

ment of Property and Supplies, trained personnel for the purpose of consulting with and advising State employes concerning the insurance authorized by this act and related problems.

Section 8. Applicability of Insurance Laws.—Except as otherwise specifically provided, all insurance contracted under the provisions of this act shall be subject to the laws of this Commonwealth relating to insurance.

Section 9. Effective Date.—This act shall take effect immediately.

APPROVED—The 26th day of September, A. D. 1961.

DAVID L. LAWRENCE

No. 693

AN ACT

Relating to the manufacture, sale and possession of drugs, devices and cosmetics; conferring powers on the courts and the secretary and Department of Health and a newly created Pennsylvania Drug, Device and Cosmetic Board; providing penalties; requiring registration of persons engaged in the drug trade and for the revocation or suspension of certain licenses and registrations; and repealing certain acts.

The Drug, Device
and Cosmetic
Act.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Short Title.—This act shall be known and may be cited as “The Drug, Device and Cosmetic Act.”

Section 2. Definitions.—As used in this act:

(a) The term “person” includes individual, partnership, corporation and association.

(b) The term “drug” means (1) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2) or (3), but not including devices or their components, parts or accessories: And provided, That the drug provisions of this act shall not apply to medicated feed intended for and used exclusively as food for animals other than man: And provided further, That the drug provisions as provided in this act shall

not apply to such vitamins, minerals and chemicals when used in the processing and manufacture of foods and non-alcoholic beverages specifically permitted under existing State and Federal statutes as food and color additives.

(c) The term "device" means instruments, apparatus and contrivances, including their components, parts and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment or prevention of disease of man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

(d) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance, and (2) articles intended for use as a component of any such articles, except that such term shall not include soap.

(e) The term "nonproprietary drug" means any drug containing any quantity of any narcotic, drug, a drug containing biologicals or substances of glandular origin (except intestinal enzymes and all liver products), drugs which are administered hypodermically, intramuscularly or *intravenously, but not any such drugs which are prepackaged with complete dosage instructions in the labeling limiting their use to the care or **treatment of poultry and livestock.

(f) The term "registrant" means any person registered under the laws of this Commonwealth to manufacture, dispense, administer or sell drugs.

(g) The term "narcotic drug" means (1) opium; (2) cocoa leaves (except decocainized cocoa leaves or extracts of cocoa leaves which extracts do not contain cocaine or egonine); (3) marihuana; (4) isonipecaine (any substance identified chemically as 1-methyl-4-phenyl-piperidine-4-carboxylic acid ethyl ester, or any salt thereof, by whatever trade name designated); (5) any drug or other substance found by the United States Secretary of the Treasury or his delegate, and proclaimed by him or his delegate after due notice and opportunity for public hearing, to have an addiction-forming or addiction-sustaining liability similar to morphine or cocaine; (6) any compound, manufacture, salt, derivative or preparation of the substance referred to in clauses (1) through (5); (7) any substance (and any compound, manufacture, salt, derivative or preparation thereof) which is chemically identical with any substance referred to in clauses (1) through (5).

For purposes of this definition, the term "manufacture" means the production of a narcotic drug, either

* "intravenously" in original.

** "treamtmet" in original.

directly or indirectly, by extraction from substances of vegetable origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis.

(h) The term "dangerous drug" means a drug other than a narcotic drug as defined in paragraph (g) of this section, which (1) contains any quantity of barbituric acid, bromal, carbromal, chloral, alpha-eucaine, beta-eucaine, paraldehyde, peyote, sulfonmethane, or any chemical derivative thereof which derivative has been, by the secretary after investigation and after consultation with and on the recommendation of the board, found to be habit-forming and by regulations designated as a dangerous drug; or (2) contains any quantity of amphetamine or any isomer thereof; or (3) because of its toxicity or other potentiality for harmful effect or the method of its use or the collateral measures necessary to its use has been found by the secretary, after investigation and after consultation with and on the recommendation of the board, not safe for use except under the supervision of a practitioner licensed by law to administer such drug and has by regulation been designated a dangerous drug; or (4) is limited under the Federal act to use under the professional supervision of a practitioner licensed by law to administer such drug.

(i) The term "official compendium" means the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary or any supplement to any of them.

(j) The term "label" means a display of written, printed or graphic matter upon the immediate container of any article, and a requirement made by or under authority of this act that any word, statement or other information *appearing on the label shall not be considered to be complied with unless such word, statement or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article or is easily legible through the outside container or wrapper.

(k) The term "immediate container" does not include package liners.

(l) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon an article or any of its containers or wrappers, or (2) accompanying such article.

(m) The term "advertisement" means any representation, disseminated in any manner or by any means other than by labeling, for the purpose of inducing or which is likely to induce, directly or indirectly, the purchase and/or use of a drug, device or cosmetic.

* "appear" in original.

(n) The term "new drug" means (1) any drug the composition of which is such that such drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs as safe for use under the conditions prescribed, recommended or suggested in the labeling thereof; or (2) any drug the composition of which is such that such drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(o) The term "contaminated with filth" means consisting, in whole or in part, of any decomposed, putrid or filthy substance, or prepared, packed or held under any unsanitary condition or exposed whereby the article or product concerned may have become contaminated with filth, dirt, dust or any foreign material, or in any manner rendered injurious to health.

(p) The term "Federal Act" means the Federal Food, Drug and Cosmetic Act (Title 21, U.S.C. 301, et seq., 52 Stat. 1040 et seq.) as amended from time to time.

(q) "Secretary" means Secretary of Health of the Commonwealth of Pennsylvania, or his duly authorized agents or employees.

(r) "Board" means the Pennsylvania Drug, Device and Cosmetic Board.

(s) "Manufacturer" means the creator, fabricator, preparer or maker of drugs but such term shall not include a registered pharmacist who makes, prepares or manufactures drugs in a licensed pharmacy for retail sale or dispensing therefrom, nor shall it be construed to permit such a person to distribute nonproprietary drugs to the ultimate consumer without a pharmacy license.

(t) "Wholesaler" means any person engaged in the activities of jobber, dealer, repackager or wholesaler, selling, repackaging or otherwise distributing any drug for resale or redistribution which he has not himself prepared, produced or compounded.

(u) Color additive means a material which is a dye, pigment or other substance made by a process of synthesis or similar artifice, or extracted, isolated or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral or other source, and, when added or applied to a drug or cosmetic or to the human body, is capable, alone or through reaction with another substance, of imparting color thereto, except that such term does not include any material which the appropriate authority, pursuant to the Federal act, determines is used or intended to be

used solely for a purpose or purposes other than coloring. The term "color" includes black, white and intermediate grays.

(v) "Contraband" means any dangerous or narcotic drug possessed by a person not authorized by law to possess such drug, or obtained or held in a manner contrary to the provisions of this act.

Section 3. Exempt Narcotics.—(a) The secretary, after consultation and upon the recommendation of the board, may, by regulation, exempt, from the provisions of this act relating to narcotic drugs to such extent as he determines to be consistent with the public welfare, pharmaceutical preparations found by the secretary:

(1) Either to possess no addiction-forming or addiction-sustaining liability or not to possess an addiction-forming or addiction-sustaining liability sufficient to warrant imposition of all of the requirements of this act, and

(2) Not to permit recovery of a narcotic drug having such an addiction-forming or addiction-sustaining liability with such relative technical simplicity and degree of yield as to create a risk of improper use.

(b) In exercising the authority granted in paragraph (a), the secretary, by regulations and without special findings, shall, unless cogent reasons require otherwise in the interest of public health, grant exempt status to such pharmaceutical preparations as are determined to be exempt under the Federal Narcotic Law and Regulations.

(c) If the secretary shall subsequently determine that any exempt pharmaceutical preparation does possess a degree of addiction liability that results in abusive use, he shall, by regulation, remove such pharmaceutical preparation from exempt status effective on a date fixed by the regulation.

Section 4. Prohibited Acts.—The following acts and the causing thereof within the Commonwealth are hereby prohibited:

(a) The manufacture, sale or delivery, holding, offering for sale, or possession of any drug, device or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any drug, device or cosmetic.

(c) The receipt in commerce of any drug, device or cosmetic that is adulterated or misbranded and the delivery or proffered delivery thereof for pay or otherwise.

(d) The sale, delivery for sale, holding for sale or offering for sale of any article in violation of section 16.

(e) The dissemination or publication of any false or materially misleading advertisement.

(f) The refusal to permit entry or inspection, or to permit the taking of a sample as provided in section 17, or to make available such records pertaining to the shipping, receiving and dispensing of drugs as are required by this act to be maintained and available for inspection.

(g) The removal or disposal of a detained or embargoed article in violation of section 12, whether or not such article is in fact adulterated or misbranded.

(h) The adulteration, mutilation, destruction, obliteration or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a drug, device or cosmetic, if such act is done while such article is held for sale and results in such article being adulterated or misbranded.

(i) Forging, counterfeiting, simulating or falsely representing, or without proper authority using any mark, stamp, tag, label or other identification device authorized or required by regulation promulgated under the provisions of this act.

(j) Placing or causing to be placed upon any drug or pharmaceutical preparation, or upon the container of any drug or pharmaceutical preparation, with intent to defraud, the trademark, trade name or other identifying mark, imprint or device of another, or any likeness of any of the foregoing.

(k) Selling, dispensing, disposing of or causing to be sold, dispensed or disposed of, or keeping in possession, control or custody, or concealing any drug or pharmaceutical preparation or any container of any drug or pharmaceutical preparation with knowledge that the trademark, trade name or other identifying mark, imprint or device of another, or any likeness of any of the foregoing, has been placed thereon in a manner prohibited by subsection (j) hereof.

(l) Making, selling, disposing of or causing to be made, sold, or disposed of, or keeping in possession, control or custody, or concealing with intent to defraud, any punch, die, plate, stone or other thing designed to print, imprint or reproduce the trademark, trade name or other identifying mark, imprint or device of another or any likeness of any of the foregoing upon any drug, pharmaceutical preparation, or container thereof.

(m) The use on the labeling of any drug, or in any advertisement relating to such drug, of any representation or suggestion that any application with respect to such drug is effective under section 16 or that such drug complies with the provisions of such section.

(n) The use of any statement or representation in advertising or promoting the retail sale of any drug that the seller of such drug is registered under this act.

(o) The manufacture, sale, offering for sale, solicitation of the purchase of, or possession with intent to sell, of any drug or device without first having registered as a manufacturer, wholesaler or retailer, if required by this act.

(p) The sale of a nonproprietary drug except by a registered pharmacist in a licensed pharmacy.

(q) The possession, control, dealing in, dispensing, selling, delivery, distribution, prescription, trafficking in, or giving of, any dangerous or narcotic drug. (i) This provision does not apply in the regular course of their business, profession, employment, occupation or duties to (1) manufacturers of drugs, (2) persons engaged in the wholesale drug trade, (3) importers or exporters of drugs, (4) registered pharmacists in any licensed pharmacy, (5) bona fide owners of pharmacies or drug stores, (6) practitioners licensed by law to administer, prescribe or dispense such drugs, (7) persons in the employ of the United States or of this Commonwealth or of any county, municipality or township of this Commonwealth and having such drugs in their possession by reason of their official duties, (8) warehousemen or common carriers engaged bona fide in handling or transporting drugs, (9) nurses under the supervision of a physician, (10) persons in charge of a laboratory where such drugs are used for the purpose of medical or scientific investigation, teaching or analysis and not for further distribution, (11) captains or proper officers of ships, upon which no regular physician is employed, for the actual medical needs of the officers and crew of their own ships only, (12) *persons in the bona fide employ of any of the persons above enumerated. (ii) The provisions of this paragraph pertaining to possession shall not apply to, in addition to the foregoing, (1) persons having said drugs in their possession for their own personal use only: Provided, That they have obtained the same in good faith, for their own use, from a practitioner licensed to prescribe or dispense such drugs, or in pursuance of a prescription given them by a practitioner licensed to prescribe such drugs, (2) persons having said drugs in their possession for the use of an animal belonging to them: Provided, That they have obtained the same in good faith, from a duly licensed veterinarian, for the use of such animal, or in pursuance of a prescription given by a duly licensed veterinarian.

* "person" in original.

(r) Using, taking, administering to the person or causing to be administered to the person, or administering to any other person or causing to be administered to any other person, any narcotic drug other than those exempted by regulation unless under the advice and direction and with the consent of a practitioner licensed by law to prescribe or administer such drugs to human beings.

(s) The sale, dispensation, distribution or gift by any manufacturer, producer, importer or person engaged in the wholesale drug trade of any narcotic drugs other than those exempted by regulation except in pursuance of a written order signed by the person authorized by law to possess, sell, dispense or prescribe such drugs to whom such drug is sold, dispensed, distributed or given. "Written order" hereunder shall include bills of lading, invoices or receipts signed by the person authorized by law to receive such drugs, showing the names and quantities of drugs purchased.

(t) The sale, dispensation, distribution or gift by any registered pharmacist in any licensed pharmacy of any narcotic drugs other than those exempted by regulation except to (1) a practitioner licensed by law to administer or prescribe such drugs, (2) a bona fide hospital, dispensary, asylum, sanatorium or public institution, (3) an individual in pursuance of a written prescription, or an oral prescription subject to the requirements hereinafter set forth, issued by a practitioner licensed by law to prescribe such drugs, which prescription shall be dated as of the day on which signed and shall be signed by the practitioner who issued the same, (4) a person in charge of a laboratory where such drugs are used in medical or scientific investigation, teaching or analysis and not for sale or further distribution, (5) the captain or proper officer of a ship upon which no regular physician is employed for the actual medical needs of the officers and crew of such ship only, (6) a person in the employ of the United States or of this Commonwealth or of any county, municipality or township thereof, purchasing or receiving the same in his official capacity.

(u) The sale, dispensation, distribution or gift by any registered pharmacist or operator of a licensed pharmacy of any narcotic drugs other than those exempted by regulation, except in pursuance of a written order signed by the person to whom such drugs are sold, dispensed, distributed or given or by oral prescription as provided for in section 6, when such drugs are sold, dispensed, distributed or given to an individual in pursuance of a prescription. Such prescription shall be regarded as the written order herein required and no

further written order shall be necessary. Such orders shall be kept and preserved for a period of two years.

(v) The sale, dispensation, distribution, prescription or gift by any practitioner otherwise authorized by law so to do of any narcotic drugs to any person known to such practitioner to be an habitual user of any said drugs, unless said drug is prescribed, administered, dispensed or given, for the cure or treatment of some malady other than the drug habit pursuant to regulations providing for such use.

(w) The administration, dispensation, delivery, gift or prescription by any practitioner otherwise authorized by law so to do of any narcotic drugs other than those exempted by regulation except after a physical examination of the person or animal for whom said drugs are intended, said examination to be made at the time said prescription is issued or at the time said drug is administered, dispensed, given away or delivered by said practitioner. No veterinarian shall sell, dispense, distribute, give or prescribe any narcotic drug for the use of a human being.

(x) The sale at retail or dispensing of any dangerous drug to any person, except to one authorized by law to sell, dispense, prescribe or possess such drugs, unless upon the written or oral prescription of a person licensed by law to prescribe such drug and unless compounded or dispensed by a registered pharmacist or under the immediate personal supervision of a registered pharmacist, or the refilling of a written or oral prescription for a dangerous drug, unless such refilling is authorized by the prescriber either in the original written prescription or by written confirmation of the original oral prescription. The provisions of this subsection shall not apply to a practitioner licensed to prescribe or dispense such drugs, who keeps a record of the amount of such drugs purchased and a dispensing record showing the date, name and quantity of the drug dispensed and the name and address of the patient.

(y) The dispensing of any dangerous drug by a pharmacist without affixing to the container in which the drug is sold or dispensed a label bearing the name and address of such pharmacist, the name and address of the patient, the date compounded and the consecutive number of the prescription under which it is recorded in his prescription files, together with the name of the practitioner prescribing it.

(z) The dispensing of a dangerous drug by a practitioner otherwise authorized by law so to do without affixing to the container in which the drug is sold or dispensed a label bearing the name and address of the practitioner, the date dispensed, the name and address

of the patient and the directions for the use of the drug by the patient.

(aa) The selling or possession by a pharmacy or wholesaler of any dangerous or narcotic drug defined herein unless the container bears a label, securely attached thereto, stating conspicuously the specific name of the drug and the proportion or amount thereof. Such label shall not be necessary when the drug is dispensed by a pharmacist upon a prescription or dispensed by a practitioner authorized by law to dispense such drugs to his own patients and the container is labeled in the manner prescribed in this act.

(bb) The operation of a drug manufacturing, wholesaling or retailing establishment, except by registered pharmacists in a licensed pharmacy, without conforming with such standards respecting sanitation, materials, equipment and supplies as the secretary, after consultation with the board, may establish by regulation for the protection of the public health and safety.

(cc) The using by any person to his own advantage or revealing other than to the secretary or officers or employees of the Department of Health or to the board or to courts or a Hearing Examiner when relevant to proceedings under this act any information acquired under authority of this act concerning any method or process which as a trade secret is entitled to protection. Such information obtained under the authority of this act shall not be admitted in evidence in any proceeding before any court of the Commonwealth except in proceedings under this act.

(dd) The purchase or receipt in commerce by any person of any drugs or devices from any person not authorized by law to sell, distribute, dispense or otherwise deal in such drugs or devices.

Section 5. Oral Prescriptions for Dangerous Drugs.— Any dangerous drug may be sold or dispensed by a registered pharmacist upon oral prescription of a practitioner authorized by law to prescribe such drugs, provided, however, said oral prescription, together with the date of its communication, the name and address of the prescriber and such other information as may be required by law or regulation in the case of written prescriptions, shall be reduced promptly to writing by the registered pharmacist and the writing filed and preserved by the licensed pharmacy for a period of two years in such a way that it will be readily accessible for inspection by the proper authorities. The practitioner giving such oral prescription shall confirm it in writing within seventy-two hours of issuing it.

Section 6. Oral Prescriptions for Narcotics.—

(a) Any narcotic drug required to be dispensed on prescription, which the secretary after considering any views expressed by the board and the respective licensing boards and associations representing (1) physicians, (2) pharmacists, (3) dentists and (4) veterinarians, shall, in his discretion, find and, by regulation, designate to possess relatively little or no addiction liability, may be sold, dispensed, distributed or given away by a registered pharmacist operating a licensed pharmacy subject to the jurisdiction of the State Board of Pharmacy upon oral prescription of a practitioner authorized by law to prescribe such drugs, which oral prescription together with the date of its communication, the name and address of the prescriber and such other information as may be required by law or regulation in the case of written prescriptions, shall be reduced promptly to writing by the registered pharmacist and the writing filed and preserved by the licensed pharmacy for a period of two years in such a way that it will be readily accessible for inspection by the proper authorities. The practitioner giving such oral prescription shall confirm it in writing within seventy-two hours.

In issuing an oral prescription, the prescriber shall furnish the pharmacist with the same information as is required by law or regulation in case of a written prescription for drugs, except for the written signature of the prescriber, and the registered pharmacist who fills such prescription shall be required to inscribe such information on the written record of the prescription made, filed and preserved by him, and shall inscribe on the label of the container of the drug the same information as is required in filling a written prescription. No such oral prescription shall be refilled.

(b) If the secretary shall subsequently determine that a drug to which the oral prescription procedure set forth in the preceding paragraphs has been made applicable possesses a degree of drug addiction liability that in his opinion has resulted or may result in abusive use of such procedure, he shall, by regulation, revoke such prior regulation.

Section 7. Prescriptions for Narcotics.—Any prescription for narcotic drugs shall be preserved for a period of two years in such a way that it will be readily accessible to inspection by the proper authorities. When such drugs are sold, dispensed, distributed or given to an individual in pursuance of a prescription, either written or oral as provided for in this act, such written prescription, or in the case of an oral prescription the written record thereof made by the pharmacist, shall be

regarded as the written order herein required and no further written order shall be necessary.

Whenever a pharmacist sells or dispenses any narcotic drug on a prescription, written or oral, he shall affix to the container in which such drug is sold or dispensed a label showing the date, his own name, address and registry number *and the name, address and registry number of the pharmacist for whom he is lawfully acting, the name and address of the patient, or if the patient is an animal, the name and address of the owner of the animal and the species of the animal, the name, address and registry number of the practitioner by whom the prescription was written or orally given, and such directions as may be stated on the prescription. Whenever a practitioner licensed by law so to do dispenses any narcotic drug to his patient, there must be affixed to the container in which said drug is dispensed a label showing the date, his own name, address and registry number, the name and address of the patient, or if the patient is an animal, the name and address of the owner of the animal and the species of the animal. No person shall alter, deface or remove any label so affixed.

A person to whom or for whose use any narcotic drug has been prescribed, sold **or dispensed, and the owner of any animal for which any such drug has been prescribed, sold or dispensed, may lawfully possess such drug only in the container in which it was delivered to him by the person selling or dispensing the same.

Section 8. Treatment of Habitual Users.—The narcotic provisions act shall not be construed to apply to the treatment of habitual users of narcotic drugs under the supervision of a duly licensed practitioner authorized by law to prescribe such drugs in hospitals, sanatoriums, poorhouses, prisons or public institutions, except that all such institutions shall render an annual report to the State Department of Health giving therein the names, addresses, ages, clinical conditions and the results of treatment of all habitual users of drugs given treatment in said institutions.

Section 9. Records of Distribution of Dangerous and Narcotic Drugs.—

(a) Every person who sells or otherwise distributes dangerous drugs or narcotic drugs other than those exempt by regulation, except practitioners licensed by law to administer, dispense or prescribe such drugs, shall keep records of all purchases or other receipt and sales or other distribution of such drugs for two years from the date of purchase or sale. Such records shall include the name and address of the person from whom

* "and" not in original.

** "or" not in original.

purchased or otherwise received or to whom sold or otherwise distributed, the date of purchase or receipt or sale or distribution, and the quantity involved.

(b) Every practitioner licensed by law to administer, dispense or distribute narcotic drugs shall keep a record of all such narcotic drugs, other than those exempt by regulation, administered, dispensed or distributed by him, showing the amount administered, dispensed or distributed, the date, the name and address of the patient, and in the case of a veterinarian, the name and address of the owners of the animal to whom such drugs are dispensed or distributed. Such record shall be kept for two years from the date of administering, dispensing or distributing such drug and shall be open for inspection by the proper authorities. No record need be kept of any such drug administered in an emergency case.

Section 10. Removal of Drugs from Dangerous Drug Classification.—Whenever the secretary, either on his own initiative or on petition of an interested party, finds that the classification of a drug as a dangerous drug is no longer necessary for the protection of the public health and safety, he shall remove such drug from such classification by regulation.

Section 11. Registration.—(a) No person shall operate within this Commonwealth as a manufacturer, wholesaler or retailer of drugs or devices nor sell, offer for sale nor solicit the purchase of drugs or devices nor hold drugs or devices for sale or resale until such person has registered under this act with the secretary.

(1) Any manufacturer or wholesaler not operating an establishment within this Commonwealth, but employing sales representatives or detailmen within this Commonwealth, shall either register as a manufacturer, or wholesaler as the case may be, or file, in lieu of registration, with the secretary the names and *addresses of such representatives and detailmen, and shall promptly inform the secretary of any changes in said list.

(2) Separate registration with the secretary shall be required for each place at which such person carries on activities as a manufacturer, wholesaler or retailer within this Commonwealth. The certificate evidencing such registration shall be conspicuously displayed and shall not be transferable.

(3) Certificates of registration issued by the State Board of Pharmacy to manufacturers shall continue to be valid for the period issued and, upon expiration, shall be renewed in the manner provided for renewal of certificates of registration issued pursuant to this section.

* "address" in original.

Nothing contained herein shall be construed to require the registration hereunder of pharmacists registered by the Board of Pharmacy nor pharmacies licensed by said board, nor to require the separate registration of agents or employees of persons registered pursuant to the provisions of this section, or of sales representatives or detailmen of manufacturers or wholesalers not operating an establishment within this Commonwealth whose names and addresses are on file with the secretary: Provided, however, That all persons registered pursuant to this section, whether located within this Commonwealth or not, shall be deemed to have accepted and shall be subject to all provisions of this act.

(b) No person shall operate as a manufacturer of drugs or devices unless such drugs or devices are manufactured under the supervision of a registered pharmacist, chemist or other person possessing at least five years' experience in the manufacture of drugs or devices or such other person approved by the secretary as qualified by scientific or technical training or experience to perform such duties of supervision as may be necessary to protect the public health and safety.

(c) Each application for registration as a manufacturer shall be accompanied by a fee of one hundred dollars (\$100.00). Each application for registration as a wholesaler shall be accompanied by a fee of twenty-five dollars (\$25.00). Each application for registration as a retailer shall be accompanied by a fee of two dollars (\$2.00). Applications shall be on forms prescribed by the secretary. Registration certificates shall be renewed annually and applications therefor shall be accompanied by the same fee as for initial applications.

(d) Registration of any person *not registered by the Board of Pharmacy on the effective date of this act shall become effective at noon of the sixtieth day after application therefor is filed: Provided, however, That the secretary shall have authority to issue a registration certificate or to issue an order denying such registration pursuant to subsection (e) hereof at any time prior to the expiration of such sixty day period. Renewal of registration shall be effective upon application.

(e) The secretary may refuse the initial registration (1) of any person who has made false representation in the application for registration, or of any person or agent or employee of any person who manufactures drugs or devices other than under the supervision of a registered pharmacist, chemist or other person possessing at least five years' experience in the manufacture of said drugs or devices, or such person approved by the secretary as provided herein, or who fails to comply

* "net" in original.

with the standards of sanitation, equipment, materials or supplies promulgated pursuant to section 4 (bb), until such person has filed a proper application and is in compliance with this section and with said standards of sanitation, equipment, materials and supplies; and (2), in addition to the foregoing, of any manufacturer or wholesaler, (i) who has been convicted of a violation of any law of this Commonwealth or of the United States relating to the sale, use or possession of narcotic drugs if such refusal shall be necessary for the protection of the public health and safety, or (ii) who knowingly employs in any capacity connected with the preparation, handling or sale of narcotic drugs any person convicted of a violation of the laws of this Commonwealth or of the United States relating to the sale, use or possession of narcotics, unless prior consent shall have been obtained from the secretary.

(f) In addition to all other penalties provided for violations of this act, the secretary may, after notice and hearing pursuant to the administrative agency law as amended, (1) in the case of a manufacturer registered hereunder, prohibit the sale in Pennsylvania of any drugs or devices involved in any violation of this act which he commits with knowledge or reason to know of said violation, (2) suspend or revoke the registration of any manufacturer if said registrant (i) makes any sale in Pennsylvania of any drug or device whose sale has been prohibited under the preceding clause, or (ii) is convicted of a violation of any law of this Commonwealth or of the United States relating to the sale, use or possession *of narcotic drugs **if such suspension or revocation shall be necessary for the protection of the public health and safety, (iii) knowingly employs in any capacity connected with the preparation, handling or sale of narcotic drugs any person convicted of a violation of the laws of this Commonwealth or of the United States relating to the sale, use or possession of narcotics, unless prior consent shall have been obtained from the secretary, (3) in the case of a wholesaler registered hereunder, suspend or revoke his registration for any violation of this act which he commits with knowledge or reason to know of said violation if such suspension or revocation shall be necessary for the protection of the public health and safety.

(g) If the secretary takes any action refusing registration or disciplining any registrant under subsections (e) and (f), the aggrieved party may, within fifteen days after the date upon which a copy of the order is delivered to the address indicated on the application or the registration certificate, whichever is applicable,

* "or" in original.

** "is" in original.

petition the board for review. The board shall, within thirty days, grant a hearing and, as soon thereafter as practicable, adopt, modify or reject the action of the secretary. Any action by the board shall be deemed an adjudication to which the provisions of the Administrative Agency Law, as amended, shall be applicable.

(h) The provisions of this section shall not be effective until April 30, 1962.

Section 12. Embargo and Seizure.—(a) Whenever a duly authorized agent of the secretary finds or has probable cause to believe that any drug, device or cosmetic is adulterated or misbranded or contraband, the same shall be deemed subject to embargo and he shall affix to such article or articles a tag or other appropriate marking, approved by the secretary, giving notice that such article is or is suspected of being adulterated, misbranded or contraband and warning all persons not to remove or dispose of such article or articles until permission so to do has been granted by such agent, or until it shall have determined by proper authority that such article or articles are not adulterated, misbranded or contraband. At the time such notice is offered, the agent shall provide the person in charge of such articles, if any, or the owner, if he is known, a statement in writing, setting forth both the basis for the embargo and supporting facts.

(b) When an article or articles is detained or embargoed under subsection (a), the secretary shall serve within three days from the date of such embargo a citation upon the claimant thereof or owner, if he is known, setting forth both the basis for the embargo and supporting facts and fixing a date for a hearing not later than ten days from the date of service of said citation at which a hearing examiner, appointed under the authority of section 18, will receive evidence pertaining to the alleged offense. Unless postponed by mutual consent, failure to serve a citation or commence hearings within the time herein specified shall operate to void such embargo.

(c) If, after hearing, the examiner is satisfied from the evidence presented that a detained or embargoed article is adulterated, misbranded or contraband, he shall, within five days of the conclusion of the hearing, order such article or articles destroyed at the expense of the claimant thereof under supervision of an agent of the secretary: Provided, That when the embargo is based on an adulteration or misbranding which can be corrected by proper labeling or processing of the article, the examiner, after entry of the order and after such costs, fees and expenses have been paid and a good and sufficient bond conditioned that such article shall be so

labeled or processed has been executed, may by order direct that such article be released to the claimant thereof for such labeling or processing under the supervision of an agent of the secretary. The expense of such supervision, if any, shall be paid by the claimant. Such article shall be released to the claimant of the article when the article is no longer in violation of this act and the expenses of such supervision have been paid.

(d) If no claimant shall appear to defend such proceedings, the Hearing Examiner may order the embargoed articles destroyed or distributed to a nonprofit institution.

Section 13. Adulteration.—A drug or device or cosmetic shall be deemed to be adulterated:

(a)(1) If it consists, in whole or in part, of any filthy, putrid or decomposed substance; (2) if it has been prepared, packed or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; (4) if it has been exposed to conditions of fire, water or extreme temperature, which may have rendered it injurious to health; (5) if (a) it bears or contains for purposes of coloring only a color additive, unless it be a hair dye which is unsafe within the meaning of section 15 of this act, or (b) it is a color additive the intended use of which in or on drugs, devices or cosmetics is for purposes of coloring only and is unsafe, unless it be a hair dye within the meaning of section 15 of this act.

(b) If it purports to be or is represented as a drug, the name of which is recognized in an official compendium and its strength differs from or its quality or purity falls below the standards set forth in such compendium. Such determination as to strength, quality or purity, shall be made in accordance with the tests or methods of assay set forth in such compendium, or in the absence of or inadequacy of such tests or methods of assay those prescribed under the authority of the Federal act. No drug defined in an official compendium shall be deemed to be adulterated under this subsection because it differs from the standard of strength, quality or purity therefor set forth in such compendium, if its difference in strength, quality or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case, it shall be subject

to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

(c) If it is a color additive and is to be used or is recommended for use as a hair dye and it is not exempt under section 15 unless its label bears the following legend conspicuously displayed thereon: "Caution. This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows, to do so may cause blindness," and the labeling bears adequate directions for such preliminary testing. For the purpose of this paragraph, the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

(d) If it is not subject to the provisions of subsection (b) of this section and its strength differs from or its purity or quality falls below that which it purports or is represented to possess.

(e) If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength, or (2) substituted wholly or in part therefor.

Section 14. Misbranding.—A drug or device or cosmetic shall be deemed to be misbranded:

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer or distributor and (2) an accurate statement of the quantity of the contents in terms of weight measure or numerical count: Provided, That under clause (2) of this paragraph, reasonable variations shall be permitted and exemptions as to small packages shall be established by regulations.

(c) If any word, statement or other information required by or under authority of this act to appear on the label, or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs or devices in the labeling), and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions or purchase and use.

(d) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alphaucaine, barbituric acid, betaucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote or sulphonmethane, or any chemical derivative of such substances, which de-

rivative has been by the secretary, after his investigation and consultation with the board, by regulations designated as habit-forming, unless its label bears the name and quantity of proportion of such substance or derivative and in juxtaposition therewith the statement "Warning. May Be Habit-Forming."

(e) If it is a drug and is not designated solely by a name recognized in an official compendium, unless its label bears (1) the common or usual name of the drug, if such there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient including the kind and quantity or proportion of any alcohol and also including whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscyne, hyoscyamine, arsenic, digitalis, glucosides, mercury, ouabain, strophanthin, strychnine, thyroid or any derivative or preparation of any such substances contained therein: Provided, That to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, exemptions shall be established by regulations.

(f) Unless its labeling bears (1) adequate directions for use, and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application in such manner and form as are necessary for the protection of users: Provided, That where any requirement of clause (1) of this paragraph as applied to any drug or device is not necessary for the protection of the public health, regulations shall be promulgated exempting such drug or device or cosmetic from such requirements.

(g) If it purports to be a drug, the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: Provided, That the method of packing may be modified with a consent of the secretary. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling, unless it is labeled and offered for sale as a homeopathic drug, in which case, it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not *to those of the United States Pharmacopoeia.

(h) If it has been found by the secretary to be a drug liable to deterioration unless it is packaged in such form and manner and its label bears a statement specifying

* "of" in original.

such precautions against deterioration as the secretary shall by regulation require as necessary for the protection of public health. No such regulation shall be established for any drug recognized in an official compendium, or for any drug which regulations specifying precautions against deterioration have been promulgated by the Secretary of Health, Education and Welfare under the Federal act.

(i) If it is offered for sale or sold under the name of another drug, device or cosmetic or brand of drug, device or cosmetic, or if it is manufactured, packaged, labeled or sold in such manner as to give rise to a reasonable probability that the purchaser will be lead to believe he is purchasing such drug, device or cosmetic as another drug, device or cosmetic or as the product of another manufacturer.

(j) If it is dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended or suggested in the labeling thereof.

(k) A drug dispensed by filling or refilling a written or oral prescription issued by a person licensed by law to administer or prescribe such drug (except a drug sold in the course of the conduct of a business of selling drugs pursuant to diagnosis by mail) shall be exempt from the requirements of this section, except paragraphs (a) and (i) if such drug bears a label containing the name and place of business of the dispenser, the serial number and date of such prescription, the name and address of the person prescribing such drug, the name and address of the patient and such directions for use and cautionary statements, if any, contained in such prescription.

(l) If it is a cosmetic and its container is so made, formed or filled as to be misleading.

Section 15. Color Additives.—A color additive shall be deemed unsafe unless there is in effect with respect to such additive a regulation issued pursuant to the Federal act permitting such use and unless such additive and use thereof conforms in all respects to the requirements of the Federal act and regulations issued pursuant thereto.

Section 16. New Drugs.—(a) No person shall sell, deliver, offer for sale, hold for sale, or give away, any new drug unless (1) an application with respect thereto has become effective under section 505 of the Federal act, or (2) when not subject to the Federal act unless such drug has been tested and has not been found to be unsafe for use under the conditions prescribed, recommended or suggested in the labeling thereof, and prior to selling or offering for sale such drug, there has been filed with the secretary an application, setting forth (a) full re-

ports of investigations which have been made to show whether or not such drug is safe for use, (b) a full list of the articles used as components of such drug, (c) a full statement of the composition of such drug, (d) a full description of the methods used in and the facilities and controls used for the manufacture, processing and packing of such drug, (e) such samples of such drug and of the articles used as components thereof as the secretary may require, and (f) specimens of the labeling proposed to be used for such drug.

(b) An application provided for in subsection (a) (2) shall be submitted to the board for its recommendations but such application shall become effective on the 60th day after the filing thereof except that if the secretary finds, after due notice to the applicant and giving him an opportunity for a hearing, that the drug is not safe for use under the conditions prescribed, recommended or suggested in the proposed labeling thereof, he shall prior to the effective date of the application issue an order refusing to permit the application to become effective.

(c) This section shall not apply:

- (1) To a drug intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety in drugs, provided the drug is plainly labeled "For investigational use only," or words of similar import, and provided such investigator furnishes a statement to the secretary showing that he has adequate facilities for such investigation,
- (2) To a drug sold in this State at any time prior to enactment of this act or introduced into interstate commerce at any time prior to the enactment of the Federal act, or
- (3) To any drug which is licensed under the animal virus serum and toxin law of March 4, 1913 (21 U. S. C. 151, et seq.) or under the Public Health Service Act of July 1, 1944 (42 U. S. C. 201, et seq.).

(d) An order refusing to permit an application under this section to become effective may be revoked by the secretary.

Section 17. Inspections.—(a) The secretary is authorized to conduct examinations and investigations for purposes of enforcement of this act through such agents or employees as he may designate. Such agents and employees, upon presenting appropriate credentials and a written notice given at the time of inspection to the owner, operator or agents in charge, if there be one, are authorized:

- (1) To enter at reasonable times any factory, warehouse, store, vehicle, carrier or establishment where drugs, devices or cosmetics are manufactured, processed, packed, held for sale or resale, transported or sold; and
 - (2) To inspect at reasonable times and within reasonable limits and in a reasonable manner such factory, warehouse, store, vehicle, carrier or establishment and all pertinent equipment, finished and unfinished materials, containers and labeling therein; and
 - (3) To take such samples of materials found therein, as may be necessary for analysis, subject to limitations set forth in paragraph (b) of this section; and
 - (4) To inspect such shipping and receiving records pertaining to the receipt and distribution of drugs, devices and cosmetics as may reasonably be necessary for proper enforcement of this act.
- (b) (1) Where a sample of a drug or cosmetic is collected for analysis, the secretary shall, upon request, provide a part of such official sample for examination for analysis by any person named on the label thereof or the owner thereof. The secretary may, by regulation, impose such reasonable terms and conditions relating to the operation of this subsection as he finds necessary for the proper enforcement of this act.
- (2) If any sample is taken in the course of any inspection, the person taking such sample shall, prior to leaving the premises, provide the owner or person in charge, if any there be, with a receipt describing the sample taken.

Section 18. Hearing Examiners.—(a) The secretary shall appoint, with the approval of the Governor, such hearing examiners as shall be necessary to conduct hearings as provided in section 12.

(b) Hearing examiners appointed under this act shall have the power to issue subpoenas requiring the attendance and testimony of, or the production of, pertinent books and papers by persons whom they believe to have information relevant to any matter pending before him. Such examiner shall also have the power to administer oaths.

(c) Any person who refuses to obey a subpoena issued hereunder or to be sworn or affirmed or to testify, or who is guilty of any contempt after summons to appear, may be punished as for contempt of court. For this purpose, an application may be made by the examiner to the court of common pleas within the territorial juris-

diction of which the offense was committed for which purpose such court is hereby given jurisdiction.

(d) In any action or proceeding before him, the hearing examiner may assess all costs incurred in connection with the prosecution of such proceeding, including investigative and laboratory costs incurred by the Commonwealth, against respondent in such proceeding; such costs to be in addition to any other penalty imposed and to be retained by the Department of Health and applied to cost to the department administering this act.

(e) Hearings shall be conducted under the provisions of the act of June 4, 1945 (P. L. 1388), the Administrative Agency Law, as amended, and subject to such other rules and regulations not inconsistent therewith as the secretary may provide and any person aggrieved by any action of the hearing examiner may appeal in accordance with the provisions of the Administrative Agency Law, as amended.

Section 19. (a) Board Creation.—There is hereby created within the Department of Health a departmental administrative board to be known as the Pennsylvania Drug, Device and Cosmetic Board.

(b) Board Membership.—The board shall consist of the Secretary of Health, his successors in office, and eight additional members whom the Governor shall appoint, by and with the advice and consent of two-thirds of all the members of the Senate. Of the members: one shall be a physician, one a dentist, and one a pharmacist, each of whom shall be duly licensed in their respective professions by the Commonwealth; one shall be a biochemist and one shall be a pharmacologist, each of whom shall have earned an advanced degree in that field from an institution of higher learning and shall have been engaged as such for three years in this State; one shall be a manufacturer registered to manufacture drugs or an employee thereof; and the two remaining persons shall be members of the general public not engaged in any of the aforementioned professional fields, who shall be citizens of this State. Two members initially shall serve for terms of one, two, three and four years, respectively, the particular term of each to be designated by the Governor at the time of appointment. The terms of all their successors shall be four years each, except that any person appointed to fill a vacancy shall serve only for the unexpired term. Every member's term shall extend until his successor is appointed and qualified. Any appointed member of the board shall be eligible for reappointment. Each member of the board shall receive compensation at a rate of thirty dollars (\$30.00) per diem in addition to expenses incurred when actually engaged in official meetings or

otherwise in the performance of their official duties as directed by the chairman.

(c) Board Government.—The Secretary of Health, or his designate, shall serve as chairman of the board. A majority of the members shall constitute a quorum for the purpose of organizing the board, conducting its business, and exercising all of its powers. A vote of the majority of the members present shall be sufficient for all actions of the board unless the bylaws require a greater number.

(d) Board Administration.—The board shall have the power to prescribe, amend and repeal bylaws, rules and regulations governing the manner in which the business of the body is conducted and the manner in which the powers granted to it are exercised. The board may delegate supervision of the administration of board activities to an administrative secretary and such other employees as the Secretary of Health shall appoint.

(e) Board Powers.—The board shall have the power to do all things necessary or convenient to carry out the powers granted to it by this act.

(f) Official Seal; Evidence.—The board may, for the authentication of its records, process and proceedings, adopt, keep and use a common seal of which seal judicial notice shall be taken in all courts of this Commonwealth and any process, writ, notice or other document, which the board may be authorized by law to issue, shall be deemed sufficient if signed by the chairman or secretary of the board and authenticated by such seal. All acts, proceedings, orders, papers, findings, minutes and records of the board, and all reports and documents filed with the board, may be proved in any court of this Commonwealth by a copy thereof certified to by the chairman or secretary of the board with the seal of the board attached.

(g) Subpoenas; Oaths.—In order to enable the board to carry out the provisions of this act, including its power to advise the secretary on various matters, it shall have the power to issue subpoenas, requiring the attendance and testimony of, or the production of, pertinent books and papers by persons whom the board believes to have information, books or papers of importance to it in carrying out the purposes and intent of this act. Each member of the board and such officers, employees or others employed in the work of the board designated by the chairman of the board also shall have the power to administer oaths and affirmations, to question witnesses thereunder, and to examine such books and papers. The board may issue commissions, letters rogatory, or other appropriate processes outside the Commonwealth.

(h) Contempt.—Any person who refuses to obey a subpoena issued hereunder, or to be sworn or affirmed, or to testify, or who is guilty of any contempt after summons to appear, may be punished as for contempt of court. For this purpose an application may be made by the board to the court of common pleas within the territorial jurisdiction of which the offense was committed, for which purpose, such court is hereby given jurisdiction.

Section 20. Penalties and Enforcement.—(a) Any person who violates any of the provisions of this act and is not subject to penalty as provided in subsections (c) and (d) of this section shall be guilty of a misdemeanor, and shall, on conviction thereof, be subject to imprisonment for not more than one year or a fine of not more than five thousand dollars (\$5,000.00), or both; but if the violation is committed after a prior conviction of such person, for a violation of this act under this section, has become final, such person shall be subject to imprisonment for not more than three years or a fine of not more than twenty-five thousand dollars (\$25,000.00), or both.

(b) No publisher, radio broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, distributor or seller of the article to which a false advertisement relates, shall be liable under this section by reason of the dissemination by him of such false advertisement unless he has refused on the request of the secretary to furnish the secretary with the name and post office address of the manufacturer, distributor, seller or advertising agency who causes him to disseminate such advertisement or unless he publishes such advertisement knowing or having good cause to know that it is false or otherwise in violation of the law.

(c) Any person who possesses any narcotic drugs in violation of the provisions of this act shall be guilty of a felony, and upon conviction thereof, shall be sentenced, as follows: For a first offense, to pay a fine not exceeding two thousand dollars (\$2,000.00) and to undergo imprisonment by separate or solitary confinement at labor of not less than two (2) years and not exceeding five (5) years; for a second offense, or in case of a first conviction of violation subject to the provisions of this subsection, the offender shall previously have been convicted of any violation of the laws of the United States or of any other state, territory or district, relating to narcotic drugs, and said violation would have been a violation of the provisions of the law to which this subsection is applicable, had it occurred in this Commonwealth, to pay a fine not exceeding five thousand dollars (\$5,000.00) and to undergo imprisonment by separate or solitary confinement at labor of not less than five (5)

years and not exceeding ten (10) years; and for a third or subsequent offense, or if the offender shall previously have been convicted two or more times in the aggregate of any violation of the law of the United States or of any other state, territory or district, relating to narcotic drugs, and said violation would have been a violation of the provisions of this act relating to sale or possession of narcotics, had it occurred in this Commonwealth, to pay a fine not exceeding seven thousand five hundred dollars (\$7,500.00) and to undergo an imprisonment by separate or solitary confinement at labor of not less than ten (10) years and not exceeding thirty (30) years.

(d) Any person who sells, dispenses or gives away any narcotic drugs in violation of the provisions of this act shall be guilty of a felony, and upon conviction thereof, shall be sentenced, as follows: For a first offense, to pay a fine not exceeding five thousand dollars (\$5,000.00) and to undergo imprisonment by separate or solitary confinement at labor of not less than five (5) years and exceeding ten (10) years; for a second offense, or if in case of the first conviction of violation of any provisions of the law to which this subsection is applicable the offender shall previously have been convicted of any violation of the laws of the United States or of any other state, territory or district, relating to narcotic drugs, and said violation would have been a violation of the provisions of this act relating to sale or possession of narcotics, had it occurred in this Commonwealth, to pay a fine not exceeding ten thousand dollars (\$10,000.00) and to undergo imprisonment by separate or solitary confinement at labor of not less than ten (10) years and not exceeding twenty (20) years, or both; and for a third or subsequent offense, or if the offender shall previously have been convicted two or more times in the aggregate of any violation of the law of the United States or of any other state, territory or district, relating to narcotic drugs, and said violation would have been a violation of the provisions of the law to which this subsection is applicable, had it occurred in this Commonwealth, to pay a fine not exceeding fifteen thousand dollars (\$15,000.00) and to undergo an imprisonment by separate or solitary confinement at labor for the term of his natural life.

(e) In the case of a conviction for a violation of the provisions of this act relating to possession or sale of narcotics, the court shall have power to suspend the imposition or execution of sentence and grant probation or parole only if the violation was a first offense.

(f) If any violation of the provisions of this act is by a corporation, copartnership or association, the officers and directors of such corporation or the members of

such copartnership or association, the agents and employees with prior guilty knowledge of the fact, shall be deemed guilty of a violation of the provisions of this act to the same extent as though said violation were committed by them personally.

(g) It shall be the duty of each District Attorney to whom the secretary reports any violation of this act to cause appropriate proceedings to be instituted in the proper courts without delay and to be prosecuted in the manner required by law.

(h) Nothing in this act shall be construed as requiring the secretary to report for the institution of proceedings under this act minor violations of this act whenever the secretary believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.

Section 21. Injunctive Relief.—In addition to the remedies hereinafter provided, the secretary is hereby authorized to apply to the court of common pleas in the county in which such violation occurs or to the Commonwealth Court in Dauphin County for, and such court shall have jurisdiction to grant, a temporary or permanent injunction restraining any person from continued violation of any provision of this act irrespective of the existence of an adequate remedy at law.

Section 22. Burden of Proving Exemptions.—In any prosecution under this act, it shall not be necessary to negative any of the exemptions of this act in any complaint, information or indictment. The burden of proving any exemption under this act shall be upon the defendant.

Section 23. Revocation of Licenses of Practitioners.—(a) Any license heretofore issued to any physician, dentist, veterinarian, pharmacist or registered nurse may be either revoked or suspended by the proper officers or boards having power to issue licenses to any of the foregoing, upon proof that the licensee is addicted to the use of any narcotic drugs, after giving such licensee reasonable notice and opportunity to be heard.

(b) The appropriate licensing boards in the Department of Public Instruction are hereby authorized to revoke or suspend the registration or license of any physician, surgeon, dentist, veterinarian, pharmacist or nurse, when such person has pleaded guilty or nolo contendere or has been found guilty by a judge or jury of violating any State or Federal law pertaining to the sale, use or distribution of narcotics. Before any such revocation or suspension, the licensee or registrant shall be given a hearing before the appropriate board. At such hearing the accused may be represented by counsel

and shall be entitled to compulsory attendance of witnesses.

Section 24. Persons Authorized to Prescribe Drugs to Remain as Heretofore.—No provision of this act or any rule or regulation promulgated pursuant to this act shall authorize or be construed as authorizing any person to prescribe drugs who is not specifically so authorized under existing law.

Section 25. Conformity with Federal Law.—No drug, device or cosmetic shall be deemed to be adulterated or misbranded under this act if such drug, device or cosmetic complies with the Federal act and/or regulations and interpretations issued pursuant thereto, unless the secretary, after consultation with and upon the recommendation of the board, shall have previously promulgated a regulation stating that the applicable provision of the Federal act and/or regulations and interpretations thereof would not be followed.

Section 26. Administration of Act.—The provisions of this act shall be administered by the Department of Health of the Commonwealth of Pennsylvania. The Secretary of Health is authorized to establish in the Department of Health an administrative unit or units for the purpose of enforcing the provisions of this act and to employ such consultants, assistants, stenographers, inspectors, clerks and other employees as, in his opinion, may be necessary and to fix their compensation subject to The Administrative Code of 1929, as amended, act of April 9, 1929 (P. L. 177).

The Secretary of Health shall employ personnel who shall be authorized and empowered to make arrests without warrants for all violations of the provisions of this act pertaining to narcotic and dangerous drugs by any person or persons who are not exempted by section 4(q) of this act.

Section 27. Promulgation of Regulations.—(a) The secretary shall have the authority to promulgate in accordance with the provisions of this section any regulations hereinbefore referred to in this act and such other regulations upon the advice of the board regarding the possession, sale, purchase or manufacture of drugs, devices or cosmetics as may be necessary to aid in the enforcement of this act.

(b) (i) Prior to the promulgation, amendment or repeal of any regulation under this act the secretary shall give at least thirty (30) days public notice of his proposed action, and shall afford all interested persons an opportunity to present their views thereon either orally or in writing. As soon as practicable thereafter,

the secretary shall either withdraw such proposal or shall promulgate the proposed regulation.

(ii) Any person aggrieved by the promulgation, amendment or repeal of a regulation, or by the refusal to promulgate, amend or repeal a regulation, may file objections with the secretary specifying, with particularity, the reason why such action is deemed objectionable and the grounds for such objection. As soon as possible after the filing of objections, the secretary shall hold a public hearing for the purpose of receiving evidence relevant to such objections. As soon as practicable after completion of hearings, the secretary shall issue an appropriate order either confirming, modifying or withdrawing the regulation in question.

(iii) Any party to proceedings, conducted pursuant to paragraph (ii) hereof, aggrieved by the order of the secretary, shall have a right of appeal in accordance with the provisions of the Administrative Agency Law, as amended, and such order shall be deemed an "adjudication" as that term is defined and used in the Administrative Agency Law, as amended.

Section 28. Administrative Procedure.—The Administrative Agency Law, as amended, shall be applicable in its entirety to the Department of Health in the administration of this act.

Section 29. Savings Provision.—The provisions of this act shall not affect any act done, liability incurred, or right accrued or vested, or affect any suit or prosecution pending to enforce any right or penalty or punish any offense under the authority of any act of Assembly, or part thereof, repealed by this act.

Section 30. Severability.—The provisions of this act are severable and, if any provision or part hereof shall be held invalid or unconstitutional or inapplicable to any person or circumstances, such invalidity, unconstitutionality or inapplicability shall not affect or impair the remaining provisions of the act. It is hereby declared to be the legislative intent that this act would have been adopted if such invalid, unconstitutional or inapplicable provisions had not been included therein.

Section 31. Repeals.—(a) The following acts are hereby repealed: Act of May 24, 1887, P. L. 189; act of May 8, 1909, P. L. 470; act of June 13, 1911, P. L. 889; act of June 7, 1917, P. L. 564; act of July 11, 1917, P. L. 758; act of April 20, 1921, P. L. 152; act of April 27, 1927, P. L. 458; act of April 9, 1929, P. L. 462; act of April 30, 1929, P. L. 882; act of June 22, 1931, P. L. 655; act of May 22, 1933, P. L. 905; act of July 18, 1935, P. L. 1303; act of May 27, 1937, P. L.

906; act of May 12, 1939, P. L. 133; act of May 21, 1943, P. L. 594; act of April 26, 1945, P. L. 318; act of April 10, 1945, P. L. 186; act of April 12, 1945, P. L. 225; act of May 2, 1945, P. L. 380; act of May 16, 1945, P. L. 615; act of June 10, 1947, P. L. 507; act of May 12, 1949, P. L. 1258; act of August 10, 1951, P. L. 1198; act of June 19, 1953, P. L. 290; act of December 13, 1955, P. L. 858; act of December 13, 1955, P. L. 849; act of May 29, 1956, P. L. (1955) 1809; act of December 28, 1955, P. L. 913; act of July 19, 1957, P. L. 1013.

(b) All other acts, or parts of acts, inconsistent with this act are hereby repealed.

Section 32. This act shall take effect on January 2, 1962. Effective date.

APPROVED—The 26th day of September, A. D. 1961.

DAVID L. LAWRENCE

—
No. 694

AN ACT

Making an appropriation to the Pennsylvania Historical and Museum Commission for the repair and restoration of the Caleb Pusey House subject to certain conditions.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows: Caleb Pusey House.

Section 1. The sum of four thousand dollars (\$4,000), or as much thereof as may be necessary, is hereby specifically appropriated to the Pennsylvania Historical and Museum Commission to be expended by said Commission for the repair and restoration of the historic Caleb Pusey House in the Borough of Upland, Delaware County, Pennsylvania. Appropriation.

Section 2. The moneys hereby appropriated shall be available and expended only at such time as a sum equal to the amount hereby appropriated by the Commonwealth is contributed to the Trustees of the Caleb Pusey House by local historical societies, associations or similar organizations, or by individuals, to be used for the repair and restoration of the said Caleb Pusey House, and upon further condition that one or more local historical societies, associations or similar organizations shall covenant with said trustees to thereafter preserve and maintain the Caleb Pusey House in a good state of repair. Conditions precedent to availability of appropriation.