CONTROLLED SUBSTANCE, DRUG, DEVICE AND COSMETIC ACT, THE

Act of Apr. 14, 1972, P.L. 233, No. 64 Cl. 35

AN ACT

Relating to the manufacture, sale and possession of controlled substances, other 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; establishing schedules of controlled substances; providing penalties; requiring registration of persons engaged in the drug trade and for the revocation or suspension of certain licenses and registrations; and repealing an act.

Compiler's Note: Section 15(c) of Act 31 of 1988, provided that Act 64 is repealed insofar as it subjects to a fine assets against which a forfeiture petition has been filed and is pending or against which the Commonwealth has indicated an intention to file a forfeiture petition.

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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 Controlled Substance, Drug, Device and Cosmetic Act."

Section 2. Definitions.--(a) The definitions contained and used in the "Pennsylvania Drug and Alcohol Abuse Control Act" shall also apply for purposes of this act.

(b) As used in this act:

"Administer" means the direct application of a controlled substance, other drug or device, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject.

"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 controlled substance, other drug, device or cosmetic.

"Agent" means an authorized person when acting on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employe of the carrier or warehouseman.

"Board" means the Pennsylvania Drug, Device and Cosmetic Board.

"Bureau" means the Bureau of Drug Control, Pennsylvania Department of Health.

"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 controlled substance, other drug, device or cosmetic to the human or animal 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.

"Commercial container" means any bottle, jar, tube, ampul, or other receptacle in which a controlled substance, other drug, device or cosmetic is held for distribution or dispensing to an ultimate user, and in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term "commercial container" does not include any package liner, package insert or other material kept with or within a commercial container, nor any carton, crate, drum, or other package in which commercial containers are stored or are used for shipment of controlled substances.

"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.

"Contraband" means any controlled substance, other drug, device or cosmetic possessed by a person not authorized by law to possess such controlled substance, other drug, device or cosmetic, or obtained or held in a manner contrary to the provisions of this act.

"Control" means to regulate, or change the placement of a controlled substance or immediate precursor; under the provisions of this act. (Def. amended Oct. 26, 1972, P.L.1048, No.263)

"Controlled substance" means a drug, substance, or immediate precursor included in Schedules I through V of this act.

"Cosmetic" means: (i) substances intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body or other animal body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance, and (ii) substances intended for use as a component of any such substances, except that such term shall not include soap.

"Council" means the Governor's Council on Drug and Alcohol Abuse.

"Counterfeit" means a controlled substance, other drug, device or cosmetic which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who in fact manufactured, distributed, or dispensed such substance and which thereby is falsely purported or represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser.

"Court" means all courts of the Commonwealth of Pennsylvania, including magistrates and justices of the peace.

"Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a controlled substance, other drug, device or cosmetic whether or not there is an agency relationship.

"Department" means the Department of Health of the Commonwealth of Pennsylvania.

"Designer drug" means a substance other than a controlled substance that is intended for human consumption and that either has a chemical structure substantially similar to that of a controlled substance in Schedules I, II or III of this act or that produces an effect substantially similar to that of a controlled substance in Schedules I, II or III. Examples of chemical classes in which designer drugs are found include, but are not limited to, the following: Phenethylamines,

N-substituted piperidines, morphinans, ecgonines, quinazolinones, substituted indoles and arylcycloalkylamines. (Def. amended Feb. 11, 2000, P.L.9, No.3)

"Device" means instruments, apparatus and contrivances, including their components, parts and accessories, intended: (i) for use in the diagnosis, cure, mitigation, treatment or prevention of disease of man or other animals; or (ii) to affect the structure or any function of the body of man or other animals.

"Dispense" means to deliver a controlled substance, other drug or device to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare such item for that delivery.

"Dispenser" means a practitioner who dispenses.

"Distribute" means to deliver other than by administering or dispensing a controlled substance, other drug, device or cosmetic.

"Distributor" means any person engaged in the activities of jobber, dealer, or wholesaler who sells, or otherwise distributes, any controlled substance, other drug, device or cosmetic for resale or redistribution which he has not himself prepared, produced or compounded.

"Drug" means: (i) substances recognized in the official United States Pharmacopeia, or official National Formulary, or any supplement to either of them; and (ii) substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; and (iii) substances (other than food) intended to affect the structure or any function of the human body or other animal body; and (iv) substances intended for use as a component of any article specified in clause (i), (ii) or (iii), but not including devices or their components, parts or accessories.

"Drug dependent person" means a person who is using a drug, controlled substance or alcohol, and who is in a state of psychic or physical dependence, or both, arising from administration of that drug, controlled substance or alcohol on a continuing basis. Such dependence is characterized by behavioral and other responses which include a strong compulsion to take the drug, controlled substance or alcohol on a continuous basis in order to experience its psychic effects, or to avoid the discomfort of its absence. This definition shall include those persons commonly known as "drug addicts."

"Drug paraphernalia" means all equipment, products and materials of any kind which are used, intended for use or designed for use in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, injecting, ingesting, inhaling or otherwise introducing into the human body a controlled substance in violation of this act. It includes, but is not limited to:

(1) Kits used, intended for use or designed for use in planting, propagating, cultivating, growing or harvesting of any species of plant which is a controlled substance or from which a controlled substance can be derived.

(2) Kits used, intended for use or designed for use in manufacturing, compounding, converting, producing, processing or preparing controlled substances.

(3) Isomerization devices used, intended for use or designed for use in increasing the potency of any species of plant which is a controlled substance.

(4) Testing equipment used, intended for use or designed for use in identifying or in analyzing the strength, effectiveness or purity of controlled substances.

(5) Scales and balances used, intended for use or designed for use in weighing or measuring controlled substances.

(6) Diluents and adulterants, such as quinine hydrochloride, mannitol, mannite, dextrose and lactose, used, intended for use or designed for use in cutting controlled substances.

(7) Separation gins and sifters used, intended for use or designed for use in removing twigs and seeds from or in otherwise cleaning or refining marihuana.

(8) Blenders, bowls, containers, spoons and mixing devices used, intended for use or designed for use in compounding controlled substances.

(9) Capsules, balloons, envelopes and other containers used, intended for use or designed for use in packaging small quantities of controlled substances.

(10) Containers and other objects used, intended for use or designed for use in storing or concealing controlled substances.

(11) Hypodermic syringes, needles and other objects used, intended for use, or designed for use in parenterally injected controlled substances into the human body.

(12) Objects used, intended for use or designed for use in ingesting, inhaling or otherwise introducing marihuana, cocaine, hashish or hashish oil into the human body, such as:

(i) Metal, wooden, acrylic, glass, stone, plastic or ceramic pipes with or without screens, permanent screens, hashish heads or punctured metal bowls.

(ii) Water pipes.

(iii) Carburetion tubes and devices.

(iv) Smoking and carburetion masks.

(v) Roach clips; meaning objects used to hold burning material such as a marihuana cigarette, that has become too small or too short to be held in the hand.

(vi) Miniature cocaine spoons and cocaine vials.

(vii) Chamber pipes.

(viii) Carburetor pipes.

(ix) Electric pipes.

(x) Air-driven pipes.

(xi) Chillums.

(xii) Bongs.

(xiii) Ice pipes or chillers.

In determining whether an object is drug paraphernalia, a court or other authority should consider, in addition to all other logically relevant factors, statements by an owner or by anyone in control of the object concerning its use, prior convictions, if any, of an owner, or of anyone in control of the object, under any State or Federal law relating to any controlled substance, the proximity of the object, in time and space, to a direct violation of this act, the proximity of the object to controlled substances, the existence of any residue of controlled substances on the object, direct or circumstantial evidence of the intent of an owner, or of anyone in control of the object, to deliver it to persons who he knows, or should reasonably know, intend to use the object to facilitate a violation of this act, the innocence of an owner or of anyone in control of the object, as to a direct violation of this act should not prevent a finding that the object is intended for use or designed for use as drug paraphernalia, instructions, oral or written, provided with the object concerning its use, descriptive materials accompanying the object which explain or

depict its use, national and local advertising concerning its use, the manner in which the object is displayed for sale, whether the owner, or anyone in control of the object, is a legitimate supplier of like or related items to the community, such as a licensed distributor or dealer of tobacco products, direct or circumstantial evidence of the ratio of sales of the objects to the total sales of the business enterprise, the existence and scope of legitimate uses for the object in the community, and expert testimony concerning its use.

This definition does not include testing products utilized in determining whether a controlled substance contains chemicals, toxic substances or hazardous compounds in quantities which can cause physical harm or death. The term "testing products" shall include, but is not limited to, fentanyl test strips.

(Def. amended Nov. 3, 2022, P.L. , No.111)

"Immediate precursor" means a substance which the secretary has found to be, and by regulation designates as being a principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance.

"Label" means a display of written, printed or graphic matter upon the commercial container of any substance or 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 substance or is easily legible through the outside container or wrapper.

"Labeling" means all labels and other written, printed, or graphic matter: (i) upon a substance or any of its containers or wrappers; or (ii) accompanying such substance.

"Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a controlled substance, other drug or device or the packaging or repackaging of such substance or article, or the labeling or relabeling of the commercial container of such substance or article, but does not include the activities of a practitioner who, as an incident to his administration or dispensing such substance or article in the course of his professional practice, prepares, compounds, packages or labels such substance or article. The term "manufacturer" means a person who manufactures a controlled substance, other drug or device.

"Marihuana" consists of all forms, species and/or varieties of the genus Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin; but shall not include tetrahydrocannabinols, the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, cake, or the sterilized seed of such plant which is incapable of germination. (Def. amended July 30, 1975, P.L.104, No.54)

"Narcotic" means any of the following, whether produced 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: (i) opium, (ii) any opiate having an addiction-forming or addiction-sustaining capacity similar to

morphine, but not including the isoquinoline alkaloids of opium, (iii) any compound, manufacture, salt, derivative, or preparation of opium or any opiate, and (iv) any substance, compound, manufacture, salt, derivative, or preparation thereof, which is chemically identical with any of the substances referred to in (i), (ii) or (iii).

"New drug" means: (i) 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 and effectiveness of drugs as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling thereof; or (ii) any drug the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness 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.

"Nonproprietary drug" means any drug containing any quantity of any controlled substance or any drug requiring a prescription, a drug containing biologicals or substances of glandular origin (except intestinal enzymes and all liver products), drugs which are administered parenterally, 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.

"Official compendium" means the official United States Pharmacopeia, the official National Formulary or any supplement to either of them.

"Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. It does not include the dextrorotatory isomer of 3-methoxy-n-methlmorphinan and its salts (dextromethorphan). It does include the racemic and levorotatory forms.

"Opium poppy" means the plant of the species Papaver somniferum L., except its seeds.

"Person" means individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

"Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

"Practitioner" means: (i) a physician, osteopath, dentist, veterinarian, pharmacist, podiatrist, nurse, scientific investigator, or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance, other drug or device in the course of professional practice or research in the Commonwealth of Pennsylvania; (ii) a pharmacy, hospital, clinic or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance, other drug or device in the course of professional practice or research in the Commonwealth of Pennsylvania.

"Production" includes the manufacture, planting, cultivation, growing or harvesting of a controlled substance, other drug, device and cosmetic.

"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 (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription order).

"Real-time stop-sale system" means a system intended to be used by law enforcement agencies and pharmacies or other business establishments that:

(1) is installed, operated and maintained free of any one-time or recurring charge to the business establishment or to the Commonwealth;

(2) is able to communicate in real time with similar systems operated in other states and similar systems containing information submitted by more than one state;

(3) complies with the security policy of the Criminal Justice Information Services Division of the Federal Bureau of Investigation or its successor;

(4) complies with information exchange standards adopted by the National Information Exchange Model or its successor;

(5) uses a mechanism to prevent the completion of a sale of a product containing ephedrine or pseudoephedrine that would violate Federal or State law regarding the purchase of a product containing those substances; and

(6) is equipped with an override of the mechanism that:

(i) may be activated by an employe of a business establishment; and

(ii) creates a record of each activation of the override. (Def. added July 9, 2013, P.L.359, No.53)

"Registrant" means any one person registered under the laws of this Commonwealth to manufacture, dispense, distribute, administer or sell drugs.

"Secretary" means the Secretary of Health of the Commonwealth of Pennsylvania.

"Structure" means any house, apartment building, shop, warehouse, barn, building, vessel, railroad car, cargo container, motor vehicle, housecar, trailer, trailer coach, camper, mine, floating home, or other enclosed structure capable of holding a child and manufacturing equipment. (Def. added Nov. 19, 2004, P.L.846, No.108)

"Temporary technological or electrical failure" means any failure of a computer system, application or device, or the loss of electrical power to that system, application or device, or any other service interruption to a computer system, application or device in a manner that reasonably prevents a practitioner from utilizing his or her certified electronic prescribing application to transmit an electronic prescription for a controlled substance in accordance with this act and Federal requirements. (Def. added Oct. 24, 2018, P.L.662, No.96)

"Ultimate user" means a person who lawfully possesses a controlled substance, other drug, device or cosmetic for his own use or for the use of a member of his household or for administering to an animal in his care.

Compiler's Note: Section 1 of Reorganization Plan No.4 of 1981 provided that the Council on Drug and Alcohol Abuse, together with its powers, functions and duties as set forth in Act 64, are transferred from the Governor's Office to the Department of Health.

Section 3. Authority to Control.--(a) The secretary shall control all substances listed in Schedules I through V of this act and may, by regulation, upon his own motion or on the petition of any interested party, add a substance as a controlled substance. Such regulations shall be adopted in accordance with the act of July 31, 1968 (P.L.769, No.240), known as the "Commonwealth Documents Law." Before so doing, the

secretary shall request the advice in writing from the board whether a substance should be added as a controlled substance. Such advice shall be rendered to the secretary within a reasonable time. The secretary shall consider with respect to each substance hereafter controlled:

(1) Its actual or relative potential for abuse;

(2) Scientific evidence of its pharmacological effect, if known;

(3) State of current scientific knowledge regarding the substance;

(4) Its history and current pattern of abuse;

(5) The scope, duration, and significance of abuse;

(6) The risk there is to the public health;

(7) Its psychic or physiological dependence liability;

(8) Whether the substance is controlled under Federal law; and

(9) Whether the substance is an immediate precursor of a substance already controlled under this section.

After considering the above factors, the secretary shall make findings with respect thereto and shall issue a regulation controlling the substance if he finds that the substance has a potential for abuse.

(b) If the secretary designates a substance as an immediate precursor, substances which are precursors of the controlled precursor shall not be subject to control solely because they are precursors of the controlled precursor.

(c) Notwithstanding subsection (a), if the secretary finds that the health and safety of the public will not be adversely affected, the secretary may:

(1) Reschedule any controlled substance to coincide with Federal law, including the Controlled Substances Act (Public Law 91-513, 84 Stat. 1236), regulations promulgated under 21 CFR Ch. 2 (relating to drug enforcement administration, department of justice) or any Federal judicial order. The secretary shall publish a notice in the Pennsylvania Bulletin of the rescheduling of a controlled substance under this clause. The rescheduling of the controlled substance to a higher schedule may not take effect earlier than thirty days after publication of the notice in the Pennsylvania Bulletin. The rescheduling of a controlled substance to a lower schedule may take effect upon publication in the Pennsylvania Bulletin.

(2) Exclude any substance or remove any controlled substance from any schedule, provided that the substance or controlled substance has been approved for over-the-counter use without a prescription under Federal law, including the Federal Food, Drug and Cosmetic Act (52 Stat. 1040, 21 U.S.C. § 301, et seq.), regulations promulgated under 21 CFR Ch. 1 (relating to food and drug administration, department of health and human services) or any Federal judicial order.

((c) amended June 8, 2016, P.L.258, No.37)

(d) If the secretary finds that the scheduling of a substance on a temporary basis is necessary to avoid an imminent hazard to public safety, the secretary may, by publishing a final notice in the Pennsylvania Bulletin and without regard to the requirements of subsection (a), schedule a substance under one of the schedules in section 4 if the substance is not listed in any other schedule in section 4 or 28 Pa. Code §§ 25.72 (relating to schedules of controlled substances) and 25.75 (relating to paregoric) and if no exception or approval is in effect for the substance under section 505 of the Federal Food, Drug and Cosmetic Act (52 Stat. 1040, 21 U.S.C. § 355). The following apply:

(1) A final order may not be issued before the expiration of fourteen days after both:

(i) The date of publication in the Pennsylvania Bulletin of a proposed notice of the intention to issue a final notice and the grounds upon which the order is to be issued.

(ii) The date the secretary transmitted the notice to the Attorney General as required by clause (4).

(2) The scheduling of a substance under this subsection shall expire at the end of one year from the date of publication of the final notice scheduling of the substance except that the secretary may, during the pendency of proceedings under subsection (a) with respect to the substance, extend the temporary scheduling for up to one additional year by publishing a subsequent notice in the Pennsylvania Bulletin prior to the expiration of the initial notice.

(3) When issuing a proposed notice under clause (1), the secretary shall be required to consider, with respect to the finding of an imminent hazard to public safety, only those factors set forth in subsection (a)(4), (5), (6) and (8), except that, if clause (8) has been met regarding the temporary or permanent scheduling of a specific substance under Federal law, the secretary shall be authorized to temporarily schedule the substance without regard to clauses (4), (5) and (6).

(4) The secretary shall transmit the proposed notice issued under clause (1) to the Attorney General. The Attorney General shall have thirty days from receipt of the proposed notice to provide written comments, if any, on relevant issues, including actual abuse, diversion from legitimate channels and clandestine importation, manufacture or distribution. In issuing a final notice under this subsection, the secretary shall take into consideration any comments submitted by the Attorney General.

(5) (i) Except as provided in subclause (ii), during the time period that a substance is temporarily scheduled, the secretary shall proceed with the permanent scheduling of the substance pursuant to the requirements under subsection (a).

(ii) If a substance has been temporarily scheduled and the secretary proceeds with permanent scheduling, the secretary shall only be required to proceed under section 5(a) of the act of June 25, 1982 (P.L.633, No.181), known as the "Regulatory Review Act," by submitting final omitted regulations.

(iii) A final notice issued under clause (1) with respect to a substance shall be vacated upon the conclusion of a subsequent rulemaking proceeding initiated under subsection (a) with respect to the substance or the enactment of law by the General Assembly permanently scheduling the substance.

(iv) While the substance is temporarily scheduled, if the secretary determines that a substance should not be permanently scheduled, and no law has been enacted by the General Assembly to permanently schedule the substance, the secretary shall publish a notice in the Pennsylvania Bulletin with a rationale as to why the substance is not being permanently scheduled. Upon publication of the notice, the substance shall no longer be considered a controlled substance. Withdrawal of a temporarily scheduled substance under this subclause shall not affect any criminal proceeding or civil action initiated based on the temporary scheduling.

(6) Temporary scheduling of a substance by the secretary under this subsection shall not be subject to section 612 of the act of April 9, 1929 (P.L.177, No.175), known as "The Administrative Code of 1929," the "Commonwealth Documents Law," the act of October 15, 1980 (P.L.950, No.164), known as the "Commonwealth Attorneys Act," or the "Regulatory Review Act."

(7) A proposed or final notice issued by the secretary under this subsection shall not be subject to judicial review.

((d) added June 8, 2016, P.L.258, No.37)

(e) At the time of publication by the secretary of a notice in the Pennsylvania Bulletin under subsection (c) or (d), the secretary shall also transmit the notice to the ABC-MAP Board. ((e) added June 8, 2016, P.L.258, No.37)

(f) As used in this section, the term "substance" shall include any group of substances, materials, mixtures, compounds, salts, isomers, salts of isomers, analogs, homologues or homologous series. ((f) added June 8, 2016, P.L.258, No.37)

Section 4. Schedules of Controlled Substances.--The following schedules include the controlled substances listed or to be listed by whatever official name, common or usual name, chemical name, or trade name designated.

(1) Schedule I--In determining that a substance comes within this schedule, the secretary shall 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:

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

1. Acetylmethadol.
2. Allylprodine.
3. Alphacetylmethadol.
4. Alphameprodine.
5. Alphamethadol.
6. Benzethidine.
7. Betacetylmethadol.
8. Betameprodine.
9. Betamethadol.
10. Betaprodine.
11. Clonitazene.
12. Dextromoramide.
13. Dextrorphan (except its methylether).
14. Diampromide.
15. Diethylthiambutene.
16. Dimenoxadol.
17. Dimepheptanol.
18. Dimethylthiambutene.
19. Dioxaphetyl butyrate.
20. Dipipanone.
21. Ethylmethylthiambutene.
22. Etonitazene.
23. Etoxeridine.
24. Furethidine.
25. Hydroxypethidine.
26. Ketobemidone.
27. Levomoramide.
28. Levophenacylmorphan.
29. Morpheridine.
30. Noracymethadol.
31. Norlevorphanol.
32. Normethadone.
33. Norpipanone.
34. Phenadoxone.
35. Phenampromide.
36. Phenomorphan.

37. Phenoperidine.
38. Piritramide.
39. Proheptazine.
40. Properidine.
41. Racemoramide.
42. Trimeperidine.

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

1. Acetorphine.
2. Acetyldihydrocodeine.
3. Benzylmorphine.
4. Codeine methylbromide.
5. Codeine-N-Oxide.
6. Cyprenorphine.
7. Desomorphine.
8. Dihydromorphine.
9. Etorphine.
10. Heroin.
11. Hydromorphinol.
12. Methyldesorphine.
13. Methylhydromorphine.
14. Morphine methylbromide.
15. Morphine methylsulfonate.
16. Morphine-N-Oxide.
17. Myrophine.
18. Nicocodeine.
19. Nicomorphine.
20. Normorphine.
21. Pholcodine.
22. Thebacon.
23. Fentanyl derivatives - any compound not listed under a different schedule, not a Federal Food and Drug Administration-approved drug or not used within legitimate and approved medical research, structurally derived from N-(1-(2-phenethyl)-4-piperidinyl-N-phenyl-propanamide. This shall include the following, their salts, isomers and salts of isomers:

(A) Acetyl fentanyl.
(B) Butyryl fentanyl.
(C) para-Fluorofentanyl.
(D) para-Fluorobutyryl fentanyl.
(E) Furanyl fentanyl.
(F) Hydroxythiofentanyl.
(G) Isobutyrylfentanyl.
(H) 4-methoxy-Butyryl fentanyl.
(I) 3-methyl Fentanyl.
(J) Ocfentanyl.
(K) Valeryl fentanyl.

((ii) amended June 8, 2016, P.L.258, No.37)

(iii) Any 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 such salts, isomers, and salts of isomers is possible within the specific chemical designation:

1. 3,4-methylenedioxy amphetamine.
2. 5-methoxy-3,4-methylenedioxy amphetamine.
3. 3,4,5-trimethoxy amphetamine.
4. Bufotenine.
5. Diethyltryptamine.

6. Dimethyltryptamine.
7. 4-methyl-2,5-dimethoxyamphetamine.
8. Ibogaine.
9. Lysergic acid diethylamide.
10. Mescaline.
11. Peyote.
12. N-ethyl-3-piperidyl benzilate.
13. N-methyl-3-piperidyl benzilate.
14. Psilocybin.
15. Psilocyn.
16. Tetrahydrocannabinols.
17. Salvia Divinorum.
18. Salvinorin A.
19. Divinorin A.
20. 3,4-Methylenedioxymethcathinone (Methylone).
21. 3,4-Methylenedioxypyrovalerone (MDPV).
22. 4-Methylmethcathinone (Mephedrone).
23. 4-Methoxymethcathinone.
24. 4-Fluoromethcathinone.
25. 3-Fluoromethcathinone.
26. 3,4-Methylenedioxymethamphetamine.
27. Methoxetamine.

((iii) amended June 8, 2016, P.L.258, No.37)

(iii.1) Substituted cathinones - any compound, except bupropion or compounds listed under a different schedule, or compounds used within legitimate and approved medical research, structurally derived from 2-aminopropan-1-one by substitution at the 1-position with monocyclic or fused polycyclic ring systems, whether or not the compound is further modified in any of the following ways:

1. By substitution in the ring system to any extent with alkyl, alkylenedioxy, alkoxy, haloalkyl, hydroxyl or halide substituents whether or not further substituted in the ring system by one or more other univalent substituents.
2. By substitution at the 3-position with an acyclic alkyl substituent.
3. By substitution at the 2-amino nitrogen atom with alkyl, dialkyl, benzyl or methoxybenzyl groups.
4. By inclusion of the 2-amino nitrogen atom in a cyclic structure.

((iii.1) amended June 8, 2016, P.L.258, No.37)

(iv) Marihuana.

(v) Any material, compound, mixture or preparation which contains any quantity of the following substances, including the salts, isomers and salts of isomers:

1. Methaqualone.

(vi) Gamma hydroxybutyric acid, any salt, hydroxybutyric compound, derivative or preparation of gamma hydroxybutyric acid, including any isomers, esters and ethers and salts of isomers, esters and ethers of gamma hydroxybutyric acid, except gamma-butyrolactone (GBL), whenever the existence of such isomers, esters and salts is possible within the specific chemical designation. For purposes of security requirements imposed by law or regulation upon registered distributors and registered manufacturers, this substance when manufactured, distributed or possessed in accordance with an exemption approved under section 505(i) of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040, 21 U.S.C. § 301 et seq.) shall, notwithstanding any other provision of this act, be classified as a controlled substance in Schedule III of this section.

(vii) Synthetic cannabinoids, including any material, compound, mixture or preparation that is not listed as a

controlled substance in Schedules I, II, III, IV and V, is not a Federal Food and Drug Administration-approved drug or not used within legitimate and approved medical research and which contains any quantity of the following substances, their salts, isomers, whether optical, positional or geometric, analogues, homologues and salts of isomers, analogues and homologues, unless specifically exempted, whenever the existence of these salts, isomers, analogues, homologues and salts of isomers, analogues and homologues if possible within the specific chemical designation:

1. Tetrahydrocannabinols meaning tetrahydrocannabinols which are naturally contained in a plant of the genus Cannabis as well as synthetic equivalents of the substances contained in the plant or in the resinous extractives of Cannabis or synthetic substances, derivatives and their isomers with analogous chemical structure and or pharmacological activity such as the following:

(A) Delta-1 cis or trans tetrahydrocannabinol and their optical isomers.

(B) Delta-6 cis or trans tetrahydrocannabinol and their optical isomers.

(C) Delta-3,4 cis or their trans tetrahydrocannabinol and their optical isomers.

2. Indole carboxaldehydes - Any compound structurally derived from 1H-indole-3-carboxaldehyde or 1H-indole-2-carboxaldehyde:

(A) substituted in both of the following ways:

(I) At the nitrogen atom of the indole ring.

(II) At the carbon of the carboxaldehyde by a phenyl, benzyl, naphthyl, adamantyl, cyclopropyl or propionaldehyde group; and

(B) whether or not the compound is further modified to any extent in any of the following ways:

(I) Substitution to the indole ring to any extent.

(II) Substitution to the phenyl, benzyl, naphthyl, adamantyl, cyclopropyl or propionaldehyde group to any extent.

(III) A nitrogen heterocyclic analog of the indole ring.

(IV) A nitrogen heterocyclic analog of the phenyl, benzyl, naphthyl, adamantyl or cyclopropyl ring.

This shall include AM 1248, AM 2201, AM 679, AM 694, EAM-2201, FUB-144, JWH 015, JWH 018, JWH 019, JWH 073, JWH 081, JWH 122, JWH 200, JWH 203, JWH 210, JWH 250, JWH 251, JWH 302, JWH 398, MAM-2201, RCS-4, RCS-8, THJ-018, THJ-2201, UR-144, WIN 55-212, WIN 48-098 and XLR-11.

2.1. Indole carboxamides - Any compound structurally derived from 1H-indole-3-carboxamide or 1H-indole-2-carboxamide:

(A) substituted in both of the following ways:

(I) At the nitrogen atom of the indole ring.

(II) At the nitrogen of the carboxamide by a phenyl, benzyl, naphthyl, adamantyl, cyclopropyl or propionaldehyde group; and

(B) whether or not the compound is further modified to any extent in any of the following ways:

(I) Substitution to the indole ring to any extent.

(II) Substitution to the phenyl, benzyl, naphthyl, adamantyl, cyclopropyl or propionaldehyde group to any extent.

(III) A nitrogen heterocyclic analog of the indole ring.

(IV) A nitrogen heterocyclic analog of the phenyl, benzyl, naphthyl, adamantyl or cyclopropyl ring.

This shall include AB-CHMINACA, AB-FUBINACA, AB-PINACA, ADBICA, ADB-PINACA, AKB-48, AMB, NNEI, STS-135 and THJ.

2.2. Indole carboxylic acids - Any compound structurally derived from 1H-indole-3-carboxylic acid or 1H-indole-2-carboxylic acid:

(A) substituted in both of the following ways:

(I) At the nitrogen atom of the indole.

(II) At the hydroxyl group of the carboxylic acid by a phenyl, benzyl, naphthyl, adamantyl, cyclopropyl or propionaldehyde group; and

(B) whether or not the compound is further modified to any extent in any of the following ways:

(I) Substitution to the indole ring to any extent.

(II) Substitution to the phenyl, benzyl, naphthyl, adamantyl, cyclopropyl or propionaldehyde group to any extent.

(III) A nitrogen heterocyclic analog of the indole ring.

(IV) A nitrogen heterocyclic analog of the phenyl, benzyl, naphthyl, adamantyl or cyclopropyl ring.

This shall include BB-22, 3-CAF, FDU-PB-22, FUB-PB-22, NM2201 and PB-22.

3. Naphthylmethylindoles or any compound containing a 1H-indol-3-yl-(1-naphthyl) methane structure with a substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. This shall include JWH 175 and JWH 184.

4. Naphthoylpyrroles or any compound containing a 3-(1-naphthoyl) pyrrole structure with substitution at the nitrogen atom of the pyrrole ring whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent. This shall include JWH 147 and JWH 307.

5. Naphthylmethylindenes or any compound containing a naphthylideneindene structure with substitution at the 3-position of the indene ring whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent. This shall include JWH 176.

6. (Deleted by amendment).

7. Cyclohexylphenols or any compound containing a 2-(3-hydroxycyclohexyl) phenol structure with a substitution at the 5-position of the phenolic ring whether or not substituted in the cyclohexyl ring to any extent. This shall include the following:

(A) CP 47,497 and its homologues and analogues.

(B) Cannabicyclohexanol.

(C) CP 55,940.

8. (Deleted by amendment).

9. [2,3-Dihydro-5 methyl-3-(4-morpholinylmethyl)pyrrolo [1,2,3-de]-1, 4-benzoxazin-6-yl]-1-naphthalenymethanone. This shall include WIN 55,212-2.

10. Dibenzopyrans or any compound containing a 11-hydroxy-delta 8-tetrahydrocannabinol structure with substitution on the 3-pentyl group. This shall include HU-210, HU-211, JWH 051 and JWH 133.

11. (Deleted by amendment).

12. (Deleted by amendment).

13. (Deleted by amendment).

14. Any other synthetic chemical compound that is a cannabinoid receptor type 1 agonist as demonstrated by binding studies and functional assays that is not listed in Schedules II, III, IV and V, not a Federal Food and Drug Administration-approved drug or not used within legitimate, approved medical research.

((vii) amended June 8, 2016, P.L.258, No.37)

(viii) Psychedelic phenethylamines, their analogues, congeners, homologues, isomers, salts and the salts of analogues, congeners, homologues and isomers as follows:

1. 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E).
2. 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D).
3. 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C).
4. 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I).
5. 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine(2C-T-2).
6. 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4).
7. 2-(2,5-Dimethoxyphenyl)ethanamine (2C-H).
8. 2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N).
9. 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P).
10. 2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl) ethanamine (25C-NBOMe).
11. 2-(4-iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl) ethanamine (25I-NBOMe).
12. 2-(4-bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl) ethanamine (25B-NBOMe).

((viii) amended June 8, 2016, P.L.258, No.37)

(2) Schedule II--In determining that a substance comes within this schedule, the secretary shall 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:

(i) Any of 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:

1. Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, including hydrocodone, morphine and oxycodone.
2. Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in subclause 1, except that these substances shall not include the isoquinoline alkaloids of opium.
3. Opium poppy and poppy straw.
4. Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but shall not include decocainized coca leaves or extracts of coca leaves, which extracts do not contain cocaine or ecgonine.

((i) amended June 8, 2016, P.L.258, No.37)

(ii) Any of 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 such isomers, esters, ethers and salts is possible within the specific chemical designation:

1. Alphaprodine.
2. Anileridine.
3. Bezitramide.
4. Dihydrocodeine.
5. Diphenoxylate.
6. Fentanyl.
7. Isomethadone.
8. Levomethorphan.

9. Levorphanol.
10. Metazocine.
11. Methadone.
12. Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane.
13. Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylic acid.
14. Pethidine.
15. Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.
16. Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.
17. Pethidine-Intermediate-C, 1-methyl-4-henylpiperidine-4-carboxylic acid.
18. Phenazocine.
19. Piminodine.
20. Racemethorphan.
21. Racemorphan.
22. Carfentanil. (22. added Nov. 25, 2020, P.L.1190, No.117)

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

1. Amphetamine, its salts, optical isomers, and salts of its optical isomers.
2. Phenmetrazine and its salts.
3. Methylphenidate.
4. Methamphetamine including its salts, isomers and salts of isomers.
5. Lisdexamfetamine.

((iii) amended June 8, 2016, P.L.258, No.37)

(iv) The phrase "opiates" as used in section 4 of this act and elsewhere throughout the act shall not include the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts, but does include its racemic and levorotatory forms.

(v) Any material, compound, mixture, or preparation unless specifically excepted which contains any quantity of:

1. Phencyclidine.

((2) amended Nov. 26, 1978, P.L.1392, No.328)

(3) Schedule III--In determining that a substance comes within this schedule, the secretary shall 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 or high psychological dependence. The following classes of controlled substances are included in this schedule:

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

1. Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid.
2. Chorhexadol.
3. Glutethimide.
4. Lysergic acid.
5. Lysergic acid amide.
6. Methyprylon.
8. Sulfondiethylmethane.
9. Sulfonethylmethane.
10. Sulfonmethane.
11. Buprenorphine.

((i) amended June 8, 2016, P.L.258, No.37)

(ii) Nalorphine.

(iii) Any material, compound, mixture, or preparation containing limited quantities of the following narcotic drugs, or any salts thereof, unless specifically excepted or listed in other schedules:

1. 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.

2. 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.

3. (Deleted by amendment).

4. (Deleted by amendment).

5. 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.

6. 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.

7. Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

8. Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams and not more than 2.5 milligrams per dosage unit with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

((iii) amended June 8, 2016, P.L.258, No.37)

(v) The secretary may by regulation except any compound, mixture, or preparation containing any drug or controlled substance listed in subclauses (i) and (ii) of this schedule above from the application of those provisions of this 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 such admixtures shall be included therein in such 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.

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

(vii) Anabolic steroid includes any material, compound, mixture or preparation that includes any of the following or any isomer, ester, salt or derivative of any of the following that acts in the same manner on the human body:

1. Chorionic gonadotropin, except when used for injection or implantation in cattle or any other nonhuman species and when that use is approved by the Federal Food and Drug Administration. ((1) amended Oct. 24, 2018, P.L.662, No.96)

2. Clostebol.

3. Dehydrochlormethyltestosterone.

4. Ethylestrenol.

5. Fluoxymesterone.

6. Mesterolone.

7. Metenolone.

8. Methandienone.

9. Methandrostenolone.
10. Methyltestosterone.
11. Nandrolone.
12. (Deleted by amendment).
13. Norethandrolone.
14. Oxandrolone.
15. Oxymesterone.
16. Oxymetholone.
17. Stanozolol.
18. Testosterone.
19. Testosterone-like related compounds.

Human Growth Hormone (HGH) shall not be included as an anabolic steroid under the provisions of this act. An anabolic steroid which is a combination of estrogen and anabolic steroid and which is expressly intended for administration to hormone-deficient women shall be exempt from the provisions of this act. A person who prescribes, dispenses or distributes an anabolic steroid which is a combination of estrogen and anabolic steroids and which is intended for administration to hormone-deficient women for use by persons who are not hormone-deficient women shall be considered to have prescribed, dispensed or distributed an anabolic steroid within the meaning of this subclause.

((vii) amended June 8, 2016, P.L.258, No.37)

(viii) Gamma hydroxybutyric acid, any salt, hydroxybutyric compound, derivative or preparation of gamma hydroxybutyric acid, including any isomers, esters and ethers and salts of isomers, esters and ethers of gamma hydroxybutyric acid, except gamma-butyrolactone (GBL), contained in a drug product for which an application has been approved under section 505 of the Federal Food, Drug, and Cosmetic Act.

(ix) Ketamine, any salt, ketamine compound, derivative or preparation of ketamine, including any isomers, esters and ethers and salts of isomers, esters and ethers of ketamine.

((ix) amended June 8, 2016, P.L.258, No.37)

((3) amended Nov. 24, 1999, P.L.894, No.55)

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

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

1. Barbital.
2. Chloral betaine.
3. Chloral hydrate.
4. Ethchlorvynol.
5. Ethinamate.
6. Methohexital.
7. Meprobamate.
8. Methylphenobarbital.
9. Paraldehyde.
10. Petrichloral.
11. Phenobarbital.
12. Zopiclone.
13. Carisoprodol.
14. Tramadol.

((i) amended June 8, 2016, P.L.258, No.37)

(ii) The secretary may by regulation except any compound, mixture, or preparation containing any drug or controlled dangerous substance listed in subclause (i) of this schedule above from the application of those provisions of this act 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 such admixtures shall be included therein in such 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.

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

((4) amended Nov. 26, 1978, P.L.1392, No.328)

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

(i) Any 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:

1. Not more than 200 milligrams of codeine, or any of its salts, per 100 milliliter or per 100 grams and not more than 10 milligrams per dosage unit.

2. 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.

3. 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.

4. Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

5. Not more than 100 milligrams of opium per 100 milliliters or per 100 grams, or not more than 5 milligrams per dosage unit.

6. Pregabalin.

(ii) (Deleted by amendment).

((5) amended June 8, 2016, P.L.258, No.37)

(6) A drug product in a finished dosage formulation that contains 2--5-pentyl-1,3-benzenediol that has been approved by the Federal Food and Drug Administration pursuant to section 505 of the Federal Food, Drug and Cosmetic Act prior to the date of enactment shall not be subject to control under this act. ((6) added Nov. 25, 2020, P.L.1190, No.117)

Section 5. Exempt Controlled Substances, Other Drugs, Devices and Cosmetics.--(a) Except as set forth in the Schedules of Controlled Substances of section 4 of this act or otherwise provided herein, the secretary, after consultation with and upon the recommendation of the board, may, by regulation, exempt from the provisions of this act relating to controlled substances, other drugs, devices and cosmetics to such extent as he determines to be consistent with the public health.

Section 6. Registration.--(a) No person shall operate within this Commonwealth as a manufacturer, distributor or retailer of controlled substances, other drugs and devices nor sell, offer for sale nor solicit the purchase of controlled substances, other drugs and devices nor hold them for sale or resale until such person has registered under this act with the secretary. Such registration must be renewed annually in accordance with rules and regulations relating thereto.

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

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

(3) Registrations issued by the secretary or under the law preceding this act to manufacturers, distributors or retailers shall continue to be valid for the period issued and, upon expiration, shall be renewed in the manner provided for renewal of registration issued pursuant to this section. Nothing contained herein shall be construed to require the registration hereunder of any practitioner registered or licensed by the appropriate State board, nor to require the separate registration of agents or employes of persons registered pursuant to the provisions of this section, or of sales representatives or agents of manufacturers or distributors 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 controlled substances or other drugs unless they are manufactured under the supervision of a registered pharmacist, chemist or other person possessing at least five years' experience in the manufacture of controlled substances, or other drugs 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, distributor or retailer shall be accompanied by a fee to be set by the secretary. Applications shall be on forms prescribed by the secretary. Registration shall be renewed annually and applications therefor shall be accompanied by the same fee as for initial applications.

(d) Initial registration shall become effective at noon on the sixtieth day after application therefor is filed: Provided, however, That the secretary shall have authority to issue a registration 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 certification by the secretary that the applicant has met all requirements for such renewal.

(e) The secretary may refuse the initial registration and may, after notice and hearing pursuant to the Administrative

Agency Law, suspend registration (i) of any person who has made material false representation in the application for registration; (ii) of any manufacturer or distributor who has been convicted of a violation of any law of this Commonwealth or of the United States relating to controlled substances, if such refusal shall be necessary for the protection of the public health and safety; (iii) of any manufacturer or distributor who knowingly employs in a capacity directly connected with the preparation, handling or sale of controlled substances, 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 controlled substances, if such refusal shall be necessary for the protection of the public health and safety.

(f) If the secretary takes any action refusing registration or revoking or suspending registration 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 whichever is applicable, 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.

(g) The following persons need not register and may lawfully possess controlled substances under this act:

(1) an agent or employe of any registered manufacturer, distributor, dispenser or any person listed in lieu of registration with the secretary if he is acting in the usual course of his business or employment;

(2) a common or contract carrier or warehouseman, or an employe thereof, whose possession of any controlled substance is in the usual course of business or employment;

(3) an ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a practitioner or in lawful possession of a Schedule V substance.

Section 7. Adulteration.--A controlled substance, other drug, device or cosmetic shall be deemed to be adulterated:

(1) (i) If it consists, in whole or in part, of any filthy, putrid or decomposed substance; (ii) if it has been prepared, packed or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; (iii) and if it is a drug or a device its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; (iv) if it has been exposed to conditions of fire, water or extreme temperature, which may have rendered it injurious to health; (v) 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 9 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 9 of this act.

(2) If it purports to be or is represented as a drug or device, 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 or device 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.

(3) 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 9 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.

(4) If it is not subject to the provisions of clause (2) of this section and its strength differs from or its purity or quality falls below that which it purports or is represented to possess.

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

Section 8. Misbranding.--A controlled substance, other drug or device or cosmetic shall be deemed to be misbranded:

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

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

(3) 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 of purchase and use.

(4) If it is for use by man and is a controlled substance designated by Federal law as habit-forming, unless its label bears the statement "Warning. May Be Habit-Forming."

(5) If it is a drug and is not designated solely by a name recognized in an official compendium, unless its label bears (i) the common or usual name of the drug, if such there be, and (ii) 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, hyoscine, hyoscyamine, arsenic, digitalis glycosides, 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 subclause (ii) of this clause is impracticable, exemptions shall be established by regulations.

(6) Unless its labeling bears (i) adequate directions for use, and (ii) 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 subclause (i) of this clause as applied to any drug, device or cosmetic is not necessary for the protection of the public health, regulations shall be promulgated exempting such drug, device or cosmetic from such requirements.

(7) If it purports to be a drug or device the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: Provided, That the method of packaging may be modified with a consent of the secretary.

(8) If it has been found by the secretary to be a drug, device or cosmetic liable to deterioration unless it is packaged in such form and manner and its label bears a statement specifying such precautions against deterioration as the secretary shall by regulation require as necessary for the protection of public health.

(9) 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 led to believe he is purchasing such drug, device or cosmetic as another drug, device or cosmetic or as the product of another manufacturer.

(10) 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.

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

(12) If it is a controlled substance, its commercial container must bear a label containing an identifying symbol for such substance in accordance with Federal regulations.

Section 9. 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 10. New Drugs.--No person shall sell, deliver, offer for sale, hold for sale, or give away, any new drug unless (i) an application with respect thereto has been approved or a notice of claimed investigational exemption for a new drug has been filed under the appropriate Federal act.

Section 11. Professional Prescription, Administration, and Dispensing.--(a) Except when dispensed or administered directly to the patient by a practitioner or his authorized agent, other than a pharmacist, to an ultimate user, no controlled substance in Schedule II shall be dispensed without an electronic prescription of a practitioner, except in situations, as prescribed by the secretary by regulation. No prescription for a controlled substance in Schedule II may be refilled. All electronic prescription applications shall meet the requirements outlined in 21 CFR § 1311.120 (relating to electronic prescription application requirements). The electronic prescription requirement under this subsection shall not apply if the prescription is issued:

(1) by a veterinarian;

(2) under circumstances when an electronic prescription is not available to be issued or received due to a temporary technological or electrical failure, and, in the instance of a

temporary technological failure, a practitioner shall, within seventy-two hours, seek to correct any cause for the failure that is reasonably within his or her control;

(3) by a practitioner and dispensed by a pharmacy located outside this Commonwealth;

(4) by a practitioner who or health care facility that does not have either of the following:

(i) Internet access; or

(ii) an electronic health record system;

(5) by a practitioner treating a patient in an emergency department or a health care facility under circumstances when the practitioner reasonably determines that electronically prescribing a controlled substance would be impractical for the patient to obtain the controlled substance prescribed by electronic prescription or would cause an untimely delay resulting in an adverse impact on the patient's medical condition;

(6) for a patient enrolled in a hospice program or for a patient residing in a nursing home or residential health care facility;

(7) for controlled substance compounded prescriptions and prescriptions containing certain elements required by the Federal Food and Drug Administration or any other governmental agency that are not able to be accomplished with electronic prescribing;

(8) pursuant to an established and valid collaborative practice agreement between a practitioner and a pharmacist, a standing order or a drug research protocol;

(9) in an emergency situation pursuant to Federal or State law and regulations of the department;

(10) under circumstances where the pharmacy that receives the prescription is not set up to process electronic prescriptions; or

(11) for controlled substances that are not required to be reported to the Prescription Drug Monitoring Program system administered by the department.

((a) amended Oct. 24, 2018, P.L.662, No.96)

(b) Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in Schedule III, IV or V shall be dispensed without an electronic prescription of a practitioner, except in situations, as prescribed by the secretary by regulation. Such prescriptions shall not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner. All electronic prescription applications shall meet the requirements outlined in 21 CFR § 1311.120. The electronic prescription requirement under this subsection shall not apply if the prescription is issued:

(1) by a veterinarian;

(2) under circumstances when an electronic prescription is not available due to a temporary technological or electrical failure;

(3) by a practitioner and dispensed by a pharmacy located outside this Commonwealth;

(4) by a practitioner who or health care facility that does not have either of the following:

(i) Internet access; or

(ii) an electronic health record system;

(5) by a practitioner treating a patient in an emergency department or a health care facility under circumstances when the practitioner reasonably determines that electronically

prescribing a controlled substance would be impractical for the patient to obtain the controlled substance prescribed by electronic prescription or would cause an untimely delay resulting in an adverse impact on the patient's medical condition;

(6) for a patient enrolled in a hospice program or for a patient residing in a nursing home or residential health care facility;

(7) for controlled substance compounded prescriptions and prescriptions containing certain elements required by the Federal Food and Drug Administration or any other governmental agency that are not able to be accomplished with electronic prescribing;

(8) for a prescription issued pursuant to an established and valid collaborative practice agreement between a practitioner and a pharmacist, a standing order or a drug research protocol;

(9) for a prescription issued in an emergency situation pursuant to Federal or State law and regulations of the board;

(10) under circumstances where the pharmacy that receives the prescription is not set up to process electronic prescriptions; or

(11) for controlled substances that are not required to be reported to the Prescription Drug Monitoring Program system administered by the department.

((b) amended Oct. 24, 2018, P.L.662, No.96)

(b.1) (1) A practitioner, pharmacy or health care facility that does not meet an exception to the electronic prescribing requirements under subsection (a) or (b) and is unable to timely comply with the electronic prescribing requirements may petition the department for an exemption from the requirements based upon economic hardship, technical limitations or exceptional circumstances.

(2) The department shall adopt rules establishing the form and specific information to be included in a request for an exemption.

(3) The department may approve an exemption for a period of time determined by the department not to exceed one year from the date of approval and may be renewed annually upon request subject to department approval.

(4) The department may grant additional exemptions beyond the exemptions provided for in subsections (a) and (b), subject to the act of June 25, 1982 (P.L.633, No.181), known as the "Regulatory Review Act."

((b.1) added Oct. 24, 2018, P.L.662, No.96)

(b.2) A prescription generated on an electronic system and printed or transmitted via facsimile is not an electronic prescription. ((b.2) added Oct. 24, 2018, P.L.662, No.96)

(b.3) (1) A pharmacist who receives a written, oral or faxed prescription shall not be required to verify that the prescription properly falls under one of the exceptions provided in subsections (a) and (b) from the requirement to electronically prescribe. A pharmacist may continue to dispense medications from the otherwise valid written, oral or faxed prescriptions that are consistent with current laws and regulations.

(2) If a pharmacist has a reasonable belief that a patient may be seeking a monitored prescription drug for a purpose other than the treatment of an existing medical condition, the pharmacist shall have the responsibility described in 21 CFR § 1306.04 (relating to purpose of issue of prescription).

(3) A practitioner shall be subject to the responsibilities described in 21 CFR § 1311.102 (relating to practitioner responsibilities).

((b.3) added Oct. 24, 2018, P.L.662, No.96)

(b.4) The department shall require the prescription origin to be submitted by dispensers under the authority of the department in compliance with the act of October 27, 2014 (P.L.2911, No.191), known as the "Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP) Act." ((b.4) added Oct. 24, 2018, P.L.662, No.96)

(b.5) A practitioner who violates subsection (a) or (b) is subject to an administrative penalty of one hundred dollars ($100) for the first through tenth violations and two hundred and fifty dollars ($250) for each subsequent violation after the tenth violation, up to a maximum of five thousand dollars ($5,000) per calendar year. Violations shall reset and shall not carry over to subsequent calendar years. The assessment of an administrative penalty pursuant to this subsection by the department to a practitioner alleged to have violated subsection (a) or (b) shall not be reported by the department to the practitioner's appropriate licensing board and shall not be considered a disciplinary action or need to be reported by the practitioner as a violation to the practitioner's appropriate licensing board. A practitioner may appeal the assessment of an administrative penalty pursuant to 2 Pa.C.S. (relating to administrative law and procedure). ((b.5) added Oct. 24, 2018, P.L.662, No.96)

(b.6) The department, within one hundred eighty days of the effective date of this subsection, shall promulgate regulations necessary to implement the requirements of this act. ((b.6) added Oct. 24, 2018, P.L.662, No.96)

(c) No controlled substance in Schedule V may be distributed or dispensed for other than a medicinal purpose.

(d) A practitioner may prescribe, administer, or dispense a controlled substance or other drug or device only (i) in good faith in the course of his professional practice, (ii) within the scope of the patient relationship, and (iii) in accordance with treatment principles accepted by a responsible segment of the medical profession. A practitioner may cause a controlled substance, other drug or device or drug to be administered by a professional assistant under his direction and supervision.

(d.1) A practitioner shall not prescribe, administer or dispense any anabolic steroid for the purpose of enhancing a person's performance in an exercise, sport or game. A practitioner may not prescribe, administer or dispense any anabolic steroid for the purpose of hormonal manipulation intended to increase muscle mass, strength or weight except when medically necessary. ((d.1) added Dec. 22, 1989 P.L.750, No.104)

(e) A veterinarian may prescribe, administer, or dispense a controlled substance, other drug or device only (i) in good faith in the course of his professional practice, and (ii) not for use by a human being. He may cause a controlled substance, other drug or device to be administered by a professional assistant under his direction and supervision.

(f) Any drug or device dispensed by a pharmacist pursuant to a prescription order shall bear a label showing (i) the name and address of the pharmacy and any registration number obtained pursuant to any applicable Federal laws, (ii) the name of the patient, or, if the patient is an animal, the name of the owner of the animal and the species of the animal, (iii) the name of the practitioner by whom the prescription order was written,

and (iv) the serial number and date of filing of the prescription order. In addition, the following statement shall be required on the label of a controlled substance: "Transfer of this drug to anyone other than the patient for whom it was prescribed is illegal." ((f) amended July 2, 1993, P.L.377, No.53)

Section 12. Records of Distribution of Controlled Substances.--(a) Every person who sells or otherwise distributes controlled substances, shall keep records of all purchases or other receipt and sales or other distribution of such substances for two years from the date of purchase or sale. Such records shall include the name and address of the person from whom 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: Provided, however, That this subsection shall not apply to a practitioner who dispenses controlled substances to his patients, unless the practitioner is regularly engaged in charging his patients, whether separately or together with charges for other professional services, for substances so dispensed.

(b) Every practitioner licensed by law to administer, dispense or distribute controlled substances shall keep a record of all such substances 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 substances are dispensed or distributed. Such record shall be kept for two years from the date of administering, dispensing or distributing such substance and shall be open for inspection by the proper authorities.

(c) Persons registered or licensed to manufacture or distribute or dispense a controlled substance, other drug or device under this act shall keep records and maintain inventories in conformity with the record-keeping, order form and inventory requirements of Federal law and with any additional regulations the secretary issues. Controlled substances in Schedules I and II shall be distributed by a registrant to another registrant only pursuant to an order form.

Section 13. Prohibited Acts; Penalties.--(a) The following acts and the causing thereof within the Commonwealth are hereby prohibited:

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

(2) The adulteration or misbranding of any controlled substance, other drug, device or cosmetic.

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

(4) The removal or disposal of a detained or embargoed substance or article, whether or not such substance or article is in fact adulterated or misbranded.

(5) 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 controlled substance, other drug, device or cosmetic, if such act is done while such substance or article is held for sale and results in such substance or article being adulterated or misbranded.

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

(7) Placing or causing to be placed upon any controlled substance, other drug, device or cosmetic, or upon the container of any controlled substance, other drug, device or cosmetic, with intent to defraud, the trademark, trade name or other identifying mark, imprint or symbol of another, or any likeness of any of the foregoing.

(8) Selling, dispensing, disposing of or causing to be sold, dispensed or disposed of, or keeping in possession, control or custody, or concealing any controlled substance, other drug, device or cosmetic or any container of any drug, device or cosmetic with knowledge that the trademark, trade name or other identifying mark, imprint or symbol of another, or any likeness of any of the foregoing, has been placed thereon in a manner prohibited by clause (7) hereof.

(9) 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 symbol of another or any likeness of any of the foregoing upon any controlled substance, other drug, device or cosmetic or container thereof.

(10) The sale at retail of a nonproprietary drug except by a registered pharmacist in a licensed pharmacy or by a practitioner.

(11) The operation of a drug manufacturing, distributing 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.

(12) The acquisition or obtaining of possession of a controlled substance by misrepresentation, fraud, forgery, deception or subterfuge.

(13) The sale, dispensing, distribution, prescription or gift by any practitioner otherwise authorized by law so to do of any controlled substance to any person known to such practitioner to be or whom such practitioner has reason to know is a drug dependent person, unless said drug is prescribed, administered, dispensed or given, for the cure or treatment of some malady other than drug dependency, except that the council, in accordance with Federal narcotic and food and drug laws, shall allocate the responsibility for approving and designating certain clinics, and shall provide or allocate the responsibility for providing regulations for such clinics at which controlled substances, including but not limited to methadone, may be prescribed, administered or dispensed for the treatment of drug dependency. This clause shall not prohibit any practitioner from prescribing, distributing or dispensing any controlled substance for a period of time not to exceed fourteen days pending confirmed admission of the patient to a hospital or rehabilitation center.

(14) The administration, dispensing, delivery, gift or prescription of any controlled substance by any practitioner or professional assistant under the practitioner's direction and supervision unless done (i) in good faith in the course of his professional practice; (ii) within the scope of the patient relationship; (iii) in accordance with treatment principles accepted by a responsible segment of the medical profession.

(15) The sale at retail or dispensing of any controlled substance listed in Schedules II, III and IV to any person, except to one authorized by law to sell, dispense, prescribe

or possess such substances, 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 pharmacy intern under the immediate personal supervision of a registered pharmacist, or the refilling of a written or oral prescription order for a drug, unless such refilling is authorized by the prescriber either in the original written prescription order or by written confirmation of the original oral prescription order. 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, as required by this act.

(16) Knowingly or intentionally possessing a controlled or counterfeit substance by a person not registered under this act, or a practitioner not registered or licensed by the appropriate State board, unless the substance was obtained directly from, or pursuant to, a valid prescription order or order of a practitioner, or except as otherwise authorized by this act.

(17) The wilful dispensing of a controlled substance 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 of the patient and the directions for the use of the drug by the patient.

(18) The selling by a pharmacy or distributor of any controlled substance or other drug unless the container bears a label, securely attached thereto, stating the specific name of the drug and the proportion or amount thereof unless otherwise specifically directed in writing by the practitioner.

(19) The intentional purchase or knowing receipt in commerce by any person of any controlled substance, other drug or device from any person not authorized by law to sell, distribute, dispense or otherwise deal in such controlled substance, other drug or device.

(20) The using by any person to his own advantage, or revealing other than to the secretary or officers or employes of the department or to the council 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.

(21) The refusal or failure to make, keep or furnish any record, notification, order form, statement, invoice or information required under this act.

(22) The refusal of entry into any premises for any inspection authorized by this act.

(23) The unauthorized removing, breaking, injuring, or defacing a seal placed upon embargoed substances or the removal or disposal of substances so placed under seal.

(24) The failure by a manufacturer or distributor to register or obtain a license as required by this act.

(25) The manufacture of a controlled substance by a registrant who knows or who has reason to know, the manufacturing is not authorized by his registration, or who knowingly distributes a controlled substance not authorized by

his registration to another registrant or other authorized person.

(26) The knowing distribution by a registrant of a controlled substance classified in Schedules I or II, except pursuant to an order form as required by this act.

(27) The use in the course of the manufacture or distribution of a controlled substance of a registration number which is fictitious, revoked, suspended, or issued to another person.

(28) The furnishing of false or fraudulent material information in, or omission of any material information from any application, report, or other document required to be kept or filed under this act, or any record required to be kept by this act.

(29) The intentional making, distributing, or possessing of any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or symbol of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render the drug a counterfeit substance.

(30) Except as authorized by this act, the manufacture, delivery, or possession with intent to manufacture or deliver, a controlled substance by a person not registered under this act, or a practitioner not registered or licensed by the appropriate State board, or knowingly creating, delivering or possessing with intent to deliver, a counterfeit controlled substance.

(31) Notwithstanding other subsections of this section, (i) the possession of a small amount of marihuana only for personal use; (ii) the possession of a small amount of marihuana with the intent to distribute it but not to sell it; or (iii) the distribution of a small amount of marihuana but not for sale.

For purposes of this subsection, thirty (30) grams of marihuana or eight (8) grams of hashish shall be considered a small amount of marihuana.

(32) The use of, or possession with intent to use, drug paraphernalia for the purpose of planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packing, repacking, storing, containing, concealing, injecting, ingesting, inhaling or otherwise introducing into the human body a controlled substance in violation of this act.

(33) The delivery of, possession with intent to deliver, or manufacture with intent to deliver, drug paraphernalia, knowing, or under circumstances where one reasonably should know, that it would be used to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, inject, ingest, inhale or otherwise introduce into the human body a controlled substance in violation of this act.

(34) The placing in any newspaper, magazine, handbill or other publication or by written or electronic means, including electronic mail, Internet, facsimile and similar transmission, any advertisement, knowing, or under circumstances where one reasonably should know, that the purpose of the advertisement, in whole or in part is to promote the sale of objects designed or intended for use as drug paraphernalia. ((34) amended Nov. 24, 1999, P.L.894, No.55)

(35) (i) Except as otherwise provided by law, manufacturing, processing, packaging, distributing, possessing with intent to distribute or selling a noncontrolled substance that has a stimulant or depressant effect on humans, other than

a prescription drug, which, or the label or container of which, substantially resembles a specific controlled substance. In determining whether there has been a violation of this subclause, the following factors shall be considered:

(A) Whether the noncontrolled substance in its overall finished dosage appearance is substantially similar in size, shape, color and markings or lack thereof to a specific controlled substance.

(B) Whether the noncontrolled substance in its finished dosage form is packaged in a container which, or the labeling of which, bears markings or printed material substantially similar to that accompanying or containing a specific controlled substance.

(ii) Except as otherwise provided by law, no person shall knowingly distribute or sell a noncontrolled substance upon the express or implied representation that the substance is a controlled substance. In determining whether there has been a violation of this subclause, the following factors shall be considered:

(A) Whether the noncontrolled substance in its overall finished dosage appearance is substantially similar in size, shape, color and markings or lack thereof to a specific controlled substance.

(B) Whether the noncontrolled substance in its finished dosage form is packaged in a container which, or the labeling of which, bears markings or printed material substantially similar to that accompanying or containing a specific controlled substance.

(C) Whether the noncontrolled substance is packaged in a manner ordinarily used for the illegal delivery of a controlled substance.

(D) Whether the consideration tendered in exchange for the noncontrolled substance substantially exceeds the reasonable value of the substance, considering the actual chemical composition of the substance and, where applicable, the price at which over-the-counter substances of like chemical composition sell.

(E) Whether the consideration tendered in exchange for the noncontrolled substance approximates or exceeds the price at which the substance would sell upon illegal delivery were it actually the specific controlled substance it physically resembles.

(iii) Except as otherwise provided by law, no person shall knowingly distribute or sell a noncontrolled substance upon the express representation that the recipient, in turn, will be able to distribute or sell the substance as a controlled substance.

(iv) In any criminal prosecution brought under this clause, it shall not be a defense that the defendant believed the noncontrolled substance actually to be a controlled substance.

(v) The provisions of this clause shall not be applicable to:

(A) Law enforcement officers acting in the course and legitimate scope of their employment.

(B) Persons who manufacture, process, package, distribute or sell noncontrolled substances to licensed medical practitioners for use as placebos in the course of professional practice or research or for use in FDA approved investigational new drug trials.

(C) Licensed medical practitioners, pharmacists and other persons authorized to dispense or administer controlled

substances and acting in the legitimate performance of their professional license pursuant to subclause (v)(B).

(D) A noncontrolled substance that was initially introduced into commerce prior to the initial introduction into commerce of the controlled substance which it is alleged to imitate.

(36) The knowing or intentional manufacture, distribution, possession with intent to distribute, or possession of a designer drug. Nothing in this section shall be construed to apply to a person who manufactures or distributes a substance in conformance with the provisions of an approved new drug application or an exemption for investigational use within the meaning of section 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355). For purposes of this section, no new drug shall be introduced or delivered for introduction except upon approval of an application pursuant to section 505 of the Federal Food, Drug and Cosmetic Act. ((36) amended Feb. 11, 2000, P.L.9, No.3)

(37) The possession by any person, other than a registrant, of more than thirty doses labeled as a dispensed prescription or more than three trade packages of any anabolic steroids listed in section 4(3)(vii). ((37) added Dec. 22, 1989, P.L.750, No.104)

(38) The unlawful manufacture of methamphetamine or phencyclidine or their salts, isomers and salts of isomers, whenever the existence of such salts, isomers or salts of isomers is possible within the specific chemical designation:

(i) in a structure where any child under 18 years of age is present; or

(ii) where the manufacturing of methamphetamine or phencyclidine causes any child under 18 years of age to suffer bodily injury.

((38) added Nov. 19, 2004, P.L.846, No.108)

(39) The knowing possession of ephedrine, pseudoephedrine or phenylpropanolamine, or any of their salts, optical isomers or salts of optical isomers with the intent to manufacture methamphetamine. ((39) added Feb. 17, 2010, P.L.137, No.8, and amended April 29, 2010, P.L.182, No.21)

(40) (Reserved). ((40) amended July 9, 2013, P.L.359, No.53)

(b) Any person who violates any of the provisions of clauses (1) through (11), (13) and (15) through (20) or (37) of subsection (a) shall be guilty of a misdemeanor, and except for clauses (4), (6), (7), (8), (9) and (19) shall, on conviction thereof, be sentenced to imprisonment not exceeding one year or to pay a fine not exceeding five thousand dollars ($5,000), or both, and for clauses (4), (6), (7), (8), (9) and (19) shall, on conviction thereof, be sentenced to imprisonment not exceeding three years or to pay a fine not exceeding five thousand dollars ($5,000), 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 sentenced to imprisonment not exceeding three years or to pay a fine not exceeding twenty-five thousand dollars ($25,000), or both. ((b) amended Dec. 22, 1989, P.L.750, No.104)

(c) Any person who violates the provisions of clauses (21), (22), (24) and (39) of subsection (a) shall be guilty of a misdemeanor, and shall, on conviction thereof, be punished only as follows:

(1) Upon conviction of the first such offense, he shall be sentenced to imprisonment not exceeding six months, or to pay a fine not exceeding ten thousand dollars ($10,000), or both.

(2) Upon conviction of the second and subsequent offense, he shall be sentenced to imprisonment not exceeding two years, or to pay a fine not exceeding twenty-five thousand dollars ($25,000), or both.

((c) amended July 9, 2013, P.L.359, No.53)

(d) Any person who knowingly or intentionally violates clause (23) of subsection (a) is guilty of a misdemeanor and upon conviction thereof shall be sentenced to imprisonment not exceeding three years, or to pay a fine not exceeding fifteen thousand dollars ($15,000), or both.

(e) Any person who violates clauses (25) through (29) of subsection (a) is guilty of a misdemeanor and upon conviction shall be sentenced to imprisonment not exceeding three years, or to pay a fine not exceeding twenty-five thousand dollars ($25,000), or both.

(f) Any person who violates clause (12), (14) or (30) of subsection (a) with respect to:

(1) A controlled substance or counterfeit substance classified in Schedule I or II which is a narcotic drug, is guilty of a felony and upon conviction thereof shall be sentenced to imprisonment not exceeding fifteen years, or to pay a fine not exceeding two hundred fifty thousand dollars ($250,000), or both or such larger amount as is sufficient to exhaust the assets utilized in and the profits obtained from the illegal activity.

(1.1) Phencyclidine; methamphetamine, including its salts, isomers and salts of isomers; coca leaves and any salt, compound, derivative or preparation of coca leaves; any salt, compound, derivative or preparation of the preceding which is chemically equivalent or identical with any of these substances, except decocanized coca leaves or extracts of coca leaves, which extracts do not contain cocaine or ecgonine; and marihuana in a quantity in excess of one thousand (1,000) pounds, is guilty of a felony and upon conviction thereof shall be sentenced to imprisonment not exceeding ten years, or to pay a fine not exceeding one hundred thousand dollars ($100,000), or both, or such larger amount as is sufficient to exhaust the assets utilized in and the profits obtained from the illegal manufacture or distribution of these substances.

(2) Any other controlled substance or counterfeit substance classified in Schedule I, II, or III, is guilty of a felony and upon conviction thereof shall be sentenced to imprisonment not exceeding five years, or to pay a fine not exceeding fifteen thousand dollars ($15,000), or both.

(3) A controlled substance or counterfeit substance classified in Schedule IV, is guilty of a felony and upon conviction thereof shall be sentenced to imprisonment not exceeding three years, or to pay a fine not exceeding ten thousand dollars ($10,000), or both.

(4) A controlled substance or counterfeit substance classified in Schedule V, is guilty of a misdemeanor and upon conviction thereof shall be sentenced to imprisonment not exceeding one year, or to pay a fine not exceeding five thousand dollars ($5,000), or both.

(g) Any person who violates clause (31) of subsection (a) is guilty of a misdemeanor and upon conviction thereof shall be sentenced to imprisonment not exceeding thirty days, or to pay a fine not exceeding five hundred dollars ($500), or both.

(h) Any penalty imposed for violation of this act shall be in addition to, and not in lieu of, any civil or administrative penalty or sanction authorized by law.

(i) Any person who violates clauses (32), (33) and (34) of subsection (a) is guilty of a misdemeanor and upon conviction thereof shall be sentenced to pay a fine not exceeding two thousand five hundred dollars ($2,500) or to imprisonment not exceeding one (1) year, or both. Any person who violates clause (33) by delivering drug paraphernalia to a person under eighteen (18) years of age who is three (3) or more years his junior shall be guilty of a misdemeanor of the second degree and upon conviction thereof shall be sentenced to pay a fine not exceeding five thousand dollars ($5,000) or to imprisonment not exceeding two (2) years, or both.

(j) Any person who violates any provisions of subclause (i) or (ii) or (iii) of clause (35) of subsection (a) is guilty of a felony, and upon conviction thereof shall be sentenced to imprisonment not exceeding five years, or to pay a fine not exceeding ten thousand dollars ($10,000), or both.

(k) Any person convicted of manufacture of amphetamine, its salts, optical isomers and salts of its optical isomers; methamphetamine, its salts, isomers and salts of isomers; or phenylacetone and phenyl-2-proponone shall be sentenced to at least two years of total confinement without probation, parole or work release, notwithstanding any other provision of this act or other statute to the contrary. ((k) amended July 3, 1985, P.L.138, No.39)

(l) Any person who violates clause (36) is guilty of a felony and upon conviction thereof shall be sentenced to imprisonment not exceeding fifteen years or to pay a fine not exceeding two hundred fifty thousand dollars ($250,000), or both. ((l) added Dec. 11, 1986, P.L.1488, No.154)

(m) ((m) repealed June 28, 1993, P.L.137, No.33, July 2, 1993, P.L.408, No.58 and Feb. 10, 1994, P.L.20, No.3)

(n) Any person who violates subsection (a)(12), (14), (16), (30) or (34) with respect to gamma hydroxybutyric acid, any salt, compound derivative or preparation of gamma hydroxybutyric acid, including any isomers, esters and ethers and salts of isomers, or esters and ethers of gamma hydroxybutyric acid, except gamma-butyrolactone (GBL), whenever the existence of such isomers, esters, ethers or salts is possible within the specific chemical designation, is guilty of a felony and upon conviction thereof shall be sentenced to imprisonment not exceeding fifteen years, or to pay a fine not exceeding two hundred fifty thousand dollars ($250,000), or both, or such larger amount as is sufficient to exhaust the assets utilized in and the profits obtained from the illegal activity. ((n) added Nov. 24, 1999, P.L.894, No.55)

(o) Any person who violates subsection (a)(12), (14) or (30) with respect to 3,4-methylenedioxyamphetamine (MDA); 3,4-methylenedioxymethamphetamine (MDMA); 5-methoxy-3,4-methylenedioxyamphetamine (MMDA); 3,4-methylenedioxy-N-ethylamphetamine; N-hydroxy-3,4-methylenedioxyamphetamine; or their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation, is guilty of a felony and upon conviction thereof shall be sentenced to imprisonment not exceeding fifteen years or to pay a fine not exceeding two hundred fifty thousand dollars ($250,000), or both, or such larger amount as is sufficient to exhaust the assets utilized in and the profits obtained from the illegal activity. ((o) added June 10, 2003, P.L.9, No.3)

(p) (1) Any person who violates subsection (a)(38)(i) is guilty of a felony of the third degree and upon conviction

thereof shall be sentenced to not more than seven years in prison and a fine of not more than twenty-five thousand dollars ($25,000), or such larger amount as is sufficient to exhaust the assets utilized in and the profits obtained from the illegal activity.

(2) Any person who violates subsection (a)(38)(ii) is guilty of a felony of the second degree and upon conviction thereof shall be sentenced to not more than ten years in prison and a fine of not more than fifty thousand dollars ($50,000), or such larger amount as is sufficient to exhaust the assets utilized in and the profits obtained from the illegal activity.

((p) added Nov. 19, 2004, P.L.846, No.108)

(13 amended Dec. 14, 1984, P.L.988, No.200)

Section 13.1. Liquefied Ammonia Gas; Precursors and Chemicals.--(a) The following acts are prohibited:

(1) Possessing or transporting liquefied ammonia gas:

(i) for any purpose other than legitimate agricultural or industrial use; or

(ii) in a container not approved by the Department of Agriculture or the Department of Transportation or both.

(2) Possessing or transporting liquefied ammonia gas with intent to unlawfully manufacture a controlled substance.

(3) Possessing phenylpropanolamine, phenyl acetone, methylamine, ammonium sulfate, ammonium nitrate, phenyl acetic acid or a precursor substance with intent to unlawfully manufacture a controlled substance.

(4) Possessing the esters, salts, optical isomers or salts of optical isomers of any of the substances under clause (3) with intent to manufacture a controlled substance.

(b) A person who violates subsection (a)(1) commits a misdemeanor and upon conviction shall be sentenced to imprisonment not exceeding five years and to pay a fine not exceeding ten thousand dollars ($10,000).

(c) A person who violates subsection (a)(2), (3) or (4) commits a felony and upon conviction shall be sentenced to imprisonment not exceeding seven years and to pay a fine not exceeding fifteen thousand dollars ($15,000).

(d) As used in this section, the term "precursor substance" means:

(1) red phosphorous, hypophosphoric acid, ammonium sulfate, phosphorous, iodine, hydriodic acid or ephedrine, pseudoephedrine, phenylpropanolamine or any of their salts or optical isomers;

(2) salts of optical isomers or lithium, sodium, potassium, sassafras oil or safrole oil or other oil containing safrole or equivalent, whether in powder or liquid form; and

(3) any chemical in a regulation promulgated by the secretary under section 35(b).

(13.1 amended June 8, 2016, P.L.258, No.37)

Section 13.2. Clandestine Drug Laboratory Data Repository.--The Pennsylvania State Police shall maintain a Statewide repository of data relating to clandestine drug laboratories, clandestine drug laboratory dump sites and the seizure of chemicals, glassware and other laboratory implements associated with manufacturing controlled substances and develop and implement a program to enable collection of data and reporting thereof by law enforcement agencies of this Commonwealth. Data acquired by law enforcement agencies shall be sent to the repository within twenty days of acquisition.

(13.2 added July 15, 2004, P.L.729, No.84)

Section 13.3. Methamphetamine Production.--(a) Proof that a person had in his possession more than 40 grams or 15 packages

of any drug containing ephedrine, pseudoephedrine or phenylpropanolamine, or any of their salts, optical isomers or salts of optical isomers as an active ingredient shall give rise to a rebuttable presumption that the person acted with intent to manufacture methamphetamine.

(b) Proof that a person had in his possession any amount of ephedrine, pseudoephedrine or phenylpropanolamine, or any of their salts, optical isomers or salts of optical isomers and at the same time possessed any amount of any other precursor or reagent substance under section 13.1 shall give rise to a rebuttable presumption that the person acted with intent to manufacture methamphetamine.

(c) The provisions of this section shall not apply to a licensed pharmaceutical manufacturer, wholesaler, or the sales representative of a licensed manufacturer or wholesaler, or to a licensed pharmacist or licensed health care professional, or to any other person engaged by a licensed manufacturer, wholesaler, pharmacist or health care provider, who lawfully markets, transports, delivers or dispenses a product containing ephedrine, pseudoephedrine or phenylpropanolamine, or any of their salts, optical isomers or salts of optical isomers.

(13.3 added Feb. 17, 2010, P.L.137, No.8, and amended April 29, 2010, P.L.182, No.21)

Section 13.4. Operating a Methamphetamine Laboratory and Illegal Dumping of Methamphetamine Waste.--(a) (1) A person commits the offense of operating a methamphetamine laboratory if the person knowingly causes a chemical reaction involving ephedrine, pseudoephedrine or phenylpropanolamine, or any other precursor or reagent substance under section 13.1, for the purpose of manufacturing methamphetamine or preparing a precursor or reagent substance for the manufacture of methamphetamine.

(2) Except as provided in clause (3), an offense under this subsection constitutes a felony of the second degree and is also subject to 18 Pa.C.S. § 1110 (relating to restitution for cleanup of clandestine laboratories).

(3) A person who violates this subsection commits a felony of the first degree if the chemical reaction occurs within 1,000 feet of the real property on which is located a public, private or parochial school, a college or university or a nursery school or daycare center or within 250 feet of the real property on which is located a recreation center or playground. The person shall also be subject to 18 Pa.C.S. § 1110.

(4) This subsection does not apply to the manufacturing operation of a licensed pharmaceutical company in the normal course of business.

(b) (1) A person commits a felony of the third degree if he intentionally, knowingly or recklessly deposits, stores or disposes on any property a precursor or reagent substance, chemical waste or debris, used in or resulting from the manufacture of methamphetamine or the preparation of a precursor or reagent substance for the manufacture of methamphetamine.

(2) Clause (1) does not apply to the disposal of waste products:

(i) by a licensed pharmaceutical company in the normal course of business; or

(ii) pursuant to Federal or State laws regulating the cleanup or disposal of waste products from unlawful manufacturing of methamphetamine.

(c) In addition to restitution under 18 Pa.C.S. § 1110, a person who is convicted of an offense under this section shall be ordered to reimburse the appropriate law enforcement agency,

emergency medical services organization, fire company or other organization for the costs of cleaning up the environmental hazards associated with the operation of the laboratory or the possession or use of a precursor or reagent substance to manufacture methamphetamine.

(13.4 added Feb. 17, 2010, P.L.137, No.8, and amended April 29, 2010, P.L.182, No.21)

Section 13.5. Environmental Costs.--In addition to restitution under 18 Pa.C.S. § 1110 (relating to restitution for cleanup of clandestine laboratories), a person who is convicted of an offense involving the operation of a methamphetamine laboratory or the possession or use of a precursor or reagent substance to manufacture methamphetamine shall be ordered to reimburse the appropriate law enforcement agency, emergency medical services organization, fire company or other organization for the costs of cleaning up the environmental hazards associated with the operation of the laboratory or the possession or use of a precursor or reagent substance to manufacture methamphetamine.

(13.5 added Feb. 17, 2010, P.L.137, No.8, and amended April 29, 2010, P.L.182, No.21)

Section 13.6. Ephedrine and Pseudoephedrine; Electronic Tracking.--(a) Retailers shall be prohibited from making sales to an individual of, and an individual shall be prohibited from purchasing, ephedrine or pseudoephedrine base, or their salts, isomers or salts of isomers in excess of the following amounts:

(1) 3.6 grams of ephedrine or pseudoephedrine base contained in a product or combination of products per day.

(2) 9 grams of ephedrine or pseudoephedrine base contained in a product or combination of products per thirty-day period.

(b) Nonprescription products containing ephedrine or pseudoephedrine shall be maintained behind the counter or in a locked case where the customer does not have direct access.

(c) A retailer shall require any person purchasing a nonprescription product that contains ephedrine or pseudoephedrine to present a valid government-issued photo identification, or other document considered acceptable under Federal law for this purpose, at the point of sale. The retailer shall record the following:

(1) Name and address of the purchaser.

(2) Name and quantity of product purchased.

(3) Date and time of purchase.

(4) Purchaser identification type and number, such as driver's license state and number, and require the purchaser's signature in a logbook.

(d) A retailer shall, before completing a sale under this section, electronically submit the required information to the real-time stop sale system administered by the department, provided that the system is available without a charge for retailers to access. Absent negligence, wantonness, recklessness or deliberate misconduct, any retailer using the electronic sales tracking system in accordance with this subsection shall not be civilly liable as a result of any act or omission in carrying out the duties required by this subsection and shall be immune from liability to any third party unless the retailer has violated any provision of this subsection in relation to a claim brought for such violation.

(e) If a retailer selling a nonprescription product containing ephedrine or pseudoephedrine experiences mechanical or electronic failure of the electronic sales tracking system and is unable to comply with the electronic sales tracking requirement, the retailer shall maintain a written log or an

alternative electronic recordkeeping mechanism until such time as the retailer is able to comply with the electronic sales tracking requirement. A retailer that does not have Internet access to the electronic sales tracking system is compliant with the requirements of this section if the retailer maintains a written log or an alternative recordkeeping mechanism.

(f) The vendor of the real-time stop-sale system shall forward State transaction records in the real-time stop-sale system to the department weekly and provide real-time access to the real-time stop-sale system information through the system's online portal to law enforcement in this Commonwealth as authorized by the department.

(g) The department shall work with the real-time stop-sale vendor to ensure that the real-time stop-sale system shall be capable of generating a stop-sale alert, which shall be a notification that completion of the sale would result in the retailer or purchaser violating the quantity limits set forth in this section. The retailer shall not complete the sale if the electronic system generates a stop-sale alert. The department shall work with the real-time stop-sale vendor to ensure that the system contains an override function that may be used by a retailer of ephedrine or pseudoephedrine who has a reasonable fear of imminent bodily harm if it does not complete a sale. Each instance in which the override function is used shall be logged in the system.

(h) A violation of any provision of this section is a misdemeanor, punishable by fine only.

(i) This section does not apply to a person who obtains the product pursuant to a valid prescription.

(j) This section shall supersede any other laws or regulations governing the sales of products containing ephedrine or pseudoephedrine.

(13.6 added July 9, 2013, P.L.359, No.53)

Section 13.7. Drug Overdose Response Immunity.--(a) A person may not be charged and shall be immune from prosecution for any offense listed in subsection (b) and for a violation of probation or parole if the person can establish the following:

(1) law enforcement officers only became aware of the person's commission of an offense listed in subsection (b) because the person transported a person experiencing a drug overdose event to a law enforcement agency, a campus security office or a health care facility; or

(2) all of the following apply:

(i) the person reported, in good faith, a drug overdose event to a law enforcement officer, the 911 system, a campus security officer or emergency services personnel and the report was made on the reasonable belief that another person was in need of immediate medical attention and was necessary to prevent death or serious bodily injury due to a drug overdose;

(ii) the person provided his own name and location and cooperated with the law enforcement officer, 911 system, campus security officer or emergency services personnel; and

(iii) the person remained with the person needing immediate medical attention until a law enforcement officer, a campus security officer or emergency services personnel arrived.

(b) The prohibition on charging or prosecuting a person as described in subsection (a) bars charging or prosecuting a person for probation and parole violations and for violations of section 13(a)(5), (16), (19), (31), (32), (33) and (37).

(c) Persons experiencing drug overdose events may not be charged and shall be immune from prosecution as provided in

subsection (b) if a person who transported or reported and remained with them may not be charged and is entitled to immunity under this section.

(d) The prohibition on charging or prosecuting a person as described in this section is limited in the following respects:

(1) This section may not bar charging or prosecuting a person for offenses enumerated in subsection (b) if a law enforcement officer obtains information prior to or independent of the action of seeking or obtaining emergency assistance as described in subsection (a).

(2) This section may not interfere with or prevent the investigation, arrest, charging or prosecution of a person for the delivery or distribution of a controlled substance, drug-induced homicide or any other crime not set forth in subsection (b).

(3) This section may not bar the admissibility of any evidence in connection with the investigation and prosecution for any other prosecution not barred by this section.

(4) This section may not bar the admissibility of any evidence in connection with the investigation and prosecution of a crime with regard to another defendant who does not independently qualify for the prohibition on charging or prosecuting a person as provided for by this section.

(e) In addition to any other applicable immunity or limitation on civil liability, a law enforcement officer or prosecuting attorney who, acting in good faith, charges a person who is thereafter determined to be entitled to immunity under this section shall not be subject to civil liability for the filing of the charges.

(f) As used in this section, the following words and phrases shall have the meanings given to them in this subsection unless the context clearly indicates otherwise:

"911 system." A system, including enhanced 911 service and a wireless E-911 system, that permits a person dialing 911 by telephone to be connected to a public safety answering point, via normal telephone facilities, for the reporting of police, fire, medical or other emergency situations.

"Campus security officer." An employee of an institution of higher education charged with maintaining the safety and security of the property of the institution and the persons on the property.

"Drug overdose event." An acute medical condition, including, but not limited to, severe physical illness, coma, mania, hysteria or death, which is the result of consumption or use of one or more controlled substances causing an adverse reaction. A patient's condition shall be deemed to be a drug overdose if a prudent layperson, possessing an average knowledge of medicine and health, would reasonably believe that the condition is in fact a drug overdose and requires immediate medical attention.

"Emergency services personnel." Individuals, including a trained volunteer or a member of the armed forces of the United States or the National Guard, whose official or assigned responsibilities include performing or directly supporting the performance of emergency medical and rescue services or firefighting.

"Law enforcement officer." A person who by virtue of the person's office or public employment is vested by law with a duty to maintain public order or to make arrests for offenses, whether that duty extends to all offenses or is limited to specific offenses, or a person on active State duty under 51 Pa.C.S. § 508 (relating to active duty for emergency).

(13.7 added Sept. 30, 2014, P.L.2487, No.139)

Section 13.8. Drug Overdose Medication.--(a) The department, in carrying out its duties under 28 Pa. Code Ch. 1023 (relating to personnel), shall have the following duties:

(1) Amend the prehospital practitioner scope of practice of emergency medical services providers to include the administration of an opioid antagonist.

(2) In consultation with the Pennsylvania Emergency Health Services Council, implement training, treatment protocols, equipment lists and other policies and procedures for all types of emergency medical services providers.

(3) In consultation with the Department of Drug and Alcohol Programs, develop or approve training and instructional materials about recognizing opioid-related overdoses, administering an opioid antagonist and promptly seeking medical attention. The training and instruction materials shall be provided free of charge on the Internet.

(b) A law enforcement agency, fire department or fire company may enter into written agreements with emergency medical services agencies, with the consent of that agency's medical director or a physician, to do the following:

(1) Obtain a supply of an opioid antagonist.

(2) Authorize a law enforcement officer or firefighter who has completed training under subsection (a)(2), or who has received the training and instructional materials under subsection (a)(3), to administer an opioid antagonist to an individual undergoing or believed to be undergoing an opioid-related drug overdose.

(c) Notwithstanding any other law to the contrary, a health care professional otherwise authorized to prescribe an opioid antagonist may dispense, prescribe or distribute the opioid antagonist directly or by a standing order to an authorized law enforcement officer or firefighter in accordance with an agreement under subsection (b) or to a person at risk of experiencing an opioid-related overdose or family member, friend or other person in a position to assist a person at risk of experiencing an opioid-related overdose.

(d) The provisions of the act of September 27, 1961 (P.L.1700, No.699), known as the "Pharmacy Act," shall not apply to a law enforcement officer or firefighter who stores an opioid antagonist pursuant to an agreement under subsection (b), and in accordance with directions from the health care professional that prescribed, dispensed or distributed the opioid antagonist, or to a person or organization acting at the direction of a health care professional authorized to prescribe an opioid antagonist so long as such activities are undertaken without charge or compensation.

(e) (1) A licensed health care professional who, acting in good faith, prescribes or dispenses an opioid antagonist shall not be subject to any criminal or civil liability or any professional disciplinary action for:

(i) such prescribing or dispensing; or

(ii) any outcomes resulting from the eventual administration of the opioid antagonist.

(2) The immunity under paragraph (1) shall not apply to a health professional who acts with intent to harm or with reckless indifference to a substantial risk of harm.

(f) (1) A person, law enforcement agency, fire department or fire company under subsection (b)(2) or (c) who, acting in good faith and with reasonable care, administers an opioid antagonist to another person whom the person believes to be suffering an opioid-related drug overdose:

(i) Shall be immune from criminal prosecution, sanction under any professional licensing statute and civil liability for such act.

(ii) Shall not be subject to professional review for such act.

(iii) Shall not be liable for any civil damages for acts or omissions resulting from such act.

(2) Receipt of training and instructional materials that meet the criteria of subsection (a) and the prompt seeking of additional medical assistance shall create a rebuttable presumption that the person acted with reasonable care in administering an opioid antagonist.

(g) Nothing in this section shall be interpreted to limit any existing immunities for emergency response providers and others provided for under 42 Pa.C.S. § 8332 (relating to emergency response provider and bystander good Samaritan civil immunity).

(h) As used in this section, the term "opioid antagonist" means a drug or device approved by the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040, 21 U.S.C. § 301 et seq.) for emergency reversal of known or suspected opioid overdose, including naloxone hydrochloride or other similarly acting drugs approved by the United States Food and Drug Administration for the treatment of an opioid overdose.

(13.8 amended Nov. 3, 2022, P.L.1984, No.135)

Section 14. Distribution to Persons Under Age Eighteen.--Any person who is at least twenty-one years of age and who is not himself a drug dependent person who violates this act by distributing a controlled substance listed in Schedules I through V to a person under eighteen years of age who is at least four years his junior is punishable by a term of imprisonment up to twice that otherwise authorized by subsection (f) of section 13 of this act, in addition to any fine authorized by this act.

(14 amended Oct. 26, 1972, P.L.1048, No.263)

Section 15. Second or Subsequent Offense.--(a) Any person convicted of a second or subsequent offense under clause (30) of subsection (a) of section 13 of this act or of a similar offense under any statute of the United States or of any state may be imprisoned for a term up to twice the term otherwise authorized, fined an amount up to twice that otherwise authorized, or both.

(b) For purposes of this section, an offense is considered a second or subsequent offense, if, prior to the commission of the second offense, the offender has at any time been convicted under clause (30) of subsection (a) of section 13 of this act or of a similar offense under any statute of the United States or of any state relating to controlled substances.

(15 amended Oct. 26, 1972, P.L.1048, No.263)

Section 16. Enforcement Provisions.--The following guidelines shall be applicable in the enforcement of any penalties imposed by this act:

(1) 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 section 12 of this act 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.

(2) For purposes of this section, any conviction under any Federal or State law relating to any controlled substance or other drug, other than a juvenile violation, shall constitute a prior offense if it related to the type of conduct against which a subsequent offense is directed.

(3) Any penalty relating to license or registration suspension or revocation shall be executed by the appropriate licensing or registration agency upon receipt of a court order setting forth the penalty.

(4) ((4) repealed Dec. 22, 1989, P.L.724, No.97)

Section 17. Probation Without Verdict.--Except as provided in clause (1) of this subsection, the court may place a person on probation without verdict if the person pleads nolo contendere or guilty to any nonviolent offense under this act and the person proves he is drug dependent. For the purposes of proving drug dependency, the person must present the testimony of a physician or psychologist trained in the field of drug abuse. The term of probation shall be for a specific time period not to exceed the maximum for the offense upon such reasonable terms and conditions as the court may require. The following shall apply:

(1) The following persons shall be ineligible for probation without verdict:

(i) Any person who has previously been convicted of an offense under this act or similar act of the United States or any other state.

(ii) Any person who has been convicted of a misdemeanor or felony in this Commonwealth or an equivalent crime under the laws of any other state.

(iii) Any person who has been placed on Accelerated Rehabilitative Disposition where the person was charged with a violation of this act or the commission of a misdemeanor or felony in this Commonwealth.

(iv) Any person who is charged with or has pleaded guilty or nolo contendere to multiple offenses which are based on separate conduct or arise from separate criminal episodes such that those offenses could be tried separately in accordance with 18 Pa.C.S. § 110 (relating to when prosecution barred by former prosecution for different offense).

(v) Any person who is a dangerous juvenile offender under 42 Pa.C.S. § 6302 (relating to definitions) or who was adjudicated delinquent for conduct which would constitute a violation of clause (30) or (37) of subsection (a) of section 13 of this act.

(vi) Any person who is charged with violating clause (14), (30) or (37) of subsection (a) of section 13 of this act.

(2) Upon violation of a term or condition of probation, the court may enter a judgment and proceed as in any criminal case, or may continue the probation without verdict.

(3) Upon fulfillment of the terms and conditions of probation, the court shall discharge such person and dismiss the proceedings against him. Discharge and dismissal shall be without adjudication of guilt and shall not constitute a conviction for any purpose whatever, including the penalties imposed for second or subsequent convictions: Provided, That probation without verdict shall be available to any person only once: And further provided, That notwithstanding any other provision of this act, the prosecuting attorney or the court, and the council shall keep a list of those persons placed on probation without verdict, which list may only be used to

determine the eligibility of persons for probation without verdict and the names on such lists may be used for no other purpose whatsoever.

(17 amended Dec. 28, 1994, P.L.1406, No.164)

Section 18. Disposition in Lieu of Trial or Criminal Punishment.--(a) If a person charged with a nonviolent crime claims to be drug dependent or a drug abuser and prior to trial he requests appropriate treatment, including but not limited to, admission or commitment under the Mental Health and Mental Retardation Act of 1966 in lieu of criminal prosecution, a physician experienced or trained in the field of drug dependency or drug abuse shall be appointed by the court to examine, if necessary, and to review the accused's record and advise the government attorney, the accused and the court in writing setting forth that for the treatment and rehabilitation of the accused it would be preferable for the criminal charges to be held in abeyance or withdrawn in order to institute treatment for drug dependence, or for the criminal charges to be prosecuted. The government attorney shall exercise his discretion whether or not to accept the physician's recommendation.

(b) In the event that the government attorney does not accept the physician's recommendation, the person charged shall not be eligible for relief under this section.

(c) If the government attorney accepts the physician's advice to hold in abeyance, he shall arrange for a hearing before the appropriate court to hold in abeyance the criminal prosecution. The court, upon its approval, shall proceed to make appropriate arrangements for treatment.

(d) The government attorney, upon his own application, may institute proceedings for appropriate treatment, including but not limited to, commitment pursuant to the Mental Health and Mental Retardation Act of 1966.

(e) A criminal charge may be held in abeyance pursuant to this section for no longer than the lesser of either (i) the appropriate statute of limitations or (ii) the maximum term that could be imposed for the offense charged. At the expiration of such period, the criminal charge shall be automatically dismissed. A criminal charge may not be prosecuted except by order of court so long as the medical director of the treatment facility certifies that the accused is cooperating in a prescribed treatment program and is benefiting from treatment.

(g) Disposition in lieu of trial as provided in this section shall be available to any person only once.

(18 amended Apr. 16, 1992, P.L.165, No.30)

Section 19. Expunging Criminal Records.--(a) Any records of arrest or prosecution or both for a criminal offense under this act, except for persons indicted for violations of clause (30) of subsection (a) of section 13, or under the provisions previously governing controlled substances in the Commonwealth of Pennsylvania or any political subdivision thereof shall be promptly expunged from the official and unofficial arrest and other criminal records pertaining to that individual when the charges are withdrawn or dismissed or the person is acquitted of the charges: Provided, That such expungment shall be available as a matter of right to any person only once. Within five days after such withdrawal, dismissal or acquittal the court, in writing, shall order the appropriate keepers of criminal records (i) to expunge and destroy the official and unofficial arrest and other criminal records of that individual, to request in so far as they are able the return of such records as they have made available to Federal and other State agencies,

and to destroy such records on receipt thereof; and (ii) to file with the court within thirty days an affidavit that such records have been expunged and destroyed, together with the court's expunction order and to retain no copies thereof. Upon receipt of such affidavit, the court shall seal the same together with the original and all copies of its expunction order and shall not permit any person or agency to examine such sealed documents.

The court shall file with the council a list of those persons whose record was expunged. The council shall maintain a confidential list, which list may be used only for the purpose of determining the eligibility of persons for the expunction provisions under this section and to be made available to any court upon request. ((a) amended Oct. 26, 1972, P.L.1048, No.263)

(b) Any expunged record of arrest or prosecution shall not hereafter be regarded as an arrest or prosecution for the purpose of any statute or regulation or license or questionnaire or any civil or criminal proceeding or any other public or private purpose. No person shall be permitted to learn of an expunged arrest or prosecution, or of the expunction, either directly or indirectly. Any person, except the individual arrested or prosecuted, who divulges such information in violation of this subsection shall be guilty of a summary offense and shall, upon conviction thereof, be punished by imprisonment not exceeding thirty (30) days or a fine not exceeding five hundred dollars ($500), or both.

(c) Nothing contained in this section shall prohibit a person acting pursuant to prior practice from petitioning an appropriate court for an expunction order.

Section 20. Offenses by a Corporation, Copartnership or Association.--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 employes 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.

Compiler's Note: Section 1 of Reorganization Plan No.4 of 1981 provided that the Council on Drug and Alcohol Abuse, together with its powers, functions and duties as set forth in Act 64, are transferred from the Governor's Office to the Department of Health.

Section 21. Burden of Proving Exemptions.--In any prosecution under this act, it shall not be necessary to negate any of the exemptions or exceptions of this act in any complaint, information or trial. The burden of proof of such exemption or exception shall be upon the person claiming it.

Section 22. Judicial Review.--Any person aggrieved by a final administrative decision may obtain review of the decision pursuant to the provisions of the Administrative Agency Law.

Section 23. Revocation of Licenses of Practitioners.--(a) Any license or registration heretofore issued to any practitioner may either be revoked or suspended by the proper officers or boards having power to issue licenses or registration to any of the foregoing, upon proof that the licensee or registrant is a drug dependent person on the use of any controlled substance, after giving such licensee or registrant reasonable notice and opportunity to be heard.

(b) The appropriate licensing boards in the Department of State are hereby authorized to revoke or suspend the registration or license of any practitioner when such person

has pleaded guilty or nolo contendere or has been convicted of a felony under this act or any similar State or Federal law. 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.

(c) The appropriate licensing boards in the Department of State shall automatically suspend, for a period not to exceed one year, the registration or license of any practitioner when the person has pleaded guilty or nolo contendere or has been convicted of a misdemeanor under this act. The district attorney of each county shall immediately notify the appropriate State licensing board of practitioners subject to the provisions of this section. However, the provisions of such automatic suspension may be stayed by the appropriate State licensing board in those cases where a practitioner has violated the provisions of this act only for the personal use of controlled substances by the practitioner and the practitioner participates in the impaired professional program approved by the appropriate State licensing board for a period of between three and five years, as directed by the appropriate licensing board. If the practitioner fails to comply in all respects with the standards of such a program, the appropriate licensing board shall immediately vacate the stay of the enforcement of the suspension provided for herein. Automatic suspension shall not be stayed pending any appeal of a conviction. Restoration of such license shall be made as in the case of a suspension of license. ((c) amended July 2, 1993, P.L.377, N0.53)

Section 24. Administrative Inspections and Warrants.--(a) As used in this section, the term "controlled premises" means:

(1) Places where original or other records or documents required under this act are kept or required to be kept; and

(2) Places, including factories, warehouses, or other establishments, and conveyances, where persons registered under section 6 (or exempted from registration under section 6) may lawfully hold, manufacture, or distribute, dispense, administer or otherwise dispose of controlled substances.

(b) (1) For the purpose of inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under this act and otherwise facilitating the carrying out of his functions under this act, the secretary is authorized, in accordance with this section, to enter controlled premises and to conduct administrative inspections thereof, and of the things specified in this section, relevant to those functions.

(2) Such entries and inspections shall be carried out through officers or employes (hereinafter referred to as "officers") designated by the secretary. Any such officer upon stating his purpose and presenting to the owner, operator, or officer in charge of such premises (i) appropriate credentials and (ii) a written notice of his inspection authority (which notice in the case of an inspection requiring, or in fact supported by, an administrative inspection warrant shall consist of such warrant), shall have the right to enter such premises and conduct such inspection at reasonable times.

(3) Except as may otherwise be indicated in an applicable inspection warrant, the officer shall have the right: (i) to inspect and copy records, reports, and other documents required to be kept or made under this act; (ii) to inspect, within reasonable limits and in a reasonable manner, controlled premises and all pertinent equipment, finished and unfinished drugs and other substances or materials, containers, and

labeling found therein, and, except as provided in this subsection, all other things therein (including records, files, papers, processes, controls, and facilities) appropriate for verification of the records, reports, and documents referred to in subclause (i) or otherwise bearing on the provisions of this act; and (iii) to inventory any stock of any controlled substance therein and obtain samples of any such substance or article.

(4) Except when the owner, operator, or officer in charge of the controlled premises so consents in writing, no inspection authorized by this section shall extend to: (i) financial data; (ii) sales data other than shipment data; (iii) pricing data; or (iv) research data.

(c) A warrant under this section shall not be required for the inspection of books and records pursuant to an administrative subpoena issued in accordance with any provisions of any Act of Assembly nor for entries and administrative inspections (including seizures of property):

(1) With the consent of the owner, operator, or officer in charge of the controlled premises;

(2) In situations presenting imminent danger to health or safety;

(3) In situations involving inspection of conveyances where there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant;

(4) In any other exceptional or emergency circumstance where time or opportunity to apply for a warrant is lacking; or

(5) In any other situations where a warrant is not constitutionally required.

(d) Issuance and execution of administrative inspection warrants shall be as follows:

(1) Any judge of a court, may, within his territorial jurisdiction, and upon proper oath or affirmation showing probable cause, issue warrants for the purpose of conducting administrative inspections authorized by this act or regulations thereunder, and seizures of property appropriate to such inspections. For the purposes of this section, the term "probable cause" exists upon showing a valid public interest in the effective enforcement of this act or regulations thereunder sufficient to justify administrative inspections of the area, premises, building, or conveyance, or contents thereof, in the circumstances specified in the application for the warrant.

(2) A warrant shall issue only upon an affidavit of a designated officer or employe having knowledge of the facts alleged, sworn to before the judge and establishing the grounds for issuing the warrant. If the judge is satisfied that grounds for the application exist or that there is probable cause to believe they exist, he shall issue a warrant identifying the area, premises, building, or conveyance to be inspected, the purpose of such inspection, and, where appropriate, the type of property to be inspected, if any. The warrant shall identify the items or types of property to be seized, if any. The warrant shall be directed to a person authorized under subsection (b) (2) to execute it. The warrant shall state the grounds for its issuance and the name of the person or persons whose affidavit has been taken in support thereof. It shall command the person to whom it is directed to inspect the area, premises, building, or conveyance identified for the purpose specified, and, where appropriate, shall direct the seizure of the property specified. The warrant shall direct that it be served during normal

business hours. It shall designate the judge to whom it shall be returned.

(3) A warrant issued pursuant to this section must be executed and returned within ten days of its date unless, upon a showing by the secretary of a need therefor, the judge allows additional time in the warrant. If property is seized pursuant to a warrant, the person executing the warrant shall give to the person from whom or from whose premises the property was taken a copy of the warrant and a receipt for the property taken or shall leave the copy and receipt at the place from which the property was taken. The return of the warrant shall be made promptly and shall be accompanied by a written inventory of any property taken. The inventory shall be made in the presence of the person executing the warrant and of the person from whose possession or premises the property was taken, if they are present, or in the presence of at least one credible person other than the person making such inventory, and shall be verified by the person executing the warrant. A copy of the inventory shall be delivered to the person from whom or from whose premises the property was taken and to the applicant for the warrant.

(4) The judge who has issued a warrant under this section shall attach to the warrant a copy of the return and all papers returnable filed in connection therewith and shall file them with the clerk of the court for the judicial district in which the inspection was made.

Section 25. Injunctive Relief.--In addition to the remedies provided herein, 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 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 26. Cooperation With Other Authorities.--The agencies charged with the enforcement of this act shall actively cooperate and coordinate with the agencies charged with the enforcement of all Federal and State laws relating to the regulation of the distribution of controlled substances, other drugs, devices or cosmetics.

Section 27. Embargo.--(a) Whenever a duly authorized officer of the secretary finds or has probable cause to believe that any controlled substance, other drug, device or cosmetic is adulterated or misbranded or contraband, the same shall be deemed subject to embargo and he shall affix to such substance or article a tag or other appropriate marking, approved by the secretary, giving notice that such substance or article is or is suspected of being adulterated, misbranded or contraband and warning all persons not to remove or dispose of such substance or article until permission so to do has been granted by such officer, or until it shall have determined by proper authority that such substance or article is not adulterated, misbranded or contraband. At the time such notice is offered, the officer shall provide the person in charge of such substance or article, 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 a substance or article 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 30, 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 substance or article is adulterated, misbranded or contraband, he shall, within five days of the conclusion of the hearing, order such substance or article 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 substance or 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 substance or article shall be so labeled or processed has been executed, may by order direct that such substance or article be released to the claimant thereof for such labeling or processing under the supervision of an officer of the secretary. The expense of such supervision, if any, shall be paid by the claimant. Such substance or article shall be released to the claimant when it 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 substances or articles destroyed or distributed to a nonprofit institution.

Section 28. Forfeiture.--(28 repealed June 30, 1988, P.L.464, No.79)

Section 29. Procedure With Respect to Seized Property Subject to Liens and Rights of Lienholders.--(29 repealed June 30, 1988, P.L.464, No.79)

Section 30. 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 27.

(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 jurisdiction 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 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 31. Board Creation.--(a) 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) The board shall consist of the Secretary of Health, his successors in office, and ten additional members whom the Governor shall appoint, by and with the consent of a majority of all the members of the Senate. Of the members: one shall be a physician, one a dentist, one a veterinarian, one a psychologist or psychiatrist 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 employe thereof; and the two remaining persons shall be members of the general public not engaged in any of the aforementioned but one of whom shall be well informed on the problems caused by the abuse and misuse of drugs or other chemicals. 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. Any additional member, the appointment of whom is authorized by amending act, shall serve for a term of four years. Thereafter, the term of office of each member shall be four years from his appointment, or until his successor has been appointed and qualified, but no longer than six months beyond the four-year period. In the event that any member shall die or resign or otherwise become disqualified during his term of office, his successor shall be appointed in the same way and with the same qualifications as above set forth and shall hold office for the unexpired term. Any appointed member of the board shall be eligible for reappointment. Each member, who is not otherwise an officer or employe of the Commonwealth, when actually engaged in official meetings or otherwise in the performances of his official duties as directed by the chairman, shall receive sixty dollars ($60) per diem and shall receive, in addition, the amount of reasonable travel, hotel and other necessary expenses incurred in performing his duties for the board. ((b) amended Dec. 20, 1985, P.L.373, No.105)

(b.1) The department shall provide the public members of the board with orientation and training. ((b.1) added Dec. 20, 1985, P.L.373, No.105)

(c) 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. The board shall meet at least four times yearly. A member of the board who fails to attend three consecutive meetings shall forfeit his seat unless the Secretary of Health, upon written request from the member, finds that the member should be excused from a meeting because of illness or the death of an immediate family member. ((c) amended Dec. 20, 1985, P.L.373, No.105)

(d) 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 employes as the Secretary of Health shall appoint.

(e) 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) 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) 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, employes 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) 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 32. 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 33. Conformity With Federal Law.--No controlled substance, other drug, device or cosmetic shall be deemed to be adulterated or misbranded under this act if it complies with the applicable 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 34. Administration of Act.--(a) Except as may be otherwise provided by law, the provisions of this act shall be administered by the department. The secretary is authorized to employ personnel and to fix their compensation subject to the act of April 9, 1929 (P.L.177, No.175), known as "The Administrative Code of 1929."

(b) The secretary is authorized and directed to establish a Bureau of Drug Control within the department and to employ therein sufficient personnel to perform the duties imposed upon the department by this act. ((b) suspended insofar as inconsistent June 25, 1973, Reorg.Pl.6, P.L.463)

(c) The secretary may designate specific officers and employes of the Bureau of Drug Control as law enforcement personnel and authorize such personnel to:

(1) Carry firearms in the performance of his official duties;

(2) Execute and serve search warrants, arrest warrants, administrative inspection warrants, subpoenas, and summonses issued under the authority of the Commonwealth;

(3) Make arrests without warrant for any offense under this act committed in his presence, or if he has probable cause to believe that the person to be arrested has committed or is committing a violation of this act which may constitute a felony;

(4) Make seizures of property pursuant to this act; or

(5) Perform other law enforcement duties as the secretary designates.

((c) suspended insofar as inconsistent June 25, 1973, Reorg.Pl.6, P.L.463)

(d) Nothing contained herein shall be deemed to limit the authority of the Bureau of Drug Control, the Pennsylvania State Police, the Department of Justice or any other law enforcement agency in dealing with law enforcement matters with respect to persons engaged in the unlawful importation, manufacture, distribution, sale and production of controlled substances, other drugs or devices or cosmetics nor the authority of the council in performing any duties imposed upon it by the "Pennsylvania Drug and Alcohol Abuse Act." ((d) suspended insofar as inconsistent June 25, 1973, Reorg.Pl.6, P.L.463)

Compiler's Note: Section 1 of Reorganization Plan No.6 of 1973 provided that the functions, powers and duties of the Department of Health and Secretary of Health with regard to the establishment and operation of the Bureau of Drug Control, as set forth in 34(b), (c) and (d), are transferred to the Department of Justice and the Attorney General.

Section 35. Promulgation of Regulations.--(a) The secretary shall have the authority to promulgate in accordance with the provisions of this section and of the act of July 31, 1968 (P.L.769, No. 240), known as the "Commonwealth Documents Law" any regulations hereinbefore referred to in this act and such other regulations with the consent of the board regarding the possession, distribution, sale, purchase or manufacture of controlled substances, other drugs or devices or cosmetics as may be necessary to aid in the enforcement of this act.

(b) The following apply to a regulation adding a chemical to the definition of "precursor substance" in section 13.1(d):

(1) The secretary may promulgate the regulation:

(i) as part of the administration of this act; or

(ii) in response to a petition of an interested party.

(2) In determining whether to add a chemical, the secretary shall consider all of the following:

(i) Whether the chemical is already a controlled substance.

(ii) The availability of the chemical for potential illegal diversion.

(iii) The historical, actual or potential use of the chemical in the illegal production of a controlled substance, including the scope, duration and significance of use.

(iv) The nature and extent of the legitimate uses of the chemical.

(v) The clandestine and legitimate importation, manufacture or distribution of the chemical.

(vi) Any other factors relevant to and consistent with public health and safety.

(3) Promulgation of the regulation is exempt from section 612 of the act of April 9, 1929 (P.L.177, No.175), known as "The Administrative Code of 1929," and the act of June 25, 1982 (P.L.633, No.181), known as the "Regulatory Review Act."

(35 amended June 8, 2016, P.L.258, No.37)

Section 36. 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 37. Cooperative Agreements and Confidentiality.--(a) The secretary shall cooperate with Federal and other State agencies in discharging his responsibilities concerning traffic in controlled substances, other drugs, devices and cosmetics and in suppressing the abuse of such substances and articles. To this end, he may:

(1) Arrange for the exchange of information among governmental officials concerning the use and abuse of such substances and articles;

(2) Coordinate and cooperate in training programs concerning law enforcement at local and State levels;

(3) Request the Federal Bureau of Narcotics and Dangerous Drugs to establish a centralized unit to collect, accept, catalogue and file nonconfidential statistics and make the information available for Federal, State and local law enforcement purposes; and

(4) Conduct programs of eradication aimed at destroying wild or illicit growth of plant species from which drugs may be extracted.

(b) Results, information, and evidence received from the bureau relating to the regulatory functions of this act, including results of inspections conducted by it may be relied and acted upon by the secretary in the exercise of his regulatory functions under this act.

(c) A practitioner engaged in medical practice or clinical research is not required nor may he be compelled to furnish the name or identity of a patient or research subject to the secretary, nor may he be compelled in any State or local civil, criminal, administrative, legislative or other proceedings to furnish the name or identity of such an individual.

(d) This section shall not exempt the practitioner from regulations of the secretary pertaining to the prescription of controlled substances to a patient over an extended period or in an increasingly large dosage.

Section 38. 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: Provided, however, That in any case final on or before June 12, 1972 in which a defendant was sentenced for the commission of acts similar to those proscribed by subsection (16) or (31), but not (30), of section 13 (a) of this act, such defendant shall be resentenced under this act upon his petition if the penalties hereunder are less than those under prior law and in such case the prior criminal record of the defendant shall be expunged to the extent that such record shall no longer contain any reference to the prior grade of the offense if

higher than the grade of the offense to which defendant is resentenced.

(38 amended July 25, 1973, P.L.219, No.54)

Section 39. Pending Proceedings.--(a) Prosecution for any violation of law occurring prior to the effective date of this act is not affected or abated by this act. In any case not yet final if the offense is similar to one set out in this act, the penalties under this act apply if they are less than those under prior law.

(b) Civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of this act are not affected by this act.

(c) All administrative proceedings pending under prior laws which are superseded by this act shall be continued and brought to a final determination in accord with the laws and rules in effect prior to the effective date of the act. Any substance controlled under prior law which is not listed within Schedules I through V, is automatically controlled without further proceedings and shall be listed in the appropriate schedule.

(d) The secretary shall initially permit persons to register who own or operate any establishment engaged in the manufacture or distribution of any controlled substance prior to the effective date of this act and who are registered or licensed by this Commonwealth.

(e) This act applies to violations of law, seizures and forfeitures, injunctive proceedings, administrative proceedings and investigations which occur following its effective date.

Section 40. Continuation of Regulations.--Any orders and regulations promulgated under any law affected by this act and in effect on the effective date of this act and not in conflict with it continue in effect until modified, superseded or repealed.

Section 41. Uniformity of Interpretation.--This act shall be so applied and construed as to effectuate its general purpose to make uniform the law with respect to the subject of this act among those states which enact similar legislation.

Section 41.1. Effect on Local Ordinances.--Nothing in this act relating to drug paraphernalia shall be deemed to supersede or invalidate any consistent local ordinance, including zoning and nuisance ordinances, relating to the possession, sale or use of drug paraphernalia.

(41.1 added Dec. 4, 1980, P.L.1093, No.186)

Section 42. Bar to Prosecution.--If a violation of this act is a violation of a Federal law or the law of another state, a conviction or acquittal under Federal law or the law of another state for the same act is a bar to prosecution in this Commonwealth.

Section 43. Repeals.--(a) The act of September 26, 1961 (P.L.1664), known as "The Drug, Device and Cosmetic Act," is hereby repealed.

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

Section 44. Effective Dates.--Sections 13, 14, 15, 20 and 39 shall take effect immediately. All other sections shall take effect on June 14, 1972.

(44 added June 27, 1972, P.L.499, No.158)