



Guardian Consulting Services, Inc.

Consultant Pharmacists for Healthcare Organizations, Industry, and the Community.

§483.45 Pharmacy Services (formerly §483.60)

(Effective November 28, 2016, except (c)(2) and (e), effective November 28, 2017)

Legend: Regular Font Text = Existing regulations; *Italics* = Existing regulations relocated to this section; **Bold Text** = New regulations

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in § 483.70(g) 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) This review must include a review of the resident's medical chart.

(3) A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories:

(i) Anti-psychotic;

(ii) Anti-depressant;

(iii) Anti-anxiety; and

(iv) Hypnotic.

(4) The pharmacist must report any irregularities to the attending physician and the facility's medical director and director of nursing, and these reports must be acted upon.

(i) Irregularities include, but are not limited to, any drug that meets the criteria set forth in paragraph (d) of this section for an unnecessary drug.

(ii) Any irregularities noted by the pharmacist during this review must be documented on a separate, written report that is sent to the attending physician and the facility's medical director and director of nursing and lists, at a minimum, the resident's name, the relevant drug, and the irregularity the pharmacist identified.

(iii) The attending physician must document in the resident's medical record that the identified irregularity has been reviewed and what, if any, action has been taken to address it. If there is to be no change in the medication, the attending physician should document his or her rationale in the resident's medical record.

(5) The facility must develop and maintain policies and procedures for the monthly drug regimen review that include, but are not limited to, time frames for the different steps in the process and steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident.

(d) Unnecessary drugs—General. Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used—

(1) In excessive dose (including duplicate drug therapy); or

(2) For excessive duration; or

(3) Without adequate monitoring; or

(4) Without adequate indications for its use; or

(5) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or

(6) Any combinations of the reasons stated in paragraphs (d)(1) through (5) of this section.

(e) Psychotropic drugs. Based on a comprehensive assessment of a resident, the facility must ensure that—

(1) Residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record;

(2) Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs;

(3) Residents do not receive psychotropic drugs pursuant to a PRN order unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record; and

(4) PRN orders for psychotropic drugs are limited to 14 days. Except as provided in § 483.45(e)(5), if the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, he or she should document their rationale in the resident's medical record and indicate the duration for the PRN order.

(5) PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication.

(f) Medication errors. The facility must ensure that its—

(1) Medication error rates are not 5 percent or greater; and

(2) Residents are free of any significant medication errors.

(g) 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.

(h) 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.