

EPHEDRINE
(09/01/98)

KEY: **ORC** - *Ohio Revised Code*
 OAC - *Ohio Administrative Code*
 USCA - *United States Code Annotated*

Section 3719.41 Schedules of controlled substances. [ORC: 07/01/96]

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SCHEDULE V

(C) Stimulants

Unless specifically exempted or excluded under federal drug abuse control laws or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a stimulant effect on the central nervous system, including their salts, isomers, and salts of isomers:

- (1) Ephedrine, except as provided in division (K) of section 3719.44 of the Revised Code;
- (2) Pyrovalerone.

Section 3719.44 State board of pharmacy may change schedules. [ORC: 07/22/98]

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- (K) (1) A drug product containing ephedrine that is known as one of the following and is in the form specified shall not be considered a schedule V controlled substance:
 - (a) Amesec capsules;
 - (b) Bronitin tablets;
 - (c) Bronkotabs;
 - (d) Bronkolixir;
 - (e) Bronkaid tablets;
 - (f) Efedron nasal jelly;
 - (g) Guiaphed elixir;
 - (h) Haysma;
 - (i) Pazo hemorrhoid ointment and suppositories;
 - (j) Primatene "M" formula tablets;
 - (k) Primatene "P" formula tablets;
 - (l) Tedrigen tablets;
 - (m) Tedral tablets, suspension and elixir;
 - (n) T.E.P.;
 - (o) Vatronol nose drops.

- (2) (a) A product containing ephedrine shall not be considered a controlled substance if the product is a food product or dietary supplement that meets all of the following criteria:
- (i) It contains, per dosage unit or serving, not more than the lesser of twenty-five milligrams of ephedrine alkaloids or the maximum amount of ephedrine alkaloids provided in applicable regulations adopted by the United States food and drug administration, and no other controlled substance.
 - (ii) It contains no hydrochloride or sulfate salts of ephedrine alkaloids.
 - (iii) It is packaged with a prominent label securely affixed to each package that states all of the following: the amount in milligrams of ephedrine in a serving or dosage unit; the amount of the food product or dietary supplement that constitutes a serving or dosage unit; that the maximum recommended dosage of ephedrine for a healthy adult human is the lesser of one hundred milligrams in a twenty-four-hour period for not more than twelve weeks or the maximum recommended dosage or period of use provided in applicable regulations adopted by the United States food and drug administration; and that improper use of the product may be hazardous to a person's health.
- (b) (i) Subject to division (K)(2)(b)(ii) of this section, no person shall dispense, sell, or otherwise give a product described in division (K)(2)(a) of this section to any individual under eighteen years of age.
- (ii) Division (K)(2)(b)(i) of this section does not apply to a physician or pharmacist who dispenses, sells, or otherwise gives a product described in division (K)(2)(a) of this section to an individual under eighteen years of age, to a parent or guardian of an individual under eighteen years of age who dispenses, sells, or otherwise gives a product of that nature to the individual under eighteen years of age, or to a person who, as authorized by the individual's parent or legal guardian, dispenses, sells, or otherwise gives a product of that nature to an individual under eighteen years of age.
- (c) No person in the course of selling, offering for sale, or otherwise distributing a product described in division (K)(2)(a) of this section shall advertise or represent in any manner that the product causes euphoria, ecstasy, a "buzz" or "high," or an altered mental state; heightens sexual performance; or, because it contains ephedrine alkaloids, increased muscle mass.
- (3) A drug product that contains the isomer pseudoephedrine, or any of its salts, optical isomers, or salts of optical isomers, shall not be considered a controlled substance if the drug product is labeled in a manner consistent with federal law or with the product's over-the-counter tentative final monograph or final monograph issued by the United States food and drug administration.
- (4) At the request of any person, the board may except any product containing ephedrine not described in division (K)(1) or (2) of this section or any class of products containing ephedrine from being included as a schedule V controlled substance if it determines that the product or class of products does not contain any other controlled substance. The board shall make the determination in accordance with this section and by rules adopted in accordance with Chapter 119. of the Revised Code.

(L) As used in this section:

- (1) "Food" has the same meaning as in section 3715.01 of the Revised Code;

- (2) "Dietary supplement" has the meaning given in the "Federal Food, Drug, and Cosmetic Act," 108 Stat. 4327(1994), 21 U.S.C.A. 321(ff), as amended.
- (3) "Ephedrine alkaloids" means ephedrine, pseudoephedrine, norephedrine, norpseudoephedrine, methylephedrine, and methylpseudoephedrine.

Section 3715.01 Definitions. [ORC: 07/22/98]

(A) * * *

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- (3) "Food" means:
 - (a) Articles used for food or drink for humans or animals;
 - (b) Chewing gum;
 - (c) Articles used for components of any such articles.

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Section 321 Definitions; generally. [21 USCA: 11/21/97]

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(ff) The term "dietary supplement" --

- (1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
 - (A) a vitamin;
 - (B) a mineral;
 - (C) an herb or other botanical;
 - (D) an amino acid;
 - (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
 - (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);
- (2) means a product that --
 - (A) (i) is intended for ingestion in a form described in section 350(c)(1)(B)(i) of this title; or
 - (ii) complies with section 350(c)(1)(B)(ii) of this title;
 - (B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and
 - (C) is labeled as a dietary supplement; and
- (3) does --

- (A) include an article that is approved as a new drug under section 355 of this title, or licensed as a biologic under section 262 of Title 42, and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 342(f) of this title; and
- (B) not include --
 - (i) an article that is approved as a new drug under section 355 of this title, certified as an antibiotic under section 357 of this title, or licensed as a biologic under section 262 of Title 42, or
 - (ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter.

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Rule 4729-11-09 Sale of schedule V controlled substance products without a prescription.

[OAC: 11/25/94]

(Amplifies 3719.05, 3719.28, 4729.26, 4729.28, 4729.51, 4729.66)

A schedule V controlled substance product which is not a prescription drug as determined under the "Federal Food, Drug and Cosmetic Act" may be sold at retail by a pharmacist without a prescription to a purchaser at retail, provided that:

- (A) The sale is made only by a pharmacist and not by a nonpharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities in this section, the actual cash, credit transaction, or delivery may be completed by a nonpharmacist).
- (B) The purchaser is at least eighteen years of age.
- (C) The pharmacist requires every purchaser of a controlled substance under this rule not known to him to furnish suitable identification (including proof of age where appropriate).
- (D) A bound record book is maintained which contains the true name and complete address of the purchaser, the legible signature of the purchaser, name and quantity of controlled substances sold, date of each sale, and the name and legible initials of the pharmacist who sold the controlled substance at retail. This book shall be maintained for a period of three years from the date of the last transaction and must be made available for inspection and copying by persons authorized to enforce the federal and state drug laws.
- (E) The schedule V controlled substance product is sold at retail.
- (F) Not more than two hundred forty cubic centimeters (eight ounces) nor more than forty-eight solid dosage units of any schedule V controlled substance product containing opium, nor more than one hundred twenty cubic centimeters (four ounces) nor more than twenty-four solid dosage units of any other narcotic controlled substance may be sold at retail to the same purchaser in any given forty-eight-hour period.

- (G) Not more than one hundred solid dosage units of any schedule V controlled substance stimulant product may be sold to any one person in any one thirty-day period.
- (H) The schedule V controlled substance is sold at retail for a legitimate medical need and the purchaser furnishes information to the pharmacist which establishes the legitimate medical need for the controlled substance.

Rule 4729-12-01 Definition of ephedrine. [OAC: 11/25/94]
(Amplifies 3719.01, 3719.28, 4729.02, 4729.66)

Ephedrine is α -[-(Methylamino)ethyl]benzene-methanol; α -[1-(methylamino) ethyl]benzyl alcohol; 2-methylamino-1-phenyl-1-propanol; 1-phenyl-1-hydroxy-2-methylaminopropane; 1-phenyl-2-methylaminopropanol; α - hydroxy- β -methylaminopropylbenzene; a product which occurs in the Chinese herb Ma Huang (*Ephedra vulgaris*, *Ephedra sinica* Stapf., *Ephedra equisetina* Bunge, *Gnetaceae*) and in several other *Ephedra* spp. Isomeric forms include *d*- and *l*-ephedrine as well as *d*- and *l*-pseudoephedrine with *l*-ephedrine and *d*-pseudoephedrine as the naturally occurring isomers.

Rule 4729-12-02 Registration and licensure. [OAC: 11/25/94]
(Amplifies 3719.03, 3719.05, 3719.07, 3719.09, 3719.13, 3719.15, 3719.16, 3719.27, 3719.28, 4729.26, 4729.28, 4729.54, 4729.55, 4729.66)

Any person who manufactures, sells at wholesale or retail, dispenses, imports or exports products containing ephedrine, its salts or isomers, or who proposes to engage in such activities, shall submit an application for registration as a wholesaler of dangerous drugs and controlled substances or for licensure as a category III terminal distributor of dangerous drugs to conduct such activities in accordance with Chapters 3719. and 4729. of the Revised Code.

Rule 4729-12-03 Security, storage, and sale. [OAC: 11/25/94]
(Amplifies 3719.03, 3719.05, 3719.07, 3719.09, 3719.13, 3719.15, 3719.16, 3719.27, 3719.28, 4729.26, 4729.28, 4729.54, 4729.55, 4729.66)

Schedule V products containing ephedrine may be sold at wholesale or retail, and must be maintained in accordance with Chapters 3719. and 4729. of the Revised Code and Chapters 4729-9 and 4729-11 of the Administrative Code.

Rule 4729-12-04 Inventory. [OAC: 11/25/94]
(Amplifies 3719.03, 3719.05, 3719.07, 3719.09, 3719.13, 3719.15, 3719.16, 3719.27, 3719.28, 4729.26, 4729.28, 4729.54, 4729.55, 4729.66)

Every registrant or licensee required to keep records who possesses any quantity of ephedrine or schedule V drug products containing ephedrine shall take an inventory pursuant to rules 4729-9-14 and 4729-9-16 of the Administrative Code.

Rule 4729-12-05 Records. [OAC: 11/25/94]
(Amplifies 3719.03, 3719.05, 3719.07, 3719.09, 3719.13, 3719.15, 3719.16, 3719.27, 3719.28, 4729.26, 4729.28, 4729.54, 4729.55, 4729.66)

All practitioners, registrants, and licensees required to keep records pursuant to Chapter 3719. of the Revised Code and Chapters 4729-9 and 4729-11 of the Administrative Code shall maintain such records for ephedrine and schedule V drug products containing ephedrine.

Rule 4729-12-08 Petitions for exception of ephedrine-containing products. [OAC: 11/25/94]
(Amplifies 3719.03, 3719.05, 3719.07, 3719.09, 3719.13, 3719.15, 3719.16, 3719.27, 3719.28, 4729.26, 4729.28, 4729.54, 4729.55, 4729.66)

A petition requesting that a drug product containing ephedrine be excepted by the board of pharmacy from being legally classified as a schedule V controlled substance stimulant may be submitted by any person engaged in the legitimate manufacture or wholesale sale of such products in the United States. The petition shall include the following information:

- (A) Full name, address, and telephone number of the manufacturer.
 - (1) If incorporated, the petition must include copies of the incorporation papers and the names, dates of birth, addresses, and social security numbers of the officers of the corporation and all stockholders holding more than ten percent of the stock.
 - (2) If a proprietorship, the petition must include the name, address, date of birth, and social security number of the owner(s).
 - (3) If a partnership, the petition must include the names, addresses, dates of birth, and social security numbers of the partners.
- (B) A description of the package sizes and the manner of packaging the drug product.
- (C) A limited number of samples of each dosage form marketed in the final marketed packages.
- (D) The manner of distribution, advertising, and promotion of the product, including but not limited to:
 - (1) The full name and address of all accounts located in Ohio to which the products have been or will be distributed at wholesale based on other products marketed by the petitioner.
 - (2) Copies of all advertisements used to promote the product within the last twelve months shall be included with the petition. A list of the publications in which the advertisements appeared or will appear if not presently marketed. If the product has not yet been marketed, copies of other products marketed by the petitioner shall be submitted with the petition.
- (E) A listing of all ingredients in the product, indicating the quantity of each ingredient, whether or not it has any therapeutic value, and its purpose for being included in the product. Documentation of the therapeutic value of all active ingredients in the product shall be included with the petition.
- (F) A list of all names the product is marketed or will be marketed under in the United States or any other country.
- (G) Any information regarding the product's abuse or potential for abuse in the United States or other countries where the product is marketed or will be marketed under any of the names listed in paragraph (F) of this rule.

Rule 4729-12-09 Exceptions. [OAC: 07/01/97]
(Amplifies 3719.28, 3719.44, 4729.66)

Pursuant to division (K) of section 3719.44 of the Revised Code, each of the following products containing ephedrine, its salts, its isomers, or the salts of its isomers is declared to be exempt from classification as a schedule V controlled substance:

- (A) All products that contain the isomer known as pseudoephedrine or its salts, but do not also contain any of the isomer known as ephedrine or its salts.
- (B) "Breathe Easy®" herb tea.
- (C) "Bronkaid® Dual Action" caplets.
- (D) "Hydrosal®" hemorrhoidal ointment.
- (E) "Primatene® Dual Action Formula" tablets.
- (F) "Primatene®" tablets.
- (G) "SnoreStop™" tablets.

Rule 4729-12-10 Criteria to be considered in denying a petition for exemption or removing a drug product exemption. [OAC: 03/13/95]
 (Amplifies 3719.28, 3719.44, 4729.66)

- (A) The board shall consider the following factors in determining whether a particular over-the-counter (OTC) drug product containing the schedule V controlled substance ephedrine is manufactured and distributed for legitimate use in a manner consistent with the pertinent OTC tentative or final monograph issued by the federal food and drug administration and in a manner that reduces the likelihood of inappropriate use and/or abuse:
 - (1) The package size and the manner of packaging;
 - (2) Distribution, advertising, and promotion of the product;
 - (3) Labeling and the name of the product;
 - (4) The potential, duration, scope, and significance of inappropriate use and/or abuse;
 - (5) Other facts as may be relevant to and consistent with the public health and safety.
- (B) The board shall remove a drug product exception for a particular drug product if it determines that the drug product is not manufactured and distributed for legitimate use and in a manner that reduces the likelihood of abuse.

Section 3719.99 Penalties. [ORC: 07/22/98]

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- (H) Whoever violates division (K)(2)(b) of section 3719.44 of the Revised Code is guilty of a felony of the fifth degree.
- (I) Whoever violates division (K)(2)(c) of section 3719.44 of the Revised Code is guilty of a misdemeanor of the second degree.

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Section 2925.03 Trafficking offenses. [ORC: 07/22/98]

- (A) No person shall knowingly sell or offer to sell a controlled substance.

(B) This section does not apply to any of the following:

- (1) Manufacturers, licensed health professionals authorized to prescribe drugs, pharmacists, owners of pharmacies, and other persons whose conduct is in accordance with Chapters 3719., 4715., 4729., 4731., and 4741. or section 4723.56 of the Revised Code;

* * *

(C) Whoever violates division (A) of this section is guilty of one of the following:

- (1) * * *

- (2) If the drug involved in the violation is any compound, mixture, preparation, or substance included in schedule III, IV, or V, whoever violates division (A) of this section is guilty of trafficking in drugs. The penalty for the offense shall be determined as follows:

- (a) Except as otherwise provided in division (C)(2)(b), (c), (d), or (e) of this section, trafficking in drugs is a felony of the fifth degree, and division (C) of section 2929.13 of the Revised Code applies in determining whether to impose a prison term on the offender. *[F5°(6-12 months)(not more than \$2,500)]*
- (b) Except as otherwise provided in division (C)(2)(c), (d), or (e) of this section, if the offense was committed in the vicinity of a school or in the vicinity of a juvenile, trafficking in drugs is a felony of the fourth degree, and division (C) of section 2929.13 of the Revised Code applies in determining whether to impose a prison term on the offender. *[F4°(6-18months)(not more than \$5,000)]*
- (c) Except as otherwise provided in this division, if the amount of the drug involved exceeds the bulk amount but does not exceed five times the bulk amount, trafficking in drugs is a felony of the fourth degree, and there is a presumption of a prison term for the offense. If the amount of the drug involved is within that range and if the offense was committed in the vicinity of a school or in the vicinity of a juvenile, trafficking in drugs is a felony of the third degree, and there is a presumption for a prison term for the offense. *[F4°(6-18months)(not more than \$5,000)]*
- (d) Except as otherwise provided in this division, if the amount of the drug involved exceeds five times the bulk amount but does not exceed fifty times the bulk amount, trafficking in drugs is a felony of the third degree, and there is a presumption of a prison term for the offense. If the amount of the drug involved is within that range and if the offense was committed in the vicinity of a school or in the vicinity of a juvenile, trafficking in drugs is a felony of the second degree, and there is a presumption for a prison term for the offense. *[F3°(1-5 years)(not more than \$10,000)]*
- (e) Except as otherwise provided in this division, if the amount of the drug involved exceeds fifty times the bulk amount, trafficking in drugs is a felony of the second degree, and the court shall impose as a mandatory prison term one of the prison terms prescribed for a felony of the second degree. If the amount of the drug involved exceeds fifty times the bulk amount and if the offense was committed in the vicinity of a school or in the vicinity of a juvenile, trafficking in drugs is a felony of the first degree, and the court shall impose as a mandatory prison term one of the prison terms prescribed for a felony of the first degree. *[F2°(2-8 years)(not more than \$15,000)]*

* * *

(D) In addition to any prison term authorized or required by division (C) of this section and sections 2929.13 and 2929.14 of the Revised Code, and in addition to any other sanction imposed for the offense under this section or sections 2929.11 to 2929.18 of the Revised Code, the court that sentences an offender who is convicted of or pleads guilty to a violation of division (A) of this section shall do all of the following that are applicable regarding the offender:

- (1) If the violation of division (A) of this section is a felony of the first, second, or third degree, the court shall impose upon the offender the mandatory fine specified for the offense under division (B)(1) of section 2929.18 of the Revised Code unless, as specified in that division, the court determines that the offender is indigent.
- (2) The court shall revoke or suspend the driver's or commercial driver's license or permit of the offender in accordance with division (G) of this section.
- (3) If the offender is a professionally licensed person or a person who has been admitted to the bar by order of the supreme court in compliance with its prescribed and published rules, the court forthwith shall comply with section 2925.38 of the Revised Code.

* * *

(G) When required under division (D)(2) of this section, the court either shall revoke or, if it does not revoke, shall suspend for not less than six months or more than five years, the driver's or commercial driver's license or permit of any person who is convicted of or pleads guilty to a violation of this section that is a felony of the first degree and shall suspend for not less than six months or more than five years the driver's or commercial driver's license or permit of any person who is convicted of or pleads guilty to any other violation of this section.

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Section 2925.01 Definitions. [ORC: 08/05/98]

As used in this chapter:

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(D) "Bulk amount" of a controlled substance means any of the following:

* * *

- (4) An amount equal to or exceeding two hundred fifty milliliters or two hundred fifty grams of a compound, mixture, preparation, or substance that is or contains any amount of a schedule V substance;

* * *

(E) "Unit dose" means an amount or unit of a compound, mixture, or preparation containing a controlled substance that is separately identifiable and in a form that indicates that it is the amount or unit by which the controlled substance is separately administered to or taken by an individual.

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Section 2925.38 Convictions of professionally licensed persons. [ORC: 07/01/96]

If a person who is convicted of or pleads guilty to a violation of section ... 2925.03, ... of the Revised Code is a professionally licensed person, in addition to any other sanctions imposed for the violation,

the court forthwith shall transmit a certified copy of the judgment entry of conviction to the regulatory or licensing board or agency that has the administrative authority to suspend or revoke the offender's professional license. If a person who is convicted of or pleads guilty to a violation of any section listed in this section is a person who has been admitted to the bar by order of the supreme court in compliance with its prescribed and published rules, in addition to any other sanctions imposed for the violation, the court forthwith shall transmit a certified copy of the judgment entry of conviction to the secretary of the board of commissioners on grievances and discipline of the supreme court and to either the disciplinary counsel or the president, secretary, and chairman of each certified grievance committee.

Section 3719.12 Procedure upon conviction; suspension or revocation of license or registration.
[ORC: 07/22/98]

Unless a report has been made pursuant to section 2929.24 of the Revised Code, on the conviction of a manufacturer, wholesaler, terminal distributor of dangerous drugs, pharmacist, pharmacy intern, dentist, doctor of medicine or osteopathic medicine, podiatrist, registered nurse, licensed practical nurse, physician assistant, optometrist, or veterinarian of the violation of this chapter [3719.] or Chapter 2925. of the Revised Code, the prosecutor in the case promptly shall report the conviction to the board that licensed, certified, or registered the person to practice or to carry on business. The responsible board shall provide forms to the prosecutor. Within thirty days of the receipt of this information, the board shall initiate action in accordance with Chapter 119. of the Revised Code to determine whether to suspend or revoke the person's license, certificate, or registration.

Section 3719.121 Suspension of licenses or registrations of addicts. [ORC: 07/22/98]

- (A) * * *
- (B) If the board under which a person has been issued a license, certificate, or evidence of registration determines that there is clear and convincing evidence that continuation of the person's professional practice or method of prescribing or personally furnishing controlled substances presents a danger of immediate and serious harm to others, the board may suspend the person's license, certificate, or registration without a hearing. The suspension shall remain in effect, unless removed by the board, until the board's final adjudication order becomes effective, except that if the board does not issue its final adjudication order within ninety days after the hearing, the suspension shall be void on the ninety-first day after the hearing.
- (C) On receiving notification pursuant to section 2929.24 or 3719.12 of the Revised Code, the board under which a person has been issued a license, certificate, or evidence of registration immediately shall suspend the license, certificate, or registration of that person on a plea of guilty to, a finding by a jury or court of the person's guilt of, or conviction of a felony drug abuse offense; a finding by a court of the person's eligibility for treatment in lieu of conviction; a plea of guilty to, or a finding by a jury or court of the person's guilt of, or the person's conviction of an offense in another jurisdiction that is essentially the same as a felony drug abuse offense; or a finding by a court of the person's eligibility for treatment in lieu of conviction in another jurisdiction. The board shall notify the holder of the license, certificate, or registration of the suspension, which shall remain in effect until the board holds an adjudicatory hearing under Chapter 119. of the Revised Code.