

Joint Committee on Administrative Rules

ADMINISTRATIVE CODE

**TITLE 77: PUBLIC HEALTH
CHAPTER I: DEPARTMENT OF PUBLIC HEALTH
SUBCHAPTER c: LONG-TERM CARE FACILITIES
PART 300 SKILLED NURSING AND INTERMEDIATE CARE FACILITIES CODE
SECTION 300.1610 MEDICATION POLICIES AND PROCEDURES**

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.
- l) 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)