As Reported by the House Heath and Aging Committee

131st General Assembly

Regular Session **Sub. H. B. No. 290**

2015-2016

Representatives Sprague, Anielski

Cosponsors: Representatives Blessing, Dever, Grossman, Hackett, Henne, Rezabek, Romanchuk, Thompson, Huffman, Antonio, Barnes, Bishoff, Brown, Butler, Johnson, T., Kuhns, LaTourette, Sykes

A BILL

To amend sections 4729.01, 4729.291, 4729.51, 4729.57, 4731.22, and 4731.227 and to enact sections 4729.88 and 4731.96 of the Revised Code to permit a patient with a terminal condition to be treated with a drug, product, or device that is not approved by the United States Food and Drug Administration.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That sections 4729.01, 4729.291, 4729.51, 4729.57, 4731.22, and 4731.227 be amended and sections 4729.88 and 4731.96 of the Revised Code be enacted to read as follows:

Sec. 4729.01. As used in this chapter:

(A) "Pharmacy," except when used in a context that refers to the practice of pharmacy, means any area, room, rooms, place of business, department, or portion of any of the foregoing where the practice of pharmacy is conducted.

(B) "Practice of pharmacy" means providing pharmacist care

requiring specialized knowledge, judgment, and skill derived from the principles of biological, chemical, behavioral, social, pharmaceutical, and clinical sciences. As used in this division, "pharmacist care" includes the following:

(1) Interpreting prescriptions;

(2) Dispensing drugs and drug therapy related devices;

(3) Compounding drugs;

(4) Counseling individuals with regard to their drug therapy, recommending drug therapy related devices, and assisting in the selection of drugs and appliances for treatment of common diseases and injuries and providing instruction in the proper use of the drugs and appliances;

(5) Performing drug regimen reviews with individuals by discussing all of the drugs that the individual is taking and explaining the interactions of the drugs;

(6) Performing drug utilization reviews with licensed health professionals authorized to prescribe drugs when the pharmacist determines that an individual with a prescription has a drug regimen that warrants additional discussion with the prescriber;

(7) Advising an individual and the health care professionals treating an individual with regard to the individual's drug therapy;

(8) Acting pursuant to a consult agreement with a physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery, if an agreement has been established with the physician;

(9) Engaging in the administration of immunizations to the extent authorized by section 4729.41 of the Revised Code.

(C) "Compounding" means the preparation, mixing, assembling, packaging, and labeling of one or more drugs in any of the following circumstances:

(1) Pursuant to a prescription issued by a licensed health professional authorized to prescribe drugs;

(2) Pursuant to the modification of a prescription made in accordance with a consult agreement;

(3) As an incident to research, teaching activities, or chemical analysis;

(4) In anticipation of orders for drugs pursuant to prescriptions, based on routine, regularly observed dispensing patterns;

(5) Pursuant to a request made by a licensed health professional authorized to prescribe drugs for a drug that is to be used by the professional for the purpose of direct administration to patients in the course of the professional's practice, if all of the following apply:

(a) At the time the request is made, the drug is not commercially available regardless of the reason that the drug is not available, including the absence of a manufacturer for the drug or the lack of a readily available supply of the drug from a manufacturer.

(b) A limited quantity of the drug is compounded and provided to the professional.

(c) The drug is compounded and provided to the professional as an occasional exception to the normal practice

of dispensing drugs pursuant to patient-specific prescriptions.

(D) "Consult agreement" means an agreement to manage an individual's drug therapy that has been entered into by a pharmacist and a physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.

(E) "Drug" means:

(1) Any article recognized in the United States pharmacopoeia and national formulary, or any supplement to them, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(2) Any other article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(3) Any article, other than food, intended to affect the structure or any function of the body of humans or animals;

(4) Any article intended for use as a component of any article specified in division (E)(1), (2), or (3) of this section; but does not include devices or their components, parts, or accessories.

(F) "Dangerous drug" means any of the following:

(1) Any drug to which either of the following applies:

(a) Under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, the drug is required to bear a label containing the legend "Caution: Federal law prohibits dispensing without prescription" or "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" or any similar restrictive statement, or

the drug may be dispensed only upon a prescription;

(b) Under Chapter 3715. or 3719. of the Revised Code, the drug may be dispensed only upon a prescription.

(2) Any drug that contains a schedule V controlled substance and that is exempt from Chapter 3719. of the Revised Code or to which that chapter does not apply;

(3) Any drug intended for administration by injection into the human body other than through a natural orifice of the human body.

(G) "Federal drug abuse control laws" has the same meaning as in section 3719.01 of the Revised Code.

(H) "Prescription" means both of the following:

(1) A written, electronic, or oral order for drugs or combinations or mixtures of drugs to be used by a particular individual or for treating a particular animal, issued by a licensed health professional authorized to prescribe drugs;

(2) For purposes of ~~section~~ sections 2925.61, 4723.488, 4729.44, 4730.431, and 4731.94 of the Revised Code, a written, electronic, or oral order for naloxone issued to and in the name of a family member, friend, or other individual in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

(I) "Licensed health professional authorized to prescribe drugs" or "prescriber" means an individual who is authorized by law to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice, including only the following:

(1) A dentist licensed under Chapter 4715. of the Revised

Code;

(2) A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner who holds a certificate to prescribe issued under section 4723.48 of the Revised Code;

(3) An optometrist licensed under Chapter 4725. of the Revised Code to practice optometry under a therapeutic pharmaceutical agents certificate;

(4) A physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery;

(5) A physician assistant who holds a license to practice as a physician assistant issued under Chapter 4730. of the Revised Code, holds a valid prescriber number issued by the state medical board, and has been granted physician-delegated prescriptive authority;

(6) A veterinarian licensed under Chapter 4741. of the Revised Code.

(J) "Sale" and "sell" include delivery, transfer, barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as principal proprietor, agent, or employee.

(K) "Wholesale sale" and "sale at wholesale" mean any sale in which the purpose of the purchaser is to resell the article purchased or received by the purchaser.

(L) "Retail sale" and "sale at retail" mean any sale other than a wholesale sale or sale at wholesale.

(M) "Retail seller" means any person that sells any dangerous drug to consumers without assuming control over and

responsibility for its administration. Mere advice or instructions regarding administration do not constitute control or establish responsibility.

(N) "Price information" means the price charged for a prescription for a particular drug product and, in an easily understandable manner, all of the following:

(1) The proprietary name of the drug product;

(2) The established (generic) name of the drug product;

(3) The strength of the drug product if the product contains a single active ingredient or if the drug product contains more than one active ingredient and a relevant strength can be associated with the product without indicating each active ingredient. The established name and quantity of each active ingredient are required if such a relevant strength cannot be so associated with a drug product containing more than one ingredient.

(4) The dosage form;

(5) The price charged for a specific quantity of the drug product. The stated price shall include all charges to the consumer, including, but not limited to, the cost of the drug product, professional fees, handling fees, if any, and a statement identifying professional services routinely furnished by the pharmacy. Any mailing fees and delivery fees may be stated separately without repetition. The information shall not be false or misleading.

(O) "Wholesale distributor of dangerous drugs" means a person engaged in the sale of dangerous drugs at wholesale and includes any agent or employee of such a person authorized by the person to engage in the sale of dangerous drugs at

wholesale.

(P) "Manufacturer of dangerous drugs" means a person, other than a pharmacist, who manufactures dangerous drugs and who is engaged in the sale of those dangerous drugs within this state.

(Q) "Terminal distributor of dangerous drugs" means a person who is engaged in the sale of dangerous drugs at retail, or any person, other than a wholesale distributor or a pharmacist, who has possession, custody, or control of dangerous drugs for any purpose other than for that person's own use and consumption, and includes pharmacies, hospitals, nursing homes, and laboratories and all other persons who procure dangerous drugs for sale or other distribution by or under the supervision of a pharmacist or licensed health professional authorized to prescribe drugs.

(R) "Promote to the public" means disseminating a representation to the public in any manner or by any means, other than by labeling, for the purpose of inducing, or that is likely to induce, directly or indirectly, the purchase of a dangerous drug at retail.

(S) "Person" includes any individual, partnership, association, limited liability company, or corporation, the state, any political subdivision of the state, and any district, department, or agency of the state or its political subdivisions.

(T) "Finished dosage form" has the same meaning as in section 3715.01 of the Revised Code.

(U) "Generically equivalent drug" has the same meaning as in section 3715.01 of the Revised Code.

(V) "Animal shelter" means a facility operated by a humane society or any society organized under Chapter 1717. of the Revised Code or a dog pound operated pursuant to Chapter 955. of the Revised Code.

(W) "Food" has the same meaning as in section 3715.01 of the Revised Code.

(X) "Pain management clinic" has the same meaning as in section 4731.054 of the Revised Code.

(Y) "Investigational drug or product" means a drug or product that has successfully completed phase one of the United States food and drug administration clinical trials and remains under clinical trial, but has not been approved for general use by the United States food and drug administration. "Investigational drug or product" does not include controlled substances in schedule I, as established pursuant to section 3719.41 of the Revised Code, and as amended.

(Z) "Product," when used in reference to an investigational drug or product, means a biological product, other than a drug, that is made from a natural human, animal, or microorganism source and is intended to treat a disease or medical condition.

Sec. 4729.291. (A) ~~When~~ Except when provided under section 4731.96 of the Revised Code, when a licensed health professional authorized to prescribe drugs personally furnishes drugs to a patient pursuant to division (B) of section 4729.29 of the Revised Code, the prescriber shall ensure that the drugs are labeled and packaged in accordance with state and federal drug laws and any rules and regulations adopted pursuant to those laws. Records of purchase and disposition of all drugs

personally furnished to patients shall be maintained by the prescriber in accordance with state and federal drug statutes and any rules adopted pursuant to those statutes.

(B) When personally furnishing to a patient RU-486 (mifepristone), a prescriber is subject to section 2919.123 of the Revised Code. A prescription for RU-486 (mifepristone) shall be in writing and in accordance with section 2919.123 of the Revised Code.

(C)(1) Except as provided in division (D) of this section, no prescriber shall do either of the following:

(a) In any thirty-day period, personally furnish to or for patients, taken as a whole, controlled substances in an amount that exceeds a total of two thousand five hundred dosage units;

(b) In any seventy-two-hour period, personally furnish to or for a patient an amount of a controlled substance that exceeds the amount necessary for the patient's use in a seventy-two-hour period.

(2) The state board of pharmacy may impose a fine of not more than five thousand dollars on a prescriber who fails to comply with the limits established under division (C)(1) of this section. A separate fine may be imposed for each instance of failing to comply with the limits. In imposing the fine, the board's actions shall be taken in accordance with Chapter 119. of the Revised Code.

(D)(1) None of the following shall be counted in determining whether the amounts specified in division (C)(1) of this section have been exceeded:

(a) Methadone provided to patients for the purpose of treating drug dependence or addiction, if the prescriber meets

the conditions specified in 21 C.F.R. 1306.07;

(b) Buprenorphine provided to patients for the purpose of treating drug dependence or addiction as part of an opioid treatment program that is the subject of a current, valid certification from the substance abuse and mental health services administration of the United States department of health and human services pursuant to 42 C.F.R. 8.11 and distributes both buprenorphine and methadone;

(c) Controlled substances provided to research subjects by a facility conducting clinical research in studies approved by a hospital-based institutional review board or an institutional review board accredited by the association for the accreditation of human research protection programs.

(2) Division (C)(1) of this section does not apply to a prescriber who is a veterinarian.

Sec. 4729.51. (A)(1) Except as provided in division (A)(2) of this section, no person other than a registered wholesale distributor of dangerous drugs shall possess for sale, sell, distribute, or deliver, at wholesale, dangerous drugs or investigational drugs or products, except as follows:

(a) A pharmacist who is a licensed terminal distributor of dangerous drugs or who is employed by a licensed terminal distributor of dangerous drugs may make occasional sales of dangerous drugs or investigational drugs or products at wholesale.

(b) A licensed terminal distributor of dangerous drugs having more than one establishment or place may transfer or deliver dangerous drugs from one establishment or place for which a license has been issued to the terminal distributor to

another establishment or place for which a license has been issued to the terminal distributor if the license issued for each establishment or place is in effect at the time of the transfer or delivery.

(c) A licensed terminal distributor of dangerous drugs may make occasional sales of naloxone at wholesale to a state or local law enforcement agency if the terminal distributor is any of the following:

(i) A board of health of a city or general health district;

(ii) An authority having the duties of a board of health under section 3709.05 of the Revised Code;

(iii) A health department operated by such a board or authority.

(2) A manufacturer of dangerous drugs may donate inhalers, as defined in section 3313.7113 of the Revised Code, and epinephrine autoinjectors to any of the following:

(a) The board of education of a city, local, exempted village, or joint vocational school district;

(b) A community school established under Chapter 3314. of the Revised Code;

(c) A STEM school established under Chapter 3326. of the Revised Code;

(d) A college-preparatory boarding school established under Chapter 3328. of the Revised Code;

(e) A chartered or nonchartered nonpublic school.

(B)(1) No registered wholesale distributor of dangerous

drugs shall possess for sale, or sell, at wholesale, dangerous drugs or investigational drugs or products to any person other than the following:

(a) Except as provided in division (B)(2)(a) of this section and division (B) of section 4729.541 of the Revised Code, a licensed health professional authorized to prescribe drugs;

(b) An optometrist licensed under Chapter 4725. of the Revised Code who holds a topical ocular pharmaceutical agents certificate;

(c) A registered wholesale distributor of dangerous drugs;

(d) A manufacturer of dangerous drugs;

(e) Subject to division (B)(3) of this section, a licensed terminal distributor of dangerous drugs;

(f) Carriers or warehouses for the purpose of carriage or storage;

(g) Terminal or wholesale distributors of dangerous drugs who are not engaged in the sale of dangerous drugs within this state;

(h) An individual who holds a current license, certificate, or registration issued under Title XLVII of the Revised Code and has been certified to conduct diabetes education by a national certifying body specified in rules adopted by the state board of pharmacy under section 4729.68 of the Revised Code, but only with respect to insulin that will be used for the purpose of diabetes education and only if diabetes education is within the individual's scope of practice under statutes and rules regulating the individual's profession;

(i) An individual who holds a valid certificate issued by a nationally recognized S.C.U.B.A. diving certifying organization approved by the state board of pharmacy in rule, but only with respect to medical oxygen that will be used for the purpose of emergency care or treatment at the scene of a diving emergency;

(j) Except as provided in division (B)(2)(b) of this section and division (A) of section 4729.541 of the Revised Code, a business entity that is a corporation formed under division (B) of section 1701.03 of the Revised Code, a limited liability company formed under Chapter 1705. of the Revised Code, or a professional association formed under Chapter 1785. of the Revised Code if the entity has a sole shareholder who is a licensed health professional authorized to prescribe drugs and is authorized to provide the professional services being offered by the entity;

(k) Except as provided in division (B)(2)(c) of this section and division (A) of section 4729.541 of the Revised Code, a business entity that is a corporation formed under division (B) of section 1701.03 of the Revised Code, a limited liability company formed under Chapter 1705. of the Revised Code, a partnership or a limited liability partnership formed under Chapter 1775. of the Revised Code, or a professional association formed under Chapter 1785. of the Revised Code, if, to be a shareholder, member, or partner, an individual is required to be licensed, certified, or otherwise legally authorized under Title XLVII of the Revised Code to perform the professional service provided by the entity and each such individual is a licensed health professional authorized to prescribe drugs;

(l) With respect to epinephrine autoinjectors that may be possessed under section 3313.7110, 3313.7111, 3314.143, 3326.28, or 3328.29 of the Revised Code, any of the following: the board of education of a city, local, exempted village, or joint vocational school district; a chartered or nonchartered nonpublic school; a community school established under Chapter 3314. of the Revised Code; a STEM school established under Chapter 3326. of the Revised Code; or a college-preparatory boarding school established under Chapter 3328. of the Revised Code;

(m) With respect to epinephrine autoinjectors that may be possessed under section 5101.76 of the Revised Code, any of the following: a residential camp, as defined in section 2151.011 of the Revised Code; a child day camp, as defined in section 5104.01 of the Revised Code; or a child day camp operated by any county, township, municipal corporation, township park district created under section 511.18 of the Revised Code, park district created under section 1545.04 of the Revised Code, or joint recreation district established under section 755.14 of the Revised Code;

(n) With respect to naloxone that may be possessed under section 2925.61 of the Revised Code, a law enforcement agency and its peace officers;

(o) With respect to inhalers that may be possessed under section 3313.7113, 3313.7114, 3314.144, 3326.30, or 3328.30 of the Revised Code, any of the following: the board of education of a city, local, exempted village, or joint vocational school district; a chartered or nonchartered nonpublic school; a community school established under Chapter 3314. of the Revised Code; a STEM school established under Chapter 3326. of the

Revised Code; or a college-preparatory boarding school established under Chapter 3328. of the Revised Code;

(p) With respect to inhalers that may be possessed under section 5101.77 of the Revised Code, any of the following: a residential camp, as defined in section 2151.011 of the Revised Code; a child day camp, as defined in section 5104.01 of the Revised Code; or a child day camp operated by any county, township, municipal corporation, township park district created under section 511.18 of the Revised Code, park district created under section 1545.04 of the Revised Code, or joint recreation district established under section 755.14 of the Revised Code.

(2) No registered wholesale distributor of dangerous drugs shall possess for sale, or sell, at wholesale, dangerous drugs or investigational drugs or products to any of the following:

(a) A prescriber who is employed by a pain management clinic that is not licensed as a terminal distributor of dangerous drugs with a pain management clinic classification issued under section 4729.552 of the Revised Code;

(b) A business entity described in division (B)(1)(j) of this section that is, or is operating, a pain management clinic without a license as a terminal distributor of dangerous drugs with a pain management clinic classification issued under section 4729.552 of the Revised Code;

(c) A business entity described in division (B)(1)(k) of this section that is, or is operating, a pain management clinic without a license as a terminal distributor of dangerous drugs with a pain management clinic classification issued under section 4729.552 of the Revised Code.

(3) No registered wholesale distributor of dangerous drugs

shall possess dangerous drugs or investigational drugs or products for sale at wholesale, or sell such drugs at wholesale, to a licensed terminal distributor of dangerous drugs, except as follows:

(a) In the case of a terminal distributor with a category I license, only dangerous drugs described in category I, as defined in division (A)(1) of section 4729.54 of the Revised Code;

(b) In the case of a terminal distributor with a category II license, only dangerous drugs described in category I and category II, as defined in divisions (A)(1) and (2) of section 4729.54 of the Revised Code;

(c) In the case of a terminal distributor with a category III license, dangerous drugs described in category I, category II, and category III, as defined in divisions (A)(1), (2), and (3) of section 4729.54 of the Revised Code;

(d) In the case of a terminal distributor with a limited category I, II, or III license, only the dangerous drugs specified in the certificate furnished by the terminal distributor in accordance with section 4729.60 of the Revised Code.

(C)(1) Except as provided in division (C)(4) of this section, no person shall sell, at retail, dangerous drugs.

(2) Except as provided in division (C)(4) of this section, no person shall possess for sale, at retail, dangerous drugs.

(3) Except as provided in division (C)(4) of this section, no person shall possess dangerous drugs.

(4) Divisions (C)(1), (2), and (3) of this section do not

apply to a registered wholesale distributor of dangerous drugs or a licensed terminal distributor of dangerous drugs.

Divisions (C)(1), (2), and (3) of this section do not apply to a person who possesses, or possesses for sale or sells, at retail, a dangerous drug in accordance with Chapters 3719., 4715., 4723., 4725., 4729., 4730., 4731., and 4741. of the Revised Code.

Divisions (C)(1), (2), and (3) of this section do not apply to an individual who holds a current license, certificate, or registration issued under Title XLVII of the Revised Code and has been certified to conduct diabetes education by a national certifying body specified in rules adopted by the state board of pharmacy under section 4729.68 of the Revised Code, but only to the extent that the individual possesses insulin or personally supplies insulin solely for the purpose of diabetes education and only if diabetes education is within the individual's scope of practice under statutes and rules regulating the individual's profession.

Divisions (C)(1), (2), and (3) of this section do not apply to an individual who holds a valid certificate issued by a nationally recognized S.C.U.B.A. diving certifying organization approved by the state board of pharmacy in rule, but only to the extent that the individual possesses medical oxygen or personally supplies medical oxygen for the purpose of emergency care or treatment at the scene of a diving emergency.

Division (C)(3) of this section does not apply to the board of education of a city, local, exempted village, or joint vocational school district, a school building operated by a school district board of education, a chartered or nonchartered nonpublic school, a community school, a STEM school, or a

college-preparatory boarding school for the purpose of possessing epinephrine autoinjectors under section 3313.7110, 3313.7111, 3314.143, 3326.28, or 3328.29 of the Revised Code and for the purpose of possessing inhalers under section 3313.7113, 3313.7114, 3314.144, 3326.30, or 3328.30 of the Revised Code.

Division (C)(3) of this section does not apply to a residential camp, as defined in section 2151.011 of the Revised Code, a child day camp, as defined in section 5104.01 of the Revised Code, or a child day camp operated by any county, township, municipal corporation, township park district created under section 511.18 of the Revised Code, park district created under section 1545.04 of the Revised Code, or joint recreation district established under section 755.14 of the Revised Code for the purpose of possessing epinephrine autoinjectors under section 5101.76 of the Revised Code and for the purpose of possessing inhalers under section 5101.77 of the Revised Code.

Division (C)(3) of this section does not apply to a law enforcement agency or the agency's peace officers if the agency or officers possess naloxone for administration to individuals who are apparently experiencing opioid-related overdoses.

(D) No licensed terminal distributor of dangerous drugs shall purchase for the purpose of resale dangerous drugs <u>or investigational drugs or products</u> from any person other than a registered wholesale distributor of dangerous drugs, except as follows:

(1) A licensed terminal distributor of dangerous drugs may make occasional purchases of dangerous drugs <u>or investigational drugs or products</u> for resale from a pharmacist who is a licensed terminal distributor of dangerous drugs or who is employed by a licensed terminal distributor of dangerous drugs;

(2) A licensed terminal distributor of dangerous drugs having more than one establishment or place may transfer or receive dangerous drugs or investigational drugs or products from one establishment or place for which a license has been issued to the terminal distributor to another establishment or place for which a license has been issued to the terminal distributor if the license issued for each establishment or place is in effect at the time of the transfer or receipt.

(E) No licensed terminal distributor of dangerous drugs shall engage in the sale or other distribution of dangerous drugs or investigational drugs or products at retail or maintain possession, custody, or control of dangerous drugs or investigational drugs or products for any purpose other than the distributor's personal use or consumption, at any establishment or place other than that or those described in the license issued by the state board of pharmacy to such terminal distributor.

(F) Nothing in this section shall be construed to interfere with the performance of official duties by any law enforcement official authorized by municipal, county, state, or federal law to collect samples of any drug, regardless of its nature or in whose possession it may be.

(G) Notwithstanding anything to the contrary in this section, the board of education of a city, local, exempted village, or joint vocational school district may deliver epinephrine autoinjectors to a school under its control for the purpose of possessing the epinephrine autoinjectors under section 3313.7110 of the Revised Code and may deliver inhalers to a school under its control for the purpose of possessing the inhalers under section 3313.7113 of the Revised Code.

Sec. 4729.57. (A) The state board of pharmacy may suspend, revoke, or refuse to grant or renew any license as a terminal distributor of dangerous drugs, or may impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense or one thousand dollars if the acts committed have not been classified as an offense by the Revised Code, for any of the following causes:

(1) Making any false material statements in an application for a license as a terminal distributor of dangerous drugs;

(2) Violating any rule of the board;

(3) Violating any provision of this chapter;

(4) ~~Violating~~ Except as provided in section 4729.88 of the Revised Code, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code;

(5) Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code;

(6) Falsely or fraudulently promoting to the public a dangerous drug, except that nothing in this division prohibits a terminal distributor of dangerous drugs from furnishing information concerning a dangerous drug to a health care provider or another licensed terminal distributor;

(7) Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code;

(8) Except as provided in division (B) of this section:

(a) Waiving the payment of all or any part of a deductible or copayment that an individual, pursuant to a health insurance

or health care policy, contract, or plan that covers the services provided by a terminal distributor of dangerous drugs, would otherwise be required to pay for the services if the waiver is used as an enticement to a patient or group of patients to receive pharmacy services from that terminal distributor;

(b) Advertising that the terminal distributor will waive the payment of all or any part of a deductible or copayment that an individual, pursuant to a health insurance or health care policy, contract, or plan that covers the pharmaceutical services, would otherwise be required to pay for the services.

(B) Sanctions shall not be imposed under division (A)(8) of this section against any terminal distributor of dangerous drugs that waives deductibles and copayments as follows:

(1) In compliance with a health benefit plan that expressly allows such a practice. Waiver of the deductibles or copayments shall be made only with the full knowledge and consent of the plan purchaser, payer, and third-party administrator. Documentation of the consent shall be made available to the board on request.

(2) For professional services rendered to any other person licensed pursuant to this chapter to the extent allowed by this chapter and the rules of the board.

(C)(1) Upon the suspension or revocation of a license issued to a terminal distributor of dangerous drugs or the refusal by the board to renew such a license, the distributor shall immediately surrender the license to the board.

(2) The board may place under seal all dangerous drugs that are owned by or in the possession, custody, or control of a

terminal distributor at the time the license is suspended or revoked or at the time the board refuses to renew the license. Except as otherwise provided in this division, dangerous drugs so sealed shall not be disposed of until appeal rights under Chapter 119. of the Revised Code have expired or an appeal filed pursuant to that chapter has been determined.

The court involved in an appeal filed pursuant to Chapter 119. of the Revised Code may order the board, during the pendency of the appeal, to sell sealed dangerous drugs that are perishable. The proceeds of such a sale shall be deposited with that court.

Sec. 4729.88. (A) As used in this section, "eligible patient," "investigational drug, product, or device," "terminal condition," and "treating physician" have the same meanings as in section 4731.96 of the Revised Code.

(B) A manufacturer of dangerous drugs may, in accordance with section 4731.96 of the Revised Code, provide an investigational drug, product, or device for treatment of a terminal condition to an eligible patient or to the treating physician who is treating the eligible patient's terminal condition. In doing so, the manufacturer may do all of the following:

(1) Provide the investigational drug, product, or device to the eligible patient or treating physician directly or through a terminal distributor of dangerous drugs;

(2) Provide the investigational drug, product, or device either with or without charge for the costs associated with manufacturing and providing the investigational drug, product, or device;

(3) Require the eligible patient to participate in data collection relating to use of the investigational drug, product, or device.

(C) Except for actions or omissions constituting willful or wanton misconduct, a manufacturer or terminal distributor of dangerous drugs that provides or distributes an investigational drug, product, or device pursuant to this section and section 4731.96 of the Revised Code is not liable for or subject to damages in any civil action or prosecution in any criminal proceeding for actions or omissions related to providing or distributing the investigational drug, product, or device.

(D) Nothing in this section shall be interpreted as requiring a manufacturer or terminal distributor to provide an investigational drug, product, or device to an eligible patient or the patient's treating physician.

Sec. 4731.22. (A) The state medical board, by an affirmative vote of not fewer than six of its members, may limit, revoke, or suspend an individual's certificate to practice, refuse to grant a certificate to an individual, refuse to renew a certificate, refuse to reinstate a certificate, or reprimand or place on probation the holder of a certificate if the individual or certificate holder is found by the board to have committed fraud during the administration of the examination for a certificate to practice or to have committed fraud, misrepresentation, or deception in applying for, renewing, or securing any certificate to practice issued by the board.

(B) The board, by an affirmative vote of not fewer than six members, shall, to the extent permitted by law, limit, revoke, or suspend an individual's certificate to practice,

refuse to issue a certificate to an individual, refuse to renew a certificate, refuse to reinstate a certificate, or reprimand or place on probation the holder of a certificate for one or more of the following reasons:

(1) Permitting one's name or one's certificate to practice to be used by a person, group, or corporation when the individual concerned is not actually directing the treatment given;

(2) Failure to maintain minimal standards applicable to the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease;

(3) ~~Selling~~ Except as provided in section 4731.96 of the Revised Code, selling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes or a plea of guilty to, a judicial finding of guilt of, or a judicial finding of eligibility for intervention in lieu of conviction of, a violation of any federal or state law regulating the possession, distribution, or use of any drug;

(4) Willfully betraying a professional confidence.

For purposes of this division, "willfully betraying a professional confidence" does not include providing any information, documents, or reports under sections 307.621 to 307.629 of the Revised Code to a child fatality review board; does not include providing any information, documents, or reports to the director of health pursuant to guidelines established under section 3701.70 of the Revised Code; does not include written notice to a mental health professional under

section 4731.62 of the Revised Code; and does not include the making of a report of an employee's use of a drug of abuse, or a report of a condition of an employee other than one involving the use of a drug of abuse, to the employer of the employee as described in division (B) of section 2305.33 of the Revised Code. Nothing in this division affects the immunity from civil liability conferred by section 2305.33 or 4731.62 of the Revised Code upon a physician who makes a report in accordance with section 2305.33 or notifies a mental health professional in accordance with section 4731.62 of the Revised Code. As used in this division, "employee," "employer," and "physician" have the same meanings as in section 2305.33 of the Revised Code.

(5) Making a false, fraudulent, deceptive, or misleading statement in the solicitation of or advertising for patients; in relation to the practice of medicine and surgery, osteopathic medicine and surgery, podiatric medicine and surgery, or a limited branch of medicine; or in securing or attempting to secure any certificate to practice issued by the board.

As used in this division, "false, fraudulent, deceptive, or misleading statement" means a statement that includes a misrepresentation of fact, is likely to mislead or deceive because of a failure to disclose material facts, is intended or is likely to create false or unjustified expectations of favorable results, or includes representations or implications that in reasonable probability will cause an ordinarily prudent person to misunderstand or be deceived.

(6) A departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established;

(7) Representing, with the purpose of obtaining compensation or other advantage as personal gain or for any other person, that an incurable disease or injury, or other incurable condition, can be permanently cured;

(8) The obtaining of, or attempting to obtain, money or anything of value by fraudulent misrepresentations in the course of practice;

(9) A plea of guilty to, a judicial finding of guilt of, or a judicial finding of eligibility for intervention in lieu of conviction for, a felony;

(10) Commission of an act that constitutes a felony in this state, regardless of the jurisdiction in which the act was committed;

(11) A plea of guilty to, a judicial finding of guilt of, or a judicial finding of eligibility for intervention in lieu of conviction for, a misdemeanor committed in the course of practice;

(12) Commission of an act in the course of practice that constitutes a misdemeanor in this state, regardless of the jurisdiction in which the act was committed;

(13) A plea of guilty to, a judicial finding of guilt of, or a judicial finding of eligibility for intervention in lieu of conviction for, a misdemeanor involving moral turpitude;

(14) Commission of an act involving moral turpitude that constitutes a misdemeanor in this state, regardless of the jurisdiction in which the act was committed;

(15) Violation of the conditions of limitation placed by the board upon a certificate to practice;

(16) Failure to pay license renewal fees specified in this chapter;

(17) Except as authorized in section 4731.31 of the Revised Code, engaging in the division of fees for referral of patients, or the receiving of a thing of value in return for a specific referral of a patient to utilize a particular service or business;

(18) Subject to section 4731.226 of the Revised Code, violation of any provision of a code of ethics of the American medical association, the American osteopathic association, the American podiatric medical association, or any other national professional organizations that the board specifies by rule. The state medical board shall obtain and keep on file current copies of the codes of ethics of the various national professional organizations. The individual whose certificate is being suspended or revoked shall not be found to have violated any provision of a code of ethics of an organization not appropriate to the individual's profession.

For purposes of this division, a "provision of a code of ethics of a national professional organization" does not include any provision that would preclude the making of a report by a physician of an employee's use of a drug of abuse, or of a condition of an employee other than one involving the use of a drug of abuse, to the employer of the employee as described in division (B) of section 2305.33 of the Revised Code. Nothing in this division affects the immunity from civil liability conferred by that section upon a physician who makes either type of report in accordance with division (B) of that section. As used in this division, "employee," "employer," and "physician" have the same meanings as in section 2305.33 of the Revised

Code.

(19) Inability to practice according to acceptable and prevailing standards of care by reason of mental illness or physical illness, including, but not limited to, physical deterioration that adversely affects cognitive, motor, or perceptive skills.

In enforcing this division, the board, upon a showing of a possible violation, may compel any individual authorized to practice by this chapter or who has submitted an application pursuant to this chapter to submit to a mental examination, physical examination, including an HIV test, or both a mental and a physical examination. The expense of the examination is the responsibility of the individual compelled to be examined. Failure to submit to a mental or physical examination or consent to an HIV test ordered by the board constitutes an admission of the allegations against the individual unless the failure is due to circumstances beyond the individual's control, and a default and final order may be entered without the taking of testimony or presentation of evidence. If the board finds an individual unable to practice because of the reasons set forth in this division, the board shall require the individual to submit to care, counseling, or treatment by physicians approved or designated by the board, as a condition for initial, continued, reinstated, or renewed authority to practice. An individual affected under this division shall be afforded an opportunity to demonstrate to the board the ability to resume practice in compliance with acceptable and prevailing standards under the provisions of the individual's certificate. For the purpose of this division, any individual who applies for or receives a certificate to practice under this chapter accepts the privilege of practicing in this state and, by so doing, shall be deemed to

have given consent to submit to a mental or physical examination when directed to do so in writing by the board, and to have waived all objections to the admissibility of testimony or examination reports that constitute a privileged communication.

(20) Except when civil penalties are imposed under section 4731.225 or 4731.282 of the Revised Code, and subject to section 4731.226 of the Revised Code, violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provisions of this chapter or any rule promulgated by the board.

This division does not apply to a violation or attempted violation of, assisting in or abetting the violation of, or a conspiracy to violate, any provision of this chapter or any rule adopted by the board that would preclude the making of a report by a physician of an employee's use of a drug of abuse, or of a condition of an employee other than one involving the use of a drug of abuse, to the employer of the employee as described in division (B) of section 2305.33 of the Revised Code. Nothing in this division affects the immunity from civil liability conferred by that section upon a physician who makes either type of report in accordance with division (B) of that section. As used in this division, "employee," "employer," and "physician" have the same meanings as in section 2305.33 of the Revised Code.

(21) The violation of section 3701.79 of the Revised Code or of any abortion rule adopted by the director of health pursuant to section 3701.341 of the Revised Code;

(22) Any of the following actions taken by an agency responsible for authorizing, certifying, or regulating an individual to practice a health care occupation or provide

health care services in this state or another jurisdiction, for any reason other than the nonpayment of fees: the limitation, revocation, or suspension of an individual's license to practice; acceptance of an individual's license surrender; denial of a license; refusal to renew or reinstate a license; imposition of probation; or issuance of an order of censure or other reprimand;

(23) The violation of section 2919.12 of the Revised Code or the performance or inducement of an abortion upon a pregnant woman with actual knowledge that the conditions specified in division (B) of section 2317.56 of the Revised Code have not been satisfied or with a heedless indifference as to whether those conditions have been satisfied, unless an affirmative defense as specified in division (H)(2) of that section would apply in a civil action authorized by division (H)(1) of that section;

(24) The revocation, suspension, restriction, reduction, or termination of clinical privileges by the United States department of defense or department of veterans affairs or the termination or suspension of a certificate of registration to prescribe drugs by the drug enforcement administration of the United States department of justice;

(25) Termination or suspension from participation in the medicare or medicaid programs by the department of health and human services or other responsible agency for any act or acts that also would constitute a violation of division (B)(2), (3), (6), (8), or (19) of this section;

(26) Impairment of ability to practice according to acceptable and prevailing standards of care because of habitual or excessive use or abuse of drugs, alcohol, or other substances

that impair ability to practice.

For the purposes of this division, any individual authorized to practice by this chapter accepts the privilege of practicing in this state subject to supervision by the board. By filing an application for or holding a certificate to practice under this chapter, an individual shall be deemed to have given consent to submit to a mental or physical examination when ordered to do so by the board in writing, and to have waived all objections to the admissibility of testimony or examination reports that constitute privileged communications.

If it has reason to believe that any individual authorized to practice by this chapter or any applicant for certification to practice suffers such impairment, the board may compel the individual to submit to a mental or physical examination, or both. The expense of the examination is the responsibility of the individual compelled to be examined. Any mental or physical examination required under this division shall be undertaken by a treatment provider or physician who is qualified to conduct the examination and who is chosen by the board.

Failure to submit to a mental or physical examination ordered by the board constitutes an admission of the allegations against the individual unless the failure is due to circumstances beyond the individual's control, and a default and final order may be entered without the taking of testimony or presentation of evidence. If the board determines that the individual's ability to practice is impaired, the board shall suspend the individual's certificate or deny the individual's application and shall require the individual, as a condition for initial, continued, reinstated, or renewed certification to practice, to submit to treatment.

Before being eligible to apply for reinstatement of a certificate suspended under this division, the impaired practitioner shall demonstrate to the board the ability to resume practice in compliance with acceptable and prevailing standards of care under the provisions of the practitioner's certificate. The demonstration shall include, but shall not be limited to, the following:

(a) Certification from a treatment provider approved under section 4731.25 of the Revised Code that the individual has successfully completed any required inpatient treatment;

(b) Evidence of continuing full compliance with an aftercare contract or consent agreement;

(c) Two written reports indicating that the individual's ability to practice has been assessed and that the individual has been found capable of practicing according to acceptable and prevailing standards of care. The reports shall be made by individuals or providers approved by the board for making the assessments and shall describe the basis for their determination.

The board may reinstate a certificate suspended under this division after that demonstration and after the individual has entered into a written consent agreement.

When the impaired practitioner resumes practice, the board shall require continued monitoring of the individual. The monitoring shall include, but not be limited to, compliance with the written consent agreement entered into before reinstatement or with conditions imposed by board order after a hearing, and, upon termination of the consent agreement, submission to the board for at least two years of annual written progress reports

made under penalty of perjury stating whether the individual has maintained sobriety.

(27) A second or subsequent violation of section 4731.66 or 4731.69 of the Revised Code;

(28) Except as provided in division (N) of this section:

(a) Waiving the payment of all or any part of a deductible or copayment that a patient, pursuant to a health insurance or health care policy, contract, or plan that covers the individual's services, otherwise would be required to pay if the waiver is used as an enticement to a patient or group of patients to receive health care services from that individual;

(b) Advertising that the individual will waive the payment of all or any part of a deductible or copayment that a patient, pursuant to a health insurance or health care policy, contract, or plan that covers the individual's services, otherwise would be required to pay.

(29) Failure to use universal blood and body fluid precautions established by rules adopted under section 4731.051 of the Revised Code;

(30) Failure to provide notice to, and receive acknowledgment of the notice from, a patient when required by section 4731.143 of the Revised Code prior to providing nonemergency professional services, or failure to maintain that notice in the patient's file;

(31) Failure of a physician supervising a physician assistant to maintain supervision in accordance with the requirements of Chapter 4730. of the Revised Code and the rules adopted under that chapter;

(32) Failure of a physician or podiatrist to enter into a standard care arrangement with a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner with whom the physician or podiatrist is in collaboration pursuant to section 4731.27 of the Revised Code or failure to fulfill the responsibilities of collaboration after entering into a standard care arrangement;

(33) Failure to comply with the terms of a consult agreement entered into with a pharmacist pursuant to section 4729.39 of the Revised Code;

(34) Failure to cooperate in an investigation conducted by the board under division (F) of this section, including failure to comply with a subpoena or order issued by the board or failure to answer truthfully a question presented by the board in an investigative interview, an investigative office conference, at a deposition, or in written interrogatories, except that failure to cooperate with an investigation shall not constitute grounds for discipline under this section if a court of competent jurisdiction has issued an order that either quashes a subpoena or permits the individual to withhold the testimony or evidence in issue;

(35) Failure to supervise an oriental medicine practitioner or acupuncturist in accordance with Chapter 4762. of the Revised Code and the board's rules for providing that supervision;

(36) Failure to supervise an anesthesiologist assistant in accordance with Chapter 4760. of the Revised Code and the board's rules for supervision of an anesthesiologist assistant;

(37) Assisting suicide, as defined in section 3795.01 of

the Revised Code;

(38) Failure to comply with the requirements of section 2317.561 of the Revised Code;

(39) Failure to supervise a radiologist assistant in accordance with Chapter 4774. of the Revised Code and the board's rules for supervision of radiologist assistants;

(40) Performing or inducing an abortion at an office or facility with knowledge that the office or facility fails to post the notice required under section 3701.791 of the Revised Code;

(41) Failure to comply with the standards and procedures established in rules under section 4731.054 of the Revised Code for the operation of or the provision of care at a pain management clinic;

(42) Failure to comply with the standards and procedures established in rules under section 4731.054 of the Revised Code for providing supervision, direction, and control of individuals at a pain management clinic;

(43) Failure to comply with the requirements of section 4729.79 or 4731.055 of the Revised Code, unless the state board of pharmacy no longer maintains a drug database pursuant to section 4729.75 of the Revised Code;

(44) Failure to comply with the requirements of section 2919.171 of the Revised Code or failure to submit to the department of health in accordance with a court order a complete report as described in section 2919.171 of the Revised Code;

(45) Practicing at a facility that is subject to licensure as a category III terminal distributor of dangerous drugs with a

pain management clinic classification unless the person operating the facility has obtained and maintains the license with the classification;

(46) Owning a facility that is subject to licensure as a category III terminal distributor of dangerous drugs with a pain management clinic classification unless the facility is licensed with the classification;

(47) Failure to comply with the requirement regarding maintaining notes described in division (B) of section 2919.191 of the Revised Code or failure to satisfy the requirements of section 2919.191 of the Revised Code prior to performing or inducing an abortion upon a pregnant woman;

(48) Failure to comply with the requirements in section 3719.061 of the Revised Code before issuing for a minor a prescription for an opioid analgesic, as defined in section 3719.01 of the Revised Code.

(C) Disciplinary actions taken by the board under divisions (A) and (B) of this section shall be taken pursuant to an adjudication under Chapter 119. of the Revised Code, except that in lieu of an adjudication, the board may enter into a consent agreement with an individual to resolve an allegation of a violation of this chapter or any rule adopted under it. A consent agreement, when ratified by an affirmative vote of not fewer than six members of the board, shall constitute the findings and order of the board with respect to the matter addressed in the agreement. If the board refuses to ratify a consent agreement, the admissions and findings contained in the consent agreement shall be of no force or effect.

A telephone conference call may be utilized for

ratification of a consent agreement that revokes or suspends an individual's certificate to practice. The telephone conference call shall be considered a special meeting under division (F) of section 121.22 of the Revised Code.

If the board takes disciplinary action against an individual under division (B) of this section for a second or subsequent plea of guilty to, or judicial finding of guilt of, a violation of section 2919.123 of the Revised Code, the disciplinary action shall consist of a suspension of the individual's certificate to practice for a period of at least one year or, if determined appropriate by the board, a more serious sanction involving the individual's certificate to practice. Any consent agreement entered into under this division with an individual that pertains to a second or subsequent plea of guilty to, or judicial finding of guilt of, a violation of that section shall provide for a suspension of the individual's certificate to practice for a period of at least one year or, if determined appropriate by the board, a more serious sanction involving the individual's certificate to practice.

(D) For purposes of divisions (B)(10), (12), and (14) of this section, the commission of the act may be established by a finding by the board, pursuant to an adjudication under Chapter 119. of the Revised Code, that the individual committed the act. The board does not have jurisdiction under those divisions if the trial court renders a final judgment in the individual's favor and that judgment is based upon an adjudication on the merits. The board has jurisdiction under those divisions if the trial court issues an order of dismissal upon technical or procedural grounds.

(E) The sealing of conviction records by any court shall

have no effect upon a prior board order entered under this section or upon the board's jurisdiction to take action under this section if, based upon a plea of guilty, a judicial finding of guilt, or a judicial finding of eligibility for intervention in lieu of conviction, the board issued a notice of opportunity for a hearing prior to the court's order to seal the records. The board shall not be required to seal, destroy, redact, or otherwise modify its records to reflect the court's sealing of conviction records.

(F)(1) The board shall investigate evidence that appears to show that a person has violated any provision of this chapter or any rule adopted under it. Any person may report to the board in a signed writing any information that the person may have that appears to show a violation of any provision of this chapter or any rule adopted under it. In the absence of bad faith, any person who reports information of that nature or who testifies before the board in any adjudication conducted under Chapter 119. of the Revised Code shall not be liable in damages in a civil action as a result of the report or testimony. Each complaint or allegation of a violation received by the board shall be assigned a case number and shall be recorded by the board.

(2) Investigations of alleged violations of this chapter or any rule adopted under it shall be supervised by the supervising member elected by the board in accordance with section 4731.02 of the Revised Code and by the secretary as provided in section 4731.39 of the Revised Code. The president may designate another member of the board to supervise the investigation in place of the supervising member. No member of the board who supervises the investigation of a case shall participate in further adjudication of the case.

(3) In investigating a possible violation of this chapter or any rule adopted under this chapter, or in conducting an inspection under division (E) of section 4731.054 of the Revised Code, the board may question witnesses, conduct interviews, administer oaths, order the taking of depositions, inspect and copy any books, accounts, papers, records, or documents, issue subpoenas, and compel the attendance of witnesses and production of books, accounts, papers, records, documents, and testimony, except that a subpoena for patient record information shall not be issued without consultation with the attorney general's office and approval of the secretary and supervising member of the board.

(a) Before issuance of a subpoena for patient record information, the secretary and supervising member shall determine whether there is probable cause to believe that the complaint filed alleges a violation of this chapter or any rule adopted under it and that the records sought are relevant to the alleged violation and material to the investigation. The subpoena may apply only to records that cover a reasonable period of time surrounding the alleged violation.

(b) On failure to comply with any subpoena issued by the board and after reasonable notice to the person being subpoenaed, the board may move for an order compelling the production of persons or records pursuant to the Rules of Civil Procedure.

(c) A subpoena issued by the board may be served by a sheriff, the sheriff's deputy, or a board employee designated by the board. Service of a subpoena issued by the board may be made by delivering a copy of the subpoena to the person named therein, reading it to the person, or leaving it at the person's

usual place of residence, usual place of business, or address on file with the board. When serving a subpoena to an applicant for or the holder of a certificate issued under this chapter, service of the subpoena may be made by certified mail, return receipt requested, and the subpoena shall be deemed served on the date delivery is made or the date the person refuses to accept delivery. If the person being served refuses to accept the subpoena or is not located, service may be made to an attorney who notifies the board that the attorney is representing the person.

(d) A sheriff's deputy who serves a subpoena shall receive the same fees as a sheriff. Each witness who appears before the board in obedience to a subpoena shall receive the fees and mileage provided for under section 119.094 of the Revised Code.

(4) All hearings, investigations, and inspections of the board shall be considered civil actions for the purposes of section 2305.252 of the Revised Code.

(5) A report required to be submitted to the board under this chapter, a complaint, or information received by the board pursuant to an investigation or pursuant to an inspection under division (E) of section 4731.054 of the Revised Code is confidential and not subject to discovery in any civil action.

The board shall conduct all investigations or inspections and proceedings in a manner that protects the confidentiality of patients and persons who file complaints with the board. The board shall not make public the names or any other identifying information about patients or complainants unless proper consent is given or, in the case of a patient, a waiver of the patient privilege exists under division (B) of section 2317.02 of the Revised Code, except that consent or a waiver of that nature is

not required if the board possesses reliable and substantial evidence that no bona fide physician-patient relationship exists.

The board may share any information it receives pursuant to an investigation or inspection, including patient records and patient record information, with law enforcement agencies, other licensing boards, and other governmental agencies that are prosecuting, adjudicating, or investigating alleged violations of statutes or administrative rules. An agency or board that receives the information shall comply with the same requirements regarding confidentiality as those with which the state medical board must comply, notwithstanding any conflicting provision of the Revised Code or procedure of the agency or board that applies when it is dealing with other information in its possession. In a judicial proceeding, the information may be admitted into evidence only in accordance with the Rules of Evidence, but the court shall require that appropriate measures are taken to ensure that confidentiality is maintained with respect to any part of the information that contains names or other identifying information about patients or complainants whose confidentiality was protected by the state medical board when the information was in the board's possession. Measures to ensure confidentiality that may be taken by the court include sealing its records or deleting specific information from its records.

(6) On a quarterly basis, the board shall prepare a report that documents the disposition of all cases during the preceding three months. The report shall contain the following information for each case with which the board has completed its activities:

(a) The case number assigned to the complaint or alleged

violation;

(b) The type of certificate to practice, if any, held by the individual against whom the complaint is directed;

(c) A description of the allegations contained in the complaint;

(d) The disposition of the case.

The report shall state how many cases are still pending and shall be prepared in a manner that protects the identity of each person involved in each case. The report shall be a public record under section 149.43 of the Revised Code.

(G) If the secretary and supervising member determine both of the following, they may recommend that the board suspend an individual's certificate to practice without a prior hearing:

(1) That there is clear and convincing evidence that an individual has violated division (B) of this section;

(2) That the individual's continued practice presents a danger of immediate and serious harm to the public.

Written allegations shall be prepared for consideration by the board. The board, upon review of those allegations and by an affirmative vote of not fewer than six of its members, excluding the secretary and supervising member, may suspend a certificate without a prior hearing. A telephone conference call may be utilized for reviewing the allegations and taking the vote on the summary suspension.

The board shall issue a written order of suspension by certified mail or in person in accordance with section 119.07 of the Revised Code. The order shall not be subject to suspension by the court during pendency of any appeal filed under section

119.12 of the Revised Code. If the individual subject to the summary suspension requests an adjudicatory hearing by the board, the date set for the hearing shall be within fifteen days, but not earlier than seven days, after the individual requests the hearing, unless otherwise agreed to by both the board and the individual.

Any summary suspension imposed under this division shall remain in effect, unless reversed on appeal, until a final adjudicative order issued by the board pursuant to this section and Chapter 119. of the Revised Code becomes effective. The board shall issue its final adjudicative order within seventy-five days after completion of its hearing. A failure to issue the order within seventy-five days shall result in dissolution of the summary suspension order but shall not invalidate any subsequent, final adjudicative order.

(H) If the board takes action under division (B)(9), (11), or (13) of this section and the judicial finding of guilt, guilty plea, or judicial finding of eligibility for intervention in lieu of conviction is overturned on appeal, upon exhaustion of the criminal appeal, a petition for reconsideration of the order may be filed with the board along with appropriate court documents. Upon receipt of a petition of that nature and supporting court documents, the board shall reinstate the individual's certificate to practice. The board may then hold an adjudication under Chapter 119. of the Revised Code to determine whether the individual committed the act in question. Notice of an opportunity for a hearing shall be given in accordance with Chapter 119. of the Revised Code. If the board finds, pursuant to an adjudication held under this division, that the individual committed the act or if no hearing is requested, the board may order any of the sanctions identified under division (B) of this

section.

(I) The certificate to practice issued to an individual under this chapter and the individual's practice in this state are automatically suspended as of the date of the individual's second or subsequent plea of guilty to, or judicial finding of guilt of, a violation of section 2919.123 of the Revised Code, or the date the individual pleads guilty to, is found by a judge or jury to be guilty of, or is subject to a judicial finding of eligibility for intervention in lieu of conviction in this state or treatment or intervention in lieu of conviction in another jurisdiction for any of the following criminal offenses in this state or a substantially equivalent criminal offense in another jurisdiction: aggravated murder, murder, voluntary manslaughter, felonious assault, kidnapping, rape, sexual battery, gross sexual imposition, aggravated arson, aggravated robbery, or aggravated burglary. Continued practice after suspension shall be considered practicing without a certificate.

The board shall notify the individual subject to the suspension by certified mail or in person in accordance with section 119.07 of the Revised Code. If an individual whose certificate is automatically suspended under this division fails to make a timely request for an adjudication under Chapter 119. of the Revised Code, the board shall do whichever of the following is applicable:

(1) If the automatic suspension under this division is for a second or subsequent plea of guilty to, or judicial finding of guilt of, a violation of section 2919.123 of the Revised Code, the board shall enter an order suspending the individual's certificate to practice for a period of at least one year or, if determined appropriate by the board, imposing a more serious

sanction involving the individual's certificate to practice.

(2) In all circumstances in which division (I)(1) of this section does not apply, enter a final order permanently revoking the individual's certificate to practice.

(J) If the board is required by Chapter 119. of the Revised Code to give notice of an opportunity for a hearing and if the individual subject to the notice does not timely request a hearing in accordance with section 119.07 of the Revised Code, the board is not required to hold a hearing, but may adopt, by an affirmative vote of not fewer than six of its members, a final order that contains the board's findings. In that final order, the board may order any of the sanctions identified under division (A) or (B) of this section.

(K) Any action taken by the board under division (B) of this section resulting in a suspension from practice shall be accompanied by a written statement of the conditions under which the individual's certificate to practice may be reinstated. The board shall adopt rules governing conditions to be imposed for reinstatement. Reinstatement of a certificate suspended pursuant to division (B) of this section requires an affirmative vote of not fewer than six members of the board.

(L) When the board refuses to grant or issue a certificate to practice to an applicant, revokes an individual's certificate to practice, refuses to renew an individual's certificate to practice, or refuses to reinstate an individual's certificate to practice, the board may specify that its action is permanent. An individual subject to a permanent action taken by the board is forever thereafter ineligible to hold a certificate to practice and the board shall not accept an application for reinstatement of the certificate or for issuance of a new certificate.

(M) Notwithstanding any other provision of the Revised Code, all of the following apply:

(1) The surrender of a certificate issued under this chapter shall not be effective unless or until accepted by the board. A telephone conference call may be utilized for acceptance of the surrender of an individual's certificate to practice. The telephone conference call shall be considered a special meeting under division (F) of section 121.22 of the Revised Code. Reinstatement of a certificate surrendered to the board requires an affirmative vote of not fewer than six members of the board.

(2) An application for a certificate made under the provisions of this chapter may not be withdrawn without approval of the board.

(3) Failure by an individual to renew a certificate to practice in accordance with this chapter shall not remove or limit the board's jurisdiction to take any disciplinary action under this section against the individual.

(4) At the request of the board, a certificate holder shall immediately surrender to the board a certificate that the board has suspended, revoked, or permanently revoked.

(N) Sanctions shall not be imposed under division (B)(28) of this section against any person who waives deductibles and copayments as follows:

(1) In compliance with the health benefit plan that expressly allows such a practice. Waiver of the deductibles or copayments shall be made only with the full knowledge and consent of the plan purchaser, payer, and third-party administrator. Documentation of the consent shall be made

available to the board upon request.

(2) For professional services rendered to any other person authorized to practice pursuant to this chapter, to the extent allowed by this chapter and rules adopted by the board.

(O) Under the board's investigative duties described in this section and subject to division (F) of this section, the board shall develop and implement a quality intervention program designed to improve through remedial education the clinical and communication skills of individuals authorized under this chapter to practice medicine and surgery, osteopathic medicine and surgery, and podiatric medicine and surgery. In developing and implementing the quality intervention program, the board may do all of the following:

(1) Offer in appropriate cases as determined by the board an educational and assessment program pursuant to an investigation the board conducts under this section;

(2) Select providers of educational and assessment services, including a quality intervention program panel of case reviewers;

(3) Make referrals to educational and assessment service providers and approve individual educational programs recommended by those providers. The board shall monitor the progress of each individual undertaking a recommended individual educational program.

(4) Determine what constitutes successful completion of an individual educational program and require further monitoring of the individual who completed the program or other action that the board determines to be appropriate;

(5) Adopt rules in accordance with Chapter 119. of the

Revised Code to further implement the quality intervention program.

An individual who participates in an individual educational program pursuant to this division shall pay the financial obligations arising from that educational program.

Sec. 4731.227. An individual authorized to practice medicine and surgery or osteopathic medicine and surgery may use alternative medical treatments if the individual has provided the information necessary to obtain informed consent from the patient and the treatment meets the standards enforced by the state medical board pursuant to section 4731.22 of the Revised Code and any rules adopted by the board.

As used in this section, "alternative medical treatment" means care that is complementary to or different from conventional medical care but is reasonable when the benefits and risks of the alternative medical treatment and the conventional medical care are compared. "Alternative medical treatment" does not include treatment with an investigational drug, product, or device under section 4731.96 of the Revised Code.

Sec. 4731.96. (A) As used in this section:

(1) "Investigational drug, product, or device" means a drug, product, or device that has successfully completed phase one of United States food and drug administration clinical trials and remains under clinical trial, but has not been approved for general use by the United States food and drug administration. "Investigational drug, product, or device" does not include controlled substances in schedule I, as established pursuant to section 3719.41 of the Revised Code, and as amended.

(2) "Drug" has the same meaning as in section 4729.01 of the Revised Code.

(3) "Product" means a biological product, other than a drug, that is made from a natural human, animal, or microorganism source and is intended to treat a disease or medical condition.

(4) "Device" means a medical device that is intended for use in the diagnosis or treatment of a disease or medical condition.

(5) "Physician" means an individual authorized by this chapter to practice medicine and surgery or osteopathic medicine and surgery.

(6) "Terminal condition" means any of the following conditions, if irreversible, incurable, and untreatable through a method of treatment approved by the United States food and drug administration:

(a) A progressive form of cancer;

(b) A progressive neurological disorder;

(c) A progressive musculoskeletal disorder;

(d) A condition that, based on reasonable medical standards and a reasonable degree of medical certainty, appears likely to cause death within a period of time that is relatively short but does not exceed twelve months.

(7) "Treating physician" means the physician primarily responsible for providing medical care and treating an eligible patient's terminal condition. "Treating physician" does not include the patient's primary care physician unless that physician is treating the patient's terminal condition and no

other physician is primarily responsible for treating the terminal condition. The patient may have more than one treating physician.

(B)(1) Subject to division (B)(2) of this section, an individual is an eligible patient if all of the following conditions are met:

(a) The individual has a terminal condition, as determined by the individual's treating physician and by one other physician who has examined the individual.

(b) The individual, as determined by the individual's treating physician, has considered all treatment options for the terminal condition that are approved by the United States food and drug administration and determined that there are no satisfactory or comparable approved treatments and that the risk from the investigational drug, product, or device is no greater than the probable risk from not treating the terminal condition.

(c) The individual's treating physician recommends the use of the investigational drug, product, or device, attests that it represents the individual's best chance at survival, and agrees to either administer or personally furnish it or has issued a prescription to the individual for the investigational drug, product, or device.

(d) The treating physician includes documentation in the patient's medical record that all of the foregoing conditions have been met.

(2) An individual who meets the requirements of division (B)(1) of this section is not an eligible patient if a clinical trial using the investigational drug, product, or device is actively being conducted within the individual's county of

residence or an adjoining county, unless the individual applied for participation but was denied access to that clinical trial.

(C)(1) A treating physician may treat an eligible patient with an investigational drug, product, or device after securing the patient's informed consent in a signed statement. If the patient is a minor or lacks the capacity to consent, the informed consent must be obtained from a parent, guardian, or other person legally responsible for the patient.

(2) To secure informed consent, the treating physician must do all of the following:

(a) Record all of the following in the document that is to be signed:

(i) An explanation of the approved treatment options for the terminal condition from which the patient suffers;

(ii) The specific proposed investigational drug, product, or device;

(iii) The potentially best and worst outcomes of using the investigational drug, product, or device with a realistic description of the most likely outcome, including the possibility that new, unanticipated, different, or worse symptoms might result, and that death could be hastened by the investigational drug, product, or device;

(iv) An explanation that the manufacturer of the investigational drug, product, or device may hold the patient liable for all expenses that arise from the patient's use of the investigational drug, product, or device.

(b) Have the individual giving consent sign the document in the conscious presence of a competent witness;

(c) Have the witness also sign the document and attest that the individual giving consent appeared to do all of the following:

(i) Concur with the treating physician in believing that all approved treatment options would be unlikely to prolong the patient's life;

(ii) Understand the risks involved with using the investigational drug, product, or device;

(iii) Willingly desire to use the investigational drug, product, or device to treat the terminal condition.

(3) An eligible patient, or the patient's parent, guardian, or other person legally responsible for the patient, may revoke consent to treatment with an investigational drug, product, or device at any time and in any manner that communicates the revocation.

(D) Except for actions constituting willful or wanton misconduct, a treating physician who recommends or treats an eligible patient with an investigational drug, product, or device in compliance with this section is not liable for or subject to any of the following for an action or omission related to treatment with the investigational drug, product, or device: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

(E) An official, employee, or agent of this state shall not, solely because an investigational drug, product, or device has not been approved for general use by the United States food and drug administration, prevent or attempt to prevent access by an eligible patient or eligible patient's treating physician to an investigational drug, product, or device that is being

provided or is to be provided in accordance with this section or section 4729.88 of the Revised Code.

(F) If an eligible patient dies while being treated with an investigational drug, product, or device and there are any outstanding costs related to treating the patient, the patient's estate, devisees, and heirs shall not be held liable by any person or government entity for those costs.

(G) Nothing in this section requires a health care insurer, the medicaid program or any other government health care program, or any other entity that offers health care benefits to provide coverage for the costs incurred from the use of any investigational drug, product, or device.

(H) Nothing in this section condones, authorizes, or approves of assisted suicide, as defined in section 3795.01 of the Revised Code, or any action that is considered mercy killing or euthanasia.

Section 2. That existing sections 4729.01, 4729.291, 4729.51, 4729.57, 4731.22, and 4731.227 of the Revised Code are hereby repealed.

Section 3. Section 4729.01 of the Revised Code is presented in this act as a composite of the section as amended by both Am. Sub. H.B. 4 and Sub. S.B. 110 of the 131st General Assembly. The General Assembly, applying the principle stated in division (B) of section 1.52 of the Revised Code that amendments are to be harmonized if reasonably capable of simultaneous operation, finds that the composite is the resulting version of the section in effect prior to the effective date of the section as presented in this act.