

CHAPTER 61-03-02
CONSULTING PHARMACIST REGULATIONS FOR LONG-TERM CARE FACILITIES
(SKILLED, INTERMEDIATE, AND BASIC CARE)

Section

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61-03-02-01. Definitions.

In this chapter, unless the context or subject matter otherwise requires:

1. "Consulting pharmacist" means a pharmacist in a long-term care facility, who:
 - a. Establishes the procedures and rules for distribution and storage of drugs;
 - b. Supervises the distribution and storage of drugs;
 - c. Visits the facility on a regularly scheduled basis;
 - d. Monitors the therapeutic response and utilization of all medications prescribed for the patients, utilizing as guidelines the indicators of the health care financing administration;
 - e. Provides regular pharmacy educational opportunities to the institution.
2. "Provider pharmacist" means a pharmacist who supplies medication to a patient in a long-term care facility and maintains separate pharmacy patient profiles from the facility.

History: Effective August 1, 1983.

General Authority: NDCC 28-32-02, 43-15-10(12), 43-15-10(14)

Law Implemented: NDCC 28-32-02, 43-15-10(12), 43-15-10(14)

61-03-02-02. Absence of provider or consulting pharmacist.

1. **General.** During such time at the long-term care facility that the pharmacist is not available, arrangements shall be made in advance by the consulting and provider pharmacist for provision of drugs to the staff of the institutional facility by use of an emergency medication kit located at the facility.
2. **Emergency medication kit.**
 - a. **Emergency medications defined.** Emergency medications are those medications which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients because of delay resulting from obtaining such medications from such other source.
 - b. **Supply pharmacist.** All emergency medications shall be provided by a provider pharmacist.
 - c. **Medications included.** The consulting pharmacist and the physicians representing the facility shall jointly determine and prepare a list of medications, by identity and quantity, to be included in such emergency supply. Such list of medications shall be reviewed quarterly by the pharmaceutical services committee. Only prepackaged drugs shall be available therein, in amounts sufficient for immediate therapeutic requirements.

- d. **Storage.** The emergency medication kit shall be stored in areas suitable to prevent unauthorized access and to ensure a proper environment for preservation of the medications within them, as required in official compendia.
- e. **Labeling - Exterior.** The exterior of an emergency kit shall be labeled to clearly and unmistakably indicate that it is an emergency drug kit and it is for use in emergencies only; such label shall also contain a listing of the name, strength, and quantity of the drugs contained therein and an expiration date.
- f. **Labeling - Interior.** All drugs contained in the emergency medication kit shall be labeled in accordance with subsection 7 of North Dakota Century Code section 43-15-01.
- g. **Removal of medication.** Medications shall be removed from the emergency medication kit only pursuant to a valid prescriber order and by authorized personnel, or by the provider pharmacist.
- h. **Notifications.** Whenever an emergency medication kit is opened or has expired, the provider pharmacist shall be notified and the pharmacist shall replace the medication within a reasonable time so as to prevent risk of harm to the patients.
- i. **Expiration date.** The expiration date of an emergency kit shall be the earliest expiration date on any drug supplied in the kit. Upon the occurrence of the expiration date, the provider pharmacist shall open the kit and replace expired drugs.
- j. **Procedures.** The consulting pharmacist shall, in communication with the appropriate committee, develop and implement written policies and procedures to ensure compliance.

History: Effective August 1, 1983.

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61-03-02-03. Physical requirements of provider pharmacy licensed on premises or other pharmacy.

- 1. **Area.** The pharmacy serving a long-term care facility as an institutional drug outlet shall have floor space allocated to it to ensure that drugs are prepared in sanitary, well-lighted and enclosed places, and meet the other requirements of this section. Floor space shall be allotted to conduct the activities involved with the scope of pharmaceutical services provided.
- 2. **Equipment and materials.** The pharmacy serving a long-term care facility as an institutional drug outlet shall have equipment and physical facilities for proper compounding, dispensing, and storage for drugs, including parenteral preparations. As a minimum, the pharmacy shall have the following:
 - a. Minimum equipment listed in section 61-02-01-03.
 - b. Drugs to meet the needs of the patients of the long-term care facility.
 - c. A pharmacy policy and procedures manual in compliance with section 61-02-01-18.
 - d. Pharmaceutical reference books, which shall include one recent edition (not over five years from publication date) from at least two of the following categories, one of which must include dispensing information:
 - (1) Drug dispensing information from one of the following:
 - (a) United States pharmacopoeia dispensing information.

(b) Facts and comparisons.

(c) Hospital formulary.

(2) Categories to choose from:

Drug interactions - poison and antidote information - chemistry toxicology - pharmacology - bacteriology - sterilization and disinfection - patient counseling - rational therapy - parenteral admixtures.

3. **Drug room.** The drug room of a long-term care facility may utilize the technical equipment and other requirements of a licensed pharmacy for compliance.

4. **Storage.**

a. All drugs shall be stored in designated areas within the pharmacy to ensure proper sanitation, temperature, light, ventilation, moisture control, and security.

Unattended areas: In the absence of a pharmacist, and whenever any area of a pharmacy serving a long-term facility as an institutional drug outlet is not under the personal and direct supervision of a pharmacist, such areas shall be locked. All areas occupied by a pharmacy serving a long-term care facility as an institutional drug outlet shall be capable of being locked by key or combination, so as to prevent access by unauthorized personnel.

b. When drugs to be dispensed are stored in a long-term facility drug room, the consulting pharmacist shall verify that space will be available at each unit for storage, safeguarding, and preparation of medication doses for administration and shall include provision of at least the following:

(1) A locked drug cabinet or room shall be equipped to ensure physical separation of individual patient prescribed medications. Medications may be stored in these secured individual patient storage areas, or secured portable storage carts providing separate compartments for individual patients may be used.

(2) A container or compartment which is capable of securing controlled substances with a lock or other safeguard system shall be permanently attached to storage carts or medication rooms.

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61-03-02-04. Distribution and control.

1. General. The consulting pharmacist shall establish written procedures for the safe and efficient distribution of pharmaceutical products; which shall be on hand for inspections.

2. Responsibility of consulting pharmacist. The consulting pharmacist shall be responsible for the safe and efficient distribution of, control of, and accountability of medications by developing procedures subject to the approval of the pharmaceutical services committee of the long-term care facility, to include:

a. Establishment of specifications for the storage, distribution, and procurement of medications and biologicals.

b. Participation in those aspects of the long-term care patient evaluation program which relate to drug utilization and effectiveness.

- c. Providing information on a twenty-four-hour basis for assistance in emergency situations.
 - d. Assuring all medication shall be stored in a locked area or locked cart.
 - e. Review, evaluate, and make recommendations monthly regarding drug utilization to the pharmaceutical services committee.
 - f. Minimum standards that all provider pharmacists must meet to include the following:
 - (1) Expected delivery times for new orders and reorders.
 - (2) Procedures to ensure accountability during delivery.
 - (3) Methods to document receipt of medications by the facility.
 - (4) Procedure to obtain emergency medications and for the provider pharmacist to receive orders.
 - (5) Procedures used by the facility to reorder medications and for the provider pharmacist to receive reorders.
 - (6) Expected scope of services and medications to be provided by the provider pharmacist. If the provider pharmacist cannot provide the complete scope of services and medications, the provider pharmacist shall designate alternative sources.
 - g. Procedures that allow for use of or repackaging of medications received which are not in the packaging system used by the facility.
 - h. Policy that is included as a part of the patient admissions packet that describes the responsibility of the patient or provider pharmacist to compensate a secondary pharmacist for medications or packaging services that the provider pharmacist chosen by the patient is either unwilling or unable to provide.
3. Responsibility of provider pharmacist. All provider pharmacists shall meet the minimum standards established by the consulting pharmacist.
4. Discontinued drugs.
- a. The consulting pharmacist shall develop and implement policies and procedures to ensure that all discontinued or outdated drugs or containers with worn, illegible or missing labels are destroyed or disposed of so as to render them unusable.
 - b. Controlled drugs shall be destroyed at the nursing facility according to policies and procedures set by the consultant pharmacist. Destruction must render the medication nonretrievable. Destruction must be witnessed and documented on a log by a combination of at least two licensed staff members or pharmacists.
 - c. Noncontrolled drugs may be destroyed at the institution according to policies and procedures set by the consultant pharmacist or returned to the provider pharmacy, for possible credit or destruction.
5. Practitioner's orders. A pharmacist shall review the medication order, or a copy thereof.
- a. Authorization. Any licensed practitioner authorized by law to prescribe drugs within the scope of the practitioner's license may prescribe for the practitioner's patient in a long-term facility.

- b. Abbreviations. Orders employing abbreviations or chemical symbols will be only those which are customarily used in the practice of medicine and pharmacy or those on a list of approved abbreviations developed by the pharmaceutical services committee of the facility.
 - c. Requirements. Orders for drugs for use by patients of the facility shall, at a minimum, contain patient name, drug name and strength, directions for use, date of order, and name of prescriber. On the facility reorder form, include all of the above except for directions.
 - d. Emergency medication order. In cases where an emergency medication order is written when pharmacy services are unavailable, the medication order shall be reviewed by the pharmacist as soon as reasonably possible.
 - e. Verification. Verification of the accuracy of any medication dispensed and of any transcriptions made of that order shall be done by handwritten initials of the pharmacist so certifying.
 - f. Duration. The prescribed medications should be for a specific time.
6. An automated dispensing system is authorized for use in long-term care facilities to store controlled bulk drugs.
- a. Drugs in the automated dispensing system are not considered dispensed until taken out by authorized personnel at the long-term care facility, once released by the pharmacy pursuant to a prescription.
 - b. Only single doses may be removed from the automated dispensing system at one time.
 - c. The pharmacy must have a separate drug enforcement administration number for the automated dispensing system at each location.
 - d. All records of dispensing must be kept at the central pharmacy.
 - e. The automated dispensing system shall permit access to only one controlled substance at each authorized entry.
 - f. Only retail pharmacies are authorized to use an automated dispensing system.
 - g. Pharmacies cannot share an automated dispensing system at a long-term care facility.
 - h. North Dakota controlled substance registration is required.
7. Controlled drug accountability. The consulting pharmacist shall establish and implement effective procedures and assure that adequate records be maintained regarding use and accountability of controlled substances which meet federal and state laws and regulations, and which shall at least specify the following:
- a. Name of drug.
 - b. Dose.
 - c. Prescriber.
 - d. Patient.
 - e. Date and time of administration.
 - f. Person administering the drug.

8. Recall. The consulting pharmacist shall develop and implement a recall procedure that can readily be activated to assure the medical staff of the facility, the provider pharmacy, and the consulting pharmacist that all drugs included in the recall, located within the facility, are returned to the provider pharmacy for proper disposition.
9. Records and reports. The consulting pharmacist shall supervise the maintenance of such records and reports as are required to ensure patient health, safety, and welfare and, at a minimum, the following:
 - a. Pharmacy patient profiles and medication administration records.
 - b. Reports of suspected adverse drug reactions.
 - c. Inspections of drug storage areas.
 - d. Controlled drug and accountability reports, including board of pharmacy destroyed medication forms for controlled and noncontrolled medications.
 - e. Such other and further records and reports as may be required by law and this chapter.
10. Labeling.
 - a. All stock drugs intended for use within the facility shall be in appropriate containers and adequately labeled as to identify at a minimum: brand name or generic name and manufacturer, and strength. An internal code which centrally references manufacturer and lot number can be utilized.
 - b. Whenever any drugs are added to parenteral solutions, whether within or outside the direct and personal supervision of a pharmacist, such admixtures shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, date and time of addition, expiration date, administration time and infusion rate when applicable, and name or initials of person so adding. This excludes any single dose medication prepared and totally administered immediately.

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