

Effective Date: 12/27/2006

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 in 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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