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

Subch. Sec.
A. CONTROLLED SUBSTANCES, DRUGS, DEVICES AND 
COSMETICS ................................................. 25.1
B. HEARING AID SALES AND REGISTRATION ................. 25.201

Authority

The provisions of this Chapter 25 issued under the Controlled Substance, Drug, Device and Cos-
metic Act (35 P. S. §§ 780-101—780-144), unless otherwise noted.

Source

The provisions of this Chapter 25 amended July 5, 1974, effective July 6, 1974, 4 Pa.B. 1371, 
unless otherwise noted.

Cross References

This chapter cited in 28 Pa. Code § 113.15 (relating to locked storage); 28 Pa. Code § 113.23 
(relating to records); 28 Pa. Code § 561.1 (relating to drugs and biologicals); 28 Pa. Code § 561.15 
(relating to locked storage); 28 Pa. Code § 601.3 (relating to requirements for home health care agen-
cies); and 49 Pa. Code § 21.284b (relating to prescribing, administering and dispensing controlled 
substances).

Subchapter A. CONTROLLED SUBSTANCES, DRUGS, DEVICES AND 
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Cross References

This subchapter A cited in 49 Pa. Code § 27.201 (relating to electronically transmitted prescriptions).

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:


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 infra-red.
(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


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:

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(i) Orderly placement of equipment and materials to minimize any risk of mixups 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 micro-organisms 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 backsiphonage.

(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.

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.


(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.


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 mixups 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:

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§ 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 mixups, 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 followup.

(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

§ 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 mixups 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 mixups 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 mixups 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 micro-organisms 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.


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. Hand-washing 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


§ 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); 49 Pa. Code § 18.6a (relating to prescribing, dispensing and administering drugs); 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs, pharmaceutical aids and devices); 49 Pa. Code § 25.177 (relating to prescribing and dispensing drugs, pharmaceutical aids and devices); and 49 Pa. Code § 21.284a (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); 49 Pa. Code § 18.6a (relating to prescribing, dispensing and administering drugs); 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs, pharmaceutical aids and devices); 49 Pa. Code § 25.177 (relating to prescribing and dispensing drugs, pharmaceutical aids and devices); and 49 Pa. Code § 21.284a (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.
(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:

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


Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions); 49 Pa. Code § 18.6a (relating to prescribing, dispensing and administering drugs); 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs, pharmaceutical aids and devices); 49 Pa. Code § 25.177 (relating to prescribing and dispensing drugs, pharmaceutical aids and devices); and 49 Pa. Code § 21.284a (relating to prescribing and dispensing drugs).

§ 25.54. Posting notice.

(a) Every pharmacy shall post a sign which shall read as follows: “PENN-SYLVANIA 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 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); 49 Pa. Code § 18.6a (relating to prescribing, dispensing and administering drugs); 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs, pharmaceutical aids and devices); 49 Pa. Code § 25.177 (relating to prescribing and dispensing drugs, pharmaceutical aids and devices); and 49 Pa. Code § 21.284a (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 the Pennsylvania Department of Health Formulary. 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 the Formulary 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 the Formulary developed by the Department and found at § 25.58 (relating to generically equivalent drug products).

(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).

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(366329) No. 464 Jul. 13
Cross References
This section cited in 28 Pa. Code § 551.3 (relating to definitions); 49 Pa. Code § 18.6a (relating to prescribing, dispensing and administering drugs); 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs); 49 Pa. Code § 25.177 (relating to prescribing and dispensing drugs, pharmaceutical aids and devices); 49 Pa. Code § 21.284a (relating to prescribing and dispensing drugs); and 49 Pa. Code § 43b.7 (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.

(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

Cross References
This section cited in 28 Pa. Code § 551.3 (relating to definitions); 49 Pa. Code § 18.6a (relating to prescribing, dispensing and administering drugs); 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs); 49 Pa. Code § 25.177 (relating to prescribing and dispensing drugs, pharmaceutical aids and devices) and 49 Pa. Code § 43b.7 (relating to schedule of civil penalties—pharmacists and pharmacies).

§ 25.57. Nonprescription orders.

A controlled substance listed in Schedules III, IV, or 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**


**Cross References**

This section cited in 28 Pa. Code § 551.3 (relating to definitions); 49 Pa. Code § 18.6a (relating to prescribing, dispensing and administering drugs); 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs); 49 Pa. Code § 21.284a (relating to prescribing and dispensing drugs); and 49 Pa. Code § 25.177 (relating to prescribing drugs, pharmaceutical aids and devices).

### § 25.58. Generically equivalent drug products.

The following is a formulary of generically equivalent drug products and the names of their corresponding distributors and manufacturers:

#### ACETAMINOPHEN

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<th>Distributed By:</th>
<th>Manufactured By:</th>
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<td>Danbury Pharmacal</td>
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### ACETAMINOPHEN

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### ACETAMINOPHEN/BUTALBITAL/CAFFEINE

| Butalbital, APAP and Caffeine | Halsey Drug | Halsey Drug |
| Butalbital, APAP and Caffeine | United Research Labs | Halsey Drug |
| Butalbital, Acetaminophen and Caffeine | Geneva Generics | Halsey Drug |

### ACETAMINOPHEN/CHLORPHENIRAMINE MALEATE/PSEUDOEPHEDRINE HCL

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### ACETAMINOPHEN/CODEINE PHOSPHATE Tablets

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Copyright © 1995 Commonwealth of Pennsylvania
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### ACETAMINOPHEN/OXYCODONE HCL Tablets

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### ACETIC ACID - NONAQUEOUS

| Acetic Acid Thames Pharmacal          | Thames Pharmacal |
| Acetic Acid Rugby Labs                | National Pharmaceutical |
| Acetosol Qualitest                    | National Pharmaceutical |
| Acetasol Barre Drug                   | National Pharmaceutical |
| Bio-Sol Biscraft Labs                 | National Pharmaceutical |
| Acetasol Goldline Labs                | Barre National |

### ACETIC ACID - NONAQUEOUS/HYDROCORTISONE

| Acetasol HC Barre Drug                | National Pharmaceutical |
| Acetic Acid w/ Hydro Rugby Labs       | National Pharmaceutical |
| Bio-Sol HC Biscraft Labs              | National Pharmaceutical |
| Hydrocortisone/Acetic Acid Thames Pharmacal | Thames Pharmacal |
| Acetasol HC Goldline Labs             | Barre National |

### ACETOHEXAMIDE

| Acetohexamide Pharmaceutical Basics Pharmaceutical Basics |
| Acetohexamide Best Generics Pharmacetical Basics |
| Acetohexamide Barr Labs Pharmaceuticals |
| Acetohexamide Danbury Pharmacal Pharmaceuticals |

### ALLANTOIN/AMINACRINE HCL/SULFANILAMIDE

#### Vaginal Cream

| Vaginal Sulf a Cream G & W Labs | Clay-Park Labs |
| Vaginal Sulf a Cream United Research Labs | Clay-Park Labs |
| Vaginal Sulf a Cream Interstate Drug Exchange | Clay-Park Labs |
| Vaginal Sulf a Cream Rugby Labs | Clay-Park Labs |
| Vaginal Sulf a Cream J J Balan | Clay-Park Labs |
| Vaginal Sulf a Cream Henry Schein | Clay-Park Labs |
| Vaginal Sulf a Cream Bioline Labs | Clay-Park Labs |
| Vaginal Sulf a Cream H L Moore Drug Exchange | Clay-Park Labs |
| Vaginal Sulf a Cream Cooper | Clay-Park Labs |
| Vaginal Sulf a Cream Goldline Labs | Clay-Park Labs |
| Vaginal Sulf a Cream Clarity Labs | Clay-Park Labs |
| Vaginal Sulf a Cream Qualitest | Clay-Park Labs |
| Vaginal Sulf a Cream Clay-Park Labs | Clay-Park Labs |
| Par Cream Parmed Pharmaceuticals | Clay-Park Labs |

### ALLANTOIN/AMINACRINE HCL/SULFANILAMIDE

#### Vaginal Suppositories

| AAS Rugby Labs | Burroughs Wellcome |
| CPB Crown Drug | Burroughs Wellcome |
| Asulam Cooper | Burroughs Wellcome |

### ALLOPURINOL

#### Tablets

| Zyloprim Burroughs Wellcome | Burroughs Wellcome |
| Loprin Boots Labs | Boots Labs |
| Allopurinol Rugby Labs | Boots Labs |
| Allopurinol Goldline Labs | Boots Labs |
| Allopurinol Parpac Pharmaceutical | Boots Labs |
| Allopurinol Geneva Generics | Boots Labs |
| Allopurinol Qualitest | Boots Labs |
| Allopurinol Parpac Pharmaceutical | Boots Labs |

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## ALLOPURINOL

**Tablets—Continued**

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## ALUMINUM ACETATE

**Topical Solution**

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## ALUMINUM HYDROXIDE

**Suspension**

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## ALUMINUM HYDROXIDE/MAGNESIUM HYDROXIDE

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## ALUMINUM HYDROXIDE/MAGNESIUM HYDROXIDE/SIMETHICONE

**Suspension**

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### AMINOPHYLLINE Tablets

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### AMITRIPTYLINE HCL

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### AMITRIPTYLINE HCL/CHLORDIAZEPoxide

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### AMITRIPTYLINE HCL/CHLORDIAZEPoxide

#### Tablets—Continued

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### AMITRIPTYLINE HCL/PERPHEnazine

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### AMMONIUM CHLORIDE/CHLORPHENIRAMine MALEATE/HYDROCODONE BITARTRate/PHENINDAMINE TARTRate/PHENYLEPHRINE HCL/PYRILAMINE MALEATE

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(202443) No. 253 Dec. 95
### AMOBARBITAL SODIUM

**Capsules**

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### AMOXICILLIN

**Capsules**

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**For Oral Suspension**

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### AMPICILLIN

**Capsules**

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**AMPICILLIN Oral Suspension**

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<td>H L Moore Drug Exchange</td>
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</tr>
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<td>Henry Schein</td>
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<td>Biscraft Labs</td>
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### AMPICILLIN

**Oral Suspension—Continued**

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<td>Glenlaw Labs</td>
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<td>Halsey Drug</td>
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<td>Harrel Pharmaceutical</td>
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<td>Michigan Pharmaceutical</td>
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<td>Murray Drug</td>
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<td>Pharmacist Choice</td>
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### AMPICILLIN SODIUM

**Injection**

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<td>Princepten</td>
<td>E R Squibb &amp; Sons</td>
<td>E R Squibb &amp; Sons</td>
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<td>SK-Ampicillin-N</td>
<td>Smith, Kline &amp; French Labs</td>
<td>Bristol Labs</td>
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### AMPICILLIN/PROBENECID

**For Oral Suspension**

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### ANISOTROPINE METHYL BromIDE

**Tablets**

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<td>Anisotropine Methylbromide</td>
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<td>Anisotropine Methylbromide</td>
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### ANTIZOLINE HCL

**Tablets**

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### ANTIZOLINE PHOSPHATE/NAPHAZOLINE HCL

**Ophthalmic Solution**

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<td>Naphazoline HCl/Antazoline Phosphate</td>
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### ANTIPYRINE/BENZOCAINE

**Otic Solution**

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<td>Auroto</td>
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<td>National Pharmaceutical</td>
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<td>Aronoid</td>
<td>Vanguard Labs</td>
<td>National Pharmaceutical</td>
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<tr>
<td>Aura Queen</td>
<td>Queen City Pharmaceutical</td>
<td>National Pharmaceutical</td>
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<tr>
<td>Ear Drops</td>
<td>Murray Drug</td>
<td>National Pharmaceutical</td>
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<td>Ear Drops</td>
<td>Henry Schein</td>
<td>National Pharmaceutical</td>
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<td>A/B Otic Drops</td>
<td>Clay-Park Labs</td>
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<td>Allergen Ear Drops</td>
<td>Goldline Labs</td>
<td>Clay-Park Labs</td>
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<td>Aurafair</td>
<td>Pharmasour</td>
<td>Pharmasour</td>
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<td>RX-Otic</td>
<td>Thames Pharmacal</td>
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### ASCORBIC ACID

**Injection**

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<th>Distributed By</th>
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<td>Ascorbic Acid</td>
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<tr>
<td>Ascorbic Acid</td>
<td>Schein Pharmaceutical</td>
<td>Steris Labs</td>
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<td>Ascorbic Acid</td>
<td>H L Moore Drug Exchange</td>
<td>Steris Labs</td>
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<tr>
<td>Ascorbic Acid</td>
<td>Interstate Drug Exchange</td>
<td>Steris Labs</td>
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## ASCORBIC ACID

### Syrup

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<td>National Pharmaceutical</td>
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<tr>
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<td>Rugby Labs</td>
<td>National Pharmaceutical</td>
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### Tablets

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<td>Ascorbic Acid</td>
<td>Richlyn Labs</td>
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<td>Ascorbic Acid</td>
<td>ICN Pharmaceuticals</td>
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<td>Ascorbic Acid</td>
<td>United Research Labs</td>
<td>Heather Drug</td>
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<td>Ascorbic Acid</td>
<td>Rugby Labs</td>
<td>Chelsea Labs</td>
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<td>Ascorbic Acid</td>
<td>West-ward</td>
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<td>Ascorbic Acid</td>
<td>McKesson Labs</td>
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### ASCORBIC ACID/FERROUS FUMARATE

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<td>Vitron-C</td>
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### ASCORBIC ACID/SODIUM ASCORBATE

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<td>Kalpharma</td>
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<td>Rugby Labs</td>
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### ASCORBIC ACID/LIVER/VITAMIN B COMPLEX

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<td>A H Robins</td>
<td>A H Robins</td>
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### ASCORBIC ACID/VITAMIN B COMPLEX

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<td>A H Robins</td>
<td>A H Robins</td>
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<td>Vitamin B Complex plus C</td>
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<tr>
<td>Vitamin B w/Vitamin C</td>
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<td>Mylan Pharmaceuticals</td>
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## ASPIRIN

### Capsules

<table>
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<td>Aspturn</td>
<td>G &amp; W Labs</td>
<td>G &amp; W Labs</td>
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<td>Aspturn</td>
<td>West-ward</td>
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<td>Aspturn</td>
<td>Rugby Labs</td>
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<td>United Research Labs</td>
<td>G &amp; W Labs</td>
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### Suppositories

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<td>E R Squibb &amp; Sons</td>
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### Tablets

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### ASPIRIN/BUTALBITAL/CAFFEINE

#### Capsules

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<td>Rugby Labs</td>
<td>Chelsea Labs</td>
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<tr>
<td>Butal Compound</td>
<td>Cord Labs</td>
<td>Cord Labs</td>
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#### Tablets

<table>
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<tbody>
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<td>Rugby Labs</td>
<td>Chelsea Labs</td>
</tr>
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<td>Purepac Pharmaceutical</td>
<td>Purepac Pharmaceutical</td>
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<tr>
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<td>Boots Labs</td>
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<td>Halsey Drug</td>
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### ASPIRIN/CAFFEINE/ORPHENADRINE CITRATE

#### Tablets

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### ASPIRIN/CAFFEINE/PROPOXYPHENE HCL

#### Capsules

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Copyright © 1995 Commonwealth of Pennsylvania
### ASPIRIN/CARISOPRODOL

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### ATROPINE SULFATE

#### Ophthalmic Ointment

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## ATROPINE SULFATE
### Ophthalmic Solution

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## ATROPINE SULFATE/DIPHENOXYLATE HCL
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## ATROPINE SULFATE/DIPHENOXYLATE HCL
### Tablets

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### ATROPINE SULFATE/DIPHENOXYLATE HCL

#### Tablets—Continued

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### ATROPINE SULFATE/MORPHINE SULFATE

#### Injection

| Morphine Sulfate/Atropine Sulfate         | Beecham Labs        | Beecham Labs        |

#### BACTRACIN

#### Injection

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#### Ointment

| Bactracin                                | Rugby Labs          | Naska Pharmacal     |

#### Ophthalmic Ointment

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### BACTRACIN/NEOMYCIN SULFATE/POLYMYXIN-B SULFATE

#### Ointment

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**BACITRACIN ZINC/NEOMYCIN SULFATE/POLYMYXIN-B SULFATE Ophthalmic Ointment**

| Neosporin                             | Burroughs Wellcome        | Burroughs Wellcome |
| Neosporin                             | Pharmafair                | Pharmafair         |

**BACITRACIN ZINC/NEOMYCIN SULFATE/POLYMYXIN-B SULFATE Ophthalmic Ointment**

| Neosporin                             | Burroughs Wellcome        | Burroughs Wellcome |
| Neosporin                             | Pharmafair                | Pharmafair         |

**BACITRACIN ZINC/POLYMYXIN-B SULFATE Ointment**

| Bacitracin/Polymyxin                  | Rugby Labs                | Naska Pharmacal    |

**BACITRACIN ZINC/POLYMYXIN-B SULFATE Ophthalmic Ointment**

| Bacitracin/Polymyxin                  | Rugby Labs                | Naska Pharmacal    |

**BACLOFEN Tablets**

| Baclofen                              | Pharmaceutical Basics     | Pharmaceutical Basics |
| Baclofen                              | Zenith Labs               | Zenith Labs         |

**BALSAM of PERU/CASTOR OIL/TRYPsin Aerosol**

| Granulderm                            | Copley Pharmaceutical     | Copley Pharmaceutical |

**BELLADONNA ALKALOIDS/KAOLIN/PECTIN Suspension**

| Donnagel                              | A H Robins                | A H Robins          |
| Kepectolin Gel/Belladonna             | Barre Drug                | National Pharmaceutical |
| Kepectolin Gel/Belladonna             | Murray Drug               | National Pharmaceutical |
| Kepectolin Gel/Belladonna             | Henry Schein              | National Pharmaceutical |
| Kepectolin Gel/Belladonna             | Orbit Pharmaceutical      | National Pharmaceutical |
| Kepectolin w/Belladonna               | Parque Pharmaceutical      | National Pharmaceutical |
| Quiagel                               | Rugby Labs                | Naska Pharmacal     |
| Quiagel                               | Rugby Labs                | Naska Pharmacal     |

**BELLADONNA ALKALOIDS/KAOLIN/PECTIN POWDERED OPIUM Suspension**

| Donnagel-PG                           | A H Robins                | A H Robins          |
| Kepectolin PG                         | Barre Drug                | National Pharmaceutical |
| Kepectolin PG                         | Cooper                    | National Pharmaceutical |
| Kepectolin PG                         | Murray Drug               | National Pharmaceutical |
| Kepectolin PG                         | United Research Labs      | National Pharmaceutical |
### BELLADONNA ALKALOIDS/KAOLIN/PECTIN/POWDERED OPIUM Suspension—Continued

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### BELLADONNA ALKALOIDS/PHENOBARBITAL Capsules

| Donnatal                | A H Robbins    | A H Robbins |

### BELLADONNA ALKALOIDS/PHENOBARBITAL Elixir

| Donnatal                | A H Robbins    | A H Robbins |

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### BISACODYL

Enteric Coated Tablets

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### BORIC ACID

Ointment

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### BROMODIPHENHYDRAMINE HCL/CODEINE PHOSPHATE

Syrup

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<td>Bromotuss with Codeine</td>
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<td>Bromphen Cough Syrup</td>
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### BROMPHENIRAMINE MALEATE

Elixir

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### BROMPHENIRAMINE MALEATE

Injection

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### BROMPHENIRAMINE MALEATE

Tablets

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### BROMPHENIRAMINE MALEATE/CODEINE PHOSPHATE/PHENYLPROPANOLAMINE HCL

**Syrup**

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### BROMPHENIRAMINE MALEATE/DEXTROMETHORPHAN HBR/PSEUDOEPHEDRINE HCL

**Syrup**

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### BROMPHENIRAMINE MALEATE/PHENYLEPHRINE HCL/PHENYLPROPANOLAMINE HCL

**Elixir**

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### BROMPHENIRAMINE MALEATE/PHENYLPROPANOLAMINE HCL

**Elixir**

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### BUTABARBITAL SODIUM

**Elixir**

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### BUTABARBITAL SODIUM

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### CAFFEINE/ERGOTAMINE TARTRATE

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### CARBACHOL

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### CARISOPRODOL

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### CASANTHRANOL/DOCUSATE POTASSIUM

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### CASANTHRANOL/DOCUSATE SODIUM

#### Capsules

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(202459) No. 253 Dec. 95
### CASANTHRANOL/DOCUSATE SODIUM

#### Capsules—Continued

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#### CASANTHRANOL/DOCUSATE SODIUM

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#### CASCARA SAGRADA EXTRACT

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#### CEPHALEXIN

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**Capsules**

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### CEPHRADINE

**Capsules**

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### CHLORAL HYDRATE

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### CHLORAL HYDRATE

#### Syrup

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### CHLORAMPHENICOL

#### Capsules

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### CHLORDIAZEPoxide HCl

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## CHLORDIAZEPoxide HCl

**Capsules—Continued**

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### CHLOROQUINE PHOSPHATE

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- Chloroquine Phosphate: Bioline Labs
- Chloroquine Phosphate: Consolidated Midland
- Chloroquine Phosphate: Interstate Drug Exchange
- Chloroquine Phosphate: H L Moore Drug Exchange
- Chloroquine Phosphate: Rugby Labs
- Chloroquine Phosphate: Penta Products
- Chloroquine Phosphate: Henry Schein
- Chloroquine Phosphate: Whitworth Pharmaceuticals
- Chloroquine Phosphate: West-ward
- Chloroquine Phosphate: H L Moore Drug Exchange
- Chloroquine Phosphate: Henry Schein
- Chloroquine Phosphate: Geneva Generics
- Chloroquine Phosphate: United Research Labs
- Chloroquine Phosphate: Bisucria Labs
- Chloroquine Phosphate: Intersan Drug Exchange
- Chloroquine Phosphate: Danbury Pharmacal
- Chloroquine Phosphate: Geneva Generics
- Chloroquine Phosphate: Goldline Labs

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### CHLOROTHIAZIDE

**Tablets**

- Dural: Merck, Sharpe & Dohme
- Chlorothiazide: Merck, Sharpe & Dohme
- Chlorothiazide: Bolar Pharmaceutical
- Chlorothiazide: Thrufr Drug
- Chlorothiazide: Rugby Labs
- Chlorothiazide: Purpue Pharmaceutical
- Chlorothiazide: Geneva Generics
- Chlorothiazide: Bell Pharmacal
- Chlorothiazide: Parmed Pharmaceuticals
- Chlorothiazide: E R Squibb & Sons
- Chlorothiazide: Lederle Labs
- Chlorothiazide: United Research Labs
- Chlorothiazide: Smith, Kline & French Labs
- Chlorothiazide: Mylan Pharmaceuticals
- Chlorothiazide: Rugby Labs
- Chlorothiazide: Purpue Pharmaceutical
- Chlorothiazide: Bioline Labs
- Chlorothiazide: H L Moore Drug Exchange

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## CHLOROTHIAZIDE

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## CHLORPHENIRAMINE MALEATE

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## CHLORPHENIRAMINE MALEATE/CODEINE PHOSPHATE/PHENYLEPHRINE HCL/POTASSIUM IODIDE

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### CHLORPHENIRAMINE MALEATE/CODEINE PHOSPHATE/PSEUDOEPHEDRINE HCL

**Elixir**
- **Dihistine DH**
  - Barre Drug
  - National Pharmaceutical
- **Dihistine DH**
  - Bell Pharmaceutical
  - National Pharmaceutical
- **Dihistine DH**
  - Cooper
  - National Pharmaceutical
- **Dihistine DH**
  - Geneva Generics
  - National Pharmaceutical
- **Dihistine DH**
  - H L, Morse Drug Exchange
  - National Pharmaceutical
- **Dihistine DH**
  - Bioline Labs
  - National Pharmaceutical
- **Dihistine DH**
  - Goldline Labs
  - National Pharmaceutical
- **Acanhistine DH**
  - ACA
  - National Pharmaceutical
- **Decoconant Antihistamine**
  - Henry Schein
  - National Pharmaceutical
- **Phenhist DH w/Codeine**
  - Rugby Labs
  - National Pharmaceutical
- **WW-Histine DH**
  - Whitworth Pharmaceuticals
  - National Pharmaceutical
- **Novagest DH**
  - Major Pharmaceutical Corp
  - National Pharmaceutical
- **Phenyhistine DH**
  - Life Labs
  - Life Labs
- **Myhistine DH**
  - My-K Labs
  - My-K Labs
- **Novadyne-DH**
  - LuChem Pharmaceuticals
  - LuChem Pharmaceuticals
- **Decohistine DH**
  - Pharmaceutical Basics
  - Pharmaceutical Basics

### CHLORPHENIRAMINE MALEATE/DEXTROMETHORPHAN HBR/PHENYLPROPANOLAMINE HCL

**Syrup**
- **Myminicol**
  - My-K Labs
  - My-K Labs
- **Myminicol**
  - Pharmaceutical Basics
  - Pharmaceutical Basics

### CHLORPHENIRAMINE MALEATE/PHENYLEPHRINE HCL

**Elixir**
- **Dihistine**
  - Barre Drug
  - National Pharmaceutical
- **Myhistine**
  - My-K Labs
  - My-K Labs

**Syrup**
- **Decohist**
  - Barre Drug
  - National Pharmaceutical
- **Decohist**
  - Henry Schein
  - National Pharmaceutical
- **Decohist**
  - Murray Drug
  - National Pharmaceutical
- **Decohist**
  - Rugby Labs
  - National Pharmaceutical
- **Run-Tuss Plain**
  - LuChem Pharmaceuticals
  - LuChem Pharmaceuticals

### CHLORPHENIRAMINE MALEATE/PHENYLEPHRINE HCL, PHENYLPROPANOLAMINE HCL/PHENYLTOLOXAMINE CITRATE

**Drops**
- **Naldecon**
  - Bristol Labs
  - Bristol Labs

**Syrup**
- **Naldecon**
  - Bristol Labs
  - Bristol Labs
- **Naldecrate**
  - Barre Drug
  - National Pharmaceutical
- **Naldecrate**
  - Bell Pharmaceutical
  - National Pharmaceutical
- **Naldecrate**
  - United Research Labs
  - National Pharmaceutical
- **Naldecrate**
  - Qualitest
  - National Pharmaceutical
- **Naldecrate**
  - Harber Pharmaceutical
  - National Pharmaceutical
- **Naldec**
  - Murray Drug
  - National Pharmaceutical
- **Naldec**
  - Bioline Labs
  - National Pharmaceutical
- **Naldec**
  - Richie Pharmacal
  - National Pharmaceutical
- **Tri-Phen Chlor**
  - Rugby Labs
  - National Pharmaceutical
- **Quadrahist**
  - Henry Schein
  - National Pharmaceutical
- **Nalgex**
  - Major Pharmaceutical Corp
  - National Pharmaceutical
- **New Decongest**
  - Goldline Labs
  - Barre-National
- **Phentex Compound**
  - My-K Labs
  - My-K Labs
- **Tri-Phen-Chlor**
  - Rugby Labs
  - Naska Pharmacal

### CHLORPHENIRAMINE MALEATE/PHENYLPROPANOLAMINE HCL

**Syrup**
- **Myminic**
  - My-K Labs
  - My-K Labs

### CHLORPROMAZINE HCL

**Injection**
- **Thorazine**
  - Smith, Kline & French
  - Smith, Kline & French
- **Chlorpromazine HCl**
  - Steris Labs
  - Steris Labs
- **Chlorpromazine HCl**
  - Bioline Labs
  - Steris Labs
- **Chlorpromazine HCl**
  - Interstate Drug Exchange
  - Steris Labs

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### CHLORPROMAZINE HCL

#### Injection—Continued

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### CHLORPROPAMIDE

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### CHLORTHALIDONE Tablets

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## CHLORTHALIDONE

**Brand Name/Generic Name Distributed By:**

- Chlorthalidone
  - Warner Chilcott Labs
  - Parke-Davis

**Manufactured By:**

- Warner Chilcott Labs
- Parke-Davis

### CHLORTHALIDONE/CLONIDINE HCL

**Tablets**

- **Clonidine HCl and Chlorthalidone**
  - Mylan Pharmaceuticals
  - Geneva Generics
  - Major Pharmaceutical Corp
  - H L Moore Drug Exchange
  - Bionine Labs
  - Goldline Labs
  - Rugby Labs
  - Parmed Pharmaceuticals
  - Lederle Labs
  - Texas Drug Reps
  - Warner Chilcott Labs
  - Lemmon Co

**Manufactured By:**

- Mylan Pharmaceuticals
- Geneva Generics
- Mylan Pharmaceuticals
- Mylan Pharmaceuticals
- Mylan Pharmaceuticals
- Mylan Pharmaceuticals
- Par Pharmaceutical

### CHLORZOXAZONE

**Tablets**

- Chlorzoxazone
  - Par Pharmaceutical
  - Danbury Pharmacal
  - Lemmon Co
  - Goldline Labs
  - Pioneer Pharmaceuticals

**Manufactured By:**

- Par Pharmaceutical
- Danbury Pharmacal
- Lemonon Co
- Par Pharmaceutical

### CHYMOTRYPSIN

**Ophthalmic Solution**

- Zolyse
  - Alcon Labs

**Manufactured By:**

- Alcon Labs

### CLINDAMYCIN PHOSPHATE

**Injection**

- Clindamycin Phosphate
  - Lemmon Co

**Manufactured By:**

- Lemmon Co

### CLOFIBRATE

**Capsules**

- Clofibrate
  - Chase Labs
  - Parex Pharmaceutical
  - Matrix Pharmaceutical
  - Best Generics
  - Rugby Labs
  - Geneva Generics

**Manufactured By:**

- Chase Labs
- Chase Labs
- Chase Labs
- Pharmcups

### CLOMIPHENE CITRATE

**Tablets**

- Serophene
  - Ikapharm

**Manufactured By:**

- Ikapharm

### CLONIDINE HCL

**Tablets**

- Clonidine HCl
  - Par Pharmaceutical
  - Qualitest
  - Mutual Pharmaceutical
  - Interpharm
  - Duramed Pharmaceuticals
  - Danbury Pharmacal
  - Lederle Labs
  - Parmed Pharmaceuticals
  - Warner Chilcott Labs
  - Lemmon Co
  - Goldline Labs

**Manufactured By:**

- Par Pharmaceutical
- Par Pharmaceutical
- Par Pharmaceutical
- Interpharm
- Duramed Pharmaceuticals
- Danbury Pharmacal
- Biocraft Labs
- Par Pharmaceutical

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Copyright © 1995 Commonwealth of Pennsylvania
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### CLORAZEPATE DIPOTASSIUM

#### Capsules

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#### Tablets

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### CLOTRIMAZOLE

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### CLOTRIMAZOLE

**Vaginal Tablets**

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### COAL TAR SOLUTION/SALICYLIC ACID/SULFUR

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### CODEINE PHOSPHATE

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### CODEINE PHOSPHATE/GUAIFENESIN

**Syrup**

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## CODEINE PHOSPHATE/GUAIFENESIN/PSEUDOEPHEDRINE HCL

### Elixir

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## CODEINE PHOSPHATE/GUAIFENESIN/PSEUDOEPHEDRINE HCL

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## CODEINE PHOSPHATE/IODINATED GLYCEROL

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## CODEINE PHOSPHATE/PHENYLEPHRINE HCL/PROMETHAZINE HCL

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### CODEINE PHOSPHATE/PSEUDOEPHEDRINE HCL

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### CYANOCOBALAMIN

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**CYANOCOBALAMIN Tablets**

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(202473) No. 253 Dec. 95

25-65
### CYCLOBENZAPRINE HCL

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### CYPROHEPTADINE HCL

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| Dehydrocholic Acid | Richlyn Labs | Richlyn Labs |

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| Dexamethasone | Steris Labs | Steris Labs |

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### DEXAMETHASONE/NEOMYCIN SULFATE/POLYMIXIN-B SULFATE

**Ophthalmic Suspension**

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### DEXAMETHASONE SODIUM PHOSPHATE

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### DEXAMETHASONE SODIUM PHOSPHATE

**Ophthalmic Ointment**

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### DEXAMETHASONE SODIUM PHOSPHATE/NEOMYCIN SULFATE

**Ophthalmic Solution**

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## Dexamethasone Sodium Phosphate/Neomycin Sulfate

### Ophthalmic Solution—Continued

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### DEXPANThenol

#### Injection

| Steris Labs | Steris Labs |

### Dextroamphetamine Sulfate

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### DEXTRANPHEtamine Sulfate

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### DEXTROMETHORPHAN HBR

#### Syrup

| My-K Labs | My-K Labs |

### DEXTROMETHORPHAN HBR/Guaifenesin

#### Syrup

| A H Robins | A H Robins |

### DEXTROMETHORPHAN HBR/Guaifenesin/Phenylpropanolamine HCL

#### Syrup

| A H Robins | A H Robins |

### DEXTROMETHORPHAN HBR/Guaifenesin/Pseudoephedrine HCL

#### Capsules

| A H Robins | A H Robins |

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### DEXTROMETHORPHAN HBR/GUAIFENESIN/PSEUDOEPHEDRINE HCL

**Brand Name/Generic Name Distributed By:**
- Dimacol

**Manufactured By:**
- A H Robins

#### DEXTROMETHORPHAN HBR/IODINATED GLYCEROL

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#### DEXTROMETHORPHAN HBR/PROMETHAZINE HCL

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#### DEXTROMETHORPHAN HBR/TERPIN HYDRATE

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#### DIAZEPAM

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### DICLOXACILLIN SODIUM

**Capsules**

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### DICYCLOMINE HCL

**Capsules**

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## Dimenhydrinate

### Elixir

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### DIPHENHYDRAMINE HCL

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### DIPYRIDAMOLE

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### DOXEPIN HCL

#### Capsules

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## DOXEPIN HCL

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## DOXYCYCLINE

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DOXYCYCLINE HYCLATE
Capsules—Continued

Brand Name/Generic Name Distributed By: Manufactured By:
Doxycycline Hyclate Goldline Labs Superpharm Corp
Doxycycline Hyclate Zenith Labs Zenith Labs
Doxycycline Hyclate H L Moore Drug Exchange Zenith Labs
Doxycycline Hyclate Vitamine Pharmaceutical
Doxycycline Hyclate Private Formulations Mutual Pharmaceutical
Doxycycline Hyclate Mutual Pharmaceutical
Doxycycline Hyclate United Research Labs Mutual Pharmaceutical
Doxycycline Hyclate Halsey Drug Halsey Drug
Doxycycline Hyclate Rondex Labs Kalipharma
Doxycycline Hyclate Heath Drug Heath Labs
Doxycycline Hyclate Interstate Drug Exchange Zenith Labs
Doxycycline Hyclate Major Pharmaceutical Corp Par Pharmaceutical
Doxycycline Hyclate Matroc Pharmaceutical Mutual Pharmaceutical
Doxycycline Hyclate Geneico Mutual Pharmaceutical
Doxycycline Hyclate Dixon-Shane Mutual Pharmaceutical
Doxycycline Hyclate Best Generics Mutual Pharmaceutical
Doxycycline Hyclate Towne, Paulsen Mutual Pharmaceutical
Doxycycline Hyclate J J Balan Mutual Pharmaceutical
Doxycycline Hyclate Warner Chilcott Labs Mutual Pharmaceutical
Doxycycline Hyclate Lemmon Co Par Pharmaceutical
Doxycycline Hyclate Parke-Davis Parke-Davis
Doxycycline Hyclate West-ward West-ward
Doxycycline Hyclate H L Moore Drug Exchange West-ward
Doxycycline Hyclate Dunhill Pharmaceuticals West-ward

DOXYCYCLINE HYCLATE
Tablets

Brand Name/Generic Name Distributed By: Manufactured By:
Doxycycline Hyclate Rachelle Labs Rachelle Labs
Doxycycline Hyclate Vanguard Labs Rachelle Labs
Doxycycline Hyclate United Research Labs Rachelle Labs
Doxycycline Hyclate Geneva Generics Rachelle Labs
Doxycycline Hyclate Henry Schein Rachelle Labs
Doxycycline Hyclate Rugby Labs Rachelle Labs
Doxycycline Hyclate Richic Pharmacal Rachelle Labs
Doxycycline Hyclate Regal Labs Rachelle Labs
Doxycycline Hyclate Beline Labs Rachelle Labs
Doxycycline Hyclate Parmed Pharmaceuticals Rachelle Labs
Doxycycline Hyclate Murray Drug Rachelle Labs
Doxycycline Hyclate Cooper Rachelle Labs
Doxycycline Hyclate Harber Pharmaceutical Rachelle Labs
Doxycycline Hyclate Major Pharmaceutical Corp Rachelle Labs
Doxycycline Hyclate Towne, Paulsen Rachelle Labs
Doxycycline Hyclate Unit Dose Labs Rachelle Labs
Doxycycline Hyclate Barr Labs Bar Labs
Doxycycline Hyclate Danbury Pharmacal Danbury Pharmacal
Doxycycline Hyclate Parmed Pharmaceuticals Danbury Pharmacal
Doxycycline Hyclate Geneva Generics Danbury Pharmacal
Doxycycline Hyclate United Research Labs Danbury Pharmacal
Doxycycline Hyclate Quilltest Danbury Pharmacal
Doxycycline Hyclate Lemmon Co Danbury Pharmacal
Doxycycline Hyclate Mylan Pharmaceuticals Mylan Pharmaceuticals
Doxycycline Hyclate United Research Labs Chelsea Labs
Doxycycline Hyclate Rugby Labs Chelsea Labs
Doxycycline Hyclate Heath Drug Heath Drug
Doxycycline Hyclate Zenith Labs Zenith Labs
Doxycycline Hyclate H L Moore Drug Exchange Zenith Labs
Doxycycline Hyclate Regal Labs Zenith Labs
Doxycycline Hyclate Towne, Paulsen Zenith Labs
Doxycycline Hyclate Puppar Pharmaceutical Mutual Pharmaceutical
Doxycycline Hyclate Mutual Pharmaceutical Lemmon Co
Doxycycline Hyclate Lemmon Co Zenith Labs
Doxycycline Hyclate United Research Labs Mutual Pharmaceutical
Doxycycline Hyclate Dixon-Shane Mutual Pharmaceutical
Doxycycline Hyclate Best Generics Mutual Pharmaceutical
Doxycycline Hyclate Towne, Paulsen Mutual Pharmaceutical
Doxycycline Hyclate Warner Chilcott Labs Mutual Pharmaceutical
Doxycycline Hyclate Pharbita Mutual Pharmaceutical
Doxycycline Hyclate Matroc Pharmaceutical B V Pharbita
Doxycycline Hyclate La Salle Labs B V Pharbita
Doxycycline Hyclate Poly Pharmaceuticals B V Pharbita
Doxycycline Hyclate Parke-Davis B V Pharbita
Doxycycline Hyclate Mediconpharma B V Pharbita

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## DRUGS, DEVICES, COSMETICS

### Section 25.58

#### DYPHYLLINE/GUAIFENESIN

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#### EPHEDRINE SULFATE

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(202487) No. 253 Dec. 95
## PREVENTION OF DISEASES

### Pt. III

#### 28 § 25.58

**EPINEPHRINE HCL**

**Ophthalmic Solution**

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**EPINEPHRYPH RORATE**

**Ophthalmic Solution**

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**ERGOCALCIFEROL**

**Capsules**

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**ERGOLOID MESYLATES**

**Sublingual Tablets**

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**ERGOLOID MESYLATES**

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### ERGOTAMINE TARTRATE

**Sublingual Tablets**

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### ERYTHROMYCIN

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**BASE Enteric Coated Pellets in Capsules**

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**BASE Enteric Coated Tablets**

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**ESTOLATE Oral Suspension**

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**ETHYLSUCCINATE Oral Suspension**

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## ERYTHROMYCIN ETHYL SUCCINATE

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## ERYTHROMYCIN ETHYL SUCCINATE/SULFISOXAZOLE ACETYL

### For Suspension

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## ERYTHROMYCIN STEARATE

### Tablets

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### Fluocinolone Acetonide

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DRUGS, DEVICES, COSMETICS  
28 § 25.58

(202495) No. 253 Dec. 95

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### GUAIFENESIN/PHENYLPROPANOLAMINE HCL

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### GUAIFENESIN/PSEUDOEPHEDRINE HCL

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### HALOPERIDOL

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## HALOPERIDOL LACTATE

**Injection**

| Haloperidol | Lemmon Co | Lemmon Co |

## HALOPERIDOL LACTATE

**Solution**

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## HOMATROPINE HBR

**Ophthalmic Solution**

| Isopto Homatropine | Alcon Labs | Alcon Labs |

## HOMATROPINE METHYLBROMIDE/HYDROCODONE BITARTRATE

**Syrup**

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## HOMATROPINE METHYLBROMIDE/HYDROCODONE BITARTRATE

**Tablets**

| Tusiget | Daniels Pharmaceuticals | Daniels Pharmaceuticals |

## HYDRALAZINE HCL

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### HYDROCODONE BITARTRATE/PSEUDOEPHEDRINE HCL Elixir

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### HYDROCORTISONE Lotion

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## HYDROCORTISONE

### Ointment

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### HYDROCORTISONE

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**(202506) No. 253 Dec. 95**
## HYDROCORTISONE/NEOMYCIN SULFATE/POLYMIXIN-B SULFATE

### Otic Suspension

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25-99
### HYDROXYZINE HCL

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#### Tablets

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## HYDROXYZINE HCL
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### HYDROXYZINE PAMOATE
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### L - HYOSCYAMINE SULFATE
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### L - HYOSCYAMINE SULFATE
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## IBUPROFEN

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### INDOMETHACIN

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### ISONIAZID

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### ISONIAZID

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### ISOSORBIDE DINITRATE

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### Kanamycin Sulfate

Kanamycin Sulfate: Steris Labs

### Kaolin/Paregoric/Pectin

#### Suspension

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## LACTULOSE Syrups

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**LINDANE**

**Lotion**

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**LINDANE**

**Shampoo**

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**LITHIUM CARBONATE**

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**LITHIUM CARBONATE**

**Tablets**

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**LITHIUM CITRATE**

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**LORAZEPAM**

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### Lorazepam Tablets—Continued

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### Magaldrate Suspension

| Magaldrate         | Roxane Labs |

### Mannitol Injection

| Mannitol          | Steris Labs |

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MECLIZINE HCL

Tablets

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MECLIZINE HCL

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## MEDROXYPROGESTERONE ACETATE

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## MEGERIDINE HCL

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25-115

(202523) No. 253 Dec. 95
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**METRONIDAZOLE**

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### MINERALS/MULTIPLE VITAMINS

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#### MORPHINE SULFATE

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#### MORPHINE SULFATE

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#### MULTIPLE VITAMIN

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### NALIDIXIC ACID

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#### Ophthalmic Solution

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#### Ophthalmic Solution

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### NAPHAZOLINE HCL/PHENIRAMINE MALEATE

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#### Tablets

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### NEOMYCIN SULFATE/Polymyxin B Sulfate

#### Irrigating Solution

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#### Ophthalmic Ointment

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### NEOMYCIN SULFATE/Polymyxin B Sulfate
**NEOMYCIN SULFATE/POLYMYXIN-B SULFATE**

**Ophthalmic Solution**

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**NIACIN**

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**NITROFURANTOIN**

**Capsules**

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**NITROFURANTOIN**

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**NITROFURAZONE**

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**NITROFURAZONE**

**Solution**

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**Topical Dressing**

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### NYLIDRIN HCL

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### NYSTATIN

**Cream**

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### NYSTATIN Tablets

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### NYSTATIN Vaginal Tablets

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### NYSTATIN/TRIAMCINOLONE ACETONIDE Cream

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(202529) No. 253 Dec. 95
### NYSTATIN/TRIAMCINOLONE ACETONIDE

**Cream—Continued**

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### NYSTATIN/TRIAMCINOLONE ACETONIDE

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### ORPHENADRINE CITRATE

**Injection**

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### ORPHENADRINE CITRATE

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### OXACILLIN SODIUM

**Capsules**

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### OXACILLIN SODIUM

**Injection**

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### OXACILLIN SODIUM

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(202530) No. 253 Dec. 95

Copyright © 1995 Commonwealth of Pennsylvania
### OXAZEPAM

**Capsules**

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### OXTRIPHYLLINE

**Elixir**

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**Syrup**

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### OXYMETAZOLINE HCL

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### OXYTETRACYCLINE HCL

**Capsules**

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<td>Rugby Labs</td>
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<td>Henry Schein</td>
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(202531) No. 253 Dec. 95
## OXYTOCIN

**Injection**

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## PARACHLOROMETAXYLENOL/RESORCIN/SULFUR

**Lotion**

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## PANCRELIPASE

**Capsules**

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## PAPAYERINE HCL

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## PAREGORIC

**Elixir**

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## PENICILLIN G POTASSIUM

**For Solution**

<table>
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## PENICILLIN G POTASSIUM

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# PENICILLIN G POTASSIUM

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# PENICILLIN V POTASSIUM

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### PENICILLIN V POTASSIUM

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#### PENICILLIN V POTASSIUM Tablets

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### Phenazopyridine HCl

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### PHENYL ButAZONE

**Tablets**

- **Phenybutzone**
  - Cord Labs
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- **Phenybutzone**
  - Geneva Generics
  - Cord Labs

- **Phenybutzone**
  - Rugby Labs
  - Chelsea Labs

- **Phenybutzone**
  - Zenith Labs
  - Zenith Labs

- **Phenybutzone**
  - Towne, Paulsen
  - Zenith Labs

- **Phenybutzone**
  - Qualitest
  - Zenith Labs

- **Phenybutzone**
  - Barr Labs
  - Barr Labs

- **Phenybutzone**
  - Best Generics
  - Barr Labs

- **Phenybutzone**
  - Rugby Labs
  - Barr Labs

- **Phenybutzone**
  - United Research Labs
  - Barr Labs

**Capsules**

- **Phenybutzone**
  - Cord Labs
  - Cord Labs

- **Phenybutzone**
  - Geneva Generics
  - Cord Labs

- **Phenybutzone**
  - Rugby Labs
  - Chelsea Labs

- **Phenybutzone**
  - Zenith Labs
  - Zenith Labs

- **Phenybutzone**
  - Towne, Paulsen
  - Zenith Labs

- **Phenybutzone**
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- **Phenybutzone**
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- **Phenybutzone**
  - Best Generics
  - Barr Labs

- **Phenybutzone**
  - Rugby Labs
  - Barr Labs

- **Phenybutzone**
  - United Research Labs
  - Barr Labs

### PHENYL ButAZONE

**Tablets**

- **Butazolidin**
  - Geigy Pharmaceutical
  - Ciba-Geigy

- **Phenybutzone**
  - Danbury Pharmacal
  - Danbury Pharmacal

- **Phenybutzone**
  - Bell Pharmacal
  - Danbury Pharmacal

- **Phenybutzone**
  - Qualitest
  - Danbury Pharmacal

- **Phenybutzone**
  - United Research Labs
  - Danbury Pharmacal

- **Phenybutzone**
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- **Phenybutzone**
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- **Phenybutzone**
  - H L Moon Drug Exchange
  - Barr Labs

- **Phenybutzone**
  - United Research Labs
  - Barr Labs

- **Phenybutzone**
  - Quality Research Pharm
  - Barr Labs

- **Phenybutzone**
  - Major Pharmaceutical Corp
  - Barr Labs

- **Phenybutzone**
  - Glenlawn Labs
  - Barr Labs

- **Phenybutzone**
  - Gen-King Products
  - Barr Labs

- **Phenybutzone**
  - Geneco
  - Barr Labs

- **Phenybutzone**
  - Harber Pharmaceutical
  - Barr Labs

- **Phenybutzone**
  - Rugby Labs
  - Barr Labs

### PHENYLEPHRINE HCL

**Nasal Solution**

- Phenylephrine HCl
  - Barre Drug
  - National Pharmaceutical

- Phenylephrine HCl
  - Bioline Labs
  - National Pharmaceutical

- Phenylephrine HCl
  - Rugby Labs
  - National Pharmaceutical

- Phenylephrine HCl
  - Halsey Drug
  - Halsey Drug

- Phenylephrine HCl
  - Pharmaceutical Basics
  - Pharmaceutical Basics

**Ophthalmic Solution**

- Isopto Frin
  - Alcon Labs
  - Alcon Labs

- Tearaid
  - Optopics Labs
  - Optopics Labs

- Eflucel
  - Optopics Labs
  - Optopics Labs

- Dilatair
  - Pharmalair
  - Pharmalair

- Phenylephrine HCl
  - Steris Labs
  - Steris Labs

- Phenylephrine HCl
  - Hygeia Labs
  - Steris Labs

### PHENYLEPHRINE HCL/PROMETHAZINE HCL

**Syrup**

- Prometh VC Plain
  - Barre Drug
  - National Pharmaceutical

- Prometh VC Plain
  - Qualitest
  - National Pharmaceutical

- Prometh VC Plain
  - Goldline Labs
  - Barre-National

- Promethazine VC Plain
  - My-K Labs
  - My-K Labs

- Promethazine VC Plain
  - H R Cenci Labs
  - H R Cenci Labs

- Phenazine VC
  - Halsey Drug
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### POTASSIUM CHLORIDE Powder

- K-Lor: Abbott Labs
- Klor-Con: Upsher-Smith Labs
- K-potassium Chlor: Copley Pharmaceutical
- K's Care: Alfa Labs
- Potassium Chloride: Best Generics

### POTASSIUM CHLORIDE Effervescent Tablets

- Klorvess: Dorsey Labs
- K-Electrolyte/CL: Copley Pharmaceutical

### POTASSIUM CHLORIDE/POTASSIUM GLUCONATE Liquid

- Duo-K: Barre Drug
- Duo-K: Rugby Labs
- Duo-K: Henry Schein
- Duo-K: Murray Drug
- Duo-K: Cooper

### POTASSIUM CITRATE/POTASSIUM GLUCONATE Liquid

- Kem-K: LuChem Pharmaceuticals

### POTASSIUM GLUCONATE Elixir

- Potassium Glucinate: Barre Drug
- Potassium Glucinate: Henry Schein
- Potassium Glucinate: Cooper
- Potassium Glucinate: Rugby Labs
- Potassium Glucinate: Vanguard Labs
- Potassium Glucinate: Lederle Labs
- Potassium Glucinate: United Research Labs
- Potassium Glucinate: Biofine Labs
- Potassium Glucinate: Vita-Rx
- Potassium Glucinate: Richie Pharmacal
- Potassium Glucinate: H L Moore Drug Exchange
- Potassium Glucinate: Murray Drug
- Potassium Glucinate: Bell Pharmacal
- K-Rex: C'S Rachstuhl
- K-G: Geneva Generics
- Potassium Glucinate: Goldfine Labs
- Potassium Glucinate: Roxane Labs
- Potassium Glucinate: Rugby Labs

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## PROMETHAZINE HCL

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### PROPOXYPHENE HCL

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### PROPRANOLOL HCL

**Solution**

| Propranolol HCl | Pharmaceutical Basics | Pharmaceutical Basics |

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### PSEUDOEPHEDRINE HCL

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Copyright © 1995 Commonwealth of Pennsylvania
## Quinidine Sulfate

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25-142
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## SPIRONOLACTONE

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### SULFACETAMIDE/SULFABENZAMIDE/SULFATHIAZOLE/UREA

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### SULFAMETHOXAZOLE/TRIMETHOPRIM

#### Concentrate for Injection

- **COTRIM I.V. Infusion**
  - Lemmon Co

#### Suspension

- **Bactrim**
  - Roche
- **Septra**
  - Burroughs-Wellcome
- **Sulfatrim Pediatric**
  - Lederle Labs

#### Tablets

- **Bactrim**
  - Roche
- **Septra**
  - Burroughs-Wellcome
- **Sulfatrim Pediatric**
  - Lederle Labs

### SULFAMETHOXAZOLE/TRIMETHOPRIM

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### SULFAMETHOXAZOLE/TRIMETHOPRIM

#### Concentrate for Injection

- **COTRIM I.V. Infusion**
  - Lemmon Co

#### Suspension

- **Bactrim**
  - Roche
- **Septra**
  - Burroughs-Wellcome
- **Sulfatrim Pediatric**
  - Lederle Labs

#### Tablets

- **Bactrim**
  - Roche
- **Septra**
  - Burroughs-Wellcome
- **Sulfatrim Pediatric**
  - Lederle Labs

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Vaginal Cream

Vagistrol

Lemmon Co

Lemmon Co

SULFASALAZINE

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**SULFISOXAZOLE**

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**TERPIN HYDRATE**

**Elixir**

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**TETRACAINE HCL**

**Ophthalmic Solution**

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**TETRACYCLINE HCL**

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**PREVENTION OF DISEASES**

25 § 25.58

**Pt. III**

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## TETRACYCLINE HCL

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### THIORIDAZINE HCL

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**TOLBUTAMIDE**

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(202559) No. 253 Dec. 95
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## TRIAMCINOLONE ACETONIDE

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### TRIHEXYPHENIDYL HCL

**Elixir**

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### TRIMEPRAZINE TARTRATE

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(202563) No. 253 Dec. 95
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**VALPROIC ACID**

**Capsules—Continued**

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**VANCOMYCIN**

**Injection**

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**VERAPAMIL HCL**

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**VITAMIN A (FISH LIVER OIL)**

**Capsules**

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**VITAMIN A PALMITATE**

**Capsules**

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**VITAMIN A PALMITATE**

**(Solubilized) Capsules**

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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); and 49 Pa. Code § 21.284a (relating to prescribing and dispensing drugs).


(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); and 49 Pa. Code § 21.284a (relating to prescribing and dispensing drugs).

§ 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
Cross References
This section cited in 28 Pa. Code § 551.3 (relating to definitions); 49 Pa. Code § 21.284a (relating to prescribing and dispensing drugs); and 49 Pa. Code § 43b.7 (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.
   (vi) alpha-methylfentanyl.
   (vii) Benzethidine.
   (viii) Betacetylmethadol.
   (ix) Betameprodine.
   (x) Betamethadol.
   (xi) Clonitazene.
   (xii) Dextromoramide.
   (xiii) Dextrophan (except its methylether).
   (xiv) Diampromide.
   (xv) Diethylthiambutene.
   (xvi) Dimenoxadol.
   (xvii) Dimephedantol.
   (xviii) Dimethylthiambutene.
   (xix) Dioxyphylbutyrate.
   (xx) Dipipanone.
   (xxi) Ethylmethylthiambutene.
   (xxii) Etonitazene.
   (xxiii) Etoxeridine.
   (xxiv) Furethidine.
   (xxv) Hydroxypethidine.
   (xxvi) Ketobemidone.
(xxvii) Levomoramide.
(xxviii) Levophenacylmorphan.
(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) Trimiperidine.
( xliv) [Reserved].
( xlv) 3-Methylfentanyl.
( xlv) 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) Benzylmorphone.
(iv) Codeine methylbromide.
(v) Codeine-N-Oxide.
(vi) Cyprenorphine.
(vii) Desomorphine.
(viii) Dihydromorphine.
(ix) Drotebanol (added August 6, 1978).
(x) Etorphine.
(xi) Heroin.
(xii) Hydromorphinol.
(xiii) Methyldesorphine.
(xiv) Methylhydromorphone.
(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) Fenethylline.
(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) Pindolol.
(xxiii) Tetrazepam.
(xxiv) 3, 4-Methylenedioxymethamphetamine (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.

(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-carboxylicacid.
(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).
(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.
(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.

(9) A material, compound, mixture or preparation, unless specifically excepted, which contains a quantity of Dronabinol—synthetic—in sesame oil encapsulated in a soft gelatin capsule but only those drug products approved by the United States Food and Drug Administration.

(10) Buprenorphine.

(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) Methohexitol.
(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.
(xxvi) Zolpidem.

(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) Butorphanol.
(xii) Sibutramine.
(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 will 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(a) and (c) and 4 of The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. §§ 780-103(a) and (c) and 780-104); and section 2 of the Optometric Practice and Licensure Act (63 P. S. § 244.2).

Source


Notes of Decisions

A material containing the drug cathinone is a controlled substance under § 25.72(b)(6)(xxvi). The language of the § 25.72(b)(6)(xxvi) plainly states that an unlisted material, when containing a controlled substance, is a controlled substance. Commonwealth v. Mohamud, 15 A.3d 80, 92 (Pa. Super. 2010).

Cross References

This section cited in 28 Pa. Code § 551.3 (relating to definitions); and 49 Pa. Code § 21.284a (relating to prescribing and dispensing drugs).

§ 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 pharmacist.

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§ 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."

Cross References
This section cited in 28 Pa. Code § 551.3 (relating to definitions); 49 Pa. Code § 18.6a (relating to prescribing, dispensing and administering drugs); and 49 Pa. Code § 21.284a (relating to prescribing and dispensing drugs).

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); 49 Pa. Code § 18.6a (relating to prescribing, dispensing and administering drugs); and 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs); 49 Pa. Code § 21.284a (relating to prescribing and dispensing drugs); and 49 Pa. Code § 25.177 (relating to prescribing drugs, pharmaceutical aids and devices).

§ 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.
§ 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); 49 Pa. Code § 18.6a (relating to prescribing, dispensing and administering drugs); 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs); 49 Pa. Code § 25.177 (relating to prescribing and dispensing drugs, pharmaceutical aids and devices); and 49 Pa. Code § 43b.7 (relating to schedule of civil penalties—pharmacists and pharmacies).

§ 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 § 18.6a (relating to prescribing, dispensing and administering drugs); 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs); 49 Pa. Code § 25.177 (relating to prescribing and dispensing drugs, pharmaceutical aids and devices); and 49 Pa. Code § 43b.7 (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); 49 Pa. Code § 18.6a (relating to prescribing, dispensing and administering drugs); 49 Pa. Code § 18.158 (relating to prescribing and dispensing drugs); and 49 Pa. Code § 21.284a (relating to prescribing and dispensing drugs); and 49 Pa. Code § 25.177 (relating to prescribing and dispensing drugs, pharmaceutical aids and devices).

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

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

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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.
§ 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 adddress 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


§ 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


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:

<table>
<thead>
<tr>
<th></th>
<th>Annual Fee</th>
<th>Late Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>$400</td>
<td>$50</td>
</tr>
<tr>
<td>Distributor</td>
<td>$100</td>
<td>$10</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>Annual Fee</th>
<th>Late Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>$100</td>
<td>$25</td>
</tr>
<tr>
<td>Distributor</td>
<td>$25</td>
<td>$5.00</td>
</tr>
<tr>
<td>Retailer</td>
<td>$10</td>
<td>$2.00</td>
</tr>
</tbody>
</table>

(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:

<table>
<thead>
<tr>
<th></th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual Fee</td>
<td>$25</td>
</tr>
<tr>
<td>Late fee</td>
<td>$10</td>
</tr>
</tbody>
</table>

(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).

(202583) No. 253 Dec. 95
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).


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.

SAMPLES

§ 25.121. Official samples for analysis.

(a) When any officer or employe 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 employe 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 employe 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 employe 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;

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(202584) No. 253 Dec. 95

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(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.

Subchapter B. HEARING AID SALES AND REGISTRATION

25.201. Application.
25.204. Application for and renewal of registration.
25.205. Additional registration requirements.
25.207. Categories of registrations: fee schedule.
25.208. Display of registration certificates; offices.
25.211. Medical recommendations; waiver form.
25.212. Medical recommendations by examining physicians.
25.213. Consumer review.
25.215. Denial, revocation or suspension of registrant’s certificate.
25.216. Continuing education requirements.
25.217. Approval of continuing education programs.
25.218. Credit for continuing education.
25.219. Responsibilities of persons offering continuing education programs.
25.220. Rights to enter, inspect and obtain records.
25.221. Exceptions.

Authority
The provisions of this Subchapter B issued under The Hearing Aid Sales Registration Law (35 P. S. §§ 6700-101—6700-802), unless otherwise noted.

Source

§ 25.201. Application.
(a) Scope. This subchapter applies to all persons engaged in the business of selling or fitting hearing aids in this Commonwealth; except that physicians and audiologists are exempted from all provisions regarding hearing aid fitters.

(b) Authority. This subchapter is adopted under the act.

Notes of Decisions
Since the legislature obviously believes that the license already held by physicians and audiologists is adequate proof of their competence to fit patients with hearing aids, they are not required to take a qualifying examination prior to obtaining a hearing aid dealers certificate. Pennsylvania Hearing Aid Dealers Association, Inc. v. Department of Health, 417 A.2d 1340 (Pa. Cmwlth. 1980); affirmed 430 A.2d 1150 (Pa. 1981).

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

Act—The Hearing Aid Sales Registration Law (35 P. S. §§ 6700-101—6700-802).

Advertise and any of its variants—The use of a newspaper, magazine or other publication, book, notice, circular, pamphlet, letter, handbill, poster, sign, placard, label, tag, window display, store sign, radio, television announcement, Internet, or other means or methods employed to bring to the attention of the public the practice of selling or fitting hearing aids.

Audiologist—A person who holds a current license as an audiologist issued by the State Board of Examiners in Speech-Language and Hearing, or a person who is permitted to practice audiology pursuant to an exemption to the audiologist licensure requirement under section 6(b) of the Speech-Language and Hearing Licensure Act (63 P. S. § 1706(b)).

(336929) No. 408 Nov. 08
Authorized representative—A person who is authorized by law to make a decision, required pursuant to this subchapter, for a hearing aid user or prospective hearing aid user.

Business of selling hearing aids—

(i) Selling, leasing or offering for sale or lease new, used or reconditioned hearing aids exclusive of parts, attachments or accessories, at retail, either as exact replacements for damaged or worn out units or written specifications provided by an audiologist, otologist or otolaryngologist.

(ii) The term does not include fitting or the practice of fitting and selling hearing aids.

Continuing education program—A program approved by the Department for credit towards the continuing education requirements for the renewal of the registration certificate of a hearing aid fitter.

Conviction—A plea or verdict of guilty, or a conviction following a plea of nolo contendere to a charge of a crime involving moral turpitude.

Department—The Department of Health of the Commonwealth.

Fitting—Includes the physical acts of adjusting the hearing aid to the individual, taking audiograms, making ear molds, advising the individual with respect to hearing aids, making audiogram interpretations and assisting in the selection of a suitable hearing aid to sell a hearing aid.

Hearing aid—A wearable instrument or device designed or offered to aid or compensate for impaired human hearing together with any parts, attachments or accessories for those instruments or devices, including ear molds but excluding batteries and cords.

Hearing aid dealer—A person engaged in the business of selling hearing aids.

Hearing aid fitter—An individual engaged in the practice of fitting and selling hearing aids.

Hearing aid user—An individual who uses a hearing aid.

Practice of fitting and selling hearing aids—Those practices used solely for making selections, adaptations and sales of hearing aids.

Prospective hearing aid user—An individual who is considering buying a hearing aid or whose hearing is being evaluated by a registrant.

Purchaser—An individual who has agreed to purchase a hearing aid from a registrant.

Registrant—A hearing aid dealer or fitter holding a current certificate of registration.

Secretary—The Secretary of Health of the Commonwealth.

Sponsor—An individual registered in this Commonwealth as a hearing aid fitter who agrees to supervise an apprentice hearing aid fitter.

Used hearing aid—

(i) A hearing aid that has been worn for any period of time by a user.
(ii) A hearing aid is not a used hearing aid if it has been worn only by a prospective user as part of a bona fide hearing aid evaluation conducted in the presence of the registrant or an individual selected by the registrant and authorized by law to assist the prospective user in making such an evaluation.

(a) The Advisory Council (Council) will be composed as provided for under section 201 of the act (35 P. S. § 6700-201).
(b) It will be the duty of the Council to advise the Secretary, to the best of its ability, on the administration of the act.
(c) The Council will hold at least one annual meeting at a time and place designated by the Secretary for the purpose of providing information and advice to the Department.
(d) A Council member may convey the impression, either publicly or privately, that the member is acting officially for the Council only with prior authorization from the Council.

§ 25.204. Application for and renewal of registration.
(a) Application. An application for registration or renewal of registration as a hearing aid dealer, hearing aid fitter, apprentice hearing aid fitter or temporary hearing aid fitter can be obtained from the Division of Home Health, Pennsylvania Department of Health, 132 Kline Plaza, Suite A, Harrisburg, Pennsylvania 17104.
(b) Apprentice hearing aid fitter. A completed application for registration as an apprentice hearing aid fitter shall be filed with the Department at least 30 days before the fitter’s examination that the applicant intends to take, together with a check, money order or other approved method of payment as the Department publishes in a notice in the Pennsylvania Bulletin, in the amount of $50. An additional $150 shall be paid before taking the fitter’s examination. The application fee is not refundable, but the $150 fee for the examination will be refunded to an applicant who is found to be ineligible to take the examination.
(c) All other registrations. A completed application for any registration certificate, other than a registration certificate as an apprentice hearing aid fitter, may be filed at any time, together with a check, money order or other approved method of payment as the Department publishes in a notice in the Pennsylvania Bulletin, in the amount of the appropriate application fee.
(d) Renewal of current certificate. A registrant shall apply to renew a current registration certificate by March 16 prior to the certificate’s expiration, by submitting a completed renewal application, available from the Department, along with the renewal fee of $100. To renew a hearing aid fitter’s registration certificate, the applicant shall also demonstrate satisfaction of the continuing education requirements under § 25.216 (relating to continuing education requirements).
(e) **Renewal of expired certificate.** An expired registration certificate may be renewed within 5 years after its expiration or inactive date by filing an application for renewal, with payment of the renewal fee, and payment of the delinquency fee if the application is received more than 30 days after the expiration date. To renew an expired hearing aid fitter’s registration certificate, the applicant shall also demonstrate satisfaction of the continuing education requirements under § 25.216.

(f) **Renewal of fitter’s temporary registration certificate and apprentice certificate.** Upon application, the Secretary may renew a temporary certificate or apprentice certificate for a period which shall expire 30 days after the next available fitter’s qualifying examination has been given. The Secretary will not issue more than two renewals of these certificates, except upon petition of an applicant for good and sufficient cause shown. An applicant may petition the Department for an additional renewal. The petition shall include the reasons for which the additional renewal is requested. An applicant shall send a petition for additional renewal to the Division at the address given in subsection (a). The Department will then decide whether to issue the renewal.

(g) **Late application for renewal.** A person who files for renewal of a registration certificate after March 16 may not receive the renewal before the registration certificate expires.

**Cross References**

This section cited in 28 Pa. Code § 25.205 (relating to additional registration requirements); 28 Pa. Code § 25.206 (relating to examinations); and 28 Pa. Code § 25.208 (relating to display of registration certificates; offices).

§ 25.205. **Additional registration requirements.**

(a) **Hearing aid dealers.** No requirement is imposed in addition to those imposed under § 25.204(c) (relating to application for and renewal of registration).

(b) **Hearing aid fitters.** A hearing aid fitter shall pass the qualifying examination as provided by the act.

(c) **Reciprocal registration—certificate by endorsement.**

(1) An applicant for registration to practice as a hearing aid dealer or as a hearing aid fitter who is licensed or registered in any other state, which has requirements equal to or greater than those in this Commonwealth for registration as a hearing aid dealer or fitter and which maintains reciprocal practice privileges with this Commonwealth, may be granted a registration certificate by endorsement by the Secretary. Being qualified to apply for a hearing aid fitter’s registration certificate by endorsement relieves the applicant from having to take the qualifying examination otherwise required under the act.

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(304196) No. 357 Aug. 04 Copyright © 2004 Commonwealth of Pennsylvania
(2) In all other respects, the applicant for a registration certificate by endorsement shall be registered in the same manner and meet the same requirements as other registrants.

(3) If the Commonwealth does not maintain reciprocal practice privileges with a state in which a person is registered or otherwise authorized to function as a hearing aid fitter or dealer, the person may apply for a temporary registration certificate under subsection (e).

(d) **Apprentice registration.** Apprentice registration shall conform to the following:

1. An applicant for registration as an apprentice hearing aid fitter shall have a sponsor responsible for the training and supervision of the applicant.
2. An application shall be accompanied by a statement of the sponsor:
   i. Setting forth the type of supervision which shall be given the applicant.
   ii. Providing an outline of the training program to be followed in preparing the applicant for examination. The training program shall include education and training in at least the following areas:
      A. The anatomy and physiology of the ear.
      B. The function of hearing aids.
      C. The grounds for revocation or suspension of a certificate of registration, or probation of a registrant, under the act.
      D. The violations and penalties under the act.
      E. The procedures and use of equipment established by the Department for the fitting and selling of hearing aids.
      F. The taking of ear mold impressions.
      G. The medical and rehabilitation facilities for children and adults that are available in the areas served.
      H. The criteria for medical referral when found to exist either from observation by the registrant or on the basis of information furnished by the prospective hearing aid user, to include those criteria in § 25.211(d) (relating to medical recommendations; waiver forms).
   iii. Providing the registration number of the sponsor.
3. An apprentice hearing aid fitter desiring to change sponsors shall furnish the Department a sworn or affirmed request giving reasons for the change and a sworn or affirmed statement from the new sponsor setting forth the information required by paragraph (2), and accompanied by the apprentice’s certificate of registration. An affirmed statement may be given in any form so long as it is in writing, signed, and contains a statement to the effect that it is truthful.
4. A sponsor desiring to terminate responsibilities with regard to an apprentice shall give the apprentice 10 days written notice of the reasons for the action and shall notify the Department at the same time by certified mail.
Temporary registration shall conform to the following:

1. A temporary fitter’s registration certificate will be issued to an applicant who satisfactorily demonstrates having been engaged in the fitting and selling of hearing aids at an established place of business in a state other than this Commonwealth for 2 years within a 5-year period immediately before making application and who otherwise fulfills the requirements of the act and this subchapter.

2. The temporary registrant shall take the hearing aid fitter’s examination to qualify for a regular hearing aid fitter’s registration certificate.

3. The temporary registration certificate shall expire 30 days after the administration of the qualifying examination that the temporary registrant takes. The temporary registrant shall take the qualifying examination no earlier than 90 days after the date the temporary registration certificate was issued, and no later than 1 year after the date the temporary registration certificate was issued.

Notes of Decisions
Since the legislature obviously believes that the license already held by physicians and audiologists is adequate proof of their competence to fit patients with hearing aids, they are not required to take a qualifying examination prior to obtaining a hearing aid dealers certificate. Pennsylvania Hearing Aid Dealers Association, Inc. v. Department of Health, 417 A.2d 1340 (Pa. Cmwlth. 1980); affirmed 430 A.2d 1150 (Pa. 1981).

(a) An examination to obtain registration as a hearing aid fitter shall be held at least twice each year, at a time and place to be fixed by the Secretary at least 45 days before the examination date.

(b) The date of an examination may be obtained by writing to the Division at the address given in § 25.204(a) (relating to application for and renewal of registration), by checking the Department’s website at www.health.state.pa.us, or by phone or e-mail to the Division.

(c) The passing grade on an examination will be determined by the Secretary.

§ 25.207. Categories of registrations; fee schedule.
(a) A registration certificate, other than a temporary or apprentice registration certificate, shall expire at midnight of April 15 of each year, if not renewed.

(b) For a hearing aid dealer, the initial registration fee is $200 if the Department issues the registration certificate between April 15 and October 14, and $100 if the Department issues the registration certificate between October 15 and April 14. The annual renewal fee is $100 for both dealers and fitters.

(c) For a hearing aid fitter’s registration certificate, the initial registration fee is $200, $150 of which will be refunded if the applicant is ineligible to take the qualifying fitter’s examination. The annual renewal fee is $100.
(d) For a registration certificate by endorsement the fees shall be the same as in subsection (b).

(e) For a temporary hearing aid fitter’s registration certificate, the initial registration fee is $200, $150 of which is for the examination. A refund of the $150 will be made if the applicant is ineligible to take the qualifying examination for a fitter’s registration certificate. Instead of paying the full $200 when making the application, the applicant may pay $50 when making the initial application, and $150 before taking the examination for the first time. The renewal fee is $100.

(f) For an apprentice fitter’s registration certificate, the fee is $50 plus an additional $150 before the apprentice takes the fitter’s examination. The renewal fee is $100.

(g) For a duplicate or replacement registration certificate, the fee is $10. The registrant shall obtain a duplicate certificate upon the loss of an original certificate or for a branch office. The registrant shall obtain a replacement registration certificate upon a name change by the person holding a certificate.

(h) The fee to retake the fitter’s examination for an applicant who has previously failed the examination is $50.

(i) A delinquency fee will be assessed if an applicant applies for renewal of a registration certificate after May 15. The delinquency fee is $50.

(j) For renewal of a suspended registration certificate, the fee is $100 plus the delinquency fee if one has otherwise accrued.

§ 25.208. Display of registration certificates; offices.

(a) A registrant shall display the dealer’s or fitter’s registration certificate at the place of business listed in the registrant’s application.

(b) If a registrant maintains more than one place of business within this Commonwealth, the registrant shall apply for a duplicate registration certificate for each branch office. The registrant shall display the appropriate duplicate registration certificate in each office.

(c) The place of business identified in a registrant’s application shall be an office at a fixed location. An office which is part of a building normally used as a residence shall be in a space set aside for office purposes only.

(d) A registrant shall file notice of a change in the registrant’s place of business with the Department at least 10 work days before the change by writing to the Department at the address given in § 25.204(a) (relating to application for and renewal of registration).

(e) A registrant shall make the registration certificate available for inspection on request of any client, prospective client, Department employee or law enforcement official.

§ 25.209. Facilities, procedures and instrumentation.

(a) Facilities. A registrant shall engage in the practice of fitting or selling a hearing aid only if the registrant provides:
(1) An appropriate test area, the ambient noise level of which shall have a documented readout of 55 dB or lower on the A scale of a sound level meter.

(2) A selection of hearing aid models, supplies and accessories to provide for the immediate needs of hearing aid users or prospective hearing aid users.

(b) Procedures. A registrant shall satisfy the following:

(1) The registrant shall sell a hearing aid only if within 6 months before the sale an examination of the prospective hearing aid user was conducted using pure tone air conduction, bone conduction and speech audiometry tests. This requirement does not apply when the registrant is replacing a hearing aid with another of the same make, model and response. The registrant shall sell a hearing aid replacing another of the same make, model and response only if within 12 months before the sale an examination of the prospective hearing aid user was conducted using pure tone air conduction, bone conduction and speech audiometry tests. The registrant shall verify that the tests were performed by an individual authorized by law to do so. The registrant may rely on a representation by the physician, audiologist or fitter who performed or supervised the tests that the individual who performed the tests was authorized to do so.

(2) The registrant shall:

(i) Perform air conduction tests for hearing level thresholds at frequencies of 250 Hz, 500 Hz, 1,000 Hz, 2,000 Hz, 4,000 Hz and 6,000 Hz or 8,000 Hz, with masking if necessary.

(ii) Perform bone conduction tests for hearing level thresholds at frequencies of 500 Hz, 1,000 Hz, 2,000 Hz and 4,000 Hz, with masking if necessary.

(iii) Maintain records of the test results for each ear for 7 years.

(iv) Perform a speech reception or speech awareness threshold test using an electronic speech audiometer with head or insert ear phones.

(v) Perform a word discrimination or other speech intelligibility test for conversational level speech using an electronic speech audiometer with head or insert ear phones.

(3) The registrant shall sell a hearing aid only if the hearing aid is fitted to the wearer to ensure physical and operational comfort and improvement in hearing function is demonstrated and documented in at least one of the following areas: speech detection, speech awareness levels, speech intelligibility, orientation or speech reception threshold.

(c) Instrumentation. A registrant shall satisfy the following:

(1) All test instruments shall be calibrated once each year or more often if necessary to meet current American National Standards Institute standards for pure tone and speech audiometry as identified by 1996 A.N.S.I. standards or applicable succeeding A.N.S.I. standards.

(2) Instruments transported to test sites shall be calibrated to the standard set forth in paragraph (1) every 6 months, or more frequently as needed.
(3) Calibration shall be performed by a qualified individual other than the owner.

(4) A signed certificate identifying the most recent date of calibration shall be maintained for inspection by the Department.

Cross References
This section cited in 28 Pa. Code § 25.214 (relating to recordkeeping).

(a) Receipt. Upon the sale of a hearing aid, the registrant shall provide the purchaser a signed receipt. The receipt may be made out on more than one sheet of paper and shall contain the following:
   (1) The date of sale.
   (2) The make, model and serial number or, if no serial number is applicable, an identification number of the hearing aid.
   (3) The address of the principal place of business of the registrant.
   (4) If the hearing aid is used or reconditioned, a statement which provides that information and which meets the requirements of § 25.215(23) (relating to denial, revocation or suspension of registrant’s certificate).
   (5) The registrant’s registration certificate number.
   (6) The terms of any guarantee or express warranty made to the purchaser with respect to the hearing aid.
   (7) A copy of the written forms as required by § 25.211 (relating to medical recommendations; waiver forms).
   (8) A statement on or attached to the receipt, in no smaller than 10 point type, as follows:
      “The purchaser has been advised at the outset of his relationship with the hearing aid dealer that any examination or representation made by a registered hearing aid dealer and fitter in connection with the practice of fitting and selling of this hearing aid, is not an examination, diagnosis or prescription by a person licensed to practice medicine in this Commonwealth and therefore must not be regarded as medical opinion.”
   (9) A statement on the face of the receipt, in no smaller than 10 point bold type, as follows: “If your rights are violated, you may contact the State Bureau of Consumer Protection, the Pennsylvania Department of Health in Harrisburg, or your local district attorney.”
(b) Disclosure agreement and money back written guarantee. Before the provision of any service incidental to or connected with the potential sale of a hearing aid, the registrant shall provide a disclosure agreement and money back written guarantee to the prospective hearing aid user or authorized representative, and shall explain it in detail in accordance with subsection (c). This shall be in 10
point type or larger, and may be made out on more than one sheet of paper, but
shall employ the following format or be on a form approved by the Department:

HEARING AID DISCLOSURE AGREEMENT/MONEY BACK
GUARANTEE

(Business Name) __________________ (Business Address) ________________
Telephone No. ( ) ____________________

PART A.

<table>
<thead>
<tr>
<th>Description of services included in fitting procedure or process, and sale and delivery of hearing aid.</th>
<th>FEE (State whether fee is waived if hearing aid purchased)</th>
<th>REFUNDABLE (Upon return of hearing aids)</th>
<th>NOT REFUNDABLE</th>
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THIS DISCLOSURE AGREEMENT WAS PROVIDED, PARTS A AND B WERE EXPLAINED, AND PART A (FEES FOR SERVICES NOT PART OF THE PRICE OF THE HEARING AID) WAS COMPLETED AT ________________ (time) ON ________________ (date), BEFORE ANY SERVICES WERE PROVIDED. PART B (CANCELLATION FEES THAT WILL BE INCURRED IF A HEARING AID IS RETURNED UNDER THE 30-DAY MONEY BACK GUARANTEE BELOW), WAS COMPLETED AND EXPLAINED AFTER SERVICES WERE PROVIDED AND BEFORE ANY PAYMENT WAS MADE. IF PART B IS NOT COMPLETED, IT IS BECAUSE A HEARING AID WAS NOT RECOMMENDED OR NOT DESIRED.

NOTHING IN THIS DISCLOSURE AGREEMENT SHALL RELIEVE A REGISTRANT OF THE OBLIGATION TO REFUND ALL OR PART OF THE ABOVE FEES, INCLUDING THOSE LISTED AS NOT REFUNDABLE, IF A COURT DETERMINES THAT THE REGISTRANT HAS VIOLATED A PENNSYLVANIA CONSUMER PROTECTION LAW IN THE SALE OR FITTING OF THE HEARING AID (OR SIMILAR DEVICE) AND IF THE COURT ORDERS SUCH REFUND.

__________________________  ____________________________
Customer’s Signature        Registrant’s Signature

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PART B.

<table>
<thead>
<tr>
<th>HEARING AIDS &amp; ACCESSORIES</th>
<th>DESCRIPTION of GOODS—include make, model, serial number(s)</th>
<th>PRICE</th>
<th>REFUNDABLE (upon return of hearing aid)</th>
<th>NOT REFUNDABLE (Cancellation Fee)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hearing Aid(s)</td>
<td>Right</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Left</td>
<td></td>
<td></td>
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<tr>
<td>Accessories (Describe, if applicable)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Total maximum Cancellation Fee is lesser of 10% or $150 per hearing aid including accessories.

30 Day Money Back Guarantee: If a hearing aid is returned within 30 days of date of delivery in the same condition, ordinary wear and tear excluded, you are entitled to a refund of the portion of the purchase price of the hearing aid and accessories as itemized on the receipt and above, less the cancellation fee stated above. If a cancellation fee is imposed the nonrefundable amount for each aid and accessories cannot exceed 10% of the purchase price of the hearing aid and accessories or $150.00 per aid and accessories, whichever is less. You will, however, be responsible for all nonrefundable service fees listed in Part A. If you cancel your order prior to delivery, you are entitled to full refund of the purchase price of the aid and accessories, and a full refund for services not yet rendered.

Customer’s Signature       Date and time of Sale
Registrant’s Signature     Registration No.

DATE of DELIVERY
Customer’s Signature or Initials

(c) Additional responsibilities of registrant with respect to the disclosure agreement/money back guarantee.

(1) Before providing any services incidental to the possible sale of a hearing aid to the prospective hearing aid user, the registrant shall explain Part A of the disclosure agreement/money back guarantee to the prospective hearing aid user or authorized representative and shall complete Part A. The registrant shall also give a preliminary explanation of Part B, including any cancellation fees that may be retained if a purchaser decides to return a hearing aid. The registrant shall include in Part A a complete description of what the fitting procedure or process includes, and shall itemize and disclose fees associated with the fitting procedure or process and the sale and delivery of the hearing aid. For each service provided, the registrant shall identify by dollar amount the portion

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of the fee that is refundable and the portion that is not refundable. If a fee will be waived if a hearing aid is purchased, that shall be stated. If the registrant charges no fees for services, the registrant shall note that in Part A.

(2) After Parts A and B have been explained and Part A has been completed, the registrant shall have the prospective hearing aid user or authorized representative complete the time and date lines provided under Part A. The prospective hearing aid user or authorized representative and registrant shall also sign under Part A when appropriate.

(3) After completing the necessary testing, if it is determined that a hearing aid will be recommended, the registrant shall explain and complete Part B, itemizing any cancellation fee associated with the sale and delivery of a hearing aid and its accessories by designating that amount as “not refundable.” Part B shall be fully explained and completed before any payment is made. If Part B becomes inapplicable due to a decision by the registrant, prospective hearing aid user or authorized representative not to proceed further after testing, the disclosure agreement/money back guarantee need not be fully completed. The registrant shall provide a copy of the partially completed disclosure agreement/money back guarantee to the prospective hearing aid user or authorized representative.

(4) If the registrant and the prospective hearing aid user or authorized representative decide to proceed, the registrant shall explain the 30-day money back guarantee. If the prospective user or authorized representative decides to purchase a hearing aid, the registrant shall have the purchaser sign the second signature line on the disclosure agreement/money back guarantee and complete the line for date and time of sale, and shall also sign when appropriate.

(5) The registrant may revise the relevant portion of the disclosure agreement/money back guarantee form to disclose the registrant’s policy of offering a money back guarantee return period longer than 30 days. The money back guarantee shall be for at least 30 days from the date of delivery.

(6) After the disclosure agreement/money back guarantee is fully completed except for the date of delivery block and the hearing aid serial numbers, the registrant shall provide a copy of it to the hearing aid user or authorized representative.

(7) At the time the hearing aid is delivered to the hearing aid user or authorized representative, the registrant shall ensure that the signature or initials of the user or authorized representative is obtained and the date of delivery and serial number are inserted in the block or section provided for that purpose on the disclosure agreement/money back guarantee. After the block is completed with the initials or signature and date and the serial number is inserted, the registrant shall provide a copy of the completed disclosure agreement/money back guarantee to the purchaser.
§ 25.211. Medical recommendations; waiver forms.

(a) Except when selling a replacement of a worn out or damaged hearing aid, when selling a hearing aid for the use of a prospective hearing aid user who is 19 years of age or older, a registrant shall either obtain for the prospective user a medical recommendation that complies with § 25.212 (relating to medical recommendations by examining physicians), or ensure that the prospective user or authorized representative signs a waiver form as provided under section 403 of the act (35 P. S. § 6700-403). The waiver form shall be prepared and used as follows:

(1) The waiver form shall be in 10 point type or larger.

(2) The waiver shall be read to the prospective hearing aid user or authorized representative and explained in a manner that the individual is not encouraged to waive a medical examination and so that the individual will be thoroughly aware that signing the waiver will not be in the prospective hearing aid user’s best interest.

(3) The waiver form shall read as follows:
I have been advised that my best interests would be served if I had a medical examination by an otologist or otolaryngologist or any licensed physician before my purchase of a hearing aid.
________________________ (Registrant’s Name) has fully and clearly informed me of the value of such medical examination. After such explanation, I voluntarily sign this waiver, I choose not to seek a medical examination before the purchase of the hearing aid.

________________________ (Signature of Registrant)
________________________ (Address of Registrant)
________________________ (Signature of Purchaser)
________________________ (Date of Signature)

(b) When selling a replacement of a worn out or damaged hearing aid for the use of a prospective hearing aid user who is 18 years of age or older, a registrant shall either obtain for the prospective user a medical recommendation that complies with the requirements of § 25.212, or ensure that the prospective user or authorized representative signs a legally proper waiver of the medical examination. For purposes of this subsection, a legally proper waiver includes a medical waiver form as provided under section 403 of the act and described in subsection (a), or a Federal medical waiver form as approved by the Food and Drug Administration of the United States Department of Health and Human Services.
(c) Except when a registrant is selling a hearing aid to replace an identical hearing aid, the registrant may sell a hearing aid for the use of a prospective user 18 years of age or younger only if the registrant obtains a medical recommendation that complies with the requirements of § 25.212 and is signed by a physician specializing in otolaryngology or otology. When selling an identical replacement hearing aid for the use of an individual under 18 years of age, the registrant shall obtain a medical recommendation that complies with the requirements of § 25.212.

(d) Before the sale of a hearing aid a registrant shall inform the prospective hearing aid user or authorized representative, in writing, that it would be in the best interest of the prospective hearing aid user to consult a physician specializing in or qualified to deal with diseases of the ear if the prospective hearing aid user has any of the following conditions:

1. Visible congenital or traumatic deformity of the ear.
2. Active drainage from the ear within the previous 90 days or a history of this symptom.
3. Sudden or rapidly progressive hearing loss within the previous 90 days or a history of this symptom.
4. Acute or chronic dizziness.
5. Unilateral hearing loss of sudden or recent onset within the previous 90 days.
6. Visible evidence of cerumen accumulation or a foreign body in the ear canal.
7. Significant air-borne gap of 15dB or greater at 500 Hz, 1000 Hz and 2000 Hz.
8. Pain in the ear within the previous 90 days.

Cross References


§ 25.212. Medical recommendations by examining physicians.

(a) Whenever a medical examination is performed under the act or Federal requirements, before fitting and selling a hearing aid the registrant shall ensure that a medical recommendation has been signed by the examining physician, within 180 days before the sale, on a form which includes the following statement or its equivalent:

I have medically evaluated the hearing ability of

(Patient’s Name)

and a hearing aid may be beneficial to this person.
(Signature of Physician)

(Date of Evaluation)

(b) If the prospective hearing aid user is 18 years of age or younger, the registrant shall ensure that the prospective user’s date of birth has been included on the medical recommendation form.

Cross References
This section cited in 28 Pa. Code § 25.211 (relating to medical recommendations; waiver forms); and 28 Pa. Code § 25.214 (relating to recordkeeping).

§ 25.213. Consumer review.
(a) Before signing a waiver form under § 25.211 (relating to medical recommendations; waiver forms) and before the sale of a hearing aid to or for the use of a prospective hearing aid user, the registrant shall:

(1) Provide the prospective hearing aid user or authorized representative with a copy of the User Instructional Brochure for the hearing aid that has been or may be selected for the prospective user.

(2) Review the content of the User Instructional Brochure with the prospective hearing aid user or authorized representative orally or in the predominant method of communication used during the sale.

(3) Give the prospective hearing aid user or authorized representative an opportunity to read the User Instructional Brochure.

(b) If goods or services having a sale price of $25 or more are sold or contracted to be sold to a purchaser as a result of or in connection with a contact with or call on the purchaser at the purchaser’s residence, the purchaser may avoid the contract or sale by notifying the registrant of that decision, in writing, within 3 full business days following the day on which the contract or sale was made and by returning or holding available for return to the registrant, in its original condition, any merchandise received under the contract or sale. The notice of rescission is effective when deposited in the United States mail or when service is made in another manner which gives the registrant notice of rescission. These and additional provisions relating to the sale of goods in the purchaser’s home, including specific items which shall be included on the purchase receipt, are made a part of this section by incorporation of section 7 of the Unfair Trade Practices and Consumer Protection Law (73 P.S. § 201-7).

A registrant shall, upon the consummation of a sale of a hearing aid, keep and maintain records in the registrant’s office or place of business at all times. These records shall be kept for 7 years and shall include the following:

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(1) Results of all testing conducted under § 25.209 (relating to facilities, procedures and instrumentation). The minimum acceptable test records shall be records of:

   (i) Pure tone tests including air and bone conduction with masking where appropriate, and the ambient noise level of the test area.
   (ii) Speech reception threshold expressed in decibels of hearing level.
   (iii) Most comfortable level expressed in decibels.
   (iv) Uncomfortable (tolerance) level expressed in decibels.
   (v) Word discrimination test results expressed in percentage indicating the test words used, presentation level, masking level (if applicable), and signal to noise ratio (if applicable).

(2) A copy of the written receipt, disclosure agreement and money back guarantee required by § 25.210 (relating to receipt, disclosure agreement and money back guarantee to purchaser—purchaser protection).

(3) The written physician’s recommendation required by § 25.212 (relating to medical recommendations by examining physicians) or the waiver form required by § 25.211 (relating to medical recommendations; waiver forms).

§ 25.215. Denial, revocation or suspension of registrant’s certificate.
The Secretary may deny, suspend or revoke a registration certificate provided under the act or the Secretary may impose conditions of probation upon a registrant for any of the following causes:

(1) Gross incompetency which includes the improper or unnecessary fitting of a hearing aid.
(2) Conviction of a felony or misdemeanor involving moral turpitude.
(3) Obtaining a registration certificate by fraud or deceit.
(4) Using the term “doctor” or “physician” or “clinic” or “audiologist” or any derivation thereof as part of the firm name under which the registrant fits and sells hearing aids, unless authorized by law.
(5) Fraud or misrepresentation in the repair, fitting or selling of a hearing aid.
(6) Employing a person to perform a function within the scope of practice of a hearing aid fitter who is not authorized by law to perform the function.
(7) Habitual intemperance.
(8) Gross immorality.
(9) Permitting another person to use the registration certificate for any purpose, except permitting an audiologist or physician employed by the registrant to sell hearing aids for the registrant.
(10) Violating or, with notice or knowledge permitting an employee to violate, the act or this subchapter.
(11) A cause which would be a ground for denial of an application for a registration certificate.
(12) Having been enjoined from violating a provision of the Unfair Trade Practices and Consumer Protection Law (73 P. S. §§ 201-1—209-6) or being subject to a final order of the Federal Trade Commission, the Department, or the Food and Drug Administration of the United States Department of Health and Human Services, concerning the sale or offering for sale of an unsafe, unhealthful or worthless hearing device or for engaging in conduct which has the tendency to mislead or deceive.

(13) Using, causing or promoting the use of any advertising matter, promotional literature, testimonial, guarantee, warranty, label, brand, insignia or any other representation, however disseminated or published, that is misleading, deceiving, improbable or untruthful, such as a misrepresentation relating to:

(i) The grade, quality, quantity, origin, novelty, price, dealer cost, terms of sale, use, construction, size, composition, dimensions, type, design, development, visibility, durability, performance, fit, appearance, efficacy, benefits, cost of operation, resistance to climatic conditions, or physiological benefits of a hearing aid or the psychological well-being induced by a hearing aid.

(ii) A service or adjustment offered, promised, or supplied to a purchaser of a hearing aid, or the fee associated with the service or adjustment.

(14) Making a representation that a hearing aid is “guaranteed,” without clear and conspicuous disclosure of:

(i) The nature and extent of the guarantee.

(ii) A material condition or limitation of the guarantee which is imposed by the guarantor.

(iii) The manner in which the guarantor will perform thereunder.

(iv) The identity of the guarantor, with disclosure, if applicable, that any guarantee made by the registrant which is not backed up by the manufacturer is offered by the registrant only.

(v) The meaning of “life” or “lifetime” to clarify whether it refers to the life of the purchaser, the product, or otherwise, whenever representations are made that a hearing aid is “guaranteed for life” or has a “lifetime guarantee.”

(15) Making a guarantee, warranty, or promise which, under normal conditions, is impractical of fulfillment or which is for a period of time or of a nature that may cause a purchaser to believe that the hearing aid has a greater degree of service ability, durability or performance capability in actual use than is true.

(16) Making a misrepresentation as to the character of the business conducted by the registrant. Unless it is true, a registrant may not represent directly or indirectly through the use of any word or term, in the corporate or trade name, in advertising, or otherwise, that the registrant owns or maintains a laboratory devoted to hearing aid research, testing, experimentation or development. A registrant may not misrepresent in any other material respect the character, extent or type of business conducted by the registrant.
(17) Causing deception that services or advice of a physician were used in the design or manufacture of hearing aids. Unless it is true, a registrant may not represent, directly or by implication, that the services or advice of a physician have been used in the designing or manufacturing of hearing aids. The prohibitions of this paragraph are applicable to the use of the terms “doctor,” “physician,” “otologist” or “otolaryngologist,” to the use of any abbreviations, variations or derivatives of those terms; and to the use of any symbol, depiction, or representation having a medical connotation.

(18) Making a deceptive representation as to the visibility or the construction of a hearing aid. A registrant may not do any of the following:

(i) Represent, directly or by implication, through the use of such words or expressions as “invisible,” “hidden,” “hidden hearing,” “completely out of sight,” “conceal your deafness,” “hear in secret,” “unnoticed even by your closest friends,” “no one will know you are hard of hearing,” “your hearing loss is your secret,” “no one need know you are wearing a hearingaid,” “hidden out of sight when inserted in the ear canal” or by any other words or expressions of similar import, that any hearing aid, device, or part is hidden or cannot be seen unless it is hidden or cannot be seen.

(ii) Represent directly or by implication that a hearing aid utilizing bone conduction has a specified feature such as the absence of anything in the ear or leading to the ear, or the like, without disclosing clearly and conspicuously that the instrument operates on the bone-conduction principle and that, in many cases of hearing loss, this type of instrument may not be suitable.

(19) Making an advertisement or other representation which may have the tendency or effect of misleading or deceiving a purchaser or prospective purchaser to believe that a hearing aid or device or part or accessory thereof is a new invention or involves a new mechanical or scientific principle, when that is not true. Representations of the following or similar types, when not fully justified by the facts, are among those prohibited by this paragraph: “amazing new discovery,” “revolutionary new invention,” “radically new and different,” “sensational new laboratory development,” “remarkable new electronic device,” “brand new invention,” “marvelous new hearing invention,” “new scientific aid” and “miracle.”

(20) Misrepresenting the commercial nature of the registrant’s business. A registrant may not represent, directly or by implication, that a commercial hearing aid establishment is a governmental or public one or is a nonprofit medical, educational or research institution, through the use of a term having a medical, professional or scientific connotation, such as “Hearing Center,” “Hearing Institute,” “Hearing Bureau,” “Hearing Clinic,” “State’s Hearing Clinic,” or “State’s Speech and Hearing Center.” Nothing in this paragraph precludes a registrant from representing, if true, that the registrant owns, operates or controls a “Hearing Aid Center” or from using other words or expres-
sions which clearly and nondeceptively identify the registrant’s establishment as a commercial hearing aid enterprise.

(21) Making a deceptive advertisement of a hearing aid part, accessory or component. A registrant may not use or cause to be used any type of advertising or promotional literature depicting or describing only a single part, accessory or component of a hearing aid or device, such as a battery on the finger or a transistor held in the hand, in a manner that may have the tendency to mislead or deceive a purchaser or prospective purchaser to believe that the part, accessory or component is all that must be worn or carried.

(22) Making a deceptive testimonial or other endorsement. A registrant may not advertise or otherwise represent that:

(i) A particular individual, organization or institution endorses, uses or recommends the registrant’s hearing aids or devices when that is not true.

(ii) A particular individual wears the registrant’s hearing aids or devices when that is not true.

(23) Making a representation either directly or indirectly that a hearing aid or part thereof is new, unused or rebuilt when that is not true.

(i) In the marketing of a used hearing aid or a hearing aid which contains used parts, a registrant shall make full and nondeceptive disclosure of the fact in advertising and promotional literature relating to the product on the container, box or package in which the product is packed or enclosed. The required disclosure may be made by use of words such as “used,” “second-hand,” “repaired” or “rebuilt,” whichever applies to the product involved, and it shall appear on a tag physically attached to a hearing aid.

(ii) A registrant may not misrepresent the identity of the rebuilder of a hearing aid. If the rebuilding of a hearing aid was done by other than the original manufacturer, a registrant shall disclose the fact wherever the original manufacturer is identified.

(24) Doing any of the following:

(i) Representing or using a seal, emblem, shield or other insignia which represents, directly or by implication that a hearing aid or device has been tested, accepted or approved by an individual, concern, organization, group or association unless it is true and unless the hearing aid or device has been used in a manner as will reasonably ensure the quality and performance of the instrument in relation to its intended use and the fulfillment of a material claim made, implied or intended to be supported by the representation or insignia.

(ii) Representing that a hearing aid or device tested, accepted or approved by an individual, concern, organization, group or association has been subjected to a test based on a more severe standard of performance, workmanship and quality than is true.

(iii) Making any other false, misleading or deceptive representation respecting the testing, acceptance or approval of a hearing aid device by an
individual, concern, organization, group or association. It is not necessary for an individual hearing aid or device to be tested if the method employed is a sample testing and full and nondeceptive disclosure of this fact is given in advertising and otherwise.

(iv) Making a false, misleading or deceptive representation regarding the practice of another registrant or the quality of a hearing aid product made by a hearing aid manufacturer, which enhances or is likely to enhance the registrant’s business as a repairer, fitter or seller of hearing aids.

(25) Doing any of the following:

(i) Imitating or simulating the trademark, trade name, brand or label of a competitor which may have the tendency or effect of misleading or deceiving a purchaser or prospective purchaser.

(ii) Using in advertising the name, model name or trademark of a particular manufacturer of hearing aids in a manner that implies a relationship with the manufacturer that does not exist or which otherwise may mislead or deceive a purchaser or prospective purchaser.

(iii) Using a trade name, corporate name, trademark or other designation which may have the tendency or effect of misleading or deceiving a purchaser or prospective purchaser as to the name, nature or origin of a hearing aid or of a material used therein or which is false, deceptive or misleading in another material respect.

(26) Advertising a particular model, type or kind of hearing aid for sale when a purchaser or prospective purchaser responding to the advertisement cannot purchase or is dissuaded from purchasing the advertised model, type or kind, if it is established that the purpose of the advertisement is to obtain prospects for the sale of a different model, type or kind than that advertised.

(i) In determining whether there has been a violation of this paragraph, consideration will be given to acts or practices indicating that the offer was not made in good faith for the purpose of selling the advertised product but was made for the purpose of contacting prospective purchasers and selling them a product or products other than that offered. Among acts or practices which will be considered in making that determination are the following:

(A) The creation, through the initial offer or advertisement, of a false impression of the product offered in a material respect.

(B) The refusal to show, demonstrate or sell the product offered in accordance with the terms of the offer.

(C) The disparagement, by acts or words, of the product offered or the disparagement of the guarantee; credit terms; or availability of service, repairs or parts or the disparagement in another respect, in connection with it.

(D) The showing, demonstrating and in the event of sale, delivery of a product which is unusable or impractical for the purpose represented or implied in the offer.
(E) The refusal, in the event of sale of the product offered, to deliver the product to the purchaser within a reasonable time thereafter.

(F) The failure to have available a quantity of the advertised product at the advertised price sufficient to meet reasonably anticipated demands.

(ii) It is not necessary that each act or practice set forth in subparagraph (i) be present to establish that a particular offer violates this paragraph; any one will be sufficient.

(27) Failing to furnish evidence of the required continuing education or truthful information regarding the continuing education secured when applying for renewal of a registration certificate as a hearing aid fitter.

Cross References
This section cited in 28 Pa. Code § 25.210 (relating to receipt to purchaser—purchaser protection).

§ 25.216. Continuing education requirements.

(a) General requirements. Except as provided in subsection (d), the continuing education requirement for renewal of a hearing aid fitter’s registration certificate is 20 hours of continuing education credit in the 2 years immediately preceding the expiration of the current registration certificate. If the applicant for renewal has had a registration certificate for less than 2 years, the required number of continuing education hours shall be calculated by prorating the number of credit hours required over a 2-year period by the number of months in which the applicant for renewal had the registration certificate which is about to expire. Only months in which the applicant had the registration certificate for at least 15 days shall be considered in the calculations.

(b) Requirements for renewal of an expired registration certificate. Except as provided in subsection (d), the continuing education requirement for renewal of a hearing aid fitter’s registration certificate that has expired is 20 hours of continuing education credit in the 2 years immediately preceding the filing of the application for renewal, provided that the application for renewal is filed within 5 years after expiration of the previous registration certificate. If more than 5 years have passed since the registration certificate expired, the registration certificate may not be renewed. Instead, the individual shall repeat the hearing aid fitter’s certification examination and satisfy other requirements then in effect for an original hearing aid fitter’s registration certificate.

(c) Requirements for renewal of a suspended registration certificate. The continuing education requirement for renewal of a hearing aid fitter’s registration certificate which has been suspended is the same as in subsections (a) and (d). If the individual does not satisfy the continuing education requirement during the period in which the hearing aid fitter’s registration certificate is suspended, the suspended registration certificate shall be considered to have expired, and the continuing education requirements in subsection (b) shall apply for renewal of the expired registration certificate.
(d) **Phase-in requirements.** The first 2-year period for which continuing education requirements shall be required began on April 15, 2003.

(e) **Subject matter requirements.** Any subject matter that contributes directly to the professional competence, skills and education of a hearing aid fitter is acceptable subject matter for a continuing education program. At least one-half of all continuing education credit hours by which the hearing aid fitter seeks to qualify for renewal of the registration certificate shall be secured in some combination of the following core subject matter: hearing evaluation, hearing instrumentation technology, ear mold technology, hearing aid repair and maintenance, technical devices to assist the hearing-impaired, psychology of the hearing-impaired, and office procedures and compliance with the act.

**Source**


**Cross References**

This section cited in 28 Pa. Code § 25.204 (relating to application for and renewal of registration); and 28 Pa. Code § 25.217 (relating to approval of continuing education programs).

**§ 25.217. Approval of continuing education programs.**

(a) A person may apply to the Department for approval of a continuing education program by submitting to the Department an application on a form supplied by the Department. The applicant shall supply the information requested in the application, including specification of whether the program is fully or partially devoted to any of the core subjects specified in § 25.216(e) (relating to continuing education requirements). The Department will grant approval of a continuing education program and designate whether the program is assigned full or partial credit in one of the core subjects, if the applicant satisfies the Department that the program the applicant will offer will meet the following minimum standards:

1. The program shall contribute directly to the professional competence, skills and education of a hearing aid fitter.
2. The program instructors shall possess the necessary practical and academic skills to conduct the program effectively.
3. Program materials shall be clear, informative, grammatical, carefully prepared, readable and distributed to attendees at or before the time the program is offered whenever practical.
4. The program shall be presented by a responsible instructor who is experienced and knowledgeable in the subject matter being taught, in a setting that is conducive to learning the material being taught, including any necessary equipment and facilities, and is devoted to the educational purpose of the program.
5. The program shall be open to persons who have a current, suspended or expired hearing aid fitter’s registration certificate.

(b) Approval of a continuing education program shall be effective for 3 years.
If renewal of the Department’s approval of a continuing education program is desired, at least 90 days before expiration of the 3-year period the person who offered the program shall apply to the Department to renew the Department’s approval of that program. The criteria and process applicable to the Department’s initial approval of a continuing education program shall apply to renewal of the approval of that program.

Source


§ 25.218. Credit for continuing education.

(a) Credit hour. A hearing aid fitter shall receive 1 hour of credit for each 50 minutes of instruction in a continuing education program presented in a classroom setting. Credit may not be given if attendance or other participation in the program is not adequate to meet the educational objectives of the program as determined by the person offering the program. For completing a continuing education program that is not presented in a classroom setting, the hearing aid fitter shall receive the number of credit hours assigned to the program by the Department.

(b) Program completion. A hearing aid fitter shall receive no credit for a continuing education program not completed, as evidenced by satisfaction of the check-in/check-out process for a continuing education program presented in a classroom setting and the continuing education report verifying that the hearing aid fitter completed the program, both of which are submitted to the Department by the person who offered the program. The program shall also not be considered completed if the hearing aid fitter does not satisfy other program completion requirements imposed by this subchapter and the continuing education provider.

(c) Continuing education credit for instruction. A hearing aid fitter shall receive credit equal to the number of hours served as an instructor in a continuing education program approved by the Department, or in a program that satisfies requirements for initial certification as a hearing aid fitter, except that only half of the credit hours necessary for renewal of a hearing aid fitter’s registration certificate may be obtained through serving as an instructor. The remaining credits necessary to renew a certificate shall be obtained through attendance at continuing education programs.

(d) Repeat completion or teaching of a continuing education program. The Department will not accept more than one completion or teaching of a continuing education program for credit toward renewal of a fitter’s registration certificate, but will accept a subsequent completion or teaching of the same continuing education program for a subsequent renewal of a fitter’s registration certificate.

(e) Continuing education credit through endorsement. A hearing aid fitter who attends or teaches a continuing education program offered outside this Commonwealth may apply to the Department to receive credit for the program. The hearing aid fitter shall have the burden of demonstrating to the Department that
the course meets standards substantially equivalent to the standards imposed in this subchapter. The Department will assign credit to the program, including the possibility of no credit or partial credit, based upon considerations of whether the program bears entirely upon appropriate subject matter and whether the method of presenting the program meets standards substantially equivalent to those prescribed in this subchapter.

(f) Continuing education credit assigned to self-study courses. Credit may be sought from the Department for a self-study continuing education program. The hearing aid fitter shall submit an application to the Department to approve the self-study program for credit before commencing the program and shall supply the Department with the materials the Department requests to conduct the evaluation, which may include any of the materials used in the course. The Department will assign credit to the program based upon considerations of whether the program addresses appropriate subject matter and whether the method of completing the program meets standards substantially equivalent to those prescribed in this subchapter. The Department may require modifications to the proposed self-study as a precondition to approving it for credit. If the materials are unavailable to the fitter prior to taking the course, the fitter may apply to the Department for credit after completing it. However, the Department reserves the right to disapprove the course for credit after it has been completed if it does not meet the standards prescribed in this subchapter.

(g) Continuing education credit assigned to courses not presented in a classroom setting. A hearing aid fitter shall be awarded credit for completing a continuing education program without the hearing aid fitter physically attending the program in a classroom setting, provided the program has been approved by the Department for credit when presented in that manner.

(h) Resolution of discrepancies. The Department will resolve all discrepancies between the number of continuing education credits reported and the number of continuing education credits a hearing aid fitter alleges to have earned. To help resolve disputes, the hearing aid fitter should retain the original certificate of completion of a continuing education program if a certificate of completion has been received by the hearing aid fitter.

Source

§ 25.219. Responsibilities of persons offering continuing education programs.

(a) Record of attendance. A person who offers a continuing education program shall maintain a record of attendance for a program presented in a classroom setting by maintaining a check-in/check-out process approved by the Department, and shall assign at least one person to ensure that all individuals attending the course check in when entering and check out when leaving. If an individual enters a course after the starting time, or leaves a course before the...
finishing time, the assigned person shall ensure that the time of arrival or departure is recorded for the individual.

(b) **Reporting attendance.** A person who offers a continuing education program shall report to the Department, in the manner and format prescribed by the Department, attendance at each continuing education program presented in a classroom setting.

(c) **Course evaluation.** A person who offers a continuing education program shall develop and implement methods to evaluate the program to determine its effectiveness. The methods of evaluation shall include providing a program evaluation form to each person who attends the continuing education program, and requesting each person to complete the form.

(d) **Record retention.** A person who offers a continuing education program shall retain the completed program evaluation forms and the check-in/check-out record for a program presented in a classroom setting. The person shall retain the records for at least 4 years from the presentation of the program.

(e) **Providing records.** A person who offers a continuing education program shall promptly provide the Department with complete and accurate records relating to the program as requested by the Department.

(f) **Program not presented in a classroom setting.** A person who offers a continuing education program shall be exempt from the requirements of subsections (a) and (b) for a program which is not presented in a classroom setting, if the program is approved by the Department for credit when presented in that manner. When presenting the program to the Department for approval for credit, the person shall present a procedure for monitoring, confirming and reporting hearing aid fitter participation in a manner that achieves the purposes of subsections (a) and (b).

(g) **Monitoring responsibilities.** A person who offers a continuing education program shall ensure that the program was presented in a manner that met all of the educational objectives for the program, and shall determine whether each hearing aid fitter who enrolled in the program met the requirements of this subchapter and of the continuing education program to receive credit for completing the program.

(h) **Program completion.** A person who offers a continuing education program shall report to the Department, in a manner and format prescribed by the Department, completion of a continuing education program by a hearing aid fitter who completes the program, and shall identify to the Department a hearing aid fitter who seeks credit for a program but who did not meet the requirements of the program or this subchapter to receive continuing education credit. The person who offers a continuing education program shall also provide a hearing aid fitter who completes the program with a document certifying completion of the program.

Source

§ 25.220. Right to enter, inspect and obtain records.

Upon request of a Department representative during regular and usual business hours, or at other times when that representative possesses a reasonable belief that a violation of this subchapter may exist, and upon the representative presenting documentation to identify himself as a representative of the Department, a registrant or person who offers a continuing education program shall:

(1) Produce for inspection equipment and supplies maintained pursuant to this subchapter.

(2) Produce for inspection, permit copying and provide within a reasonable period of time, records maintained under this subchapter.

Source

§ 25.221. Exceptions.

The Department may grant an exception to a requirement of this subchapter for good cause shown, except for a statutory requirement that is repeated in this subchapter.