written facility policy. The contents shall be selected by the Quality Assessment and Assurance Committee.

(b) The kit shall be sealed and stored in a manner to prevent loss of drugs, but available to authorized personnel. The vendor pharmacist shall be notified when the seal is broken. A record shall be made that identifies each use of an emergency drug. The contents shall be plainly indicated on the outside of the container.

(c) Any drug removed from the kit shall be covered by a prescription and signed by the physician within 72 hours.

(7) CHARGES FOR DRUGS; CHOICE OF SUPPLIER. See OAR 411-085-0340.

(8) DOCUMENTATION. The nursing staff shall clearly and accurately document administration of pharmaceuticals and the response thereto.

Stat. Auth: ORS 410 & 441

Stats. Implemented: ORS 441.055 & 441.615

§ 211.9. Pharmacy services.

(a) Facility policies shall ensure that:

(1) Facility staff involved in the administration of resident care shall be knowledgeable of the policies and procedures regarding pharmacy services including medication administration.
(2) Only licensed pharmacists shall dispense medications for residents. Licensed physicians may dispense medications to the residents who are in their care.

(b) Medications shall be administered by authorized persons as indicated in § 201.3 (relating to definitions).

(c) Medications and biologicals shall be administered by the same licensed person who prepared the dose for administration and shall be given as soon as possible after the dose is prepared.

(d) Medications shall be administered under the written orders of the attending physician.

(e) Each resident shall have a written physician's order for each medication received. This includes both proprietary and nonproprietary medications.

(f) Residents shall be permitted to purchase prescribed medications from the pharmacy of their choice. If the resident does not use the pharmacy that usually services the facility, the resident is responsible for securing the medications and for assuring that applicable pharmacy regulations and facility policies are met. The facility:

(1) Shall notify the resident or the resident’s responsible person, at admission and as necessary throughout the resident's stay in the facility, of the right to purchase medications from a pharmacy of the resident’s choice as well as the resident’s and pharmacy’s responsibility to comply with the facility's policies and State and Federal laws regarding packaging and labeling requirements.

(2) Shall have procedures for receipt of medications from outside pharmacies including requirements for ensuring accuracy and accountability. Procedures shall include the review of medications for labeling requirements, dosage and instructions for use by licensed individuals who are authorized to administer medications.

(3) Shall ensure that the pharmacist or pharmacy consultant will receive a monthly resident medication profile from the selected pharmacy provider.

(4) Shall have a policy regarding the procurement of medications in urgent situations. Facilities may order a 7-day supply from a contract pharmacy if the resident’s selected pharmacy is not able to comply with these provisions.

(g) If over-the-counter drugs are maintained in the facility, they shall bear the original label and shall have the name of the resident on the label of the container. The charge nurse may record the resident’s name on the nonprescription label. The use of nonprescription drugs shall be limited by quantity and category according to the needs of the resident. Facility policies shall indicate the procedure for handling and billing of nonprescription drugs.

(h) If a unit of use or multiuse systems are used, applicable statutes shall be met. Unit of use dispensing containers or multiuse cards shall be properly labeled. Individually wrapped doses shall be stored in the original container from which they were dispensed.
(i) At least quarterly, outdated, deteriorated or recalled medications shall be identified and returned to the dispensing pharmacy for disposal in accordance with acceptable professional practices. Written documentation shall be made regarding the disposition of these medications.

(j) Disposition of discontinued and unused medications and medications of discharged or deceased residents shall be handled by facility policy which shall be developed in cooperation with the consultant pharmacist. The method of disposition and quantity of the drugs shall be documented on the respective resident’s chart. The disposition procedures shall be done at least quarterly under Commonwealth and Federal statutes.

(k) The oversight of pharmaceutical services shall be the responsibility of the quality assurance committee. Arrangements shall be made for the pharmacist responsible for the adequacy and accuracy of the services to have committee input. The quality assurance committee, with input from the pharmacist, shall develop written policies and procedures for drug therapy, distribution, administration, control, accountability and use.

(l) A facility shall have at least one emergency medication kit. The kit used in the facility shall be governed by the following:

1. The facility shall have written policies and procedures pertaining to the use, content, storage and refill of the kits.

2. The quantity and categories of medications and equipment in the kits shall be kept to a minimum and shall be based on the immediate needs of the facility.

3. The emergency medication kits shall be under the control of a practitioner authorized to dispense or pre-scribe medications under the Pharmacy Act (63 P. S. §§ 390.1—390.13).

4. The kits shall be kept readily available to staff and shall have a breakaway lock which shall be replaced after each use.

Authority: The provisions of this § 211.9 amended under section 803 of the Health Care Facilities Act (35 P. S. § 448.803); and section 2102(g) of The Administrative Code of 1929 (71 P. S. § 532(g)).

Administration of Drugs

25.8 Drugs shall be administered in accordance with written orders of the attending physician and procedures established in accordance with sections 28.1 and 28.2 herein. Such procedures shall include measures to assure: (1) that drugs are checked against physicians’ orders; (2) that the resident is identified prior to administration of a drug; (3) that each resident has an individual medication record; and (4) that the dose of drug administered to each resident is properly recorded therein by the person administering the drug.

a) Drugs not specifically limited as to time or number of doses when ordered shall be controlled by automatic stop orders or other methods in accordance with written policies.

b) Physicians’ verbal orders for drugs and biologicals shall be given only to a licensed nurse, a registered pharmacist or to a physician and shall be immediately recorded and signed by the person receiving the order. Such orders shall be countersigned by the attending physician within fifteen (15) days.

Administration of Drugs by Medication Technicians

25.9 Medication technicians who have satisfactorily completed a state approved course in drug administration and have demonstrated competency in accordance with the state-approved protocol in drug administration may administer oral or topical drugs, with the exception of all Schedule II drugs, with supervision in accordance with the state-approved protocol in drug administration. If such medication technicians are from temporary employment agencies, the facility shall have onsite evidence of supervision in accordance with the state-approved protocol in drug administration.

25.10 The director of nursing or his/her registered nurse designee shall conduct and document quarterly evaluations of the medication technicians who are administering drugs. Copies of said evaluations shall be placed in the medication technicians’ personnel records.

Section 28.0 Pharmaceutical Services

28.1 Each facility shall provide pharmaceutical services either directly within the facility or per contractual arrangement. Such services shall be provided in accordance with the requirements of references 25 and 34 herein.

a) In either instance, appropriate methods and procedures for the procurement and the dispensing of drugs and biologicals shall be established in accordance with appropriate federal and state laws and regulations.

28.2 There shall be written policies and procedures relating to the pharmaceutical service which shall require no less than:

a) the authority, responsibility and duties of the registered pharmacist;

b) the selection, procurement, distribution, storage, dispensing or other disposition of drugs and biologicals in accordance with appropriate federal and state laws and regulations;
c) maintenance of records of all transactions, including recording of receipt and dispensing or other disposition of all drugs and biologicals;

d) inspection of all drug and biological storage and medication areas and documented evidence of findings;

e) automatic stop orders for drugs or biologicals;

f) the use of only approved drugs and biologicals;

g) control of medicines from any source;

h) a monitoring program to identify adverse drug reactions, interactions and incompatibilities and antibiotic antagonisms; and

i) labeling of drugs and biologicals including name of resident, name of physician, drug dosage, cautionary instructions, and expiration date.

28.3 Adequate space, equipment, supplies and locked storage areas shall be provided for the storage of drugs and biologicals based on the scope of services provided. Refrigerated food storage units shall not be utilized for storage of drugs and/or biologicals except:

a) In facilities of 30 beds or less, a refrigerated food storage unit may be used for drugs and biologicals provided they are locked in an appropriate container.

28.4 Drugs may be administered to residents from bulk inventories of non-legend and non-controlled substance items such as aspirin, milk of magnesia, etc. as ordered by a licensed physician.

28.5 An emergency medication kit, approved by the pharmaceutical service committee or its equivalent, shall be kept at each nursing station.

28.6 Each residential area shall have adequate drug and biological preparation areas with provisions for locked storage in accordance with federal and state laws and regulations.

28.7 In Nursing Facilities

a) The pharmaceutical service committee or its equivalent, consisting of not less than a registered pharmacist, a registered nurse, a physician and the administrator, shall:

i. serve as an advisory body on all matters pertaining to pharmaceutical services;

ii. establish a program of accountability for all drugs and biologicals;

iii. develop and review periodically all policies and procedures for safe and effective drug therapy in accordance with section 28.2 herein; and

iv. monitor the service.
b) A registered pharmacist shall assist in developing, coordinating and supervising all pharmaceutical services in conjunction with the pharmaceutical services committee. In addition, a registered pharmacist shall:

i. review the drug and biological regimen of each resident at least monthly;

ii. report any irregularities to the attending physician and director of nurses. These reports must show evidence of review and response; and

iii. document in writing the performance of such review, which documentation shall be kept on file by the facility and shall be made accessible to inspectors on request.

SOUTH CAROLINA

Downloaded January 2011

SECTION 1300 - MEDICATION MANAGEMENT

1301. General

A. Medications, including controlled substances, medical supplies, and those items necessary for the rendering of first aid shall be properly managed in accordance with State, Federal, and local laws and regulations. Such management shall address the securing, storing, and administering of medications, medical supplies, first aid supplies, and biologicals, their disposal when discontinued or expired, and their disposition at discharge, transfer, or death of a resident. (I)

B. Applicable medication-related reference materials such as Physicians’ Desk Reference and information on the use of medications shall be readily available at each staff work area in order to provide staff members with adequate information concerning medications. At least one (1) such reference in the facility shall have been published within the previous year and none shall be older than three (3) years.

1302. Medication and Treatment Orders (II)

A. Medication and treatment, to include oxygen, shall be administered to residents only upon orders (to include standing orders) of a physician or other legally authorized healthcare provider. (I)

B. All orders (including verbal) shall be received only by licensed nurses or other legally authorized healthcare providers, and shall be authenticated and dated by a physician or other legally authorized healthcare provider pursuant to the facility’s policies and procedures. This restriction shall not be construed to prohibit the issuance and acceptance of verbal orders in other specialized departments or services in accordance with facility policies and procedures, e.g., orders pertaining to respiratory therapy modalities; medications administered therewith may be given to respiratory therapy personnel and physical therapy orders to physical therapists. (I)
C. Physician’s orders for medication, treatment, care and diet shall be reviewed and reordered no less frequently than every two (2) months. (I)

D. All medication orders that do not specifically indicate the number of doses to be administered or the length of time the medication is to be administered shall automatically be stopped in accordance with facility policies and procedures.

1303. Administering Medication (II)

A. Medications shall be administered in accordance with orders of the attending physician, dentist or other individual legally authorized to prescribe medications or biologicals for human consumption. (I)

B. Medications and medical supplies ordered for a specific resident shall not be provided to or administered to any other resident.

C. Medications shall be administered in accordance with state practice acts. The administration of medication shall include, but not be limited to:

1. Removing an individual dose from a previously dispensed, properly labeled container (including a unit dose container);

2. Verifying the dosage with the physician’s orders;

3. Giving the individual dose to the proper resident;

4. Monitoring the ingestion or application of the dose; and

5. Promptly recording on the MAR, as it is administered, the date, time, dose given, mode of administration, and identification of the individual who administered the medication.

D. Doses of medication shall be administered by the same licensed nurse or other legally authorized healthcare provider who prepared them for administration. Preparation of doses for more than one (1) scheduled administration shall not be permitted. (I)

E. Self-administration of medications by residents is permitted only on the specific written orders of the resident’s attending physician or other legally authorized healthcare provider, verified by direct contact with the resident by a licensed nurse, and recorded on the MAR by that same person. Verification and documentation shall occur at the same frequency as the medication is taken. Facilities may elect to prohibit self-administration. The facility shall not allow residents to self-administer controlled substances. (I)

F. When residents who are unable to self-administer medications leave the facility for an extended period of time, the proper amount of medications, along with dosage, mode, date, and time of administration, shall be given to a responsible individual who will be in charge of the resident during his or her absence from the facility; these details shall be properly documented in the MAR. (I)
G. At each shift change, there shall be a documented review of all Schedule II controlled substances by outgoing licensed nurses with incoming licensed nurses who shall include verification by outgoing licensed nurses that the count was correct, and if incorrect, an explanation of the discrepancy and any corrective actions taken. The review shall include controlled substances in an unsealed emergency medication kit or cart. (I)

1304. Pharmacy Services

A. There shall be a written agreement with a consulting pharmacist to direct, supervise and be responsible for pharmacy services in the facility in accordance with accepted professional principles and appropriate State, Federal, and local laws and regulations. (II)

B. At least monthly the pharmacist shall: (II)

1. Review the medication profile for each resident for potential adverse reactions, allergies, interactions and laboratory test modifications. The attending physician shall be advised of recommended changes in the medication regimen, medication therapy duplication, incompatibilities or contraindications;

2. Review medication storage areas and emergency medication kits;

3. Review all medications in the facility for expiration dates and assure the removal of discontinued or expired medications from use as indicated;

4. Verify proper storage of medications and biologicals in the facility and make recommendations concerning the handling, storing and labeling of medications;

5. Examine the controlled substances records and affirm to the administrator that this inventory is correct;

6. Assess the facility pharmaceutical services to assure the services have been properly implemented and maintained and submit to the administrator a written report of each pharmaceutical assessment including recommendations.

C. In addition to the services enumerated in Section 1304.B, the pharmacist shall participate in the formulation of pharmacy service policies and procedures and coordinate pharmacy services. (II)

D. Facilities that maintain stocks of legend medications and biologicals for resident use within the facility shall obtain and maintain from the South Carolina Board of Pharmacy a valid, current, nondispensing drug outlet permit, displayed in a conspicuous location in the facility.

1305. Medication Containers (II)

A. The labeling of medications and biologicals shall be based on currently accepted professional principles. Labels shall identify, at a minimum, the name of the medication or biological, strength and lot number. As appropriate, labels shall include resident name and any identifying number. The prescribing physician’s name and directions for use shall be on the label if it is not documented in another effective manner. (I)
B. Medication containers that have been damaged, compromised, or without labels, or that have damaged, incomplete or makeshift labels are considered to be misbranded and are prohibited and shall be destroyed in accordance with Section 1309.

C. Medications for each resident shall be maintained in the original container(s) including unit dose systems. Opening blister packs to remove medications for destruction or adding new medications for administration, except under the direction of a pharmacist, is prohibited. (I)

D. When a physician or other legally authorized healthcare provider changes the dosage of a medication, such information shall be documented in the medication administration record and a label that does not obscure the original label shall be attached to the container that states, “Directions changed; refer to MAR and physician or other legally authorized healthcare provider orders for current administration instructions.” The new directions shall be communicated to the pharmacist upon receipt of the order. (I)

1306. Medication Storage

A. Medications shall be stored and safeguarded in a locked medicine preparation room (See Section 2808) or locked cabinet at or near the staff work area to prevent access by unauthorized individuals. If medication carts are utilized for storage, they shall be locked when not in use. Expired or discontinued medications shall not be stored with current medications. Storage areas shall not be located near sources of heat, humidity, or other hazards that may negatively impact medication effectiveness or shelf life. (I)

B. Medications requiring refrigeration or freezing shall be stored in a refrigerator or freezer as appropriate at the temperature range established by the manufacturer used exclusively for that purpose in the medicine preparation room, or in a locked refrigerator used exclusively for medications, or in a separate locked box within a multi-use refrigerator at or near the staff work area. Food and drinks shall not be stored in the same refrigerator or freezer in which medications and biologicals are stored. Blood and blood products may be stored in the same refrigerator with medications and biologicals if stored in a separate compartment from the medications and biologicals in accordance with the AABB. Refrigerators and freezers shall be provided with a thermometer accurate to plus or minus three (3) degrees Fahrenheit. (I)

C. Medications shall be stored: (I)

1. Under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, safety and security;

2. In accordance with manufacturer’s directions and in accordance with all applicable State, Federal, and local laws and regulations;

3. Separately from poisonous substances, such as cleaning and germicidal agents, or body fluids;

4. In a manner that provides for separation between topical and oral medications, and which provides for separation of each resident’s medication;

5. In medicine preparation rooms or cabinets that are well-lighted and of sufficient size to permit orderly storage and preparation of medications. Keys to the medicine preparation room, cabinet,
A refrigerator or medication cart at the staff work area shall be under the control of a designated licensed nurse.

D. Nonlegend medications that can be obtained without a prescription such as aspirin, milk of magnesia and mineral oil, may be retained and labeled as stock in the facility for administration as ordered by a physician or other legally authorized healthcare provider.

E. The medications prescribed for a resident shall be protected from use by any other individuals. For those residents who have been authorized by a physician or other legally authorized healthcare provider to self-administer medications, such medications shall be stored in accordance with facility policies and procedures. (I)

F. Prescribed and over-the-counter medications may be maintained at bedside upon physician orders if kept in an individual cabinet or compartment that is locked, such as the drawer of the resident’s night stand, in the room of each resident who has been authorized in writing to self-administer by a physician or other legally authorized healthcare provider, in accordance with facility policies and procedures. (II)

G. Medications listed in Schedule II of the Federal “Controlled Substance Act” shall be stored in separately locked, permanently affixed, compartments within a locked medicine preparation room, cabinet or a medication cart, unless otherwise authorized by a change in the State-Federal Law pertaining to the unit dose distribution system. (I)

1307. Medication Control and Accountability (II)

A. Records of receipt, administration and disposition of all medications shall be maintained in sufficient detail to enable an accurate reconciliation.

B. Medication, supplies and devices shall not be administered and/or provided to residents beyond the expiration date of those items. (I)

C. Medications that have been discontinued may be secured in the staff work area with a written order by the attending physician. Such medications shall not be held beyond a ninety-day (90-day) period unless so ordered by the physician or other legally authorized healthcare provider, but in no case held beyond the expiration date of the medication.

D. Separate control sheets shall be maintained on any controlled substances listed in Schedule II, State and Federal “Controlled Substance Act.” This record shall contain the following information: date, time administered, name of resident, dose, signature of individual administering, name of physician or other legally authorized healthcare provider ordering the medication and Schedule II controlled substances balances (See Section 1303.G).

1308. Emergency Medications (II)

A. Each facility shall maintain, upon the advice and written approval of the Medical Director and consultant pharmacist, an emergency medication kit or cart of designated medicines and equipment at each staff work area for the use of physicians or other legally authorized healthcare providers in treating the emergency needs of residents.
As an exception, the facility may determine that one (1) emergency medication kit can be readily accessible to, and adequately meet the needs of two (2) or more staff work areas. If such is the case, the facility’s written policies shall include the location(s) of the emergency medication kit(s) and the justification for this determination. There shall not be less than one (1) emergency medication kit on each resident floor.

B. The emergency medication kit or cart shall be sealed and stored in a secured area to prevent unauthorized access and to assure a proper environment for preservation of the medications within, but in such a manner as to allow immediate access.

C. An inventory of medications maintained in the kit shall be attached to or placed in the kit. Another inventory list shall be maintained at the staff work area for quick reference.

D. Whenever the emergency medication kit or cart is opened, the use of contents shall be documented by the nursing staff and it shall be restocked and resealed by the pharmacist within two (2) business days.

1309. Disposition of Medications

A. Upon discharge of a resident, unused medications, biologicals, medical supplies and solutions may be released to the resident, family member, or responsible party, unless prohibited by facility policies and procedures, the attending physician or other legally authorized healthcare provider.

B. When resident medications, biologicals, medical supplies or solutions have deteriorated or exceeded their expiration date or there are partial unused medications, or medication containers are misbranded, they shall be destroyed by a licensed nurse or other legally authorized healthcare provider or returned to the pharmacy. (II)

C. When noncontrolled legend drugs, biologicals, medical supplies and solutions are destroyed, the following shall be documented: date of destruction, medication name, strength, quantity, mode of destruction, and the name of the individual performing the destruction and witnessed by a licensed nurse or pharmacist. (I)

D. The destruction of controlled substances shall be accomplished pursuant to the requirements of R.61-4. (I)
44:04:08:02. Policies and procedures. Methods and written policies and procedures must be established to include the manner of issuance, proper storage, control, accountability, and administration of medications or drugs in each hospital or nursing facility. If any patient or resident is permitted to self-administer medications, the facility's policies and procedures related to self-administered drugs must include a description of the responsibilities of the patient or resident, the patient's or resident's family members, and the facility staff. The facility must provide written educational material explaining to the patient or resident and the patient's or resident's family the patient's or resident's rights and responsibilities associated with self-administration. Each nursing facility must keep a list of the following in the drug storage area for reference:

(1) Generic and trade names for drugs substituted within the facility;

(2) Drugs with unique requirements for administration, used within the facility, including enteric coatings, sublingual, buccal, and sustained release dosage forms; and

(3) Drugs controlled under SDCL 34-20B that are used within the facility.

Source: SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 24 SDR 90, effective January 4, 1998; 28 SDR 83, effective December 16, 2001; 29 SDR 81, effective December 11, 2002.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:08:03. Written orders for medication required. All medications or drugs administered to patients or residents must be ordered in writing and signed by the prescribing practitioner. Telephone orders for medications or drugs may be taken only when there is an urgent need to initiate or change an order and accepted only by a pharmacist or licensed nurse in both hospitals and nursing facilities. The practitioner shall sign or initial the orders for nursing facility residents on the next visit to the facility. The practitioner shall sign or initial the orders for hospital patients as soon as possible. In hospitals a policy on stop orders for antibiotics, anticoagulants, and controlled drugs must be established based on recommendations of the medical staff. In nursing facilities, a policy on stop orders for anticoagulants, antibiotics, narcotics, sedatives, hypnotics, and central nervous system stimulants must be established.


General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.
44:04:08:03.01. Drug therapy reviewed monthly. The pharmaceutical service must be under the supervision of a licensed pharmacist who is responsible to the administrator for developing, coordinating, and supervising medication control. The pharmacist must review the drug regimen of each nursing facility resident or swing bed patient at least monthly... The pharmacist must review, at a minimum, the resident’s or patient’s diagnosis, the drug regimen, and any pertinent laboratory findings and dietary considerations. The pharmacist must report potential drug therapy irregularities and make recommendations for improving the drug therapy of the residents or patients to the attending physician and the administrator. The pharmacist must document the review by preparing a monthly report of the potential irregularities and recommendations. The administrator must retain the report in the nursing facility, assisted living center with approval for medication administration, or hospital.


General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:08:04. Storage and labeling of medications and drugs. All drugs or medications must be stored in a well illuminated, locked storage area which is well ventilated, maintained at a temperature appropriate for drug storage, and inaccessible to patients, residents, or visitors at all times. Medications suitable for storage at room temperature must be maintained between 59 and 86 degrees Fahrenheit (15 and 30 degrees centigrade). Medications that require refrigeration must be maintained between 36 and 46 degrees Fahrenheit (2 and 8 degrees centigrade). Poisons and medications prescribed for external use must be stored separately from internal medications, locked and made inaccessible to patients or residents.

The medications or drugs of each patient or resident for whom medications are facility-administered must be stored in the containers in which they were originally received and may not be transferred to another container. Special modification of this requirement may be made when single dose packaging is used. Each prescription drug container, including manufacturer’s complimentary samples, must be labeled with the patient’s or resident’s name, practitioner’s name, drug name and strength, directions for use, and prescription date. Containers with contents that will not be used within 30 days of issue or with contents that expire in less than 30 days of issue must bear an expiration date. If a single dose system is used, the drug name and strength, expiration date, and a control number must be on the unit dose packet. A nursing facility, a co-located nursing facility and assisted living center, a co-located hospital and assisted living center, or an assisted living center with 24 hour per day licensed nursing staff may procure and stock, including in bulk form, nonlegend medications and administer them in accordance with written policies and procedures that provide for oversight by qualified personnel.

If a stock bottle system is used in a hospital or a nursing facility with a licensed pharmacy, the container must be labeled with the drug name and strength, expiration date, and a control number. Any container with a worn, illegible, or missing label must be destroyed pursuant to
§ 44:04:08:04.02. Licensed pharmacists are responsible for the labeling, relabeling, or altering of labels on medication containers.


General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:08:04.01. Control and accountability of medications and drugs. Medications brought from home may be used if ordered by the attending physician and, if prior to administration, is identified as the prescribed drug. Medications prescribed for one patient or resident may not be administered to another. Patients or residents in licensed health care facilities may not keep medications on their person or in their room without a physician’s order allowing self-administration. Written authorization by the attending physician must be secured for the release of any medication to a patient or resident upon discharge, transfer, or temporary leave from the facility. The release of medication must be documented in the patient’s or resident’s record, indicating quantity, drug name, and strength.


General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:08:04.02. Documentation of drug disposal. If a hospital or nursing facility has a licensed pharmacy, outdated or discontinued medications must be returned to the pharmacy for disposition. In the absence of a licensed pharmacy, the method of disposition of outdated or discontinued medications must be handled and recorded in the patient’s or resident’s medical record as follows:

(1) Legend drugs not controlled under SDCL 34-20B must be destroyed by a professional nurse and another witness;

(2) Medications controlled under SDCL 34-20B must be destroyed in the facility by a pharmacist and a registered nurse; and

(3) Medications, excluding controlled substances listed in SDCL chapter 34-20B, in unit dose packaging which meets packaging standards in § 20:51:13:02.01 may be returned to the pharmacy pursuant to § 20:51:13:02.01.

Source: 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 24 SDR 90, effective January 4, 1998.
44:04:08:05. Administration of medications and drugs. Medication administration records must be used and regularly checked against the physician's orders. Except in hospitals having admixtures programs, a person may not administer medications that have been prepared by another person. Nursing facilities must obtain solid dosage forms of medications from pharmacists in the specific dosage needed by the residents of the facility. Each medication administered must be recorded in the patient's or resident's medical record and signed by the individual responsible. Medication errors and drug reactions must be reported to the patient's or resident's physician and an entry made in the patient's or resident's medical record. Orders involving abbreviations and chemical symbols may be carried out only if the facility has a standard list of abbreviations and symbols approved by the medical staff or, in the absence of an organized medical staff, by the medical director and the list is available to the nursing staff. In hospitals and nursing facilities all medications must be administered to patients by personnel acting under delegation of a licensed nurse, or licensed to administer medications.


General Authority: SDCL 34-12-13.
Law Implemented: SDCL 34-12-13.

44:04:08:06. Administration of hospital or nursing facility pharmacy. The pharmaceutical service of each hospital or nursing facility with a licensed full or part-time pharmacy must be directed by a licensed pharmacist accountable to the administration of the hospital or nursing facility. Only prepackaged drugs or a single dose unit may be removed from the pharmacy when the pharmacist is not available. These drugs may be removed only by a designated registered nurse or physician in amounts sufficient only for immediate therapeutic needs. A record of such withdrawals must be made by the designated nurse or the physician making the withdrawal. Source: SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 24 SDR 90, effective January 4, 1998.

General Authority: SDCL 34-12-13.
Law Implemented: SDCL 34-12-13.

44:04:08:07. Stock of legend drugs prohibited in nursing facilities -- Exception. Legend drugs or medications may not be stocked in bulk form in nursing facilities except in nursing facilities which employ a licensed pharmacist full or part time to supervise, within the facility, the procurement, storage, and dispensing of such drugs and medications. Nursing facilities without a pharmacy shall
use the emergency drug box kept on the premises pursuant to § 44:04:08:07.01 or obtain emergency medications from a pharmacy licensed to distribute to outpatients.

Source: SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:08:07.01. Controlled drugs kept for emergency use. In nursing facilities, controlled drugs may be kept for emergency use under the following circumstances:

1. The pharmacist supplying the controlled drugs maintains ownership and responsibility for the drugs, including a monthly physical inventory;

2. The controlled drugs are stored in a manner that allows only those individuals authorized to administer the drugs access to them;

3. The controlled drugs are stored in a sealed emergency box or in a separate locked cabinet, with a complete and accurate record kept of the drugs in the box or cabinet and of their disposition;

4. The facility notifies the pharmacist within 36 hours after the withdrawal of a Schedule II drug and within 72 hours after the withdrawal of Schedule III and IV drugs and the pharmacist replaces the drugs within 72 hours after notification; and

5. No more than 5 different controlled drugs are stored in the emergency box, which may contain no more than 6 doses of any Schedule II controlled drug, no more than 6 doses of any Schedule III or IV injectable controlled drug, and no more than 12 doses of any oral Schedule III or IV controlled drug.


General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

TENNESSEE

Downloaded January 2011

1200-8-6-.06 BASIC SERVICES.

...(4) Nursing Services.
(i) All drugs, devices and related materials must be administered by, or under the supervision of, nursing or other personnel in accordance with federal and state laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

(j) There must be a facility procedure for reporting adverse drug reactions and errors in administration of drugs.

(6) Pharmaceutical Services.

(a) The nursing home shall have pharmaceutical services that meet the needs of the residents and are in accordance with the Tennessee Board of Pharmacy statutes and rules. The medical staff is responsible for developing policies and procedures that minimize drug errors.

(b) All internal and external medications and preparations intended for human use shall be stored separately. They shall be properly stored in medicine compartments, including cabinets on wheels, or drug rooms. Such cabinets or drug rooms shall be kept securely locked when not in use, and the key must be in the possession of the supervising nurse or other authorized persons. Poisons or external medications shall not be stored in the same compartment and shall be labeled as such.

(c) Schedule II drugs must be stored behind two (2) separately locked doors at all times and accessible only to persons in charge of administering medication.

(d) Every nursing home shall comply with all state and federal regulations governing Schedule II drugs.

(e) A notation shall be made in a Schedule II drug book and in the resident’s nursing notes each time a Schedule II drug is given. The notation shall include the name of the resident receiving the drug, name of the drug, the dosage given, the method of administration, the date and time given and the name of the physician prescribing the drug.

(f) All oral orders shall be immediately recorded, designated as such and signed by the person receiving them and countersigned by the physician within ten (10) days.

(g) All orders for drugs, devices and related materials must be in writing and signed by the practitioner or practitioners responsible for the care of the resident. Electronic and computer-generated records and signature entries are acceptable. When telephone or oral orders must be used, they shall be:

1. Accepted only by personnel that are authorized to do so by the medical staff policies and procedures, consistent with federal and state law; and,

2. Signed or initialed by the prescribing practitioner according to nursing home policy.

(h) Medications not specifically limited as to time or number of doses when ordered are controlled by automatic stop orders or other methods in accordance with written policies. No Schedule II drug shall be given or continued beyond seventy-two (72) hours without a written order by the physician.
(i) Medication administration records (MAR) shall be checked against the physician's orders. Each dose shall be properly recorded in the clinical record after it has been administered.

(j) Preparation of doses for more than one scheduled administration time shall not be permitted.

(k) Medication shall be administered only by licensed medical or licensed nursing personnel or other licensed health professionals acting within the scope of their licenses.

(l) Unless the unit dose package system is used, individual prescriptions of drugs shall be kept in the original container with the original label intact showing the name of the resident, the drug, the physician, the prescription number and the date dispensed.

(m) Legend drugs shall be dispensed by a licensed pharmacist.

(n) Any unused portions of prescriptions shall be turned over to the resident only on a written order by the physician. A notation of drugs released to the resident shall be entered into the medical record. All unused prescriptions left in a nursing home must be destroyed on the premises and recorded by a pharmacist. Such record shall be kept in the nursing home.

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**TEXAS**

Downloaded January 2011

Sec. 242.601. MEDICATION ADMINISTRATION.

(a) An institution must establish medication administration procedures.

(b) The medication administration procedures must comply with this subchapter and the rules adopted by the board under Section 242.608.


Sec. 242.602. PHARMACIST SERVICES.

(a) An institution shall:

(1) employ a licensed pharmacist responsible for operating the institution's pharmacy; or
(2) contract, in writing, with a licensed pharmacist to advise the institution on ordering, storage, administration, and disposal of medications and biologicals and related recordkeeping.

(b) The institution shall allow residents to choose their pharmacy provider from any pharmacy that is qualified to perform the services.

Added by Acts 1997, 75th Leg., ch. 1159, Sec. 1.30, eff. Sept. 1, 1997.

Sec. 242.603. STORAGE AND DISPOSAL OF MEDICATIONS.

(a) An institution shall store medications under appropriate conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security.

(b) The institution shall properly dispose of:

(1) any medication that is discontinued or outdated, except as provided by Subsection (c); and

(2) any medication in a container with a worn or illegible label or missing a label.

(c) A discontinued medication that has not been destroyed must be reinstated if reordered.

(d) An institution shall release the medications of a resident who is transferred directly to another institution or who is discharged to home to the new institution or to the resident or resident’s next of kin or guardian, as appropriate. The institution may release a medication to a resident only on the written or verbal authorization of the attending physician.


Sec. 242.604. REPORTS OF MEDICATION ERRORS AND ADVERSE REACTIONS.

An institution’s nursing staff must report medication errors and adverse reactions to the resident’s physician in a timely manner, as warranted by an assessment of the resident’s condition, and record the errors and reactions in the resident’s clinical record.

Added by Acts 1997, 75th Leg., ch. 1159, Sec. 1.30, eff. Sept. 1, 1997.

Sec. 242.605. MEDICATION REFERENCE SOURCES.

An institution shall maintain updated medication reference texts or sources. If the institution has a resident younger than 18 years of age, these texts or sources must include information on pediatric medications, dosages, sites, routes, techniques of administration of medications, desired effects, and possible side effects.

Added by Acts 1997, 75th Leg., ch. 1159, Sec. 1.30, eff. Sept. 1, 1997.
Sec. 242.606. PERMITS TO ADMINISTER MEDICATION.

A person may not administer medication to a resident unless the person:

(1) holds a license under state law that authorizes the person to administer medication; or

(2) holds a permit issued under Section 242.610 and acts under the authority of a person who holds a license under state law that authorizes the person to administer medication.


SEC. 242.607. EXEMPTIONS FOR NURSING STUDENTS AND MEDICATION AIDE TRAINEES.

(a) Sections 242.606 and 242.614 do not apply to:

(1) a graduate nurse holding a temporary permit issued by the Texas Board of Nursing;

(2) a student enrolled in an accredited school of nursing or program for the education of registered nurses who is administering medications as part of the student's clinical experience;

(3) a graduate vocational nurse holding a temporary permit issued by the Texas Board of Nursing;

(4) a student enrolled in an accredited school of vocational nursing or program for the education of vocational nurses who is administering medications as part of the student's clinical experience; or

(5) a trainee in a medication aide training program approved by the department under this subchapter who is administering medications as part of the trainee's clinical experience.

(b) The administration of medications by persons exempted under Subdivisions (1) through (4) of Subsection (a) is governed by the terms of the memorandum of understanding executed by the department and the Texas Board of Nursing.


Acts 2007, 80th Leg., R.S., Ch. 889, Sec. 69, eff. September 1, 2007.

Sec. 242.608. RULES FOR ADMINISTRATION OF MEDICATION.

The board by rule shall establish:

(1) minimum requirements for the issuance, denial, renewal, suspension, emergency suspension, and revocation of a permit to administer medication to a resident;

(2) curricula to train persons to administer medication to a resident;
(3) minimum standards for the approval of programs to train persons to administer medication to a resident and for rescinding approval; and

(4) the acts and practices that are allowed or prohibited to a permit holder.


Sec. 242.609. TRAINING PROGRAMS TO ADMINISTER MEDICATION.

(a) An application for the approval of a training program must be made to the department on a form and under rules prescribed by the board.

(b) The department shall approve a training program that meets the minimum standards adopted under Section 242.608. The department may review the approval annually.


Sec. 242.610. ISSUANCE AND RENEWAL OF PERMIT TO ADMINISTER MEDICATION.

(a) To be issued or to have renewed a permit to administer medication, a person shall apply to the department on a form prescribed and under rules adopted by the board.

(b) The department shall prepare and conduct, at the site of the training program, an examination for the issuance of a permit. The results of the examination shall be reported in accordance with Section 242.6101.

(c) The department shall require a permit holder to satisfactorily complete a continuing education course approved by the department for renewal of the permit.

(d) Subject to Subsections (h)-(m), the department shall issue a permit or renew a permit to an applicant who:

(1) meets the minimum requirements adopted under Section 242.608;

(2) successfully completes the examination or the continuing education requirements; and

(3) pays a nonrefundable application fee determined by the board.

(e) Except as provided by Subsection (g), a permit is valid for one year and is not transferable.

(f) The department may issue a permit to an employee of a state or federal agency listed in Section 242.003(a)(6)(B).
(g) The board by rule may adopt a system under which permits expire on various dates during the year. For the year in which the permit expiration date is changed, the department shall prorate permit fees on a monthly basis so that each permit holder pays only that portion of the permit fee that is allocable to the number of months during which the permit is valid. On renewal of the permit on the new expiration date, the total permit renewal fee is payable.

(h) A person who is otherwise eligible to renew a permit may renew an unexpired permit by paying the required renewal fee to the department before the expiration date of the permit. A person whose permit has expired may not engage in activities that require a permit until the permit has been renewed.

(i) A person whose permit has been expired for 90 days or less may renew the permit by paying to the department a renewal fee that is equal to 1-1/2 times the normally required renewal fee.

(j) A person whose permit has been expired for more than 90 days but less than one year may renew the permit by paying to the department a renewal fee that is equal to two times the normally required renewal fee.

(k) A person whose permit has been expired for one year or more may not renew the permit. The person may obtain a new permit by complying with the requirements and procedures, including the examination requirements, for obtaining an original permit.

(l) A person who was issued a permit in this state, moved to another state, currently holds a valid permit or license issued by the other state, and has been in practice in that state for the two years preceding the date of application may obtain a new permit without reexamination. The person must pay to the department a fee that is equal to two times the normally required renewal fee for the permit.

(m) Not later than the 30th day before the date a person's permit is scheduled to expire, the department shall send written notice of the impending expiration to the person at the person's last known address according to the records of the department.


Sec. 242.6101. RESULTS OF EXAMINATION FOR ISSUANCE OF PERMIT.

(a) Not later than the 30th day after the date a person takes an examination for the issuance of a permit under this subchapter, the department shall notify the person of the results of the examination.

(b) If the examination is graded or reviewed by a testing service:

(1) the department shall notify the person of the results of the examination not later than the 14th day after the date the department receives the results from the testing service; and
(2) if notice of the examination results will be delayed for longer than 90 days after the examination date, the department shall notify the person of the reason for the delay before the 90th day.

(c) The department may require a testing service to notify a person of the results of the person’s examination.

(d) If requested in writing by a person who fails an examination for the issuance of a permit administered under this subchapter, the department shall furnish the person with an analysis of the person’s performance on the examination.

Added by Acts 2003, 78th Leg., ch. 1169, Sec. 16, eff. Sept. 1, 2003.

Sec. 242.611. FEES FOR ISSUANCE AND RENEWAL OF PERMIT TO ADMINISTER MEDICATION.

The board shall set the fees in amounts reasonable and necessary to recover the amount projected by the department as required to administer its functions. Except as otherwise provided by Section 242.610, the fees may not exceed:

(1) $25 for a combined permit application and examination fee; and

(2) $15 for a renewal permit application fee.


Sec. 242.612. VIOLATION OF PERMITS TO ADMINISTER MEDICATION.

(a) The board shall revoke, suspend, or refuse to renew a permit or shall reprimand a permit holder for a violation of this subchapter or a rule of the board adopted under this subchapter. In addition, the board may suspend a permit in an emergency or rescind training program approval.

(b) Except as provided by Section 242.613, the procedure by which the department takes a disciplinary action and the procedure by which a disciplinary action is appealed are governed by the department’s rules for a formal hearing and by Chapter 2001, Government Code.

(c) The board may place on probation a person whose permit is suspended. If a permit suspension is probated, the board may require the person:

(1) to report regularly to the department on matters that are the basis of the probation;

(2) to limit practice to the areas prescribed by the board; or

(3) to continue or review professional education until the person attains a degree of skill satisfactory to the board in those areas that are the basis of the probation.
Sec. 242.613. EMERGENCY SUSPENSION OF PERMITS TO ADMINISTER MEDICATION.

(a) The department shall issue an order to suspend a permit issued under this subchapter if the department has reasonable cause to believe that the conduct of the permit holder creates an imminent danger to the public health or safety.

(b) An emergency suspension is effective immediately without a hearing on notice to the permit holder.

(c) If requested in writing by a permit holder whose permit is suspended, the department shall conduct a hearing to continue, modify, or rescind the emergency suspension.

(d) The hearing must be held not earlier than the 10th day or later than the 30th day after the date on which the hearing request is received.

(e) The hearing and an appeal from a disciplinary action related to the hearing are governed by the department's rules for a formal hearing and Chapter 2001, Government Code.

Sec. 242.614. ADMINISTRATION OF MEDICATION; CRIMINAL PENALTY.

(a) A person commits an offense if the person knowingly administers medication to a resident and the person:

(1) does not hold a license under state law that authorizes the person to administer medication; or

(2) does not hold a permit issued by the department under this subchapter.

(b) An offense under this section is a Class B misdemeanor.

(a) In this section, the following words and terms have the following meanings, unless the context clearly indicates otherwise:

(1) Medication-related emergency--A situation in which it is immediately necessary to administer medication to a resident to prevent:

(A) imminent probable death or substantial bodily harm (emotional or physical) to the resident; or

(B) imminent physical or emotional harm to another because of threats, attempts, or other acts the resident overtly or continually makes or commits.

(2) Psychoactive medication--A medication prescribed for the treatment of symptoms of psychosis or other severe mental or emotional disorders and used to exercise an effect on the central nervous system to influence and modify behavior, cognition, or affective state when treating the symptoms of mental illness. The term includes the following categories when used as described by this subdivision:

(A) anti-psychotics or neuroleptics;

(B) antidepressants;

(C) agents for control of mania or depression;

(D) anti-anxiety agents;

(E) sedatives, hypnotics, or other sleep-promoting drugs; and

(F) psychomotor stimulants.

(b) A person may not administer a psychoactive medication to a resident who does not consent to the prescription unless:

(1) the resident is having a medication-related emergency; or

(2) the person authorized by law to consent on behalf of the resident has consented to the prescription.

(c) Consent to the prescription of psychoactive medication given by a resident, or by a person authorized by law to consent on behalf of the resident, is valid only if:

(1) the consent is given voluntarily and without coercive or undue influence;

(2) the person who prescribes the medication, or that person’s designee, provides the resident and, if applicable, the person authorized by law to consent on behalf of the resident, with the following information in a single document identified as being for the purpose of consent to treatment with psychoactive medication:

(A) the specific condition to be treated;

(B) the beneficial effects on that condition expected from the medication;
(C) the probable clinically significant side effects and risks associated with the medication, as reported in widely available pharmacy databases or the manufacturer's package insert; and

(D) the proposed course of the medication;

(3) the resident and, if appropriate, the person authorized by law to consent on behalf of the resident, are informed in writing that consent may be revoked; and

(4) the consent is evidenced in the resident's clinical record by a signed form prescribed by the facility, or by a statement of the person who prescribes the medication or that person's designee, that documents consent was given by the appropriate person and the circumstances under which the consent was obtained.

(A) Consent is valid until:

(i) consent is withdrawn; or

(ii) the practitioner has discontinued the medication.

(B) For purposes of this rule, a medication will be considered to be discontinued if therapy has been suspended for more than 70 days. If the suspended therapy is resumed within the 70-day period, an oral explanation of side effects should be documented in the clinical record.

(d) The Health and Safety Code, Chapter 313, Consent to Medical Treatment, provides guidance on treatment decisions when a resident is comatose, incapacitated, or otherwise mentally or physically incapable of communication. An ethics committee also may prove helpful in such situations.

(e) A resident's refusal to consent to receive psychoactive medication must be documented in the resident's clinical record.

(f) If a person prescribes psychoactive medication to a resident without the resident's consent because the resident is having a medication-related emergency:

(1) the person must document the necessity of the order in the resident's clinical record in specific medical or behavioral terms; and

(2) treatment of the resident with the psychoactive medication must be provided in the manner, consistent with clinically appropriate medical care, least restrictive of the resident's personal liberty.

(g) A physician, or a person designated by the physician, is not liable for civil damages or an administrative penalty and is not subject to disciplinary action for a breach of confidentiality of medical information for a disclosure of the information provided under subsection (c)(2) made by the resident, or the person authorized by law to consent on behalf of the resident, that occurs while the information is in the possession or control of the resident or the person authorized by law to consent on behalf of the resident.

Source Note: The provisions of this §19.1207 adopted to be effective July 1, 2002, 27 TexReg 4362
RULE §19.1501 Pharmacy Services

A licensed-only facility must assist the resident in obtaining routine drugs and biologicals and make emergency drugs readily available, or obtain them under an agreement described in §19.1906 of this title (relating to Use of Outside Resources). A Medicaid-certified facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in §19.1906 of this title (relating to Use of Outside Resources). See also §19.901(12) and (13) of this title (relating to Quality of Care) for information concerning drug therapy and medication errors.

(1) Methods and procedures. The facility may permit unlicensed personnel to administer drugs, but only under the general supervision of a licensed nurse. The unlicensed individual must be a nursing student, a medication aide student, or a medication aide with a current permit issued by the Texas Department of Human Services.

(2) Accuracy in service delivery. A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

(3) Service consultation. The facility must employ or obtain the services of a pharmacist, currently licensed by the Texas State Board of Pharmacy and in good standing, who:

(A) provides consultation on all aspects of the provision of pharmacy services in the facility;

(B) establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation;

(C) determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled; and

(D) adheres to requirements in §19.1503 of this title (relating to Additional Supervision and Consultation Requirements).

(4) Drug regimen review.

(A) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist. The consultant pharmacist’s drug regimen review must be maintained in the resident’s clinical record.

(B) The pharmacist must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon.

(5) Labeling of drugs and biologicals. Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principals and in compliance with the Texas State Board of Pharmacy Laws and Regulations, §291, including the appropriate accessory and cautionary instructions and the expiration date when applicable.
(6) Storage of drugs and biologicals.

(A) In accordance with state and federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls and permit only authorized personnel to have access to the keys.

(B) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs, listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976, and of other drugs subject to abuse, except when the facility uses single-unit-package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected (see §19.1509 of this title (relating to Controlled Substances)).

Source Note: The provisions of this §19.1501 adopted to be effective May 1, 1995, 20 TexReg 2054; amended to be effective July 1, 2002, 27 TexReg 5524.

RULE §19.1502 Choice of Pharmacy Provider

(a) Unless the facility is paying for the drugs and biologicals, the resident's choice of pharmacy provider and any changes in his choice must be recorded on appropriate forms maintained by the facility.

(b) A Medicaid-certified facility must have written agreements with its provider pharmacies that define required services. These agreements will not be considered to abridge the resident's freedom of choice of pharmacy services when they require labeling, packaging, and a drug-distribution system according to facility policy. The drug-distribution system must be accessible to all pharmacies willing to meet the distribution system requirements. The agreements must require the following:

(1) that the resident's pharmacy services be provided by a pharmacy on a 24-hour basis for emergency medications; and

(2) that the resident's medications be delivered to the facility on a timely and reasonable basis.

(c) The resident's choice of pharmacy provider must be in accordance with §19.406(c) of this title (relating to Free Choice).

Source Note: The provisions of this §19.1502 adopted to be effective May 1, 1995, 20 TexReg 2054.

RULE §19.1503 Additional Supervision and Consultation Requirements

(a) The facility must provide pharmaceutical services under the responsibility and direction of the consultant pharmacist and the director of nursing.

(b) The facility must ensure that notes on the monthly visits by the consulting pharmacist are entered in the resident's clinical record.
(c) The number of hours per month the consultant pharmacist devotes to the pharmaceutical services for ordering, storage, administration, disposal, recordkeeping (documentation) of drugs and medications, and drug regimen review must be sufficient to meet the needs of the residents.

(d) A record of consultant pharmacist services, consultations, and recommendations for pharmacy procedure must be maintained at the facility.

Source Note: The provisions of this §19.1503 adopted to be effective May 1, 1995, 20 TexReg 2054.

RULE §19.1504 Drug Security

(a) The facility must establish procedures for storing and disposing of drugs and biologicals in accordance with federal, state, and local laws.

(b) When not in use, a medication cart must be secured in a designated area.

(c) Small multiple-dose drug containers which are placed into another container must be labeled in a manner so that, if the two containers become separated, the small drug container still has a strip label attached containing the name of the resident and the prescription number.

(d) Self-administered medications may be kept in a locked cabinet in the resident's room. When medications are self-administered, the facility remains responsible for medication security, accurate information, and medication compliance.

(e) The facility must store each resident's drugs in their original containers.

(f) The facility must store medications under appropriate conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security.

(g) Medications of deceased residents, medications that have passed the expiration date, and medications that have been discontinued must be securely stored and reconciled. These medications must be disposed of according to federal and state laws or rules on a quarterly basis. Discontinued drugs may be reinstated if reordered prior to destruction. These medications cannot be given to a family member or representative.

(h) When the directions for administration of a resident's medication have changed, but the existing supply of medication can still be administered accurately, the medication must not be destroyed. The facility must affix a change-of-direction ancillary sticker or similar system and use the remaining medication. The medication label must be updated at the time of next dispensing.

Source Note: The provisions of this §19.1504 adopted to be effective May 1, 1995, 20 TexReg 2054; amended to be effective September 1, 2003, 28 TexReg 6939

RULE §19.1506 Drug Orders

(a) All drugs must be prescribed by the resident's physician or consulting physician, dentist, podiatrist, or other individual allowed by law to prescribe. If drug orders are verbal, they must be taken by a licensed nurse, pharmacist, physician assistant or a physician, and immediately recorded
and signed by the person receiving the order. All drug orders must be counter-signed by the prescriber and returned to the chart in a timely manner.

(b) The facility may permit verbal orders for Schedule II drugs only in an emergency.

(c) Medications must be ordered and reordered on a timely basis so that no resident misses a dose.

(d) The facility must have written policies and procedures for stopping the administration of drugs.

Source Note: The provisions of this §19.1506 adopted to be effective May 1, 1995, 20 TexReg 2054.

RULE §19.1507 Drug Release

(a) Medications must be released to residents only on the written or verbal authorization of the attending physician. When a resident is transferred directly to another nursing facility or discharged to home, the resident’s medications must be released to the new facility or to the resident or his family, respectively.

(b) If a resident is leaving the facility on a furlough, enough prescription drugs to last throughout the furlough must be released. The facility must inventory Schedule II, III, and IV drugs in and out. Nonschedule drugs should be listed by name. The pharmacist must handle any division of the prescription, and all information on the original prescription label must appear on the furlough medication supply.

Source Note: The provisions of this §19.1507 adopted to be effective May 1, 1995, 20 TexReg 2054.

RULE §19.1508 Drug Administration

(a) The facility must establish drug administration procedures to ensure that:

(1) drugs to be administered are checked against the physician’s orders;

(2) the resident is identified before the administration of a drug;

(3) each resident has an individual medication record, where the dose of drug administered is properly recorded by the person who administered the drug;

(4) drugs and biologicals are prepared and administered by the same person, except under unit-of-use package distribution systems and as outlined in §19.418 of this title (relating to Self-Administration of Drugs); and

(5) drugs prescribed for one resident must not be administered to any other person.

(b) The facility nursing staff must report drug errors and adverse drug reactions to the resident’s physician in a timely manner, as warranted by an assessment of the resident’s condition, and record them in the resident’s record. An incident report must be completed in accordance with §19.1923 of this title (relating to Incident or Accident Reporting). Medication errors include, but are not limited to, administering the wrong medication, administering at the wrong time, administering
the wrong dosage strength, administering by the wrong route, omitting a medication, and/or administering to the wrong resident.

(c) Nursing facilities must have current medication reference texts or sources, including information on pediatric medications, dosages, sites, routes, techniques of drug administration, desired effects, and possible side effects, if facilities have pediatric residents.

(d) A licensed nurse may exercise professional judgment in the crushing of a medication, providing that the medication is not a time-released or enteric coated medication.

(1) If there is any question about crushing a medication for a resident, the licensed nurse must check with the treating physician, dispensing pharmacist, or consultant pharmacist.

(2) The crushed medication should be administered as soon as feasible once it has been added to another substance.

Source Note: The provisions of this §19.1508 adopted to be effective May 1, 1995, 20 TexReg 2054.

RULE §19.1509 Controlled Substances

The facility must adhere to the following procedures governing the use of drugs covered by the Controlled Substances Act:

(1) a separate record must be maintained for each drug covered by Schedules II, III, and IV of the Controlled Substances Act, Health and Safety Code, Chapter 481;

(2) the record for each drug must contain the prescription number, name, and strength of drug, date received by the facility, date and time administered, name of resident, dose, physician’s name, signature of person administering dose, and original amount dispensed with the balance verifiable by drug inventory at every shift change; and

(3) Schedule V drugs are exempt from the requirements in paragraphs (1) and (2) of this section.

Source Note: The provisions of this §19.1509 adopted to be effective May 1, 1995, 20 TexReg 2054.

RULE §19.1510 Emergency Medication Kits

Stocks of inventoried emergency medications may be kept in facilities.

(1) Emergency medication kits must be maintained in compliance with 22 TAC §291.20(b) (relating to Remote Pharmacy Services), with the exception of emergency medication kits in veterans homes, as defined by Natural Resources Code, §164.002. In veterans homes, a United States Department of Veterans Affairs pharmacy or another federally operated pharmacy may maintain emergency medication kits.

(2) Facilities must have contracts with the pharmacy that provides the emergency medication kit. The contract must outline the services to be provided by the pharmacy
and the responsibilities and accountabilities of each party in fulfilling the terms of the contract in compliance with federal and state laws and regulations.

Source Note: The provisions of this §19.1510 adopted to be effective May 1, 1995, 20 TexReg 2054; amended to be effective October 15, 1998, 23 TexReg 10496; amended to be effective May 1, 2002, 27 TexReg 1534; amended to be effective September 1, 2003, 28 TexReg 6939

UTAH

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(1) The facility must provide or obtain by contract routine and emergency drugs, biologicals, and pharmaceutical services to meet resident needs.

(2) The facility must employ or obtain the services of a licensed pharmacist who:

(a) provides consultation on all aspects of pharmacy services in the facility;

(b) establishes a system of records of receipt and disposition of all controlled substances which documents an accurate reconciliation; and

(c) determines that drug records are in order and that an account of all controlled substances is maintained and reconciled monthly.

(3) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

(a) The pharmacist must report any irregularities to the attending physician and the director of nursing or health services supervisor.

(b) The physician and the director of Nursing or health services supervisor must indicate acceptance or rejection of the report and document any action taken.

(4) Pharmacy personnel must ensure that labels on drugs and biologicals are in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date.

(5) The facility must store all drugs and biologicals in locked compartments under proper temperature controls according to R432-150-19 (6)(e), and permit only authorized personnel to have access to the keys.

(a) The facility must provide separately locked, permanently affixed compartments for storage of controlled substances listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit dose
package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

(b) Non-medication materials that are poisonous or caustic may not be stored with medications.

(c) Containers must be clearly labeled.

(d) Medication intended for internal use shall be stored separately from medication intended for external use.

(e) Medications stored at room temperature shall be maintained within 59 and 80 degrees F.

(f) Refrigerated medications shall be maintained within 36 and 46 degrees F.

(6) The facility must maintain an emergency drug supply.

(a) Emergency drug containers shall be sealed to prevent unauthorized use.

(b) Contents of the emergency drug supply must be listed on the outside of the container and the use of contents shall be documented by the nursing staff.

(c) The emergency drug supply shall be stored and located for access by the nursing staff.

(d) The pharmacist must inventory the emergency drug supply monthly.

(e) Used or outdated items shall be replaced within 72 hours by the pharmacist.

(7) The pharmacy must dispense and the facility must ensure that necessary drugs and biologicals are provided on a timely basis.

(8) The facility must limit the duration of a drug order in the absence of the prescriber’s specific instructions.

(9) Drug references must be available for all drugs used in the facility. References shall include generic and brand names, available strength and dosage forms, indications and side effects, and other pharmacological data.

(10) Drugs may be sent with the resident upon discharge if so ordered by the discharging physician provided that:

(a) such drugs are released in compliance R156-17a-619; and

(b) a record of the drugs sent with the resident is documented in the resident’s health record.

(11) Disposal of controlled substances must be in accordance with the Pharmacy Practice Act.

R432-200-18. Medication Administration. [small health facilities]

(1) Standing Orders.
Standing orders for medications, treatments, and laboratory procedures shall not be used. All orders shall be written for the individual resident.

(2) Administration of Medication and Treatments. Medication and treatment shall be administered as follows:

(a) No medication or treatment shall be administered except on the order of a person lawfully authorized to give such order.

(b) Medications and treatments shall be administered as prescribed and according to facility policy.

(c) All medications and treatments shall be administered by licensed medical or licensed nursing personnel. Student doctors and nurses may administer medication and treatment only in the course of study and when supervised by a licensed instructor or designated staff.

(d) Monitoring of vital signs and other observations done in conjunction with the administration of medication shall be carried out as ordered by the physician or practitioner and as indicated by accepted professional practice.

(e) Preparation of doses for more than one scheduled time of administration shall not be permitted.

(f) Medication shall be administered when ordered or as soon thereafter as possible but no more than two hours after the dose has been prepared.

(g) Medication shall be administered by the same person who prepared the dose for administration.

(h) Residents shall be identified prior to the administration of any drug or treatment.

(i) No medication shall be used for any resident other than the resident for whom it was prescribed.

(j) If the person who prescribed a medication does not limit the duration of the drug order or the number of doses, the facility’s automatic stop-order policy shall indicate how long a drug may be administered. The prescriber shall be notified before the medication is discontinued.

(k) All orders for treatment or therapy shall contain:

(i) the name of the treatment or therapy,

(ii) the frequency and time to be administered,

(iii) the length of time the treatment or therapy is to continue,

(iv) the name and professional title of the practitioner who gave the order,

(v) the date of order, and

(vi) signature of the person prescribing the treatment or therapy.

(l) All nursing personnel shall comply with the provisions for administration of medication according to standards and ethics of the profession.

(m) Injectable medications shall be administered only by authorized persons.
(i) If a physician certifies that a resident is capable of administering his own insulin or oral medications, the resident may self-inject the prescribed insulin or self-administer the prescribed medications.

(ii) The physician's order, authorizing the resident's self-administration of medications, shall be documented and available for Departmental review.

R432-200-21. Pharmacy Service. [small health facilities]

The facility shall make provision for pharmacy service.

(1) This service shall be under the direction of a qualified pharmacist currently licensed in the state of Utah.

(2) The pharmacist may be retained by contract.

(3) The pharmacist shall develop policies, direct, supervise and assume responsibility for any pharmacy services offered in the facility.

(4) Pharmacy services shall meet R432-150-19.

VERMONT

7.18 Pharmacy Services

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in subsection 11.2. All drugs must be administered in conformance with the requirements of 18 V.S.A. Chapter 84.

(a) Procedures. A facility must provide pharmaceutical services (including procedures that assure that accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

(b) Service consultation. The facility must employ or obtain the services of a licensed pharmacist who:

(1) provides consultation on all aspects of the provision of pharmacy services in the facility;

(2) establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and

(3) determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.
(c) Drug regimen review. The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

(d) The pharmacist must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon.

(e) Labeling of drugs and biologicals. Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, with the expiration date when applicable.

(f) Storage of drugs and biologicals.

(1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.

(2) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 42 U.S.C. §812, and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

(g) This section is not intended to prohibit residents from purchasing drugs or biologicals from outside sources.

Virginia

12 VAC 5-371-220. Nursing services.

B. All medications and treatments will be administered as prescribed in the resident’s medical plan of care.


A. Provision shall be made for the procurement, storage, dispensing, and accounting of drugs and other pharmacy products in compliance with 18 VAC 110-20. This may be by arrangement with an off-site pharmacy, but must include provisions for 24-hour emergency service.

B. Each nursing facility shall develop and implement policies and procedures for the handling of drugs and biologicals, including procurement, storage, administration, self-administration and disposal of drugs.
C. Each nursing facility shall have a written agreement with a qualified pharmacist to provide consultation on all aspects of the provision of pharmacy services in the facility.
D The consultant pharmacist shall make regularly scheduled visits, at least monthly, to the nursing facility for a sufficient number of hours to carry out the function of the agreement.

E. No drug or medication shall be administered to any resident without a valid verbal order or a written, dated and signed order from a physician, dentist or podiatrist, nurse practitioner or physician assistant, licensed in Virginia.

F. Verbal orders for drugs or medications shall only be given to a licensed nurse, pharmacist or physician.

G. Drugs and medications not limited as to time or number of doses when ordered shall be automatically stopped, according to the written policies of the nursing facility, and the attending physician shall be notified.

H. Each resident’s medication regimen shall be reviewed by a pharmacist licensed by the Virginia Board of Pharmacy. Any irregularities identified by the pharmacist shall be reported to the physician and the director of nursing, and their response documented.

I. Medication orders shall be reviewed at least every 60 days by the attending physician, nurse practitioner, or physician’s assistant.

J. Prescription and non-prescription drugs and medications may be brought into the facility by a resident’s family, friend or other person provided:

1. The individual delivering the drugs and medications assures timely delivery, in accordance with the nursing facility’s written policies, so that the resident’s prescribed treatment plan is not disrupted;

2. Each drug or medication is in an individual container; and

3. Delivery is not allowed directly to an individual resident.

In addition, prescription medications shall be obtained and labeled as required by law.

WASHINGTON

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388-97-1300 Pharmacy services.

(1) The nursing home must:

(a) Obtain routine and emergency drugs and biologicals for its residents under an agreement with a licensed pharmacy;

(b) Ensure that pharmaceutical services:
(i) Meet the needs of each resident;

(ii) Establish and monitor systems for the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals; and

(c) Employ or obtain the services of a licensed pharmacist who must:

(i) Provide consultation on all aspects of the provision of pharmacy services in the nursing home;

(ii) Determine that nursing home drug records are in order;

(iii) Perform regular reviews at least once each month of each resident’s drug therapy; and

(iv) Document and report drug irregularities to the attending physician and the director of nursing.

(2) Drugs and biologicals used in the nursing home must be labeled and stored in accordance with applicable state and federal laws.

(3) The nursing home must provide pharmaceutical services that:

(a) Meet recognized and accepted standards of pharmacy practice; and

(b) Comply with chapter 246-865 WAC, except nursing home staff administering drugs to residents may document administration at the time of pouring the drug or immediately after administration.

(4) The nursing home must ensure:

(a) Education and training for nursing home staff by the licensed pharmacist on drug-related subjects including, but not limited to:

(i) Recognized and accepted standards of pharmacy practice and applicable pharmacy laws and rules;

(ii) Appropriate monitoring of residents to determine desired effect and undesirable side effects of drug regimens; and

(iii) Use of psychotropic drugs.

(b) Reference materials regarding medication administration, adverse reactions, toxicology, and poison center information are readily available;

(c) Pharmacist monthly drug review reports are acted on in a timely and effective manner;

(d) Accurate detection, documentation, reporting and resolution of drug errors and adverse drug reactions; and
(e) Only individuals authorized by state law to do so will receive drug orders and administer drugs;

(5) The resident has the right to a choice of pharmacies when purchasing prescription and nonprescription drugs as long as the following conditions are met to ensure the resident is protected from medication errors:

(a) The medications are delivered in a unit of use compatible with the established system of the facility for dispensing drugs; and

(b) The medications are delivered in a timely manner to prevent interruption of dose schedule.

[Statutory Authority: Chapters 18.51 and 74.42 RCW and 42 C.F.R. 489.52. 08-20-062, § 388-97-1300, filed 9/24/08, effective 11/1/08.]

74.42.210 Pharmacist services.

The facility shall either employ a licensed pharmacist responsible for operating the facility's pharmacy or have a written agreement with a licensed pharmacist who will advise the facility on ordering, storage, administration, disposal, and recordkeeping of drugs and biologicals.

[1979 ex.s. c 211 § 21.]

Physician or authorized practitioner to prescribe medication.

(1) The resident's attending or staff physician or authorized practitioner approved by the attending physician shall order all medications for the resident. The order may be oral or written and shall be limited by time. An "authorized practitioner," as used in this section, is a registered nurse under chapter 18.79 RCW when authorized by the nursing care quality assurance commission, an osteopathic physician assistant under chapter 18.57A RCW when authorized by the committee of osteopathic examiners, or a physician assistant under chapter 18.71A RCW when authorized by the medical quality assurance commission.

(2) An oral order shall be given only to a licensed nurse, pharmacist, or another physician. The oral order shall be recorded and signed immediately by the person receiving the order. The attending physician shall sign the record of the oral order in a manner consistent with good medical practice.

[1994 sp.s. c 9 § 751; 1982 c 120 § 2; 1979 ex.s. c 211 § 23.]

74.42.240 Administering medication.
(1) No staff member may administer any medication to a resident unless the staff member is licensed to administer medication: PROVIDED, That nothing herein shall be construed as prohibiting graduate nurses or student nurses from administering medications when permitted to do so under chapter 18.79 RCW and rules adopted thereunder.

(2) The facility may only allow a resident to give himself or herself medication with the attending physician’s permission.

(3) Medication shall only be administered to or used by the resident for whom it is ordered.

[1994 sp.s. c 9 § 752; 1989 c 372 § 5; 1979 ex.s. c 211 § 24.]

74.42.250 Medication stop orders — Procedure for persons with developmental disabilities.

(1) When the physician’s order for medication does not include a specific time limit or a specific number of dosages, the facility shall notify the physician that the medication will be stopped at a date certain unless the medication is ordered continued by the physician. The facility shall so notify the physician every thirty days.

(2) A facility for the developmentally disabled shall have an automatic stop order on all drugs, unless such stoppage will place the patient in jeopardy.

[1979 ex.s. c 211 § 25.]

74.42.260 Drug storage, security, inventory.

(1) The facility shall store drugs under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security. Poisons, drugs used externally, and drugs taken internally shall be stored on separate shelves or in separate cabinets at all locations. When medication is stored in a refrigerator containing other items, the medication shall be kept in a separate compartment with proper security. All drugs shall be kept under lock and key unless an authorized individual is in attendance.

(2) The facility shall meet the drug security requirements of federal and state laws that apply to storerooms, pharmacies, and living units.

(3) If there is a drug storeroom separate from the pharmacy, the facility shall keep a perpetual inventory of receipts and issues of all drugs from that storeroom.

[1979 ex.s. c 211 § 26.]

74.42.270 Drug disposal.
Any drug that is discontinued or outdated and any container with a worn, illegible, or missing label shall be properly disposed.

74.42.280 Adverse drug reaction.

Medication errors and adverse drug reactions shall be recorded and reported immediately to the practitioner who ordered the drug. The facility shall report adverse drug reactions consistent with good medical practice.

[1979 ex. s. c 211 § 28.]


8.19.a. A nursing home shall provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in Subsection 11.4 of this rule.

8.19.b. All drugs shall be provided in conformance with the requirements of federal, state and local laws, regulations and rules.

8.19.c. Procedures. A nursing home shall provide pharmaceutical services, including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals, to meet the needs of each resident.

8.19.d. Service consultation. A nursing home shall employ or obtain the services of a licensed pharmacist who:

8.19.d.1. Provides consultation on all aspects of the provision of pharmacy services in the nursing home;

8.19.d.2. Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and

8.19.d.3. Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

8.19.e. Drug regimen review.

8.19.e.1. The drug regimen of each resident shall be reviewed, by a licensed pharmacist, at least every thirty-seven (37) days.
8.19.e.2. The drug regimen review shall include substances that are regarded as herbal products or dietary supplements.

8.19.f. The nursing home shall conduct a drug regimen review on the premises.

8.19.g. The pharmacist shall report any irregularities in the drug regimen review to the attending physician and the director of nursing, who shall act upon these reports.

8.19.h. Labeling of drugs and biologicals.

8.19.h.1. Drugs and biologicals used in the nursing home shall be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, with the expiration date when applicable.

8.19.i. Storage of drugs and biologicals.

8.19.i.1. In accordance with state and federal laws, the nursing home, shall store all drugs and biologicals in locked compartments under proper temperature controls and permit only authorized personnel to have access to the keys.

8.19.i.2. A nursing home shall provide separately locked, permanently affixed compartments for the storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 42 U.S.C.' 812, and other drugs subject to abuse, except when the nursing home uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

8.19.j. A nursing home shall establish policy to assure that residents’ requests for prescription medications from sources other than the contracted pharmacy be honored.
HFS 132.60 Resident care.

...(5) TREATMENT AND ORDERS. (a) Orders. 1. ‘Restriction.’

Medications, treatments and rehabilitative therapies shall be administered as ordered by an authorized prescriber subject to the resident’s right to refuse them. No medication, treatment or changes in medication or treatment may be administered to a resident without an authorized prescriber’s written order which shall be filed in the resident’s clinical record.

2. ‘Oral orders.’ Oral orders shall be immediately written, signed and dated by the nurse, pharmacist or therapist on the prescriber’s order sheet, and shall be countersigned by the prescriber and filed in the resident’s clinical record within 10 days of the order.

4. ‘Review of medications.’ Each resident’s medication shall be reviewed by a registered nurse at the time of the review of the plan of care.

(b) Stop orders. 1. ‘Compliance with stop order policies.’ Medications not specifically limited as to time or number of doses when ordered shall be automatically stopped in accordance with the stop order policy required by s. HFS 132.65.

2. ‘Notice to physicians or dentists.’ Each resident’s attending physician or dentist shall be notified of stop order policies and contacted promptly for renewal of orders which are subject to automatic termination.

(d) Administration of medications. 1. ‘Personnel who may administer medications.’ In a nursing home, medication may be administered only by a nurse, a practitioner, as defined in s. 450.01(17), Stats., or a person who has completed training in a drug administration course approved by the department.

2. ‘Responsibility for administration.’ Policies and procedures designed to provide safe and accurate acquisition, receipt, dispensing and administration of medications shall be developed by the facility and shall be followed by personnel assigned to prepare and administer medications and to record their administration.

The same person shall prepare, administer, and immediately record in the resident’s clinical record the administration of medications, except when a single unit dose package distribution system is used.

3. ‘Omitted doses in unit dose system.’ If, for any reason, a medication is not administered as ordered in a unit dose system, an “unadministered dose slip” with an explanation of the omission shall be placed in the resident’s medication container and a notation shall be made in the clinical record.

4. ‘Self-administration.’ Self-administration of medications by residents shall be permitted on order of the resident’s physician or dentist or in a predischarge program under the supervision of a registered nurse or designee.
5. ‘Errors and reactions.’ Medication errors and suspected or apparent drug reactions shall be reported to the nurse in charge or on call as soon as discovered and an entry made in the resident’s clinical record. The nurse shall take appropriate action.

6. ‘Day care.’ The handling and administration of medications for day care clients shall comply with the requirements of this subsection.

(e) Reference sources. Up-to-date medication reference texts and sources of information shall be available to the nurse in charge or on call.

Note: See s. HFS 132.65, pharmaceutical services, for additional requirements.

### HFS 132.65 Pharmaceutical services. (1) DEFINITIONS. As used in this section:

(a) “Medication” has the same meaning as the term “drug” defined in s. 450.06, Stats.

(b) “Prescription medication” has the same meaning as the term “prescription drug” defined in s. 450.07, Stats.

(c) “Schedule II drug” means any medication listed in s. 961.16, Stats.

(2) SERVICES. (a) Each facility shall provide for obtaining medications for the residents directly from licensed pharmacies.

(b) The facility shall establish, maintain, and implement such policies and procedures as are necessary to comply with this section and assure that resident needs are met.

(3) SUPERVISION. (a) SNF medication consultant. Each skilled nursing facility shall retain a registered pharmacist who shall visit the facility at least monthly to review the drug regimen of each resident and medication practices. The pharmacist shall submit a written report of findings at least quarterly to the facility’s quality assessment and assurance committee.

(b) ICF medication consultant. Each intermediate care facility shall retain a registered pharmacist who shall visit the facility at least monthly to review medication practices and the drug regimen of each resident and who shall notify the attending physician if changes are appropriate. The pharmacist shall submit a written report of findings at least quarterly to the facility’s quality assessment and assurance committee.

(4) EMERGENCY MEDICATION KIT. (a) A facility may have one or more emergency medication kits. All emergency medication kits shall be under the control of a pharmacist.

(b) The emergency kit shall be sealed and stored in a locked area.

(5) CONTINGENCY SUPPLY OF MEDICATIONS. (a) Maintenance. A facility may have a contingency supply of medications not to exceed 10 units of any medication. Any contingency supply of medications must be under the control of a pharmacist.
(b) Storage. Contingency drugs shall be stored at a nursing unit, except that those medications requiring refrigeration shall be stored in a refrigerator.

(c) Single units. Contingency medications shall be stored in single unit containers, a unit being a single capsule, tablet, ampule, tube, or suppository.

(d) Committee authorization. The quality assessment and assurance committee shall determine which medications and strengths of medications are to be stocked in the contingency storage unit and the procedures for use and re-stocking of the medications.

(e) Control. Unless controlled by a “proof-of-use” system, as provided by sub. (6) (e), a copy of the pharmacy communication order shall be placed in the contingency storage unit when any medication is removed.

(6) REQUIREMENTS FOR ALL MEDICATION SYSTEMS. (a) Obtaining new medications.

1. When medications are needed which are not stocked, a registered nurse or designee shall telephone an order to the pharmacist who shall fill the order and release the medication in return for a copy of the physician’s written order.

2. When new medications are needed which are stocked, a copy of the resident’s new medication order shall be sent to the pharmacist filling medication orders for the resident.

(b) Storing and labeling medications. Unless exempted under par. (f), all medications shall be handled in accordance with the following provisions:

1. 'Storage.' Medications shall be stored near nurse’s stations, in locked cabinets, closets or rooms, conveniently located, well lighted, and kept at a temperature of no more than 85º F. (29º C.).

2. 'Transfer between containers.' Medications shall be stored in their original containers, and not transferred between containers, except by a physician or pharmacist.

3. 'Controlled substances.' Separately locked and securely fastened boxes or drawers, or permanently affixed compartments, within the locked medication area shall be provided for storage of schedule II drugs, subject to 21 USC ch. 13, and Wisconsin’s uniform controlled substance act, ch. 961, Stats.

4. 'Separation of medications.' Medications packaged for individual residents shall be kept physically separated.

5. 'Refrigeration.' Medications requiring refrigeration shall be kept in a separate covered container and locked, unless the refrigeration is available in a locked drug room.

6. 'External use of medications.' Poisons and medications for external use only shall be kept in a locked cabinet and separate from other medications, except that time-released transdermal drug delivery systems, including nitroglycerin ointments, may be kept with internal medications.

7. 'Accessibility to drugs.' Medications shall be accessible only to the registered nurse or designee. In facilities where no registered nurse is required, the medications shall be
accessible only to the administrator or designee. The key shall be in the possession of the
person who is on duty and assigned to administer the medications.

8. ‘Labeling medications.’ Prescription medications shall be labeled with the expiration date
and as required by s. 450.11 (4), Stats. Non-prescription medications shall be labeled with
the name of the medication, directions for use, the expiration date and the name of the
resident taking the medication.

c) Destruction of medications.

1. ‘Time limit.’ Unless otherwise ordered by a physician, a resident’s medication not
returned to the pharmacy for credit shall be destroyed within 72 hours of a physician’s
order discontinuing its use, the resident’s discharge, the resident’s death or passage of its
expiration date. No resident’s medication may be held in the facility for more than 30 days
unless an order is written every 30 days to hold the medication.

2. ‘Procedure.’ Records shall be kept of all medication returned for credit. Any medication
not returned for credit shall be destroyed in the facility and a record of the destruction shall
be witnessed, signed and dated by 2 or more personnel licensed or registered in the health
field.

(d) Control of medications.

1. ‘Receipt of medications.’ The administrator or a physician, nurse, pharmacist, or the
designee of any of these may be an agent of the resident for the receipt of medications.

2. ‘Signatures.’ When the medication is received by the facility, the person completing the
control record shall sign the record indicating the amount received.

3. ‘Discontinuance of schedule II drugs.’ The use of schedule II drugs shall be discontinued
after 72 hours unless the original order specifies a greater period of time not to exceed 60
days.

(e) Proof-of-use record. 1. For schedule II drugs, a proof-of-use record shall be maintained
which lists, on separate proof-of-use sheets for each type and strength of schedule II drug,
the date and time administered, resident’s name, physician’s name, dose, signature of the
person administering dose, and balance.

2. Proof-of-use records shall be audited daily by the registered nurse or designee, except
that in facilities in which a registered nurse is not required, the administrator or designee
shall perform the audit of proof-of-use records daily.

(f) Resident control and use of medications. 1. Residents may have medications in their
possession or stored at their bedside on the order of a physician.

2. Medications which, if ingested or brought into contact with the nasal or eye mucosa,
would produce toxic or irritant effects shall be stored and used only in accordance with the
health, safety, and welfare of all residents.

Note: See s. HFS 132.60 (5) (d) 4. for permission for self-administration of medications.
(7) ADDITIONAL REQUIREMENTS FOR UNIT DOSE SYSTEMS. (a) Scope. When a unit dose drug delivery system is used, the requirements of this subsection shall apply in addition to those of sub. (6).

(b) General procedures.

1. The individual medication shall be labeled with the drug name, strength, expiration date, and lot or control number.

2. A resident’s medication tray or drawer shall be labeled with the resident’s name and room number.

3. Each medication shall be dispensed separately in single unit dose packaging exactly as ordered by the physician, and in a manner to ensure the stability of the medication.

4. An individual resident’s supply of drugs shall be placed in a separate, individually labeled container and transferred to the nursing station and placed in a locked cabinet or cart. This supply shall not exceed 4 days for any one resident.

5. If not delivered from the pharmacy to the facility by the pharmacist, the pharmacist’s agent shall transport unit dose drugs in locked containers.

6. The individual medication shall remain in the identifiable unit dose package until directly administered to the resident. Transferring between containers is prohibited.

7. Unit dose carts or cassettes shall be kept in a locked area when not in use.

History: Cr. Register, July, 1982, No. 319, eff. 8-1-82; r. and recr. (3) (b), am. (6) (a), (b) 6. and (c), Register, January, 1987, No. 373, eff. 2-1-87; am. (3) (b) 2., (6) (b) 8. and (c) 1. and 3., Register, February, 1989, No. 398, eff. 3-1-89; correction in (1) (c) made under s. 13.93 (2m) (b) 7., Stats., Register, August, 2000, No. 536; correction made to (6) (d) 1. under s. 13.93 (2m) (b) 7., Stats., Register December 2003 No. 576; CR 04-053: am. (2) and (5) (d), r. (3) (a), renum. and am. (3) (b) 1. and 2., r. (6) (c) 3. Register October 2004 No. 586, eff. 11-1-04.

WYOMING

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(f) Administration of Drugs. Drugs shall be administered in compliance with federal and state laws, and in accordance with accepted professional principles.
(i) Drugs shall be administered only by licensed nursing personnel in accordance with the Wyoming Nurse Practice Act.

(ii) Drugs prescribed for one (1) resident shall not be administered to any other resident.

(iii) Current information on the clinical use of drugs shall be readily available at the nurses’ station.

(iv) Drugs shall be released to residents upon discharge for temporary outside visits. A notation of such drugs taken with the resident shall be entered in the resident’s clinical record.

(g) Storage of Drugs and Biologicals. Drugs and biologicals shall be stored in locked rooms, cabinets, or carts. Procedures for storing and disposing of medications at the nurses’ station shall be established in consultation with the pharmacist.

(i) Drugs for external use and poisons shall be kept separate from other medications and under lock.

(ii) Antiseptics, disinfectants, and germicides shall be issued in containers that bear clear, legible, distinctive labels that identify the contents, strength and shall include instructions for use.

(iii) The refrigerator in which drugs and biologicals are stored shall not be accessible to residents, shall be used only for the storage of drugs and biologicals, and shall be in a locked refrigerator or a locked box in a refrigerator or in a protected area. The refrigerator shall be maintained at the proper temperature.

(iv) An emergency medical kit approved by the Pharmaceutical Committee shall be readily available.

Section 13. Pharmaceutical Services.

The Nursing Care Facility shall provide appropriate methods and procedures for the dispensing and administering of drugs and biologicals. Whether drugs and biologicals are obtained from community pharmacists or stocked by the facility, the facility shall be responsible for providing such drugs and biologicals for its residents and for ensuring that pharmaceutical services are provided in accordance with acceptable professional principles and appropriate federal, state and local laws.

(a) Supervision of Services. The pharmaceutical services shall be under the general supervision of a licensed pharmacist.

(i) The pharmacist, if not a full-time employee, shall devote a sufficient number of hours, based upon the needs of the facility, during regularly scheduled visits to carry out his/her responsibilities.
(b) Pharmaceutical Services Committee.

(i) Pharmaceutical Services committee or its equivalent shall be responsible for developing policies and procedures for safe and effective drug therapy, distribution, control and use.

(A) The committee shall be comprised of at least the pharmacist, the director of nursing service, the administrator and one (1) physician.

(B) The committee shall oversee the pharmaceutical service in the facility, make recommendations for improvement and monitor the service to ensure accuracy and adequacy.

(C) The committee shall meet at least quarterly and document its activities, findings and recommendations.

(ii) The pharmacist shall submit a written report at least quarterly to the pharmaceutical services committee on the status of the facility’s pharmaceutical services and staff performance.

FEDERAL REGULATIONS

§ 483.60 Pharmacy services.

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in §483.75(h) of this part. The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

(a) Procedures. A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

(b) Service consultation. The facility must employ or obtain the services of a licensed pharmacist who—

(1) Provides consultation on all aspects of the provision of pharmacy services in the facility;

(2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and

(3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.
(c) Drug regimen review.

(1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

(2) The pharmacist must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon.

(d) Labeling of drugs and biologicals. Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.

(e) Storage of drugs and biologicals.

(1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.

(2) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.