As Reported by the House Health Committee

134th General Assembly
Regular Session **H. B. No. 236**
2021-2022

Representatives Fraizer, Lipps
Cosponsors: Representatives Lightbody, West

A BILL

To amend sections 3719.41 and 4729.01 and to enact sections 930.01, 930.02, 930.03, 930.04, 930.05, 930.06, 930.07, and 930.99 of the Revised Code to regulate the processing, sale, and distribution of kratom.

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

Section 1. That sections 3719.41 and 4729.01 be amended and sections 930.01, 930.02, 930.03, 930.04, 930.05, 930.06, 930.07, and 930.99 of the Revised Code be enacted to read as follows:

Sec. 930.01. As used in this chapter:

(A) "Kratom" means the plant mitragyna speciosa and any part of that plant, including the seeds thereof and all derivatives and extracts.

(B) "Kratom product" means any product that is made with kratom. "Kratom product" includes dietary supplements or food intended for human consumption.

(C) "Kratom processing license" means a license to process

kratom issued under this chapter.

(D) "Process" or "processing" means converting kratom into a kratom product.

Sec. 930.02. (A) The director of agriculture shall establish a program to monitor and regulate kratom processing and the sale of kratom products in this state. Under the program, the director shall issue kratom processing licenses in accordance with rules adopted under section 930.03 of the Revised Code.

(B) Any person that wishes to process kratom shall apply for and obtain a kratom processing license from the director in accordance with rules adopted under section 930.03 of the Revised Code. Such licenses are valid for three years, unless earlier suspended or revoked by the director.

(C) Subject to section 930.04 of the Revised Code, any person may, without a kratom processing license, possess, buy, or sell kratom or kratom products.

Sec. 930.03. The director of agriculture, in consultation with the governor and attorney general, shall adopt rules in accordance with Chapter 119. of the Revised Code establishing standards and procedures for the regulation of kratom processing. The rules shall include all of the following:

(A) The form of an application for a kratom processing license and the information required to be included in each license application;

(B) The amount of an initial application fee that an applicant shall submit along with an application for a kratom processing license, and the amount of an annual license fee that a licensee shall submit for a kratom processing license. In

adopting rules under division (B) of this section, the director shall ensure both of the following:

(1) That the amount of the application fee and annual license fee does not exceed an amount sufficient to cover the costs incurred by the department of agriculture to administer and enforce this chapter;

(2) That there is one uniform application fee and one uniform annual license fee that applies to all applicants for a kratom processing license.

(C) Requirements and procedures regarding standards of financial responsibility for each applicant for a kratom processing license;

(D) Procedures and requirements for the issuance, renewal, denial, suspension, and revocation of a kratom processing license, including providing for a hearing under Chapter 119. of the Revised Code with regard to such a denial, suspension, or revocation;

(E) Grounds for the denial, suspension, and revocation of a kratom processing license;

(F) A requirement that any person that materially falsifies information in an application for a kratom processing license is ineligible to receive the license;

(G) A procedure for testing kratom products for purposes of determining compliance with this chapter and rules adopted under it;

(H) Requirements and procedures for the issuance, administration, and enforcement of corrective action plans issued under section 930.05 of the Revised Code;

(I) A procedure for conducting annual inspections of, at a minimum, a random sample of kratom processing license holders to verify that kratom plants are not being processed in violation of this chapter and rules adopted under it;

(J) A procedure for the effective disposal of all products derived from plants processed in violation of this chapter and rules adopted under it;

(K) Annual reporting requirements and procedures for kratom processing license holders;

(L) Recordkeeping and documentation maintenance requirements and procedures for kratom processing license holders;

(M) Fees for the laboratory testing of plants and products;

(N) Standards for the labeling of kratom products that require a label to include, at a minimum, specific directions necessary for the safe and effective use of a kratom product by consumers and a recommended serving size;

(O) Procedures and requirements for the transportation and distribution of kratom products;

(P) Any other requirements or procedures necessary to administer and enforce this chapter.

Sec. 930.04. (A) As used in this section:

(1) "Controlled substance" has the same meaning as in section 4729.01 of the Revised Code.

(2) "Drug" has the same meaning as in section 3719.01 of the Revised Code.

(B) No person shall process kratom without a kratom processing license issued by the director of agriculture under this chapter.

(C) No person who holds a kratom processing license shall violate this chapter or rules adopted under it.

(D) No person subject to a corrective action plan issued by the director of agriculture under section 930.05 of the Revised Code shall fail to comply with the plan.

(E) No person shall transport a kratom product in violation of rules adopted under section 930.03 of the Revised Code.

(F) No person shall distribute, sell, or expose for sale any of the following:

(1) A kratom product that is adulterated with a dangerous non-kratom substance. A kratom product is adulterated with a dangerous non-kratom substance if the kratom product is mixed or packed with a non-kratom substance and that substance affects the quality or strength of the kratom product to such a degree as to render the kratom product injurious to a consumer.

(2) A kratom product that is contaminated with a dangerous non-kratom substance. A kratom product is contaminated with a dangerous non-kratom substance if the kratom product contains a poisonous or otherwise deleterious non-kratom ingredient, including, but not limited to, any drug or controlled substance.

(3) A kratom product containing a level of 7-hydroxymitragynine in the alkaloid fraction that is greater than two per cent of the overall alkaloid composition of the kratom product.

(4) A kratom product containing any synthetic alkaloids including synthetic mitragynine, synthetic 7-hydroxymitragynine, or any other synthetically derived compounds of the kratom plant.

(5) A kratom product that is not properly labeled in accordance with rules adopted under section 930.03 of the Revised Code.

(6) A kratom product with a label containing claims that the kratom product is intended to diagnose, treat, cure, or prevent any medical condition or disease.

Sec. 930.05. (A) The director of agriculture shall issue a corrective action plan to any person that the director determines has negligently violated section 930.04 of the Revised Code. The director shall include in the corrective action plan both of the following:

(1) A reasonable date by which the person shall correct the violation;

(2) A requirement that the person report to the director regarding the person's compliance with the requirements of this chapter, rules adopted under it, and the corrective action plan for two calendar years immediately following the date of the violation.

(B) If the director determines that a person negligently violated section 930.04 of the Revised Code three or more times in any five-year period, the director shall revoke the person's kratom processing license, if any, and shall refuse to issue a kratom processing license to that person for a period of five years beginning on the date that the director determines that the person committed the most recent violation.

(C) The director shall report a person who the director determines has violated section 930.04 of the Revised Code with a culpable mental state greater than negligence to the attorney general and the applicable county prosecutor.

Sec. 930.06. There is hereby created in the state treasury the kratom program fund. The fund shall consist of all fees collected under rules adopted under section 930.03 of the Revised Code; money appropriated to the fund; and any other money received from gifts or federal grants. All investment earnings of the fund shall be credited to the fund. The director of agriculture shall use money in the fund to administer and enforce this chapter and rules adopted under it.

Sec. 930.07. (A) The director of agriculture may enter at reasonable times upon any public or private property at which kratom is being processed, distributed, or sold for the purpose of determining compliance with this chapter and rules adopted under it. The director may apply for and any judge of an appropriate court of record may issue a search warrant, necessary to achieve the purposes of this chapter within the court's territorial jurisdiction.

(B)(1) If the director determines that emergency conditions exist requiring immediate action necessary to protect public health or safety or the environment, the director may issue an order stating the existence of such conditions and requiring specific actions be taken to mitigate those conditions without providing prior notice or an adjudication hearing in accordance with Chapter 119. of the Revised Code.

(2) Any person to whom such an order is issued shall immediately comply with that order, and may apply to the director for an adjudication hearing. Upon receiving an

application for an adjudication hearing, the director shall hold the hearing as soon as practicable and not later than thirty days after receipt of the application. On the basis of the hearing, the director shall continue the order in effect, revoke it, or modify it.

(C) In addition to any other available remedies, the director of agriculture, the attorney general, or a county prosecutor may apply to a court of common pleas in the county where any provision of section 930.04 of the Revised Code or an order issued under division (B) of this section is being violated for an injunction restraining any person from continuing the violation.

Sec. 930.99. (A) Whoever recklessly violates section 930.04 of the Revised Code is guilty of the following:

(1) For a first offense, a minor misdemeanor;

(2) For each subsequent offense, a misdemeanor of the fourth degree.

The court shall order an offender who is convicted of or pleads guilty to a third or subsequent offense ineligible to receive a kratom processing license under this chapter. The court shall provide written notice of that order to the director of agriculture. Upon receipt of the notice, the director shall revoke any kratom processing license that the offender holds and shall refuse to issue a kratom processing license to the offender beginning on the date of the court order.

(B) The prosecuting attorney of the applicable county or the attorney general may prosecute an action under this section.

Sec. 3719.41. (A) For purposes of administration, enforcement, and regulation of the manufacture, distribution,

dispensing, and possession of controlled substances, the state board of pharmacy shall adopt rules in accordance with Chapter 119. of the Revised Code establishing schedule I, schedule II, schedule III, schedule IV, and schedule V incorporating the five schedules of controlled substances under the federal drug abuse control laws.

The board may include in the schedules any compound, mixture, preparation, or substance that was included in the schedules immediately prior to March 22, 2020, as long as the inclusion does not have the effect of providing less stringent control of the compound, mixture, preparation, or substance than is provided under the federal drug abuse control laws or regulations adopted under those laws.

(B) Except as provided in section 3719.45 of the Revised Code, the board periodically shall update the schedules by rule adopted in accordance with Chapter 119. of the Revised Code to correspond to any change in the federal drug abuse control laws or regulations adopted under those laws, any addition, transfer, or removal by congress or the attorney general of the United States as described in section 3719.43 of the Revised Code, and any addition, transfer, or removal by the board by rule adopted under section 3719.44 of the Revised Code.

(C) Notwithstanding divisions (A) and (B) of this section, the board shall not adopt rules including hemp ~~or~~, a hemp product, kratom, or a kratom product in a schedule as a controlled substance.

(D) As used in this section~~, "hemp"~~:

(1) "Hemp" and "hemp product" have the same meanings as in section 928.01 of the Revised Code;

(2) "Kratom" and "kratom product" have the same meanings as in section 930.01 of the Revised Code.

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, if an agreement has been established;

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

(10) Engaging in the administration of drugs to the extent authorized by section 4729.45 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 that has been entered into under section 4729.39 of the Revised Code.

(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.

"Drug" does not include "hemp" or a "hemp product" as those terms are defined in section 928.01 of the Revised Code. <u>"Drug" does not include "kratom" or a "kratom product" as those</u>

terms are defined in section 930.01 of the Revised Code.

(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;

(4) Any drug that is a biological product, as defined in section 3715.01 of the Revised Code.

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

(H) "Prescription" means all 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 sections 2925.61, 4723.484, 4730.434, 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.

(3) For purposes of section 4729.44 of the Revised Code, a written, electronic, or oral order for naloxone issued to and in the name of either of the following:

(a) An individual who there is reason to believe is at risk of experiencing an opioid-related overdose;

(b) 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.

(4) For purposes of sections 4723.4810, 4729.282, 4730.432, and 4731.93 of the Revised Code, a written, electronic, or oral order for a drug to treat chlamydia, gonorrhea, or trichomoniasis issued to and in the name of a patient who is not the intended user of the drug but is the sexual partner of the intended user;

(5) For purposes of sections 3313.7110, 3313.7111, 3314.143, 3326.28, 3328.29, 4723.483, 4729.88, 4730.433, 4731.96, and 5101.76 of the Revised Code, a written, electronic, or oral order for an epinephrine autoinjector issued to and in the name of a school, school district, or camp;

(6) For purposes of Chapter 3728. and sections 4723.483, 4729.88, 4730.433, and 4731.96 of the Revised Code, a written, electronic, or oral order for an epinephrine autoinjector issued to and in the name of a qualified entity, as defined in section

3728.01 of the Revised Code;

(7) For purposes of sections 3313.7115, 3313.7116, 3314.147, 3326.60, 3328.38, 4723.484, 4730.434, 4731.92, and 5101.78 of the Revised Code, a written, electronic, or oral order for injectable or nasally administered glucagon in the name of a school, school district, or camp.

(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 current, valid license issued under Chapter 4723. of the Revised Code to practice nursing as an advanced practice registered nurse;

(3) A certified registered nurse anesthetist who holds a current, valid license issued under Chapter 4723. of the Revised Code to practice nursing as an advanced practice registered nurse, but only to the extent of the nurse's authority under sections 4723.43 and 4723.434 of the Revised Code;

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

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

(6) 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;

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

(J) "Sale" or "sell" includes any transaction made by any person, whether as principal proprietor, agent, or employee, to do or offer to do any of the following: deliver, distribute, broker, exchange, gift or otherwise give away, or transfer, whether the transfer is by passage of title, physical movement, or both.

(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" or "wholesale distributor" 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" or "manufacturer" means a person, other than a pharmacist or prescriber, who manufactures dangerous drugs and who is engaged in the sale of those dangerous drugs.

(Q) "Terminal distributor of dangerous drugs" or "terminal distributor" means a person who is engaged in the sale of dangerous drugs at retail, or any person, other than a

manufacturer, repackager, outsourcing facility, third-party logistics provider, wholesale distributor, or pharmacist, who has possession, custody, or control of dangerous drugs for any purpose other than for that person's own use and consumption. "Terminal distributor" 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, licensed health professional authorized to prescribe drugs, or other person authorized by the state board of pharmacy.

(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)(1) "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.

(2) "County dog warden" means a dog warden or deputy dog warden appointed or employed under section 955.12 of the Revised Code.

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

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

(W) "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 defined in section 3719.01 of the Revised Code.

(X) "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.

(Y) "Third-party logistics provider" means a person that provides or coordinates warehousing or other logistics services pertaining to dangerous drugs including distribution, on behalf of a manufacturer, wholesale distributor, or terminal distributor of dangerous drugs, but does not take ownership of the drugs or have responsibility to direct the sale or disposition of the drugs.

(Z) "Repackager of dangerous drugs" or "repackager" means a person that repacks and relabels dangerous drugs for sale or distribution.

(AA) "Outsourcing facility" means a facility that is engaged in the compounding and sale of sterile drugs and is registered as an outsourcing facility with the United States food and drug administration.

(BB) "Laboratory" means a laboratory licensed under this chapter as a terminal distributor of dangerous drugs and entrusted to have custody of any of the following drugs and to use the drugs for scientific and clinical purposes and for purposes of instruction: dangerous drugs that are not controlled substances, as defined in section 3719.01 of the Revised Code; dangerous drugs that are controlled substances, as defined in that section; and controlled substances in schedule I, as defined in that section.

Section 2. That existing sections 3719.41 and 4729.01 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 H.B. 24, H.B. 197, H.B. 203, H.B. 231, H.B. 341, and S.B. 57, all of the 133rd 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.