

CHAPTER 113. PHARMACY SERVICES

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Cross References

This chapter cited in 28 Pa. Code § 101.31 (relating to hospital requirements).

Subchapter A. GENERAL PROVISIONS

GENERAL

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Cross References

This chapter cited in 55 Pa. Code § 6100.2 (relating to applicability).

GENERAL**§ 113.1. Principle.**

The hospital shall provide for pharmaceutical services which are administered in accordance with accepted ethical and professional practices.

§ 113.2. Organization and staffing.

The pharmaceutical service shall be directed by a licensed pharmacist. When there is a pharmacy, it shall be staffed by a sufficient number of competent personnel, in keeping with the size and scope of services of the hospital.

§ 113.3. Pharmacist.

(a) When there is a pharmacy, it shall be directed by a licensed pharmacist. If a hospital does not have a pharmacy or full-time staff pharmacist, a consulting or part-time pharmacist shall have responsibility for control and dispensing of drugs and shall have responsibility for the pharmaceutical functions of nursing stations.

(b) The pharmacist shall be trained in the specialized functions of hospital pharmacy.

(c) The pharmacist shall be responsible to the chief executive officer or his designee for developing, supervising, and coordinating all the activities of the pharmacy.

(d) In the absence of a pharmacist, the dispensing of drugs shall be limited to emergencies and shall be performed only under the direct supervision of a practitioner licensed under State law to prescribe and dispense drugs.

Authority

The provisions of this § 113.3 issued under 67 Pa.C.S. §§ 6101—6104; and Reorganization Plan No. 2 of 1973 (71 P.S. § 755-2).

Source

The provisions of this § 113.3 amended September 19, 1980, effective September 20, 1980, 10 Pa.B. 3761. Immediately preceding text appears at serial page (37825).

§ 113.4. Staff.

The pharmacist shall be assisted by an adequate number of additional pharmacists and such other personnel as the activities of the pharmacy may require to ensure adequate pharmaceutical services.

§ 113.5. Pharmacy and therapeutics committee.

(a) A pharmacy and therapeutics committee or its equivalent, to include physicians, nurses, and pharmacists, shall be established.

(b) The committee shall meet at least quarterly, record its proceedings and report to the medical staff. It shall assist in the formulation of broad professional

policies regarding the evaluation, appraisal, selection, procurement, storage, distribution, use and safety procedures, and all other matters relating to drugs in the hospital. This should include some mechanism to review and evaluate adverse drug reactions and make appropriate recommendations if necessary. The committee shall:

- (1) serve as an advisory group to the hospital medical staff and the pharmacist on matters pertaining to the choice of drugs;
- (2) develop and review periodically a formulary or drug list for use in the hospital;
- (3) recommend standards regarding the use and control of investigational drugs and concerning research in the use of recognized drugs;
- (4) evaluate clinical data concerning new drugs or preparations requested for use in the hospital;
- (5) make recommendations concerning drugs to be stocked on the nursing unit floors and by other services;
- (6) establish procedures which will prevent unnecessary duplication in stocking drugs and drugs in combination having identical amounts of the same therapeutic ingredients;
- (7) make recommendations concerning drugs for which automatic stop drug orders are necessary; and
- (8) make recommendations regarding proper procedures and policies on the administration of drugs.

Authority

The provisions of this § 113.5 issued under 67 Pa.C.S. §§ 6101—6104; and Reorganization Plan No. 2 of 1973 (71 P. S. § 755-2).

Source

The provisions of this § 113.5 amended September 19, 1980, effective September 20, 1980, 10 Pa.B. 3761. Immediately preceding text appears at serial page (37825).

Cross References

This section cited in 28 Pa. Code § 107.26 (relating to additional committees).

PHARMACY FACILITIES

§ 113.11. Principle.

When there is a pharmacy, the hospital shall provide equipment and supplies for the pharmaceutical service to carry out 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.

§ 113.12. Supplies.

The pharmacy shall maintain a supply of drugs and devices adequate to meet the needs of the patients and the medical staff. Pharmacy supplies shall conform to the provisions of 49 Pa. Code § 27.14 (relating to supplies).

§ 113.13. Cabinets.

Any area in the hospital where drugs are stored shall be periodically checked by the pharmacist as specified by the pharmacy and therapeutic committee. All floor stocks shall be controlled by the pharmacist.

Authority

The provisions of this § 113.13 issued under section 2102(g) of The Administrative Code of 1929 (71 P. S. § 532(g)); and section 803 of the Health Care Facilities Act (35 P. S. § 448.803).

Source

The provisions of this § 113.13 amended through December 3, 1982, effective December 4, 1982, 12 Pa.B. 4129. Immediately preceding text appears at serial page (52791).

§ 113.14. Space.

There shall be adequate space provided for all pharmacy 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—27.16 (relating to sanitary standards and construction requirements).

§ 113.15. Locked storage.

Special locked storage space shall be provided to meet the 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(4) and 27.17 (relating to construction requirements and security for Schedule II controlled substances).

POLICIES AND PROCEDURES**§ 113.21. Principle.**

The scope of the pharmaceutical service shall be consistent with the medication needs of the patients. Hospital pharmaceutical policies shall include a program for the control and accountability of drug products throughout the hospital.

§ 113.22. [Reserved].**Source**

The provisions of this § 113.22 reserved September 19, 1980, effective September 20, 1980, 10 Pa.B. 3761. Immediately preceding text appears at serial pages (37827) to (37828).

§ 113.23. Records.

(a) All drug transactions of the pharmacy shall be recorded, and those records shall be correlated with other hospital records. Such special records as are required by the provisions of Chapter 25 (relating to controlled substances, drugs, devices and cosmetics) shall also be kept.

(b) The pharmacy shall establish and maintain a system of records and book-keeping in accordance with the policies of the hospital in order to maintain adequate control over the requisitioning and dispensing of all drugs and pharmaceutical supplies and over patient billing for all drugs and pharmaceutical supplies.

(c) Records for drugs dispensed from the pharmacy shall be maintained in the pharmacy, and records of drugs administered to patients shall be maintained in the medical record of the patient.

(d) Oral orders for drugs for immediate administration shall be subject to the medical staff policies on oral orders, set forth in § 107.62 (relating to oral orders).

(e) Copies of records of all adverse drug reactions and drug sensitivities shall be maintained in accordance with the provisions of § 109.65 (relating to recording of drugs administered). Copies of records of all adverse drug reactions and drug sensitivities shall be maintained in the pharmacy for two years.

Authority

The provisions of this § 113.23 issued under 67 Pa.C.S. §§ 6101—6104; and Reorganization Plan No. 2 of 1973 (71 P. S. § 755-2).

Source

The provisions of this § 113.23 amended September 19, 1980, effective September 20, 1980, 10 Pa.B. 3761. Immediately preceding text appears at serial page (37828).

Cross References

This section cited in 28 Pa. Code § 109.65 (relating to recording of drugs administered).

§ 113.24. Medications dispensed.

(a) The hospital shall dispense only drugs which are listed in one or more of the references listed in subsection (b) or as provided in subsection (c). Any drug unfavorably evaluated in any of these references shall be used only in accordance with standards established by the hospital's pharmacy and therapeutics committee.

(b) References containing lists of drugs which may be dispensed by hospitals shall be as follows:

- (1) *United States Pharmacopoeia.*
- (2) *National Drug Formulary.*
- (3) *AMA Drug Evaluation.*
- (4) *Accepted Dental Remedies.*

(5) *Pennsylvania Generic Drug Formulary.*

(6) *The Physician's Desk Reference.*

(c) Any drug approved for use as an experimental drug or otherwise by the Food and Drug Administration but not listed in subsection (b) may be used in accordance with standards established by the hospital's pharmacy and therapeutics committee, or its equivalent, and approved by the Food and Drug Administration.

§ 113.25. Drug distribution systems.

(a) The pharmacy and therapeutics committee or its equivalent shall develop written policies and procedures pertaining to the intra-hospital drug distribution system. In developing such policies, the committee shall utilize, as necessary, representatives of other disciplines within the hospital.

(b) The label of each patient's individual medication container shall bear all information required by section 8 of the Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. § 780.108), 49 Pa. Code § 27.18(d) (relating to standards of practice) and § 25.18 (relating to packaging and labeling).

(c) The pharmacist, with the advice and guidance of the pharmacy and therapeutics committee, or its equivalent, shall be responsible for specifications as to quality, quantity, and source of supplies of all drugs.

(d) There shall be a formulary or list of drugs accepted for use in the hospital which shall be developed and amended at regular intervals by the pharmacist and the appropriate committee. Drugs included in the Pennsylvania Generic Drug Formulary shall be considered for inclusion in the hospital's formulary.

§ 113.26. Administration of drugs.

(a) The pharmacy and therapeutics committee, or its equivalent, in cooperation with representatives of such other disciplines as necessary, shall develop written policies and procedures governing the safe administration of drugs. Such policies and procedures shall be approved by the governing body or its designee.

(b) The policies and procedures developed in accordance with subsection (a) shall establish controls governing the administration of dangerous drugs, as provided in this section.

(1) Dangerous drugs shall include controlled substances, sedatives, anticoagulants, antibiotics, oxytoxics, and corticosteroids.

(2) Policies shall be established regarding appropriate dosage and duration of order of dangerous drugs.

(3) Automatic stop procedures shall be established for dangerous drugs not specifically prescribed as to time or number of doses. The execution of automatic stop drug orders is subject to § 107.65 (relating to automatic stop drug orders).

Cross References

This section cited in 28 Pa. Code § 107.65 (relating to automatic stop drug orders).

§ 113.27. Emergency pharmaceutical services.

Provision shall be made for emergency pharmaceutical services. A secure emergency medication kit, stocked and approved by the pharmacist, shall be kept readily available and under the control of either the pharmacy, a practitioner licensed by law to prescribe or dispense drugs, or, during emergency periods, a staff member designated by the chief executive officer, or his designee.

Cross References

This section cited in 28 Pa. Code § 109.68 (relating to emergency drug cart or kit).

§ 113.28. Distressed drugs, devices and cosmetics.

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

§ 113.29. Commercial pharmaceutical service.

A hospital using an outside pharmacist or pharmaceutical service must have a contract with that pharmacist or service. As part of the contract, the pharmacist or service shall be required to maintain at least the standards for operation of the pharmaceutical services outlined in this chapter.

§ 113.30. Mishandling of drugs.

If there is reason to suspect mishandling of scheduled or controlled drugs, the administration shall contact the Bureau of Drug Control of the Office of Attorney General.

Authority

The provisions of this § 113.30 issued under section 2102(g) of The Administrative Code of 1929 (71 P. S. § 532(g)); and section 803 of the Health Care Facilities Act (35 P. S. § 448.803).

Source

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