WEST VIRGINIA LEGISLATURE

2020 REGULAR SESSION

Introduced

Senate Bill 763

FISCAL NOTE

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[Introduced February 13, 2020; referred

to the Committee on Health and Human Resources;

and Finance]

A BILL to amend the Code of West Virginia, 1931, as amended, by adding thereto a new section, designated §16-1-20; to amend and reenact §30-5-4 of said code; and to amend said code by adding thereto three new sections, designated §30-5-25, §30-5-25a and §30-5-25b, all relating to improving accountability of opioid manufacturers; requiring the submission of opioid medication distribution information; authorizing a manufacturer of an opioid medication registration fee; authorizing an opioid medication product registration fee; providing exceptions to opioid medication product registration fee; establishing a method of calculating units of opioid medications sold, delivered, or distributed; and requiring an opioid medication product registration fee review and report.

Be it enacted by the Legislature of West Virginia:

CHAPTER 16. PUBLIC HEALTH.

ARTICLE 1. STATE PUBLIC HEALTH SYSTEM.

§16-1-20. Opioid use disorder prevention and treatment fund.

(a) The Opioid Use Disorder Prevention and Treatment Fund is hereby created in the State Treasury as a special revenue account. The fund shall be administered by the Secretary of the Department of Health and Human Resources and shall consist of:

(1) Money received from the registration fees imposed by §30-5-25a and §30-5-25b of this code; and

(2) Grants, bequests or transfers from any source, any moneys that may be appropriated and designated for those purposes by the Legislature and all interest or other return earned from investment of the fund, gifts, and all other sums available for deposit to the special revenue account from any source, public or private.

(b) Expenditures from the fund shall be for the purposes set forth in this section and are not authorized from collections but are to be made only in accordance with appropriation by the Legislature and in accordance with the provisions of §12-3-1 *et seq.* of this code and upon the

fulfillment of the provisions set forth in §11B-2-1 *et seq.* of this code.

(c) Amounts deposited in the fund may be used only for the following purposes:

(1) Programs authorized and operating pursuant to chapter 16 of this code that employ evidence-based behavioral health treatment or medically assisted treatment for inmates with opioid addiction or other substance abuse disorders;

(2) Opioid use disorder prevention services; and

(3) Opioid use disorder treatment services, including:

(A) Inpatient and outpatient treatment programs and facilities, including short-term and long-term residential treatment programs and sober living facilities;

(B) Treating substance use disorder for the underinsured and uninsured; and

(C) Research regarding opioid use disorder prevention and treatment.

(d) Any moneys remaining in the fund at the close of a fiscal year shall be carried forward for use in the next fiscal year.

(e) Any interest earnings of the fund shall become a part of the fund and do not lapse.

(f) Moneys deposited in the fund are hereby appropriated for the purposes set forth in this section and may not be appropriated or transferred by the Legislature for any other purposes.

CHAPTER 30. PROFESSIONS AND OCCUPATIONS.

ARTICLE 5. PHARMACISTS, PHARMACY TECHNICIANS, PHARMACY INTERNS AND PHARMACIES.

§30-5-4. Definitions.

As used in this article:

(1) “Ambulatory health care facility” includes any facility defined in §16-5B-1 of this code, that also has a pharmacy, offers pharmacist care, or is otherwise engaged in the practice of pharmacist care.

(2) “Active Ingredients” means chemicals, substances, or other components of articles

intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in humans or animals or for use as nutritional supplements.

(3) “Administer” means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion or any other means.

(4) “Board” means the West Virginia Board of Pharmacy.

(5) “Board authorization” means a license, registration or permit issued under this article.

(6) “Chain Pharmacy Warehouse” means a permanent physical location for drugs and/or devices that acts as a central warehouse and performs intracompany sales and transfers of prescription drugs or devices to chain pharmacies, which are members of the same affiliated group, under common ownership and control.

(7) “Charitable clinic pharmacy” means a clinic or facility organized as a not-for-profit corporation that has a pharmacy, offers pharmacist care, or is otherwise engaged in the practice of pharmacist care and dispenses its prescriptions free of charge to appropriately screened and qualified indigent patients.

(8) “Collaborative pharmacy practice” is that practice of pharmacist care where one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more physicians under written protocol where the pharmacist or pharmacists may perform certain patient care functions authorized by the physician or physicians under certain specified conditions and limitations.

(9) “Collaborative pharmacy practice agreement” is a written and signed agreement, which is a physician directed approach, that is entered into between an individual physician or physician group, an individual pharmacist or pharmacists and an individual patient or the patient's authorized representative who has given informed consent that provides for collaborative pharmacy practice for the purpose of drug therapy management of a patient, which has been approved by the board, the Board of Medicine in the case of an allopathic physician or the West Virginia Board of Osteopathic Medicine in the case of an osteopathic physician.

(10) “Common Carrier” means any person or entity who undertakes, whether directly or by any other arrangement, to transport property including prescription drugs for compensation.

(11) “Component” means any active ingredient or added substance intended for use in the compounding of a drug product, including those that may not appear in such product.

(12) “Compounding” means:

(A) The preparation, mixing, assembling, packaging or labeling of a drug or device:

(i) As the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice for sale or dispensing; or

(ii) For the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing; and

(B) The preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(13) “Deliver” or “delivery” means the actual, constructive or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

(14) “Device” means an instrument, apparatus, implement or machine, contrivance, implant or other similar or related article, including any component part or accessory, which is required under federal law to bear the label, “Caution: Federal or state law requires dispensing by or on the order of a physician.”

(15) “Digital Signature” means an electronic signature based upon cryptographic methods of originator authentication, and computed by using a set of rules and a set of parameters so that the identity of the signer and the integrity of the data can be verified.

(16) “Dispense” or “dispensing” means the interpretation, evaluation, and implementation of a prescription drug order, including the preparation, verification and delivery of a drug or device to a patient or patient’s agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

(17) “Distribute” or “Distribution” means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a drug, whether by passage of title, physical movement, or both. The term does not include:

(A) To dispense or administer;

(B) (i) Delivering or offering to deliver a drug by a common carrier in the usual course of business as a common carrier; or providing a drug sample to a patient by a practitioner licensed to prescribe such drug;

(ii) A health care professional acting at the direction and under the supervision of a practitioner; or the pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample in accordance with the Prescription Drug Marketing Act and regulations to administer or dispense;

(iii) Intracompany sales.

(18) “Drop shipment” means the sale of a prescription drug to a wholesale distributor by the manufacturer of the prescription drug or by that manufacturer’s colicensed product partner, that manufacturer’s third party logistics provider, that manufacturer’s exclusive distributor, or by an authorized distributor of record that purchased the product directly from the manufacturer or from one of these entities whereby:

(A) The wholesale distributor takes title to but not physical possession of such prescription drug;

(B) The wholesale distributor invoices the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer such drug; and

(C) The pharmacy, pharmacy warehouse or other person authorized by law to dispense or administer such drug receives delivery of the prescription drug directly from the manufacturer or from that manufacturer’s colicensed product partner, that manufacturer’s third party logistics provider, that manufacturer’s exclusive distributor, or from an authorized distributor of record that purchased the product directly from the manufacturer or from one of these entities.

(19) “Drug” means:

(A) Articles recognized as drugs by the United States Food and Drug Administration, or in any official compendium, or supplement;

(B) An article, designated by the board, for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

(C) Articles, other than food, intended to affect the structure or any function of the body of human or other animals; and

(D) Articles intended for use as a component of any articles specified in paragraph (A), (B) or (C) of this subdivision.

(20) “Drug regimen review” includes, but is not limited to, the following activities:

(A) Evaluation of the prescription drug orders and if available, patient records for:

(i) Known allergies;

(ii) Rational therapy-contraindications;

(iii) Reasonable dose and route of administration; and

(iv) Reasonable directions for use.

(B) Evaluation of the prescription drug orders and patient records for duplication of therapy.

(C) Evaluation of the prescription drug for interactions and/or adverse effects which may include, but are not limited to, any of the following:

(i) Drug-drug;

(ii) Drug-food;

(iii) Drug-disease; and

(iv) Adverse drug reactions.

(D) Evaluation of the prescription drug orders and if available, patient records for proper use, including overuse and underuse and optimum therapeutic outcomes.

(21) “Drug therapy management” means the review of drug therapy regimens of patients

by a pharmacist for the purpose of evaluating and rendering advice to a physician regarding adjustment of the regimen in accordance with the collaborative pharmacy practice agreement. Decisions involving drug therapy management shall be made in the best interest of the patient. Drug therapy management is limited to:

(A) Implementing, modifying and managing drug therapy according to the terms of the collaborative pharmacy practice agreement;

(B) Collecting and reviewing patient histories;

(C) Obtaining and checking vital signs, including pulse, temperature, blood pressure and respiration;

(D) Ordering screening laboratory tests that are dose related and specific to the patient's medication or are protocol driven and are also specifically set out in the collaborative pharmacy practice agreement between the pharmacist and physician.

(22) “Electronic data intermediary” means an entity that provides the infrastructure to connect a computer system, hand-held electronic device or other electronic device used by a prescribing practitioner with a computer system or other electronic device used by a pharmacy to facilitate the secure transmission of:

(A) An electronic prescription order;

(B) A refill authorization request;

(C) A communication; or

(D) Other patient care information.

(23) “E-prescribing” means the transmission, using electronic media, of prescription or prescription-related information between a practitioner, pharmacist, pharmacy benefit manager or health plan as defined in 45 CFR §160.103, either directly or through an electronic data intermediary. E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the pharmacist. E-prescribing may also be referenced by the terms “electronic prescription” or “electronic order”.

(24) “Electronic Signature” means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

(25) “Electronic transmission” means transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.

(26) “Emergency medical reasons” include, but are not limited to, transfers of a prescription drug by one pharmacy to another pharmacy to alleviate a temporary shortage of a prescription drug; sales to nearby emergency medical services, i.e., ambulance companies and firefighting organizations in the same state or same marketing or service area, or nearby licensed practitioners of prescription drugs for use in the treatment of acutely ill or injured persons; and provision of minimal emergency supplies of prescription drugs to nearby nursing homes for use in emergencies or during hours of the day when necessary prescription drugs cannot be obtained.

(27) “Exclusive distributor” means an entity that:

(A) Contracts with a manufacturer to provide or coordinate warehousing, wholesale distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer’s prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer’s prescription drug; and

(B) Is licensed as a wholesale distributor under this article.

(28) “FDA” means the Food and Drug Administration, a federal agency within the United States Department of Health and Human Services.

(29) “Health care entity” means a person that provides diagnostic, medical, pharmacist care, surgical, dental treatment, or rehabilitative care but does not include a wholesale distributor.

(30) “Health information” means any information, whether oral or recorded in a form or medium, that:

(A) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse, and

(B) Relates to the past, present, or future physical or mental health or condition of an individual; or the past, present, or future payment for the provision of health care to an individual.

(31) “HIPAA” is the federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191).

(32) “Immediate container” means a container and does not include package liners.

(33) “Individually identifiable health information” is information that is a subset of health information, including demographic information collected from an individual and is created or received by a health care provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and that identifies the individual; or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

(34) “Intracompany sales” means any transaction between a division, subsidiary, parent, and/or affiliated or related company under the common ownership and control of a corporate or other legal business entity.

(35) “Label” means a display of written, printed, or graphic matter upon the immediate container of any drug or device.

(36) “Labeling” means the process of preparing and affixing a label to a drug container exclusive, however, of a labeling by a manufacturer, packer or distributor of a nonprescription drug or commercially packaged prescription drug or device.

(37) “Long-Term care facility” means a nursing home, retirement care, mental care, or other facility or institution that provides extended health care to resident patients.

(38) “Mail-order pharmacy” means a pharmacy, regardless of its location, which dispenses greater than 25 percent prescription drugs via the mail or other delivery services.

(39) “Manufacturer” means any person who is engaged in manufacturing, preparing, propagating, processing, packaging, repackaging or labeling of a prescription drug, whether within

or outside this state.

(40) “Manufacturing” means the production, preparation, propagation or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes any packaging or repackaging of the substance or substances or labeling or relabeling of its contents and the promotion and marketing of the drugs or devices. Manufacturing also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners or other persons.

(41) “Medical order” means a lawful order of a practitioner that may or may not include a prescription drug order.

(42) “Medication therapy management” is a distinct service or group of services that optimize medication therapeutic outcomes for individual patients. Medication therapy management services are independent of, but can occur in conjunction with, the provision of a medication or a medical device. Medication therapy management encompasses a broad range of professional activities and responsibilities within the licensed pharmacist’s scope of practice.

These services may include the following, according to the individual needs of the patient:

(A) Performing or obtaining necessary assessments of the patient’s health status pertinent to medication therapy management;

(B) Optimize medication use, performing medication therapy, and formulating recommendations for patient medication care plans;

(C) Developing therapeutic recommendations, to resolve medication related problems;

(D) Monitoring and evaluating the patient's response to medication therapy, including safety and effectiveness;

(E) Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events;

(F) Documenting the care delivered and communicating essential information to the

patient’s primary care providers;

(G) Providing verbal education and training designed to enhance patient understanding and appropriate use of his or her medications;

(H) Providing information, support services and resources designed to enhance patient adherence with his or her medication therapeutic regimens;

(I) Coordinating and integrating medication therapy management services within the broader health care management services being provided to the patient; and

(J) Such other patient care services as may be allowed by law.

(43) “Misbranded” means a drug or device that has a label that is false or misleading in any particular; or the label does not bear the name and address of the manufacturer, packer, or distributor and does not have an accurate statement of the quantities of the active ingredients in the case of a drug; or the label does not show an accurate monograph for prescription drugs.

(44) “Nonprescription drug” means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the requirements of the laws and rules of this state and the federal government.

(45) “Normal distribution channel” means a chain of custody for a prescription drug that goes directly or by drop shipment, from a manufacturer of the prescription drug, the manufacturer’s third-party logistics provider, or the manufacturer’s exclusive distributor to:

(A) A wholesale distributor to a pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient;

(B) A wholesale distributor to a chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient;

(C) A chain pharmacy warehouse to that chain pharmacy warehouse’s intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient;

(D) A pharmacy or to other designated persons authorized by law to dispense or administer such prescription drug to a patient; or

(E) As prescribed by the board's legislative rules.

(46) “Opioid medication” means a controlled substance containing an opioid included in §60A-2-206 of this code.

~~(46)~~ (47) “Patient counseling” means the communication by the pharmacist of information, as prescribed further in the rules of the board, to the patient to improve therapy by aiding in the proper use of drugs and devices.

~~(47)~~ (48) “Pedigree” means a statement or record in a written form or electronic form, approved by the board, that records each wholesale distribution of any given prescription drug (excluding veterinary prescription drugs), which leaves the normal distribution channel.

~~(48)~~ (49) “Person” means an individual, corporation, partnership, association or any other legal entity, including government.

~~(49)~~ (50) “Pharmacist” means an individual currently licensed by this state to engage in the practice of pharmacist care.

~~(50)~~ (51) “Pharmacist care” means the provision by a pharmacist of patient care activities, with or without the dispensing of drugs or devices, intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process and as provided ~~for~~ in §30-5-10 of this code.

~~(51)~~ (52) “Pharmacist-in-charge” means a pharmacist currently licensed in this state who accepts responsibility for the operation of a pharmacy in conformance with all laws and legislative rules pertinent to the practice of pharmacist care and the distribution of drugs and who is personally in full charge of the pharmacy and pharmacy personnel.

~~(52)~~ (53) “Pharmacist’s scope of practice pursuant to the collaborative pharmacy practice agreement” means those duties and limitations of duties placed upon the pharmacist by the collaborating physician, as jointly approved by the board and the Board of Medicine or the West

Virginia Board of Osteopathic Medicine.

~~(53)~~ (54) “Pharmacy” means any place within this state where drugs are dispensed and pharmacist care is provided and any place outside of this state where drugs are dispensed and pharmacist care is provided to residents of this state.

~~(54)~~ (55) “Pharmacy intern” or “intern” means an individual who is currently licensed to engage in the practice of pharmacist care while under the supervision of a pharmacist.

~~(55)~~ (56) “Pharmacy related primary care” means the pharmacist’s activities in patient education, health promotion, selection and use of over the counter drugs and appliances and referral or assistance with the prevention and treatment of health related issues and diseases.

~~(56)~~ (57) “Pharmacy technician” means a person registered with the board to practice certain tasks related to the practice of pharmacist care as permitted by the board.

~~(57)~~ (58) “Physician” means an individual currently licensed, in good standing and without restrictions, as an allopathic physician by the West Virginia Board of Medicine or an osteopathic physician by the West Virginia Board of Osteopathic Medicine.

~~(58)~~ (59) “Practice of telepharmacy” means the provision of pharmacist care by properly licensed pharmacists located within United States jurisdictions through the use of telecommunications or other technologies to patients or their agents at a different location that are located within United States jurisdictions.

~~(59)~~ (60) “Practitioner” means an individual authorized by a jurisdiction of the United States to prescribe drugs in the course of professional practices, as allowed by law.

~~(60)~~ (61) “Prescription drug” means any human drug required by federal law or regulation to be dispensed only by prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug and Cosmetic Act.

~~(61)~~ (62) “Prescription or prescription drug order” means a lawful order from a practitioner for a drug or device for a specific patient, including orders derived from collaborative pharmacy practice, where a valid patient-practitioner relationship exists, that is communicated to a

pharmacist in a pharmacy.

~~(62)~~ (63) “Product Labeling” means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article.

~~(63)~~ (64) “Repackage” means changing the container, wrapper, quantity, or product labeling of a drug or device to further the distribution of the drug or device.

~~(64)~~ (65) “Repackager” means a person who repackages.

~~(65)~~ (66) “Therapeutic equivalence” mean drug products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product which contain the same active ingredient(s); dosage form and route of administration; and strength.

~~(66)~~ (67) “Third-party logistics provider” means a person who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug’s sale or disposition. A third-party logistics provider shall be licensed as a wholesale distributor under this article and, in order to be considered part of the normal distribution channel, shall also be an authorized distributor of record.

~~(67)~~ (68) “Valid patient-practitioner relationship” means the following have been established:

(A) A patient has a medical complaint;

(B) A medical history has been taken;

(C) A face-to-face physical examination adequate to establish the medical complaint has been performed by the prescribing practitioner or in the instances of telemedicine through telemedicine practice approved by the appropriate practitioner board; and

(D) Some logical connection exists between the medical complaint, the medical history, and the physical examination and the drug prescribed.

~~(68)~~ (69) “Wholesale distribution” and “wholesale distributions” mean distribution of

prescription drugs, including directly or through the use of a third-party logistics provider or any other situation in which title, ownership or control over the prescription drug remains with one person or entity but the prescription drug is brought into this state by another person or entity on his, her or its behalf, to persons other than a consumer or patient, but does not include:

(A) Intracompany sales, as defined in ~~subdivision thirty-four of this subsection~~ this section;

(B) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(C) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug by a charitable organization described in section 501(c)(3) of the United States Internal Revenue Code of 1986 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(D) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug among hospitals or other health care entities that are under common control. For purposes of this article, “common control” means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise;

(E) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug for “emergency medical reasons” for purposes of this article includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five percent of the total prescription drug sales revenue of either the transferor or transferee pharmacy during any 12 consecutive month period;

(F) The sale, purchase or trade of a drug, an offer to sell, purchase, or trade a drug or the dispensing of a drug pursuant to a prescription;

(G) The distribution of drug samples by manufacturers’ representatives or distributors’

representatives, if the distribution is permitted under federal law [21 U. S. C. 353(d)];

(H) Drug returns by a pharmacy or chain drug warehouse to wholesale drug distributor or the drug's manufacturer; or

(I) The sale, purchase or trade of blood and blood components intended for transfusion.

~~(69)~~ (70) "Wholesale drug distributor" or "wholesale distributor" means any person or entity engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers, repackers, own-label distributors, jobbers, private-label distributors, brokers, warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses and wholesale drug warehouses, independent wholesale drug traders, prescription drug repackagers, physicians, dentists, veterinarians, birth control and other clinics, individuals, hospitals, nursing homes and/or their providers, health maintenance organizations and other health care providers, and retail and hospital pharmacies that conduct wholesale distributions, including, but not limited to, any pharmacy distributor as defined in this section. A wholesale drug distributor shall not include any for hire carrier or person or entity hired solely to transport prescription drugs.

§30-5-25. Opioid medication distribution monitoring information.

A manufacturer of an opioid medication that is available in this state and a wholesaler that sells or distributes an opioid medication in this state shall submit to the board, by electronic means or other format specified in a waiver granted by the board, information for this state submitted to the United States Drug Enforcement Administration's Automation of Reports and Consolidated Orders System pursuant to 21 U.S.C., Subchapter I and 21 C.F.R. §1304.33 at the time that information is submitted to the United States Drug Enforcement Administration.

§30-5-25a. Manufacturer of an opioid medication fee.

The board shall assess an annual registration fee on the manufacturer of an opioid medication in the amount of $55,000: *Provided,* That this fee does not apply to a manufacturer of an opioid medication if all of that manufacturer's opioid medications are approved by the United States Food and Drug Administration for use only in veterinary medicine.

§30-5-25b. Opioid medication product registration fee.

(a) *Registration fee.* Except as provided in subsection (b) of this section, a manufacturer that sells, delivers or distributes an opioid medication in this state shall pay an annual registration fee of $250,000 to the board on December 31 of each year for each opioid medication manufactured sold, delivered or distributed in the state.

(b) *Exception*. A manufacturer that does not sell, deliver or distribute 2 million or more units of an opioid medication within this state in the year in which a registration fee is due is not required to pay the registration fee. To qualify for the exception under this subsection, a manufacturer must demonstrate to the board, by January 31 of the year following the year in which the registration fee is due, in a manner determined by the board, that the manufacturer did not sell, deliver or distribute 2 million or more units of an opioid medication within this state in the year in which the manufacturer seeks to claim the exception. The board may adopt rules pursuant to chapter 29A to implement this section.

(c) *Calculation of units of an opioid medication sold, delivered or distributed.* When calculating the number of units of an opioid medication sold, delivered or distributed by a manufacturer under subsection (b) of this section, units of an opioid medication may be excluded when prescribed for the purpose of medication-assisted treatment of substance use disorder. The board periodically shall provide to the Office Drug Control Policy a list of medications exempted under this subsection.

(d) *Registration fee review and report.* By March 1 of each year following calendar years 2021, 2022 and 2023, the board shall evaluate and report whether the registration fee due under this section and the fee due under §30-5-25a of this code have affected the prescribing practices of opioid medications by reducing the number of opioid medication prescriptions issued during calendar years 2021, 2022 and 2023 or whether the fees have created any unintended consequences in the availability of opioid medications for the treatment of chronic or intractable pain, to the extent the board has the ability to identify a correlation. The board shall provide the

report to the Legislative Oversight Commission on Health and Human Resources.

(e) As used in this section, “unit of an opioid medication” means the lowest identifiable quantity of the opioid medication that is dispensed.

NOTE: The purpose of this bill is to improve the accountability of opioid manufacturers by requiring the submission of opioid medication distribution information; authorizing a manufacturer of an opioid medication registration fee; authorizing an opioid medication product registration fee; and requiring an opioid medication product registration fee review and report.

Strike-throughs indicate language that would be stricken from a heading or the present law and underscoring indicates new language that would be added.