

COMPOUNDING REGULATIONS FINALIZED

The Pennsylvania State Board of Pharmacy's Compounding Regulations were published as final in *The Pennsylvania Bulletin* on June 22, 2019. The new regulations are provided here.

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 27. STATE BOARD OF PHARMACY

GENERAL PROVISIONS

§ 27.1. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

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Drug order—

(i) An oral or written order issued by a medical practitioner which is either written on or entered by computer into the medical record of a patient in an institution for the dispensing of a drug or device for administration to the patient.

(ii) The term does not include an order for a drug for a patient in an institution which the patient will self-administer which will be considered a prescription.

FDA—The United States Food and Drug Administration, a division of the United States Department of Health and Human Services.

FDLE—Federal Drug Law Examination.

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Satellite pharmacy—

(i) A pharmacy in an institution which provides specialized services for the patients of the institution and which is dependent upon the centrally located pharmacy for administrative control, staffing and drug procurement.

(ii) The term does not include a pharmacy serving the public on the premises of an institution nor does it include a pharmacy located off premises from the centrally located pharmacy of the institution regardless of whether the pharmacy is owned by the same person or entity which owns the institution.

USP—The United States Pharmacopeia—A compendium of drug information published by the United States Pharmacopeial Convention.

STANDARDS

§ 27.12. Practice of pharmacy and delegation of duties.

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(d) *Pharmacy technicians.*

(1) A pharmacy technician may work only under the direct, immediate, personal supervision of a pharmacist in accordance with subsection (b)(2).

(2) The following are examples of the types of activities which a pharmacy technician may perform:

* * * * *

(vi) Enter prescription, drug order or patient information in a patient profile.

(vii) Assist the pharmacist in the compounding of drug products, as permitted by the written protocol created and maintained in accordance with paragraph (4).

(3) A pharmacy technician may not:

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COMPOUNDING

§ 27.601. Compounding of preparations.

The compounding of sterile and nonsterile preparations shall be done in accordance with section 503a of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 353a), Federal regulations promulgated thereunder, and the current version of the USP chapters governing compounding.

§ 27.602. Compounding prohibited.

Pharmacists may not compound any of the following:

(1) Drugs that have been identified by the FDA as withdrawn or removed from the market because the drugs were found to be unsafe or ineffective as set forth in 21 CFR 216.24 (relating to drug products withdrawn or removed from the market for reasons of safety or effectiveness) unless the drug is being used as part of a clinical trial and is approved by an institution's institutional review board.

(2) Drugs that are essentially copies of a commercially available drug product, except as provided in section 503a(b)(1)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 353a(b)(1)(D)).

(3) Drugs that have been identified by the FDA in the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. §§ 301—399h) or the *Code of Federal Regulations* as products which may not be compounded.

§ 27.603. Pharmacist responsibilities.

(a) As in the dispensing of all prescription drugs, the pharmacist has the responsibility for all of the following:

(1) Inspection and approval or rejection of all components, bulk drug substances (that is, active pharmaceutical ingredients), drug product containers, closures, in-process materials and labeling.

(2) Preparation and review of all compounding records to assure that errors have not occurred in the compounding process.

(3) Proper maintenance, cleanliness and use of all facilities and equipment used in compounding practice.

(b) If errors have occurred, the pharmacist is responsible for conducting a full investigation, and creating and maintaining a record of the investigation which must include conclusions and corrective action.

§ 27.604. Drug compounding controls.

Accountability for quality control is the responsibility of the compounding pharmacist.

§ 27.605. Label information required.

The label affixed to or on the dispensing container of a compounded drug product dispensed by a pharmacy pursuant to a prescription or drug order must bear the information as required in § 27.18(d) (relating to standards of practice) and any

additional information required by USP provisions pertaining to label information requirements.

§ 27.606. Compounding records.

Compounding records required by this chapter shall be retained as the original records and shall be readily available at the pharmacy for inspection and photocopying by agents of the Board or other authorized authorities for at least 2 years following the date of the record. Prescriptions for all products compounded at the pharmacy shall be maintained on file at the pharmacy as required under § 27.18(b) (relating to standards of practice).

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