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Title 28. Health & Safety

Department of Health

Chapter 25. Controlled Substances, Drugs, Devices, and
Cosmetics

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**CHAPTER 25 CONTROLLED SUBSTANCES, DRUGS, DEVICES, AND
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CHAPTER 25 CONTROLLED SUBSTANCES, DRUGS, DEVICES, AND COSMETICS

GENERAL PROVISIONS

§ 25.1. Definitions.

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

Act—The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. § § 780-101—780-144).

Department—The Department of Health of the Commonwealth.

Device—Includes the following:

(i) An instrument, apparatus or contrivance, including their components, parts and accessories, intended as follows:

(A) For use in the diagnosis, cure, mitigation, treatment or prevention of disease of man or other animals.

(B) To affect the structure or a function of the body of man or other animals.

(ii) The term device shall include the following:

(A) Artificial eyes.

(B) Artificial limbs.

(C) Bandages and dressings, including, but not limited to, adhesive bandages, sterile gauze and cotton products, and elastic bandages and braces.

(D) Birth control devices, including, but not limited to, intrauterine devices, prophylactics, and vaginal diaphragms.

(E) Blood pressure testing apparatus.

(F) Body braces and supports, including, but not limited to, crutches, walkers and orthopedic braces and supports.

(G) Cardiac pacemakers and accessories.

(H) Colostomy and ileostomy appliances, bags and supplies.

(I) Corn pads or plasters.

(J) Dental materials which are transferred to the patient, including, but not limited to, dentures, fillings, crowns, inlays, bridges, and apparatus.

(K) Dialysis machines and artificial kidneys.

(L) Electronic therapeutic or diagnostic products.

(M) Eyeglasses and hard contact lenses.

(N) Hearing aids.

(O) Inhalation therapy equipment and emergency breathing equipment, including but not limited to atomizers, intermittent positive pressure breathing units, iron lungs, vaporizers, and oxygen equipment.

(P) Lamps, ultra-violet or infrared.

(Q) Needles.

(R) Syringes.

(S) Physical therapy equipment for professional or home use, including but not limited to diathermy machines, electronic muscle stimulators, traction units, therapeutic vibrators, and whirlpool units.

(T) Surgical implants.

(U) Sutures.

(V) Thermometers.

(W) Urine test kits sold over-the-counter for home use.

(X) Wheelchairs.

Secretary—The Secretary of Health of the Commonwealth.

Authority

The provisions of this § 25.1 issued under section 2102 of The Administrative Code of 1929 (71 P. S. § 532); and sections 6 and 35 of the Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. § § 780-106 and 780-135).

Source

The provisions of this § 25.1 amended April 8, 1977, 7 Pa.B. 997. Immediately preceding text appears at serial page (17625).

**GOOD MANUFACTURING PRACTICE IN MANUFACTURE,
PROCESSING, PACKING OR HOLDING OF DRUGS****§ 25.11. Buildings.**

Buildings shall be maintained in a clean and orderly manner and shall be of suitable size, construction, and location to facilitate adequate cleaning, maintenance, and proper operations in the manufacturing, processing, packing, labeling or holding of a drug. The buildings shall conform with the following:

(1) Provide adequate space for the following:

- (i) Orderly placement of equipment and materials to minimize any risk of mix-ups between different drugs, drug components, in-process materials, packaging materials or labeling, and to minimize the possibility of contamination.
- (ii) The receipt, storage and withholding from use of components pending sampling, identification, and testing prior to release by the materials approval unit for manufacturing and packaging.
- (iii) The holding of rejected components prior to disposition to preclude the possibility of their use in manufacturing or packaging procedures for which they are unsuitable.
- (iv) The storage of components, containers, packaging materials, and labeling.
- (v) Any manufacturing and processing operations performed.
- (vi) Any packaging or labeling operations.
- (vii) Storage of finished products.
- (viii) Control and production-laboratory operations.

(2) Provide adequate lighting, ventilation and screening and, when necessary for the intended production or control purposes, provide facilities for adequate air-pressure, microbiological, dust, humidity and temperature controls to insure the following:

(i) Minimize contamination of products by extraneous adulterants, including cross-contamination of one product by dust or particles of ingredients arising from the manufacture, storage or handling of another product.

(ii) Minimize dissemination of microorganisms from one area to another.

(iii) Provide suitable storage conditions for drug components, in-process materials and finished drugs in conformance with stability information as derived under § 25.21 (relating to stability).

(3) Provide adequate locker facilities and hot and cold water washing facilities, including soap or detergent, air dryer or single service towels and clean toilet facilities near working areas.

(4) Provide an adequate supply of potable water under continuous positive pressure in a plumbing system free of defects that could cause or contribute to contamination of any drug. Drains shall be of adequate size and, where connected directly to a sewer, shall be equipped with traps to prevent back-siphonage.

(5) Provide suitable housing and space for the care of all laboratory animals.

(6) Provide for safe and sanitary disposal of sewage, trash and other refuse within and from the buildings and immediate premises.

§ 25.12. Equipment.

Equipment used for the manufacture, processing, packing, labeling, holding, testing or control of drugs shall be maintained in a clean and orderly manner and shall be of suitable design, size, construction and location to facilitate cleaning, maintenance and operation for its intended purpose. These regulations permit the use of precision automatic, mechanical or electronic equipment in the production of drugs when adequate inspection and checking procedures are used to assure proper performance. The equipment shall conform with the following:

(1) Be so constructed that all surfaces that come into contact with a drug product shall not be reactive, additive or absorptive so as to alter the safety, identity, strength, quality or purity of the drug or its components beyond the official or other established requirements.

(2) Be so constructed that any substances required for operation of the equipment, such as lubricants or coolants, do not contact drug products so as to alter the safety, identity, strength,

quality or purity of the drug or its components beyond the official or other established requirements.

(3) Be constructed and installed to facilitate adjustment, disassembly, cleaning and maintenance to assure the reliability of control procedures, uniformity of production, and exclusion from the drugs of contaminants from previous and current operations that might affect the safety, identity, strength, quality or purity of the drug or its components beyond the official or other established requirements.

(4) Be of suitable type, size and accuracy for any testing, measuring, mixing, weighing or other processing or storage operations.

§ 25.13. Personnel.

(a) A person may not operate as a manufacturer of drugs unless the drugs are manufactured under the supervision of a registered pharmacist, chemist or other person possessing at least 5 years' experience in the manufacture of drugs or another person approved by the secretary as qualified by scientific or technical training or experience to perform the duties of supervision as may be necessary to protect the public health and safety.

(b) A person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesions that may adversely affect the safety or quality of drugs shall be excluded from direct contact with drug products until the condition is corrected. Employees shall be instructed to report to supervisory personnel conditions that may have an adverse effect on drug products.

§ 25.14. Components.

Components and other materials used in the manufacture, processing and packaging of drug products, and materials necessary for building and equipment maintenance, upon receipt shall be stored and handled in a safe, sanitary and orderly manner. Adequate measures shall be taken to prevent mix-ups and cross-contamination affecting drugs and drug products. Components shall be withheld from use until they have been identified, sampled and tested for conformance with established specifications and are released by a materials approval unit. Control of components shall include the following:

(1) Each container of component shall be examined visually for damage or contamination prior to use, including examination for breakage of seals when indicated.

(2) An adequate number of samples shall be taken from a representative number of component containers from each lot and shall be subjected to one or more tests to establish the specific identity.

(3) Representative samples of components liable to contamination with filth, insect infestation, or other extraneous contaminants shall be appropriately examined.

- (4) Representative samples of all components intended for use as active ingredients shall be tested to determine their strength in order to assure conformance with appropriate specifications.
- (5) Representative samples of components liable to microbiological contamination shall be subjected to microbiological tests prior to use. Such components shall not contain microorganisms that are objectionable in view of their intended use.
- (6) Approved components shall be appropriately identified and retested as necessary to assure that they conform to appropriate specifications of identity, strength, quality, and purity at time of use. This requires the following:
- (i) Approved components shall be handled and stored to guard against contaminating or being contaminated by other drugs or components.
 - (ii) Approved components shall be rotated in such a manner that the oldest stock is used first.
 - (iii) Rejected components shall be identified and held to preclude their use in manufacturing or processing procedures for which they are unsuitable.
- (7) Appropriate records shall be maintained, including the following:
- (i) The identity and quantity of the component, the name of the supplier, the supplier's lot number, and the date of receipt.
 - (ii) Examinations and tests performed and rejected components and their disposition.
 - (iii) An individual inventory and record for each component used in each batch of drug manufactured or processed.
- (8) An appropriately identified reserve sample of all active ingredients consisting of at least twice the quantity necessary for all required tests, except those for sterility and determination of the presence of pyrogens, shall be retained for at least 2 years after distribution of the last drug lot incorporating the component has been completed or 1 year after the expiration date of this last drug lot, whichever is longer.

Cross References

This section cited in 28 Pa. Code § 25.19 (relating to laboratory controls).

§ 25.15. Production and control records.

(a) To assure uniformity from batch to batch, a master production and control record for each drug product and each batch size of drug product shall be prepared, dated, and signed or initialed by a competent and responsible individual and shall be independently checked,

reconciled, dated and signed by a second competent and responsible individual. The master production and control record shall include:

(1) The name of the product, description, of the dosage form, and a specimen or copy of each label and all other labeling associated with the retail or bulk unit, including copies of such labeling signed or initialed and dated by the person or persons responsible for approval of such labeling.

(2) The name and weight or measure of each active ingredient per dosage unit or per unit of weight or measure of the finished drug, and a statement of the total weight or measure of any dosage unit.

(3) A complete list of ingredients designated by names or codes sufficiently specific to indicate any special quality characteristic; and accurate statement of the weight or measure of each ingredient regardless of whether it appears in the finished product, except that reasonable variations may be permitted in the amount of components necessary in the preparation in dosage form provided that provisions for such variations are included in the master production and control record; an appropriate statement concerning any calculated excess of an ingredient; an appropriate statement of theoretical weight or measure at various stages of processing; and a statement of the theoretical yield.

(4) A description of the containers, closures, and packaging and finishing materials.

(5) Manufacturing and control instructions, procedures, specifications, special notations, and precautions to be followed.

(b) The batch production and control record shall be prepared for each batch of drug produced and shall include complete information relating to the production and control of each batch. These records shall be retained for at least two years after the batch distribution is complete or at least 1 year after the batch expiration date, whichever is longer. These records shall identify the specific labeling and lot or control numbers used on the batch and shall be readily available during such retention period. The batch record shall include:

(1) An accurate reproduction of the appropriate master formula record checked, dated, and signed or initialed by a competent and responsible individual.

(2) A record of each significant step in the manufacturing, processing, packaging, labeling, testing, and controlling of the batch, including dates, individual major

equipment and lines employed; specific identification of each batch of components used; weights and measures of components and products used in the course of processing; in-process and laboratory control results; and identifications of the individuals actively performing and the individuals directly supervising or checking each significant step in the operation.

(3) A batch number that identifies all the production and control documents relating to the history of the batch and all lot or control numbers associated with the batch.

(4) A record of any investigation made according to § 25.16(8) (relating to production and control procedures).

§ 25.16. Production and control procedures.

Production and control procedures shall include all reasonable precautions, including the following, to assure that the drugs produced have the safety, identity, strength, quality, and purity they purport to possess:

(1) Each significant step in the process, such as the selection, weighing, and measuring of components, the addition of ingredients during the process, weighing and measuring during various stages of the processing, and the determination of the finished yield, shall be performed by a competent and responsible individual and checked by a second competent and responsible individual; or if such steps in the processing are controlled by precision automatic, mechanical, or electronic equipment, their proper performance is adequately checked by one or more competent and responsible individuals. The written record of the significant steps in the process shall be identified by the individual performing these tests and by the individual charged with checking these steps. Such identifications shall be recorded immediately following the completion of such steps.

(2) All containers, lines, and equipment used during the production of a batch of a drug shall be properly identified at all times to accurately and completely indicate their contents and, when necessary, the stage of processing of the batch.

(3) To minimize contamination and prevent mix-ups, equipment, utensils, and containers shall be thoroughly and appropriately cleaned and properly stored and have previous batch identification removed or obliterated between batches or at suitable intervals in continuous production operations.

(4) Appropriate precautions shall be taken to minimize microbiological and other contamination in the production of drugs purporting to be sterile or which by virtue of their intended use should be free from objectionable microorganisms.

(5) Appropriate procedures shall be established to minimize the hazard of cross-contamination of any drugs while being manufactured or stored.

(6) To assure the uniformity and integrity of products, there shall be adequate in-process controls, such as checking the weights and disintegration times of tablets, the adequacy of mixing, the homogeneity of suspensions, and the clarity of solutions. In-process sampling shall be done at appropriate intervals using suitable equipment.

(7) Representative samples of all dosage form drugs shall be tested to determine their conformance with the specifications for the product before distribution.

(8) Procedures shall be instituted whereby review and approval of all production and control records, including packaging and labeling, shall be made prior to the release or distribution of a batch. A thorough investigation of any unexplained discrepancy or the failure of a batch to meet any of its specifications shall be undertaken whether or not the batch has already been distributed. This investigation shall be undertaken by a competent and responsible individual and shall extend to other batches of the same drug and other drugs that may have been associated with the specific failure. A written record of the investigation shall be made and shall include the conclusions and follow-up.

(9) Returned goods shall be identified as such and held. If the conditions under which returned goods have been held, stored, or shipped prior to or during their return, or the condition of the product, its container, carton, or labeling as a result of storage or shipping, cast doubt on the safety, identity, strength, quality, or purity of the drug, the returned goods shall be destroyed or subjected to adequate examination or testing to assure that the material meets all appropriate standards or specifications before being returned to stock for warehouse distribution or repacking. If the product is neither destroyed nor returned to stock, it may be reprocessed provided the final product meets all its standards and specifications. Records of returned goods shall be maintained and shall indicate the quantity returned, date, and actual disposition of the product. If the reason for returned goods implicates associated batches, an appropriate investigation shall be made in accordance with the requirements of paragraph (8).

Cross References

This section cited in 28 Pa. Code § 25.15 (relating to production and control records); 28 Pa. Code § 25.18 (relating to packaging and labeling); 28 Pa. Code § 25.23 (relating to complaint files).

§ 25.17. Product containers and their components.

Suitable specifications, test methods, cleaning procedures and, when indicated, sterilization procedures shall be used to assure that containers, closures and other component parts of drug packages are suitable for their intended use. Product containers and their components shall not be reactive, additive or absorptive so as to alter the safety, identity, strength, quality or purity of the drug or its components beyond the official or established requirements and shall provide adequate protection against external factors that can cause deterioration or contamination of the drug.

§ 25.18. Packaging and labeling.

Packaging and labeling operations shall be adequately controlled: To assure that only those drug products that have met the standards and specifications established in their master production and control records shall be distributed; to prevent mix-ups between drugs during filling, packaging, and labeling operations; to assure that correct labels and labeling are employed for the drug; and to identify the finished product with a lot or control number that permits determination of the history of the manufacture and control of the batch. An hour, day, or shift code is appropriate as a lot or control number for drug products manufactured or processed in continuous production equipment. Packaging and labeling operations shall conform with the following:

- (1) Be separated, physically or spatially, from operations on other drugs in a manner adequate to avoid mix-ups and minimize cross-contamination. Two or more packaging or labeling operations having drugs, containers, or labeling similar in appearance shall not be in process simultaneously on adjacent or nearby lines unless these operations are separated either physically or spatially.
- (2) Provide for an inspection of the facilities prior to use to assure that all drugs and previously used packaging and labeling materials have been removed.
- (3) Include the following labeling controls:
 - (i) The holding of labels and package labeling upon receipt pending review and proofing against an approved final copy by a competent and responsible individual to assure that they are accurate regarding identity, content, and conformity with the approved copy before release to inventory.
 - (ii) The maintenance and storage of each type of label and package labeling representing different products, strength, dosage forms, or quantity of contents in such a manner as to prevent mix-ups and provide proper identification.
 - (iii) A suitable system for assuring that only current labels and package labeling are retained and that stocks of obsolete labels and package labeling are destroyed.
 - (iv) Restriction of access to labels and package labeling to authorized personnel.
 - (v) Avoidance of gang printing of cut labels, cartons, or inserts when the labels, cartons, or inserts are for different products or different strengths of the same products or are of the same size and have identical or similar format and/or color schemes. If gang printing is employed, packaging and labeling operations shall provide for added control procedures. These added controls should consider sheet layout, stacking, cutting and handling during and after printing.

(4) Provide strict control of the package labeling issued for use with the drug. Such issue shall be carefully checked by a competent and responsible person for identity and conformity to the labeling specified in the batch production record. Said record shall identify the labeling and the quantities issued and used and shall reasonably reconcile any discrepancy between the quantity of drug finished and the quantities of labeling issued. All excess package labeling bearing lot or control numbers shall be destroyed. In event of any significant unexplained discrepancy, an investigation should be carried out according to § 25.16(h) (relating to production and control procedures).

(5) Provide for adequate examination or laboratory testing of representative samples of finished products after packaging and labeling to safeguard against any errors in the finishing operations and to prevent distribution of any batch until all specified tests have been met.

Cross References

This section cited in 28 Pa. Code § 113.25 (relating to drug distribution systems).

§ 25.19. Laboratory controls.

Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, and test procedures to assure that components, in-process drugs, and finished products conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include the following:

(1) The establishment of master records containing appropriate specifications for the acceptance of each lot of drug components, product containers, and their components used in drug production and packaging and a description of the sampling and testing procedures used for them. Said samples shall be representative and adequately identified. Such records shall also provide for appropriate retesting of drug components, product containers, and their components subject to deterioration.

(2) A reserve sample of all active ingredients as required by § 25.14 (8) (relating to components).

(3) The establishment of master records, when needed, containing specifications and a description of sampling and testing procedures for in-process drug preparations. Such samples shall be adequately representative and properly identified.

(4) The establishment of master records containing a description of sampling procedures and appropriate specifications for finished drug products. Such samples shall be adequately representative and properly identified.

(5) Adequate provisions for checking the identity and strength of drug products for all active ingredients and for assuring:

- (i) Sterility of drugs purported to be sterile and freedom from objectionable microorganisms for those drugs which should be so by virtue of their intended use.
 - (ii) The absence of pyrogens for those drugs purporting to be pyrogen-free.
 - (iii) Minimal contamination of ophthalmic ointments by foreign particles and harsh or abrasive substances.
 - (iv) That the drug release pattern of sustained release products is tested by laboratory methods to assure conformance to the release specifications.
- (6) Adequate provision for auditing the reliability, accuracy, precision, and performance of laboratory test procedures and laboratory instruments used.
- (7) A properly identified reserve sample of the finished product (stored in the same immediate container closure system in which the drug is marketed) consisting of at least twice the quantity necessary to perform all the required tests, except those for sterility and determination of the absence of pyrogens, and stored under conditions consistent with product labeling shall be retained for at least 2 years after the drug distribution has been completed or at least 1 year after the drug's expiration date, whichever is longer.
- (8) Provision for retaining complete records of all laboratory data relating to each batch or lot of drug to which they apply. Such records shall be retained for at least 2 years after distribution has been completed or 1 year after the drug's expiration date, whichever is longer.
- (9) Provision that animals shall be maintained and controlled in a manner that assures suitability for their intended use. They shall be identified and appropriate records maintained to determine the history of use.
- (10) Provision that firms which manufacture non penicillin products, including certifiable antibiotic products, on the same premises or use the same equipment as that used for manufacturing penicillin products, or that operate under any circumstances that may reasonably be regarded as conducive to contamination of other drugs by penicillin, shall test such non penicillin products to determine whether any have become cross-contaminated by penicillin. Such products shall not be marketed if intended for use in man or animals and the product is contaminated with an amount of penicillin equivalent to 0.05 unit or more of penicillin G per maximum single dose recommended in the labeling of a drug intended for parenteral administration or an amount of penicillin equivalent to 0.5 unit or more of penicillin G per maximum single dose recommended in the labeling of a drug intended for oral use.

§ 25.20. Distribution records.

(a) Finished goods warehouse control and distribution procedures shall include a system by which the distribution of each lot of drug can be readily determined to facilitate its recall if necessary. Records within the system shall contain the name and address of the consignee, date and quantity shipped, and lot or control number of the drug. Records shall be retained for at least 2 years after the distribution of the drug has been completed or 1 year after the expiration date of the drug, whichever is longer.

(b) To assure the quality of the product, finished goods warehouse control shall also include a system whereby the oldest approved stock is distributed first whenever possible.

§ 25.21. Stability.

There shall be assurance of the stability of finished drug products. This stability shall be in accordance with the following:

- (1) Determined by reliable, meaningful, and specific test methods.
- (2) Determined on products in the same container closure systems in which they are marketed.
- (3) Determined on any dry drug product that is to be reconstituted at the time of dispensing, as directed in its labeling, as well as on the reconstituted product.
- (4) Recorded and maintained in such manner that the stability data may be utilized in establishing product expiration dates.

Cross References

This section cited in 28 Pa. Code § 25.11 (relating to buildings); and 28 Pa. Code § 25.22 (relating to expiration date).

§ 25.22. Expiration dating.

To assure that drug products liable to deterioration meet appropriate standards of identity, strength, quality, and purity at the time of use, the label of all such drugs shall have suitable expiration dates which relate to stability tests performed on the products.

- (1) Expiration dates appearing on the drug labeling shall be justified by readily available data from stability studies such as described in § 25.21 (relating to stability).
- (2) Expiration dates shall be related to appropriate storage conditions stated on the labeling wherever the expiration date appears.

(3) When the drug is marketed in the dry state for use in preparing a liquid product, the labeling shall bear expiration information for the reconstituted product as well as an expiration date for the dry product.

§ 25.23. Complaint files.

Records shall be maintained of all written and oral complaints regarding each product. An investigation of each complaint shall be made in accordance with § 25.16(8) (relating to production and control procedures). The record of each investigation shall be maintained for at least 2 years after distribution of the drug has been completed or 1 year after the expiration date of the drug, whichever is longer.

**STANDARDS OF OPERATION FOR DRUG, DEVICE OR
COSMETIC DISTRIBUTORS**

§ 25.31. Sanitation requirements.

Those areas of drug, device or cosmetic distributing establishments where drugs, devices or cosmetics are warehoused or stored shall be maintained in a clean, orderly condition, free from vermin infestations, accumulated waste and debris. Preventive measures shall include, but shall not be limited to, the following:

- (1) Warehousing facilities shall be of construction, material, and finish that will permit the ready and efficient cleaning of all surfaces, having regard to the nature of the operations being performed.
- (2) Adequate lighting shall be provided in all working areas.
- (3) Sufficient working and storage space shall be provided to permit adequate cleaning and housekeeping.
- (4) The establishments shall be free from accumulations of water not necessary for operational or sanitation procedures.
- (5) Proper and adequate toilet facilities shall be provided and kept in satisfactory condition at all times with sufficient lighting and ventilation. Such facilities shall be separate from operational areas of such establishments. Handwashing facilities shall be available and rules shall require their use before returning to work.
- (6) The establishment shall have a proper program for maintaining the conditions specified above.

§ 25.32. Warehousing requirements.

- (a) Establishments warehousing products which require refrigeration shall be equipped with adequate facilities for storage at the proper reduced temperatures.
- (b) Distributors dealing in controlled substances shall have adequate storage facilities and safeguards to comply with the regulations of the Federal Drug Enforcement Administration.
- (c) Distributors dealing in drugs shall have adequate storage facilities and safeguards to prevent loss or minimize deterioration.
- (d) Each distributor's establishment shall provide for a systematic rotation of stock.
- (e) Damaged, out-dated or otherwise unfit drugs, devices or cosmetics not in conformity with the provisions of the act or regulations thereunder, shall be removed from active stock and held for proper disposition in a quarantine or other clearly defined area.
- (f) A distributor dealing in nonproprietary drugs or controlled substances shall have operating and storage facilities which have entrances used only by that distributor and which are separate from living quarters. Facilities shall be secured so that persons in an adjoining structure, business or residence cannot traverse through the operating and storage areas used for nonproprietary drugs or controlled substances.

Authority

The provisions of this § 25.32 issued under section 35 of the Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. § 780-135); and section 2102(g) of The Administrative Code of 1929 (71 P. S. § 532(g)).

Source

The provisions of this § 25.32 amended September 12, 1986, effective September 13, 1986, 16 Pa.B. 3396. Immediately preceding text appears at serial page (96886).

§ 25.33. Distribution.

- (a) Distributing establishments shall not distribute nonproprietary drugs or controlled substances to persons unauthorized by the act to receive them.
- (b) No person shall buy, sell, cause to be sold or offer for sale any drug or device which bears or which package bears or originally did bear, the inscription "sample" or "not for sale" or words of similar import. This subsection does not apply to the production of promotional samples by one manufacturer for distribution by another manufacturer.
- (c) Distributors shall keep records of all purchases or other receipts and sales or other distribution of drugs, devices and controlled substances, other than those exempt by

regulation, for 2 years from the date of receipt and distribution. Such records shall include the following:

- (1) Name and address of person from whom received.
- (2) Name and address of person to whom distributed.
- (3) Date of receipt and distribution.
- (4) Quantity involved.

§ 25.34. Personnel.

(a) The personnel responsible for the supervision of a drug, device or cosmetic distributing establishment shall have appropriate technical qualifications or shall be qualified by job training and experience, to assure the proper handling of products in the establishment.

(b) No person may operate as a distributor of nonproprietary drugs or controlled substances unless the distribution is performed while a registered pharmacist, chemist or other person who possesses at least 3 years experience in the distribution or sale of drugs or controlled substances is present in the distributing establishment and is responsible for the activities. Other persons may meet this requirement for supervision, if approved by the Secretary as qualified by scientific training to perform the duties of supervision.

Authority

The provisions of this § 25.34 issued under section 35 of the Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. § 780-135); and section 2102(g) of The Administrative Code of 1929 (71 P. S. § 532(g)).

Source

The provisions of this § 25.34 amended September 12, 1986, effective September 13, 1986, 16 Pa.B. 3396. Immediately preceding text appears at serial page (96886).

EMERGENCY DISPENSING

§ 25.41. Pharmacist.

A pharmacist may dispense to the ultimate user a controlled substance listed in Schedule II which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 812 upon receiving oral authorization without the written prescription order of a licensed practitioner only under the following emergency situations:

- (1) That immediate administration of the controlled substance is necessary for proper

treatment of the intended ultimate user.

- (2) That no appropriate alternative treatment is available including administration of a drug that is not a controlled substance under Schedule II of the act, 21 U.S.C.A. § 812.

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions).

§ 25.42. Emergency conditions.

The quantity prescribed and dispensed under emergency conditions is limited to the amount adequate to treat the patient during the emergency period.

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions).

§ 25.43. Immediate writing required.

The prescription shall be immediately reduced to writing by the pharmacist and shall contain all the information required under section 4 of the act (35 P. S. § 780-104) except the signature of the prescribing licensed practitioner.

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions).

§ 25.44. Unfamiliar practitioners.

If the prescribing practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a licensed practitioner, which may include a call back to the practitioner using the phone number listed in the telephone directory of other good faith efforts to insure his identity.

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions).

§ 25.45. Emergency oral prescription.

Within 72 hours after authorizing an emergency oral prescription, the prescribing practitioner shall have a written prescription for the emergency quantity prescribed delivered to the dispensing pharmacist. In addition to conforming to the requirements of these regulations, and the act, the prescription shall have written on its face “Authorization for Emergency Dispensing” and the date of the oral order. Upon receipt the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing.

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions).

§ 25.46. Failure to deliver written prescription.

The pharmacist shall notify the nearest office of the Federal Drug Enforcement Administration if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority conferred by this section to dispense a controlled substance without a written prescription of a prescribing individual practitioner.

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions).

PRESCRIPTIONS**§ 25.51. Definition of “prescription.”**

The term “prescription” or “prescription order” means an order for a controlled substance, other drug, or device for medication which is dispensed to or for an ultimate user, but does not include an order for a controlled substance, other drug, or device for medication which is dispensed for immediate administration to the ultimate user. For example, an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription order.

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions); and 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs).

§ 25.52. Purpose.

(a) A prescription for a controlled substance must be issued for a legitimate medical purpose by a licensed practitioner in the usual course of professional practice. The responsibility for proper prescribing of controlled substances is upon the practitioner but a corresponding responsibility rests with the pharmacist who dispenses the medication and interprets the directions of the prescriber to the patient.

(b) A prescription may not be issued by a practitioner to obtain controlled substances for use in his routine office practice nor for general dispensing to his patients.

(c) A prescription may not be issued for the dispensing of controlled substances listed in any schedule to a drug dependent person for the purpose of continuing his dependence upon such drugs, nor in the course of conducting an authorized clinical investigation in a narcotic dependency rehabilitation program.

Notes of Decisions

A pharmacist who fills numerous prescriptions emanating from a dentist for medications which clearly do not comport with a dental practice (such as birth control drugs and unusually large dosages of Valium) violates the standards of his profession and the duty imposed by the provisions of this section. *Askin v. Department of Public Welfare*, 423 A.2d 1371 (Pa. Cmwlth. 1981).

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions); and 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs).

§ 25.53. Prescription orders.

(a) Prescription orders may be written on prescription blanks or may be oral, if allowed by law. ((*Editor's note see PA Bulletin December 11, 2010 and PA Bulletin May 27, 2006 for more clarification*):

(b) If prescriptions are issued in writing, the bottom of every prescription blank shall be imprinted with the words "substitution permissible" and shall contain one signature line for the physician's or other authorized prescriber's signature. The prescriber's signature shall validate the prescription, and unless the prescriber handwrites "brand necessary" or "brand medically necessary" shall designate approval of substitution of a drug by a pharmacist, pursuant to the act. Imprinted conspicuously on the prescription blanks shall be the words: IN ORDER FOR A BRAND NAME PRODUCT TO BE DISPENSED, THE PRESCRIBER MUST HANDWRITE "BRAND NECESSARY" OR "BRAND MEDICALLY NECESSARY" IN THE SPACE BELOW." Information printed on the prescription blank shall be in 8 point, upper-case print. The following example would be acceptable:

SUBSTITUTION PERMISSIBLE M.D.*

IN ORDER FOR A BRAND NAME PRODUCT TO BE DISPENSED, THE PRESCRIBER MUST HANDWRITE "BRAND NECESSARY" OR "BRAND MEDICALLY NECESSARY" IN THE SPACE BELOW.

*as appropriate

(c) If prescription orders are given orally, substitution is permissible unless the prescriber expressly indicates to the pharmacist that the brand name drug is necessary and that substitution is not allowed.

(d) Prescriptions for controlled substances shall be written in indelible ink, indelible pencil or typewriter and shall include the following information (*Editor's note see PA Bulletin December 11, 2010 and PA Bulletin May 27, 2006 for more clarification*):

- (1) The date of issue.
 - (2) The name and address of the patient, or if the patient is an animal, the name and address of the owner and the species of the animal.
 - (3) Directions for administration.
 - (4) The name, address and Federal Drug Enforcement Administration registration number of the prescribing practitioner.
 - (5) The signature of the prescribing practitioner in the manner described in subsection (b).
- (e) The Federal Drug Enforcement Administration registration number cannot be preprinted on the prescription form.

Authority

The provisions of this § 25.53 issued under section 5(a) of the act of November 24, 1976 (P. L. 1163, No. 259) (35 P. S. § 960.5); amended under section 3 of the act of November 24, 1976 (P. L. 1163, No. 259) (35 P. S. § 960.5); and section 2102(g) of The Administrative Code of 1929 (71 P. S. § 532(g)).

Source

The provisions of this § 25.53 amended through June 24, 1977, 7 Pa.B. 1815; amended October 26, 1990, effective October 27, 1990, 20 Pa.B. 5426. Immediately preceding text appears at serial pages (116446) to (116447).

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions); and 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs).

§ 25.54. Posting notice.

(a) Every pharmacy shall post a sign which shall read as follows: “PENNSYLVANIA LAW PERMITS PHARMACISTS TO SUBSTITUTE A LESS EXPENSIVE GENERICALLY EQUIVALENT DRUG FOR A BRAND NAME DRUG UNLESS YOU OR YOUR PHYSICIAN DIRECT OTHERWISE.” This sign will be printed in boldface letters not less than one inch or 2.54 centimeters in height on a white background and posted in a prominent place that is in clear and unobstructed public view at or near the place where prescriptions are dispensed.

(b) Every pharmacy shall post in a conspicuous place, easily accessible to the general public, a list of commonly used generically equivalent drug products from the Department Formulary or "Approved Drug Products with Therapeutic Equivalence Evaluations", (Food and Drug Administration "Orange Book") Publication containing brand names, names of the manufacturers, and generic names. This list shall be alphabetized by brand name, each of which shall be followed by the generic name, and printed in boldface type clearly legible and accessible to the general public.

(c) Every pharmacy shall have available to the public a listing of the regular and customary retail prices of that pharmacy for brand name and generic equivalent drug products, with the name of the manufacturer, available for selection by the person presenting the prescription.

Authority

The provisions of this § 25.54 issued under section 5(a) of the act of November 24, 1976 (P. L. 1163, No. 259) (35 P. S. § 960.5).

Source

The provisions of this § 25.54 amended June 24, 1977, 7 Pa.B. 1742. Immediately preceding text appears at serial page (17641).

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions); and 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs).

§ 25.55. Dispensing.

(a) Where the pharmacist is to substitute a less expensive generically equivalent drug for a brand name drug at the pharmacy, notification to the person presenting the prescription shall be made by the pharmacist, either directly or through a pharmacy intern or other person under the supervision of the pharmacist authorized to assist the pharmacist by the State Board of Pharmacy. Such notification shall be limited to advising the person presenting the prescription that substitution is possible, to advising the person of the amount of the retail price difference between the brand name and the generically equivalent drug product substituted for it, and to informing the person that he may refuse the substitution. Questions by the person presenting the prescription for drug product information shall be answered only by the pharmacist or pharmacy intern. The notification described in this subsection of a possible substitution and retail price difference may be oral or may be in a written statement similar to the following: "Your physician has indicated that this prescription, identified as _____, may be filled with one of the generic drug products listed in Department Formulary or the "Approved Drug Products with Therapeutic Equivalence Evaluations", (Food and Drug Administration "Orange Book") Publication. This lower cost generically equivalent product has been selected by our pharmacy in order to save you, the purchaser, a total of \$ _____. Please indicate whether you do ! or do not wish to have the lower priced drug. Signed _____."

(b) Where the pharmacist is to substitute a less expensive generically equivalent drug product for a brand name drug by mail, the following provisions must be complied with:

(1) The mail order pharmacy, in all communications in connection with the solicitations of mail order customers, whether by direct mailings, general advertising, or on order forms, shall include notice in upper case letters and in boldface type as follows:

PENNSYLVANIA LAW PERMITS PHARMACISTS TO SUBSTITUTE A LESS EXPENSIVE GENERICALLY EQUIVALENT DRUG FOR A BRAND NAME DRUG UNLESS YOU OR YOUR PHYSICIAN DIRECT OTHERWISE CHECK HERE IF YOU DO NOT WISH A LESS EXPENSIVE BRAND OR GENERIC DRUG "PRODUCT"

(2) After receiving a prescription order by mail, a mail order pharmacy shall substitute a less expensive generically equivalent drug product listed in Department Formulary or “Approved Drug Products with Therapeutic Equivalence Evaluations”, (Food and Drug Administration “Orange Book”) Publication unless expressly directed otherwise by the person presenting the prescription or the prescribing physician.

(3) When a generically equivalent drug product is dispensed by mail, the pharmacy shall notify the person presenting the prescription of the substitution and shall indicate the retail price difference between the brand name drug and the generic equivalent drug product substituted for it.

(c) Any pharmacist substituting a less expensive drug product shall charge the person presenting the prescription the regular and customary retail price of that pharmacy for the generically equivalent drug.

(d) No pharmacist shall substitute a generically equivalent drug product for a prescribed brand name drug product if the brand name drug product or the generic drug type is not included in Department Formulary or “Approved Drug Products with Therapeutic Equivalence Evaluations”, (Food and Drug Administration “Orange Book”) Publication provided, however, that drug products found by the United States Food and Drug Administration to have a narrow therapeutic range shall not be considered generically equivalent for the purposes of this act.

(e) Prescription refills, where permitted by the practitioner, shall be completed using the identical product (same distributor and manufacturer) as dispensed on the original, unless the person presenting the prescription and the practitioner authorize in advance a different manufacturer’s generic equivalent product. Advance authorization is not required in an emergency, but the physician shall be notified by the pharmacist as soon as possible thereafter.

Authority

The provisions of this § 25.55 issued under section 5(a) of the act of November 24, 1976 (P. L. 1163, No. 259) (35 P. S. § 960.5).

Source

The provisions of this § 25.55 amended June 24, 1977, effective June 25, 1977, 7 Pa.B. 1742. Immediately preceding text appears at serial pages (17641) and (17642).

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions); 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs); and 49 Pa. Code § 43a.9 (relating to schedule of civil penalties—pharmacists and pharmacies).

§ 25.56. Prescription record keeping.

(a) Prescription orders for controlled substances in Schedules I and II shall be maintained in a file separate from all other records of the pharmacy.

(b) Prescription orders for controlled substances in Schedules III, IV and V shall be maintained either in a separate prescription file or in such form that they are readily retrievable from the other prescription records of the pharmacy. They will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is marked in red ink in the lower right corner with the letter “C,” no less than one inch high and filed in the usual consecutively numbered prescription file for noncontrolled substances. (*Editor’s note see PA Bulletin December 11, 2010 and PA Bulletin May 27, 2006 for more clarification*):

(c) When a pharmacist substitutes a generically equivalent drug product for a brand name product, he shall maintain a record of the substitution by making a notation indicating the generic equivalent drug name, using abbreviations if necessary, and the name of the manufacturer and distributor of the product dispensed on the original prescription order retained by the pharmacist, or the pharmacist may store it in a functionally equivalent retrieval system.

Authority

The provisions of this § 25.56 issued under section 5(a) of the act of November 24, 1976 (P. L. 1163, No. 259) (35 P. S. § 960.5).

Source

The provisions of this § 25.56 adopted June 24, 1977, effective June 25, 1977, 7 Pa.B. 1742.

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions); 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs); and 49 Pa. Code § 43a.9 (relating to schedule of civil penalties—pharmacists and pharmacies).

§ 25.57. Nonprescription orders.

A controlled substance listed in Schedules V which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § § 301—392, may be dispensed without a prescription to a purchaser at retail provided that the following conditions are met:

(1) Such distribution is made only by a registered pharmacist and not by a nonpharmacist employee even if under the direct supervision of a pharmacist; although, after the pharmacist has fulfilled his professional and legal responsibilities, the actual cash, credit transaction, or delivery may be completed by a nonpharmacist.

(2) Not more than 240 milliliters, eight fluid or avoirdupois ounces of any such controlled substance listed in Schedule V containing opium nor more than 120 milliliters, four fluid or avoirdupois ounces of any other controlled substance listed in Schedule V may be distributed at retail to the same purchaser in a given 72-hour period, except under a written or oral prescription of a licensed practitioner in possession of a DEA number.

(3) The purchaser is at least 18 years of age.

(4) The pharmacist requires every purchaser of a controlled substance listed in Schedule V not known to him to furnish suitable identification, including proof of age where appropriate.

(5) A bound record book for distributions of controlled substances, other than by prescription order, is maintained by the pharmacist. This book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the dispensing pharmacist.

(6) No individual other than a registered manufacturer, distributor, practitioner, or pharmacy in possession of a Federal DEA registration shall acquire or attempt to acquire controlled substances containing opium listed in Schedule V in excess of eight fluid or avoirdupois ounces nor any other controlled substance if listed in Schedule V in excess of four fluid or avoirdupois ounces for any individual in a 72-hour period, except when dispensed pursuant to a prescription or prescription order.

Authority

The provisions of this § 25.57 issued under section 5(a) of the act of November 24, 1976 (P. L. 1163, No. 259) (35 P. S. § 960.5).

Source

The provisions of this § 25.57 adopted June 24, 1977, effective June 25, 1977, 7 Pa.B. 1742.

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions); and 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs).

§ 25.58. Generically equivalent drug products.

Refer to the Department Formulary or “ Approved Drug Products with Therapeutic Equivalence Evaluations”. (Food and Drug Administration “Orange Book”) Publication provided, however, that drug products found by the United States Food and Drug Administration to have a narrow therapeutic range shall not be considered generically equivalent for the purposes of this act. for a list of generically equivalent drug products .

Authority

The provisions of this § 25.58 issued and amended under section 2102(g) of The Administrative Code of 1929 (71 P. S. § 532(g)); and section 5 of the act of November 24, 1976 (P. L. 1163, No. 259) (35 P. S. § 960.5).

Source

The provisions of this § 25.58 amended September 12, 1986, effective September 13, 1986, 16 Pa.B. 3397; amended April 17, 1987, effective April 18, 1987, 17 Pa.B. 1567; amended April 1, 1988, effective April 2, 1988, 18 Pa.B. 1489; amended April 7, 1989, effective April 8, 1989, 19 Pa.B. 1527; amended September 1, 1989, effective September 2, 1989, 19 Pa.B. 3760; amended June 8, 1990, effective June 9, 1990, 20 Pa.B. 3062. Immediately preceding text appears at serial pages (140369) to (140510).

Cross References

This section cited in 6 Pa. Code § 22.2 (relating to definitions); 28 Pa. Code § 25.55 (relating to dispensing); 28 Pa. Code § 551.3 (relating to definitions); and 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs).

SECURITY REQUIREMENTS**§ 25.61. General provisions.**

(a) Persons maintaining stocks or having controlled substances in production areas or on hand for distribution shall provide effective controls and procedures to guard against theft and diversion of the substances.

(b) Physical security controls shall be commensurate with the schedules and quantity of controlled substances on hand and required for normal business operations. If a controlled substance is transferred to a different schedule or a noncontrolled substance is listed on a

schedule, or the quantity of controlled substances on hand significantly increases, physical security controls shall be expanded and extended accordingly.

(c) Persons who receive or transfer substantial quantities of controlled substances shall employ security procedures to guard against losses in transit.

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions).

§ 25.62. Security controls for distributors.

(a) Before distributing a controlled substance to a person who is not known to be registered to possess the controlled substance, the distributor shall make a good faith inquiry with the Federal Drug Enforcement Administration to determine that the person is legally permitted to possess the controlled substance.

(b) No complimentary samples of controlled substances may be distributed except on the specific written request of a licensed practitioner.

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions).

§ 25.63. Security controls for practitioners and research personnel.

(a) Controlled substances listed in Schedule I shall be stored in substantially constructed, securely locked cabinets with access restricted to approved personnel.

(b) Controlled substances listed in Schedules II, III, IV and V shall be stored in substantially constructed, securely locked cabinets. However, pharmacies and practitioners as defined in section 2 of the act (35 P. S. § 780-102) may disperse the substances throughout the stocks of noncontrolled substances in a manner as to obstruct the theft or diversion of the substances.

Source

The provisions of this § 25.63 amended August 20, 1976, effective August 21, 1976, 6 Pa.B. 1985. Immediately preceding text appears at serial page (24405).

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions); and 49 Pa. Code § 43a.9 (relating to schedule of civil penalties—pharmacists and pharmacies).

SCHEDULES OF CONTROLLED SUBSTANCES**Source**

The provisions of these § § 25.72—25.76 amended February 23, 1979, 9 Pa.B. 611, unless otherwise noted.

§ 25.72. Schedules of controlled substances.

(a) *General.* In accordance with sections 3 and 4 of the act (35 P. S. § § 780-103 and 780-104), this section lists all controlled substances. Section 4 of the act (35 P. S. § 780-104) designates specific substances for inclusion under the five schedules. The substances listed in this section include those listed by section 4 of the act (35 P. S. § 780-104) and those that have been added by the Secretary after consultation with the Drug, Device and Cosmetic Board.

(b) *Schedule I.* In determining that a substance comes within this schedule, the Secretary will find: a high potential for abuse; no currently accepted medical use in the United States; and a lack of accepted safety for use under medical supervision. The following controlled substances are included in this schedule:

(1) The following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted whenever the existence of the isomers, esters, ethers, and salts is possible within the specific chemical designation:

- (i) [Reserved].
- (ii) Allylprodine.
- (iii) Alphacetylmethadol.
- (iv) Alphameprodine.
- (v) Alphamethadol.
- (v.1) Alpha-methylfentanyl.
- (vi) Benzethidine.
- (vii) Betacetylmethadol.
- (viii) Betameprodine.
- (ix) Betamethadol.
- (x) Betaprodine.

- (xi) Clonitazene.
- (xii) Dextromoramide.
- (xiii) Dextrorphan (except its methylether).
- (xiv) Diampromide.
- (xv) Diethylthiambutene.
- (xvi) Dimenoxadol.
- (xvii) Dimepheptanol.
- (xviii) Dimethylthiambutene.
- (xix) Dioxaphetyl butyrate.
- (xx) Dipipanone.
- (xxi) Ethylmethylthiambutene.
- (xxii) Etonitazene.
- (xxiii) Etoxidine.
- (xxiv) Furethidine.
- (xxv) Hydroxypethidine.
- (xxvi) Ketobemidone.
- (xxvii) Levomoramide.
- (xxviii) Levophenacymorphan.
- (xxix) Morpheridine.
- (xxx) Noracymethadol.
- (xxxi) Norlevorphanol.
- (xxxii) Normethadone.

- (xxxiii) Norpipanone.
- (xxxiv) Phenadoxone.
- (xxxv) Phenampromide.
- (xxxvi) Phenomorphan.
- (xxxvii) Phenoperidine.
- (xxxviii) Piritramide.
- (xxxix) Proheptazine.
- (xl) Properidine.
- (xli) Racemoramide.
- (xlii) Tilidine.
- (xliii) Trimeperidine.
- (xliv) [Reserved].
- (xlv) 3-Methylfentanyl.
- (xlvi) 1-Methyl-4-Phenyl-4-Propionoxypiperidine (MPPP).
- (xlvii) 1-(2-Phenylethyl)-4-Phenyl-4-etyloxypiperidine (PEPAP).
- (xlviii) Para-fluorofentanyl.
- (xlix) Acetyl-alpha-methylfentanyl.
- (l) Alph-methylthiofentanyl.
- (li) Beta-hydroxyfentanyl.
- (lii) 3 Methylthiofentanyl.
- (liii) Thiofentanyl.
- (liv) Beta-hydroxy-3-methylfentanyl.

(2) The following opium derivatives, their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (i) Acetorphine.
- (ii) Acetyldihydrocodeine.
- (iii) Benzylmorphine.
- (iv) Codeine methylbromide.
- (v) Codeine-N-Oxide.
- (vi) Cyprenorphine.
- (vii) Desomorphine.
- (viii) Dihydromorphine.
- (ix) Drotebanol (added August 6, 1978).
- (x) Etorphine.
- (xi) Heroin.
- (xii) Hydromorphanol.
- (xiii) Methyldesorphine.
- (xiv) Methylhydromorphine.
- (xv) Morphine methylbromide.
- (xvi) Morphine methylsulfonate.
- (xvii) Morphine-N-Oxide.
- (xviii) Myrophine.
- (xix) Nicocodeine.
- (xx) Nicomorphine.
- (xxi) Normorphine.

(xxii) Pholcodine.

(xxiii) Thebacon.

(3) A material, compound, mixture or preparation which contains any quantity of the following hallucinogenic substances, their salts, isomers, and salts of isomers, unless specifically excepted, whenever the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation:

(i) 3,4-methylenedioxy amphetamine.

(ii) 5-methoxy-3, 4-methylenedioxy amphetamine.

(iii) 3,4,5-trimethoxy amphetamine.

(iv) Bufotenine.

(v) Diethyltryptamine.

(vi) Dimethyltryptamine.

(vii) 4-methyl-2, 5-dimethoxyamphetamine.

(viii) Ibogaine.

(ix) Lysergic acid diethylamide.

(x) Mescaline.

(xi) Peyote.

(xii) N-ethyl-3-piperidyl benzilate.

(xiii) N-methyl-3-piperidyl benzilate.

(xiv) Psilocybin.

(xv) Psilocyn.

(xvi) Tetrahydrocannabinols.

(xvii) 3, 4-methylenedioxy-N-ethylamphetamine.

(xviii) N-hydroxy-3, 4-methylenedioxyamphetamine.

(xix) 2, 5-Dimethoxy-4-ethylamphetamine (DOET).

(xx) 4 Bromo 2, 5 Dimethoxyphenethylamine.

(4) Marihuana.

(5) 4-Bromo-2, 5 Dimethoxyamphetamine (4-Bromo, 2, 5 DMA) (added October 17, 1975).

(6) Unless specifically excepted or unless listed in another schedule, a material, compound, mixture or preparation which contains any quantity of the following substances including the salts, isomers and salts of isomers:

(i) Fenethylamine.

(ii) N-ethylamphetamine.

(iii) Methaqualone.

(iv) Bromazepam.

(v) Camazepam.

(vi) Clobazam.

(vii) Clotiazepam.

(viii) Cloxazolam.

(ix) Delorazepam.

(x) Ethyl loflazepate.

(xi) Fludiazepam.

(xii) Flunitrazepam.

(xiii) Haloxazolam.

(xiv) Ketazolam.

(xv) Loprazolam.

(xvi) Lormetazepam.

(xvii) Medazepam.

- (xviii) Nimetazepam.
- (xix) Nitrazepam.
- (xx) Nordiazepam.
- (xxi) Oxazolam.
- (xxii) Pinazepam.
- (xxiii) Tetrazepam.
- (xxiv) 3, 4-Methylenedioxyamphetamine (MDMA).
- (xxv) 4-methylaminorex.
- (xxvi) Cathinone.
- (xxvii) Methcathinone HCL.
- (xxviii) Dimethylamphetamine.
- (xxix) 1-(3-trifluoromethylphenyl) Piperazine (TFMPP)
- (xxx) N-Benzylpiperazine (BZP)
- (xxxi) Alpha-Methyltryptamine (AMT)
- (xxxii) 2-5 Dimethoxy-4-(N)-Propylthiophenethylamine (2C-T-7)
- (xxxiii) 5-Methoxy-N, N-Diisopropyltryptamine (5-MEO-DIPT)

(c) *Schedule II*. In determining that a substance comes within this schedule, the Secretary will find: a high potential for abuse; currently accepted medical use in the United States; or currently accepted medical use with severe restrictions and abuse may lead to severe psychic or physical dependence. The following controlled substances are included in this schedule:

(1) The following substances of any quantity, except those narcotics specifically excepted or listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

- (i) Opium and opiate, and a salt, compound, derivative or preparation of opium or opiate.

(ii) A salt, compound, derivative or preparation thereof which is chemically equivalent or identical with the substances referred to in subparagraph (i) except that these substances may not include the isoquinoline alkaloids of opium.

(iii) Opium poppy and poppy straw.

(iv) Coca leaves and a salt, compound, derivative or preparation of coca leaves, and a salt, compound, derivative or preparation thereof which is chemically equivalent or identical with these substances, but may not include decocanized coca leaves or extracts of coca leaves, which extracts do not contain cocaine or ecgonine.

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(2) The following opiates, including their isomers, esters, ethers, salts and salts of isomers, esters and ethers, of any quantity, unless specifically excepted or listed in another schedule, whenever the existence of the isomers, esters, ethers and salts is possible within the specific chemical designation:

(i) Alphaprodine.

(ii) Anileridine.

(iii) Bezitramide.

(iv) Dihydrocodeine.

(v) Diphenoxylate.

(vi) Fentanyl.

(vii) Isomethadone.

(viii) Levomethorphan.

(ix) Levorphanol.

(x) Metazocine.

(xi) Methadone.

(xii) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane.

(xiii) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid.

(xiv) Pethidine.

(xv) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.

(xvi) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.

(xvii) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.

(xviii) Phenazocine.

(xix) Piminodine.

(xx) Propiram (added August 5, 1978).

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(xxi) Racemethorphan.

(xxii) Racemorphan.

(xxiii) Sufentanil.

(xxiv) Alfentanil.

(xxv) Carfentanil.

(xxvi) Levo-Alpha Acetyl-Methadol.

(3) Unless specifically excepted or unless listed in another schedule, a material, compound, mixture or preparation which contains any quantity of the following substances:

(i) Amphetamine, its salts, optical isomers and salts of its optical isomers.

(ii) Phenmetrazine and its salts.

(iii) Methylphenidate.

(iv) Methamphetamine including its salts, isomers and salts of isomers.

(v) Phenylacetone.

(vi) Nabilone.

(vii) Glutethimide.

(4) The phrase “opiates” as used in section 4 of the act (35 P. S. § 780-104) and elsewhere throughout the act may not include the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts, but does include its racemic and levorotatory forms.

(5) A material, compound, mixture or preparation, unless specifically excepted, which contains a quantity of:

- (i) Phencyclidine.
- (ii) 1-phenylcyclohexylamine.
- (iii) 1-piperidinocyclohexanecarbonitrile.
- (iv) Nabilone.

(6) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts, isomers and salts of isomers whenever the existence of the salts, isomers and salts of isomers is possible within the specific chemical designation:

(i) Amobarbital (added August 21, 1976).

(ii) Secobarbital (added August 21, 1976).

(iii) Pentobarbital (added August 21, 1976).

(d) *Schedule III*. In determining that a substance comes within this schedule, the Secretary will find: a potential for abuse less than the substances listed in Schedules I and II; well documented and currently accepted medical use in the United States; and abuse may lead to moderate or low physical dependence. The following classes of controlled substances are included in this schedule:

(1) A material, compound, mixture or preparation unless specifically excepted or unless listed in another schedule which contains any quantity of the following substances:

(i) A substance which contains any quantity of a derivative of barbituric acid, or a salt of a derivative of barbituric acid.

(ii) Chorhexadol.

(iii) Lysergic acid.

(iv) Lysergic acid amide.

(v) Methyprylon.

(vi) Sulfondiethylmethane.

(vii) Sulfonethylmethane.

(viii) Sulfonmethane.

(ix) Dronabinol—synthetic—in sesame oil and encapsulated in a soft gelatin capsule but only those drug products approved by the United States Food and Drug Administration. (rescheduled May 5, 2001)

(x) Buprenorphine (rescheduled May 22, 2004)

(2) Nalorphine.

(3) A material, compound, mixture, or preparation containing limited quantities of the following narcotic drugs, or salts thereof, unless specifically excepted or listed in other schedules.

(i) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(ii) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(iii) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinolene alkaloid of opium.

(iv) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(v) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(vi) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(vii) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 2.5 milligrams per dosage unit with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(4) Unless specifically excepted or unless listed in another schedule, a material, compound, mixture, or preparation which contains any quantity of the following substances including its salts, isomers, whether optical position or geometric, and salts of the isomers whenever the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation, Schedule III shall include the following:

(i) Benzphetamine (added August 21, 1976).

(ii) Chlorphentermine (added August 21, 1976).

(iii) Clortermine (added August 21, 1976).

(iv) [Reserved].

(v) Phendimetrazine (added August 21, 1976).

(5) A compound, mixture or preparation or a salt thereof including one or more other active medicinal ingredients which are not listed in a schedule containing the following:

(i) Amobarbital.

(ii) Secobarbital.

(iii) Pentobarbital.

(6) A suppository dosage form or a salt thereof approved by the Food and Drug Administration for marketing only as a suppository containing the following:

(i) Amobarbital.

(ii) Secobarbital.

(iii) Pentobarbital.

(7) The Secretary may, by regulation, except a compound, mixture, or preparation containing a drug or controlled substance listed in this schedule from the application of those provisions of the act covering controlled substances, if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system; provided, that the admixtures shall be included therein in the combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the substances which do have a stimulant or depressant effect on the central nervous system.

(8) The Secretary will, by regulation, exempt a nonnarcotic substance from the control under the act if the substance may, under the provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 301 et seq.), be lawfully sold over the counter without a prescription.

(e) *Schedule IV*. In determining that a substance comes within this schedule, the Secretary will find: a low potential for abuse relative to substances in Schedule III; currently accepted medical use in the United States; and limited physical or psychological dependence liability relative to the substances listed in Schedule III. The following controlled substances are included in this schedule:

(1) A material, compound, mixture or preparation, unless specifically excepted or unless listed in another schedule, which contains a quantity of the following substances:

- (i) Barbital.
- (ii) Chloral betaine.
- (iii) Chloral hydrate.
- (iv) Ethchlorvynol.
- (v) Ethinamate.
- (vi) Methohexital.
- (vii) Meprobamate.
- (viii) Methylphenobarbital.
- (ix) Paraldehyde.
- (x) Petrichloral.
- (xi) Phenobarbital.
- (xii) Chlordiazepoxide (added August 21, 1976).
- (xiii) Diazepam (added August 21, 1976).
- (xiv) Oxazepam (added August 21, 1976).
- (xv) Clorazepate (added August 21, 1976).
- (xvi) Flurazepam (added August 21, 1976).
- (xvii) Clonazepam (added August 21, 1976).
- (xviii) Mebutamate (added August 21, 1976).
- (xix) Temazepam.
- (xx) Alprazolam.
- (xxi) Halazepam.
- (xxii) Triazolam.
- (xxiii) Midazolam.

(xxiv) Quazepam.

(xxv) Estazolam. (rescheduled May 22, 2004)

(xxvi) Zolpidem (added May 22, 2004)

(2) A material, compound, mixture, or preparation which contains any quantity of the following substance including its salts, isomers whether optical position or geometric, and salts of the isomers, whenever the existence of the salts, isomers, and salts of isomers is possible:

(i) Fenfluramine (added August 21, 1976).

(ii) Pentazocine (added January 19, 1980).

(iii) Lorazepam (added January 19, 1980).

(iv) Prazepam (added January 19, 1980).

(v) Dextropropoxyphene (added January 19, 1980).

(3) Unless specifically excepted or unless listed in another schedule, a material, compound, mixture or preparation which contains any quantity of the following substances including its salts, isomers whether optical position or geometric, and salts of the isomers whenever the existence of the salts, isomers and salts of isomers is possible within the specific chemical designation:

(i) Diethylpropion (added August 21, 1976).

(ii) Phentermine (added August 21, 1976).

(iii) Pemoline (added August 21, 1976).

(iv) Mazindol.

(v) Pipradol.

(vi) SPA (1-dimethylamino-1-2-diphenylethane).

(vii) Cathine.

(viii) Fencamfamin.

(ix) Fenproporex.

(x) Mefenorex.

(xi) Butrophanol (added May 22, 2004)

(xii) Sibutramine (added May 22, 2004)

(4) The Secretary may, by regulation, except a compound, mixture, or preparation containing a drug or controlled dangerous substance listed in paragraph (1) from the application of those provisions of the act, sections 3 and 4 of the act (35 P. S. § § 780-103 and 780-104), covering controlled drugs, if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system; provided that the admixtures shall be included therein in combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the substances which do have a stimulant or depressant effect on the central nervous system.

(5) The Secretary shall by regulation exempt a nonnarcotic substance from the control under the act if the substance may, under the provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 301 *et seq.*) be lawfully sold over the counter without a prescription.

(6) A compound, mixture, or preparation which purports to have a cough suppressant effect and which contains a limited quantity of the following narcotics or their salts, and which contains in addition one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the narcotic alone shall be included under this schedule:

(i) Not more than 200 milligrams of codeine, or any of its salts, per 100 milliliters or per 100 grams and not more than 10 milligrams per dosage unit.

(ii) Not more than 100 milligrams of dihydrocodeine, or any of its salts, per 100 milliliters or per 100 grams and not more than 5 milligrams per dosage unit.

(iii) Not more than 100 milligrams of ethylmorphine, or any of its salts, per 100 milliliters or per 100 grams and not more than 5 milligrams per dosage unit.

(f) *Schedule V.* In determining that a substance comes within this schedule, the Secretary shall find: a low potential for abuse relative to the substances listed in Schedule IV; currently accepted medical use in the United States; and limited physical dependence or psychological dependence liability relative to the substances listed in Schedule IV. The following controlled substances are included in this schedule:

(1) A compound, mixture, or preparation containing limited quantities of any of the following narcotics or any of their salts, which shall include one or more nonnarcotic

active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the narcotic alone:

- (i) Not more than 200 milligrams of codeine, or any of its salts, per 100 milliliters or per 100 grams and not more than 10 milligrams per dosage unit.
 - (ii) Not more than 100 milligrams of dihydrocodeine or any of its salts, per 100 milliliters or per 100 grams and not more than 5 milligrams per dosage unit.
 - (iii) Not more than 100 milligrams of ethylmorphine, or any of its salts, per 100 milliliters or per 100 grams and not more than 5 milligrams per dosage unit.
 - (iv) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.
 - (v) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams, or not more than 5 milligrams per dosage unit.
- (2) Propylhexadrine, except when labeled for over-the-counter drug sale in conformity with 21 CFR 1308.15 (relating to schedule V).
- (3) Pyrovalerone.

Authority

The provisions of this § 25.72 amended under section 2102(g) of The Administrative Code of 1929 (71 P. S. § 532(g)); sections 3 and 4 of The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. § § 780-103 and 780-104); and section 2 of the Optometric Practice and Licensure Act (63 P. S. § 244.2).

Source

The provisions of this § 25.72 amended August 29, 1986, effective August 30, 1986, 16 Pa.B. 3209; corrected February 13, 1987, 17 Pa.B. 717; amended April 17, 1987, effective April 18, 1987, 17 Pa.B. 1567; amended May 20, 1988, effective May 21, 1988, 18 Pa.B. 2298; amended May 20, 1988, effective May 21, 1988, 18 Pa.B. 2299; corrected July 1, 1988, effective April 16, 1977, 18 Pa.B. 2905; amended February 17, 1989, effective February 18, 1989, 19 Pa.B. 638; amended March 10, 1989, effective March 11, 1989, 19 Pa.B. 997; amended November 21, 1997, effective November 22, 1997, 27 Pa.B. 6088. Immediately preceding text appears at serial pages (202567) to (202577).

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions).

§ 25.73. [Reserved].

§ 25.74. [Reserved].

§ 25.75. Paregoric.

Paregoric, otherwise known as camphorated tincture of opium, shall be included under Schedule III of the act. No pharmacist shall sell, dispense or give away a paregoric except under an oral or written prescription order of a licensed practitioner; provided, however, that this section may not be construed to apply to paregoric in the combinations, quantity, proportion or concentration as to vitiate the potential for abuse.

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions).

§ 25.76. [Reserved].**NONPROPRIETARY DRUGS****§ 25.81. Classification of nonproprietary drugs.**

Nonproprietary drugs are considered to be drugs which carry the following, or similarly worded, legend as required by the Federal Food, Drug and Cosmetic Act (21 U.S.C.A. § 301 et seq.):

- (1) “Caution: Federal law prohibits dispensing without a prescription.”
- (2) “Warning: May be habit-forming.”
- (3) “Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian.”
- (4) “Caution: New Drug—Limited by Federal law to investigational use.”

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions).

LABELING OF DRUGS, DEVICES AND COSMETICS**§ 25.91. Labeling.**

No label, labeling or advertisement of a drug, device or cosmetic shall contain the words “approved by the Pennsylvania Department of Health,” or a similar wording or reference thereto.

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions); and 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs).

§ 25.92. Control numbers in labeling of controlled substances and other drugs but excluding prescription orders.

Each manufacturer and each distributor, as to material removed by it from the manufacturer's original container and repackaged, shall insure that the label of the immediate container or the immediate container itself of a drug or controlled substance bears characteristic markings or numbers commonly referred to as "lot" or "control" numbers, to make it possible to determine the complete manufacturing history of the package of the drug.

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions); 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs); and 49 Pa. Code § 43a.9 (relating to schedule of civil penalties—pharmacists and pharmacies).

§ 25.93. Labeling—drug code number.

The label on a dispensed drug container shall include the name of the drug, using abbreviations if necessary, the quantity, and the name of the manufacturer if the drug is a "generic" drug. In those situations where a practitioner specifically indicates that the name of the drug should not appear on the label, the recognized national drug code number should be placed on the label if such a number is available for the product. When a drug is dispensed by a practitioner other than a pharmacist, the label shall also bear the name and address of the practitioner, the date dispensed, the name of the patient, and the directions for the use of the drug by the patient.

Source

The provisions of this § 25.93 amended June 24, 1977, 7 Pa.B. 1742. Immediately preceding text appears at serial page (24407).

Cross References

This section cited in 28 Pa. Code § 25.95 (relating to mandatory compliances); 28 Pa. Code § 551.3 (relating to definitions); and 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs).

§ 25.94. Expiration date of drug.

Drugs which at the time of their dispensing have full potency for less than one year, as determined by the expiration date placed on the original label by the manufacturer, may only be dispensed by a practitioner with a label that indicates said expiration date. The label should include the statement: "Do not use after (manufacturer's expiration date)" or similar wording.

Cross References

This section cited in 28 Pa. Code § 25.95 (relating to mandatory compliances); 28 Pa. Code § 551.3 (relating to definitions); 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs); and 49 Pa. Code § 43a.9 (relating to schedule of civil penalties—pharmacists and pharmacies.).

§ 25.95. Mandatory compliances.

Any practitioner who is registered or licensed by the appropriate State Board to dispense drugs to patients is required to comply with § § 25.93 and 25.94 (relating to labeling—drug code number; and expiration date of drug).

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions); and 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs).

MISBRANDING**§ 25.101. Standards.**

(a) No drug, device, or cosmetic shall be deemed misbranded under the act if such drug, device, or cosmetic would—if introduced into interstate commerce—comply with 21 U.S.C.A. § 352 and the rules, regulations, and interpretations adopted thereunder relating to misbranding, except where the act or this chapter provides otherwise.

(b) Any drug in a solid dosage form other than a nonproprietary drug that contains any quantity of caffeine, phenylpropanolamine, or pseudoephedrine or any of their salts or that contains any quantity of ingredients which have a stimulant or depressant effect on humans will be deemed misbranded—with all attendant criminal penalties found in the act—regardless of its label, labeling, or packaging if its size, shape, and color or its imprinted symbols, numbers, or letters are substantially identical in appearance to a controlled substance as displayed in the color product identification section of the current edition of the *Physician's Desk Reference*.

(c) Any solid dosage form which contains markings which bear a distinctive trademark, trade name, brand name, or manufacturer's name so as not to appear substantially identical to a controlled substance will not be in violation of this section.

Authority

The provisions of this § 25.101 issued under sections 2102(g) and 2108 of The Administrative Code of 1929 (71 P. S. § § 532(g) and 538).

Source

The provisions of this § 25.101 amended February 5, 1982, effective March 8, 1982, 12 Pa.B. 522. Immediately preceding text appears at serial page (37618).

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions).

SALVAGE OF DISTRESSED DRUGS, DEVICES AND COSMETICS**§ 25.102. Definition.**

Distressed drugs, devices and cosmetics, as used in this section, shall mean those items which have been subjected to damage by fire, flood, excessive heat or cold or other conditions which affect or may have affected their fitness for use or consumption.

§ 25.103. Distressed drugs, devices or cosmetics.

All persons knowingly having in their possession regardless of ownership, distressed drugs, devices or cosmetics, shall notify the Department of Health in order that such items may be inspected to determine their fitness for use or consumption before they are sold or distributed.

§ 25.104. Prohibitions.

No person shall sell, trade, auction or dispose of any distressed drugs, devices or cosmetics, either as owner, agent or insurer, or in any other agent capacity, when such has been declared unfit for use by the Department of Health.

§ 25.105. Normal return for credit.

Nothing in this section shall prevent the normal return for credit of drugs, devices or cosmetics to distributors or manufacturers, or to prevent the absolute destruction of unfit drugs, devices or cosmetics.

REGISTRATION**§ 25.113. Requirements for registration.**

(a) Every person who manufactures, distributes or retails drugs or devices within the Commonwealth or proposes to engage in the manufacture, distribution or retail sale of drugs or devices within the Commonwealth shall obtain annually a registration unless exempted under § 25.114 (relating to persons exempt from registration).

(b) Only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons not engaged in such activities are not required to be registered. (For

example, a stockholder or parent corporation of a corporation manufacturing drugs or devices is not required to obtain a registration.)

(c) Any manufacturer or distributor of drugs or devices not operating an establishment within the Commonwealth shall either obtain a registration or maintain with the secretary an up-to-date listing of the names and addresses of its representatives operating within the Commonwealth.

(d) Separate registration is required for each place where drugs or devices are manufactured or sold. (For example, establishments whose locations are not contiguous are separate places.)

(e) Registration as a distributor is required by every person not exempt under the act who sells or otherwise distributes any of the following:

(1) Controlled substances.

(2) Nonproprietary drugs.

(3) Devices which are labeled to require a physician's order.

(4) Any drug having a stimulant or depressant effect which is sold or otherwise distributed to one person or address in quantities of a 1000 or more doses within a given 30-day period.

(f) The sales described in subsection (e) will be considered to be for resale or redistribution and not for personal use.

Authority

The provisions of this § 25.113 issued under sections 2102(g) and 2108 of The Administrative Code of 1929 (71 P. S. § § 532(g) and 538).

Source

The provisions of this § 25.113 amended February 5, 1982, effective March 8, 1982, 12 Pa.B. 522. Immediately preceding text appears at serial page (37619).

§ 25.114. Persons exempt from registration.

The following persons are exempt from registration:

(1) An official or agency of the United States Army, Navy, Marine Corps, Air Force, Coast Guard, Veterans Administration or Public Health Service.

(2) An official employee or other civil officer of an agency of the United States or of the Commonwealth or its political subdivisions, otherwise authorized to manufacture, distribute, or retail drugs or devices in the course of his official duties or employment.

- (3) Practitioners licensed by law to prescribe, administer or dispense drugs or devices when operating under the authority of the licensure. Registration is required if practitioners engage in the manufacture or distribution of drugs or devices.
- (4) An agent or employee of any registered manufacturer, distributor or retailer of drugs or devices when acting in the regular course of his business or employment.
- (5) A common or contract carrier or warehouseman, or an employee thereof whose possession of drugs or devices is in the usual course of his business or employment.
- (6) An ultimate user who possesses drugs or devices for his own use which have been obtained in good faith from a practitioner licensed to prescribe or dispense.
- (7) Exemption from registration requirements does not relieve persons from compliance with other requirements or duties prescribed by law.
- (8) For purposes of registration, the term retailer shall not include a person who sells external application drugs or devices as an independent direct seller of the drugs or devices, unless the person's primary business is the sale of drugs or devices, or the person sells controlled substances, nonproprietary drugs, or devices required to be prescribed by a physician. For purposes of this section, the term independent direct seller means a person engaged in a trade or business who in the course of trade or business sells consumer products to a buyer not for resale—by the buyer or another person—and who does not sell from a permanently located retail business establishment, but who usually sells in the purchaser's home.

Authority

The provisions of this § 25.114 issued under section 2102(g) of The Administrative Code of 1929 (71 P. S. § 532(g)); and sections 6 and 35 of the Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. § § 780-106 and 780-135).

Source

The provisions of this § 25.114 amended April 27, 1984, effective April 28, 1984, 14 Pa.B. 1451. Immediately preceding text appears at serial page (59705).

Cross References

This section cited in 28 Pa. Code § 25.113 (relating to requirements for registration).

§ 25.115. Registration fees.

(a) *General.* This subsection lists annual registration fees, applicable late registration fees, and compulsory registration fees. All late fees shall accrue on a calendar month basis, the amount to be determined by multiplying the appropriate fee by the number of months—any portion of a month shall be considered a full month—by which the registrant is late. The late fee will commence from the month a manufacturer, distributor, or retailer has been notified they are not registered as required by law. The compulsory registration fees listed in subsection (d) are in

addition to the fees listed in subsections (b) and (c). They shall apply to any of the unregistered categories upon the filing of any lawsuit to compel compliance with the registration requirements of the act.

(b) *Fees for controlled substances and nonproprietary drugs.* The fees for manufacturing or distributing controlled substances and nonproprietary drugs are as follows:

| | | | |
|-----|--------------|-------------|-------|
| (1) | Manufacturer | —Annual Fee | \$400 |
| | | —Late Fee | \$50 |
| (2) | Distributor | —Annual Fee | \$100 |
| | | —Late Fee | \$10 |

(c) *Fees for other drugs.* The fees for manufacturing, distributing, or retailing other drugs are as follows:

| | | | |
|-----|--------------|-------------|--------|
| (1) | Manufacturer | —Annual Fee | \$100 |
| | | —Late Fee | \$25 |
| (2) | Distributor | —Annual Fee | \$25 |
| | | —Late Fee | \$5.00 |
| (3) | Retailer | —Annual Fee | \$10 |
| | | —Late Fee | \$2.00 |

(d) *Fees for devices.* The fees for manufacturing, distributing, or retailing devices for those persons not registered under subsections (b) or (c) are as follows:

| | | |
|-----|------------|-------|
| (1) | Annual Fee | \$25. |
| (2) | Late fee | \$10. |

(e) *Compulsory registration fees.* In the event that litigation is required to enforce the registration requirements of the act, the additional following compulsory registration fee shall apply for all categories of establishments listed in this section:

\$250.

(f) Only the single highest fee will apply at a given location.

(g) Such fees shall not be required of organizations which qualify for exemption under section 501(c)(3) of the Internal Revenue Code of 1954 as amended, 26 U.S.C.A. § 501(c)(3).

Authority

The provisions of this § 25.115 issued under sections 6 and 25 of the Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. § § 780-106 and 780-135); and section 2102(g) of The Administrative Code of 1929 (71 P. S. § 532(g)).

Source

The provisions of this § 25.115 amended through November 4, 1983, effective January 4, 1984, 13 Pa.B 3375. Immediately preceding text appears at serial pages (59705) and (59706).

§ 25.116. Time and method of payment; refund.

Registration and renewal fees shall be paid at the time when the application for registration or renewal is submitted for filing. Payment should be made in the form of a personal, certified or cashiers' check or money order made payable to the Commonwealth of Pennsylvania. Payments made in the form of stamps, foreign currency or third party endorsed checks will not be accepted. In the event the application is not accepted for filing or is denied, the payment shall be refunded to the applicant.

§ 25.121. Official samples for analysis.

(a) When any officer or employee of the Department collects a sample of a drug, device, or cosmetic for analysis under the act, the sample shall be designated as an official sample if records or other evidence is obtained by him or any other officer or employee of the Department indicating that the lot of the material from which such sample was collected was introduced or delivered for introduction into commerce or was offered for or otherwise held for sale. Only samples so designated by an officer or employee of the Department shall be considered to be official samples.

(b) For the purpose of determining whether or not a sample is collected for analysis, the term "analysis" includes examination and tests.

(c) The owner of a drug, device or cosmetic of which an official sample is collected is the person who owns the shipment or other lot of the article from which the sample is collected.

§ 25.122. Quantity of sample.

When an officer or employee of the Department collects an official sample of a drug, device or cosmetic for analysis under the act, he shall collect at least twice the quantity estimated by him to be sufficient for analysis, unless:

(1) The amount of the article available and reasonably accessible for sampling is less than twice the quantity so estimated.

(2) The cost of twice the quantity so estimated exceeds \$20;

(3) The article is perishable;

- (4) The sample is collected from a person named on the label of the article, or his agent, and such person is also the owner of the article;
- (5) The sample is collected from the owner of the article or his agent, and such article bears no label or, if it bears a label, no person is named thereon; or
- (6) The analysis consists principally of rapid, analytical procedures, organoleptic examination, or other field, inspection examination or tests, made at the place where the sample is collected or in a mobile or temporary laboratory. In addition to the quantity of sample prescribed above, the officer or employee shall, if practicable, collect as part of the sample such further amount of the article as he estimates to be sufficient for use as exhibits in the trial of any case that may arise under the act based on the sample.

§ 25.123. Disposition of sample.

After the Department has completed such analysis of an official sample of a drug, device or cosmetic as it determines, in the course of analysis and interpretation of analytical results, to be adequate to establish the respects, if any, in which the article is adulterated or misbranded within the meaning of the act, or otherwise subject to the prohibitions of the act, and has reserved an amount of the article it estimates to be adequate for use as exhibits in the trial of any case that may arise under the Act based on the sample, a part of the sample, if any remains available, shall be provided for analysis, upon written request, by any person named on the label of the article, or the owner thereof, or the attorney or agent of such person or owner, except under the following circumstances:

- (1) After collection, the sample or remaining part thereof has become decomposed or otherwise unfit for analysis, or
- (2) The request is not made within a reasonable time before the trial of any case under the act, based on the sample, to which such person or owner is a party. The person, owner, attorney, or agent who requests the part of sample shall specify the amount desired. A request from an owner shall be accompanied by a showing of ownership, and a request from an attorney or agent by a showing of authority from such person or owner to receive the part of sample. When two or more requests for parts of the same sample are received the requests shall be complied with in the order in which they were received so long as any part of the sample remains available therefrom.

§ 25.124. Destruction of samples.

The Department is authorized to destroy:

- (1) Any official sample when it determines that no analysis of such sample will be made.
- (2) Any official sample or part thereof when it determines that no case under the act, is or will be based on such sample.

(3) Any official sample of part thereof when the sample was the basis of a case under the act which has gone to final judgment, and when it determines that no other such case is or will be based on such sample.

(4) Any official sample or part thereof if the article is perishable.

(5) Any official sample or part thereof, when, after collection, such sample or part has become decomposed or otherwise unfit for analysis.

(6) That part of any official sample which is in excess of three times the quantity it estimates to be sufficient for analysis.

§ 25.125. Payment for samples.

Compensation for the samples taken pursuant to the provisions of the act shall be made under the following conditions:

(1) When the samples are found to be in compliance with the provisions of the act.

(2) Upon presentation of proper billing to the Department.

REPORTS OF SCHEDULE II CONTROLLED SUBSTANCES

§ 25.131. Every dispensing practitioner.

Every pharmacy shall, at the end of each month, on forms issued for this purpose by the Office of the Attorney General of the Commonwealth, provide the Office of the Attorney General of the Commonwealth with the name of each person to whom a drug or preparation, which is classified by the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C.A. § 3801 and the act as a controlled substance in Schedule II, was sold, dispensed, distributed or given away, except when used in anesthetic procedures, together with such other information as may be required, under the act.

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