

**CHAPTER 561. PHARMACEUTICAL SERVICES****GENERAL PROVISIONS**

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**Authority**

The provisions of this Chapter 561 issued under Chapter 8 of the Health Care Facilities Act (35 P. S. §§ 448.801a—448.820), specifically sections 448.801a and 448.803; and section 2102(a) and (g) of The Administrative Code of 1929 (71 P. S. § 532(a) and (g)), unless otherwise noted.

**Source**

The provisions of this Chapter 561 adopted January 23, 1987, effective March 25, 1987, 17 Pa.B. 376, unless otherwise noted.

**GENERAL PROVISIONS****§ 561.1. Drugs and biologicals.**

The ASF shall provide drugs and biologicals in a safe and effective manner to meet the needs of the patients and to adequately support the organization's clinical capabilities commensurate with their license classification, in accordance with accepted ethical and professional practice and applicable State and Federal law, including the Pharmacy Act (63 P. S. §§ 390.1—390.13), 49 Pa. Code Chapter 27 (relating to State Board of Pharmacy), The Controlled Substance, Drug, Device

and Cosmetic Act (35 P. S. §§ 780-101—780-144) and Chapter 25 (relating to controlled substances, drugs, devices and cosmetics).

**Source**

The provisions of this § 561.1 amended October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial page (256575).

**§ 561.2. Pharmaceutical service.**

(a) Pharmaceutical services shall be supervised by a physician or dentist who is qualified to assume professional, organization and administrative responsibility for the quality of services rendered. Practitioners may dispense drugs only to the patients who are in their care.

(b) A pharmacy owned and operated by the ASF shall be supervised by a licensed pharmacist.

(c) Contracted pharmaceutical services shall be provided in accordance with the same ethical and professional practices and legal requirements that would be required if these services are provided directly by the organization.

**Source**

The provisions of this § 561.2 amended October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial page (256576).

**PHARMACEUTICAL FACILITIES**

**§ 561.11. Principle.**

The ASF shall provide equipment and supplies for the pharmaceutical service to implement its professional and administrative functions and to ensure patient safety through the proper storage and dispensing of drugs. Facilities shall be provided for the storage, safeguarding, preparation and dispensing of drugs.

**§ 561.12. Supplies.**

The pharmacist or practitioner in charge of the pharmaceutical service shall maintain a supply of drugs and devices adequate to meet the needs of the patients. Pharmacy supplies shall conform to 49 Pa. Code § 27.14 (relating to supplies).

**§ 561.13. Storage.**

The area in the ASF where drugs are stored shall be periodically checked by the responsible pharmacist or practitioner and proper logs maintained.

**Source**

The provisions of this § 561.13 amended October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial page (256576).

**§ 561.14. Space.**

There shall be adequate space provided for pharmaceutical operations, and the storage of drugs at a satisfactory location provided with proper lighting. Ventilation and temperature controls shall be in accordance with 49 Pa. Code §§ 27.15 and 27.16 (relating to sanitary standards; and construction requirements).

**§ 561.15. Locked storage.**

Special locked storage space shall be provided to meet requirements for storage of controlled substances, alcohol and other prescribed drugs as set forth in Chapter 25 (relating to controlled substances, drugs, devices and cosmetics) and 49 Pa. Code §§ 27.16(b)(4) and 27.17 (relating to construction requirements; and security for Schedule II controlled substances).

**POLICIES AND PROCEDURES****§ 561.21. Principle.**

The scope of the pharmaceutical service shall be consistent with the medication needs of the patients and congruent with the license classification of the ASF. The pharmaceutical policies shall include a program for the control and accountability of drug products throughout the ASF. If drugs are used for an experimental purpose, the use thereof shall be approved by an Institutional Review Board (IRB) or an IRB shall waive review and proper consent for use shall be obtained.

**Source**

The provisions of this § 561.21 amended October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial page (256577).

**§ 561.22. Records.**

(a) Drug transactions of the pharmaceutical service shall be recorded, and those records shall be correlated with other ASF records. Records and security shall be maintained to assure the control and safe dispensing of drugs and compliance with Federal and Commonwealth statutes.

(b) Drugs ordered and administered to patients shall be documented in the medical record of the patient.

(c) Oral orders for drugs for immediate administration shall be followed by a written order, signed by the prescribing practitioner, prior to the discharge of the patient.

(d) Adverse drug reactions and drug sensitivities shall be recorded in the patient's medical record and copies maintained for review by the quality assurance committee.

**§ 561.23. Use of controlled substances and other drugs.**

There shall be policies and procedures developed and approved by the medical staff which establish controls governing the use of controlled substances and other drugs, including sedatives, anticoagulants, antibiotics, oxytoxics and corticosteroids. Policies shall be established regarding written orders for appropriate dosage of all drugs.

**Source**

The provisions of this § 561.23 amended October 22, 1999, effective November 22, 1999, 29 Pa.B. 5583. Immediately preceding text appears at serial page (256577).

**§ 561.24. Emergency pharmaceutical services.**

Provision shall be made for emergency pharmaceutical services. Emergency drugs shall be kept readily available and under the control of either the pharmacist or the practitioner in charge of pharmaceutical services.

**§ 561.25. Distressed drugs, devices and cosmetics.**

Drugs, devices and cosmetics which are outdated, visibly deteriorated, unlabeled or inadequately labeled, recalled, discontinued or obsolete shall be identified by the licensed pharmacist or responsible practitioner and shall be disposed of in compliance with applicable Commonwealth and Federal regulations.

**§ 561.26. Mishandling of drugs.**

If there is reason to suspect mishandling of scheduled or controlled drugs, the person in charge of the ASF shall contact the Bureau of Drug Control of the Office of Attorney General or State or local police.

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