Ohio Revised Code

Section 3719.44 Board of pharmacy authority to change schedules.

Effective: March 22, 2020
Legislation: Senate Bill 229 - 132nd General Assembly

(A) Pursuant to this section, and by rule adopted in accordance with Chapter 119. of the Revised Code, the state board of pharmacy may do any of the following with respect to schedules I, II, III, IV, and V established by rule adopted under section 3719.41 of the Revised Code:

(1) Add a previously unscheduled compound, mixture, preparation, or substance to any schedule;

(2) Transfer a compound, mixture, preparation, or substance from one schedule to another, provided the transfer does not have the effect under this chapter of providing less stringent control of the compound, mixture, preparation, or substance than is provided under the federal drug abuse control laws;

(3) Remove a compound, mixture, preparation, or substance from the schedules where the board had previously added the compound, mixture, preparation, or substance to the schedules, provided that the removal shall not have the effect under this chapter of providing less stringent control of the compound, mixture, preparation, or substance than is provided under the federal drug abuse control laws.

(B) In making a determination to add, remove, or transfer pursuant to division (A) of this section, the board shall consider the following:

(1) The actual or relative potential for abuse;

(2) The scientific evidence of the pharmacological effect of the substance, if known;

(3) The state of current scientific knowledge regarding the substance;

(4) The history and current pattern of abuse;

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

(6) The risk to the public health;

(7) The potential of the substance to produce psychic or physiological dependence liability;

(8) Whether the substance is an immediate precursor.

(C) The board may add or transfer a compound, mixture, preparation, or substance to schedule I when it appears that there is a high potential for abuse, that it has no accepted medical use in treatment in this state, or that it lacks accepted safety for use in treatment under medical supervision.

(D) The board may add or transfer a compound, mixture, preparation, or substance to schedule II when it appears that there is a high potential for abuse, that it has a currently accepted medical use in treatment in this state, or currently accepted medical use in treatment with severe restrictions, and that its abuse may lead to severe physical or severe psychological dependence.

(E) The board may add or transfer a compound, mixture, preparation, or substance to schedule III when it appears that there is a potential for abuse less than the substances included in schedules I and II, that it has a currently accepted medical use in treatment in this state, and that its abuse may lead to moderate or low physical or high psychological dependence.

(F) The board may add or transfer a compound, mixture, preparation, or substance to schedule IV when it appears that it has a low potential for abuse relative to substances included in schedule III, that it has a currently accepted medical use in treatment in this state, and that its abuse may lead to limited physical or psychological dependence relative to the substances included in schedule III.

(G) The board may add or transfer a compound, mixture, preparation, or substance to schedule V when it appears that it has lower potential for abuse than substances included in schedule IV, that it has currently accepted medical use in treatment in this state, and that its abuse may lead to limited physical or psychological dependence relative to substances included in schedule IV.

(H) Even though a compound, mixture, preparation, or substance does not otherwise meet the criteria

in this section for adding or transferring it to a schedule, the board may nevertheless add or transfer it to a schedule as an immediate precursor when all of the following apply:

(1) It is the principal compound used, or produced primarily for use, in the manufacture of a controlled substance.

(2) It is an immediate chemical intermediary used or likely to be used in the manufacture of such a controlled substance.

(3) Its control is necessary to prevent, curtail, or limit the manufacture of the scheduled compound, mixture, preparation, or substance of which it is the immediate precursor.

(I) Authority to control under this section does not extend to distilled spirits, wine, or beer, as those terms are defined or used in Chapter 4301. of the Revised Code.

(J) Authority to control under this section does not extend to any nonnarcotic substance if the substance may, under the Federal Food, Drug, and Cosmetic Act and the laws of this state, be lawfully sold over the counter without a prescription. If a pattern of abuse develops for any nonnarcotic drug sold over the counter, the board may, by rule adopted in accordance with Chapter 119. of the Revised Code, after a public hearing and a documented study to determine that the substance actually meets the criteria listed in division (B) of this section, place the abused substance on a controlled substance schedule.

(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 rule adopted in accordance with Chapter 119. of the Revised Code.

(L) If the board adds, transfers, or removes a compound, mixture, preparation, or substance to or from a schedule pursuant to division (A), (B), (C), (D), (E), (F), (G), or (H) of this section, the board shall incorporate the addition, transfer, or removal into the schedules in its next update of the schedules under division (B) of section 3719.41 of the Revised Code.

(M) 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 same meaning as 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.