AN ACT REVISING LICENSING AND REGULATIONS FOR WHOLESALE DISTRIBUTORS, THIRD-PARTY LOGISTICS PROVIDERS, MANUFACTURERS, AND REPACKAGERS OF PRESCRIPTION DRUGS; INCORPORATING REFERENCES TO FEDERAL DRUG SUPPLY CHAIN AND OTHER FEDERAL LAWS; DEFINING "OUTSOURCING FACILITY" AND PROVIDING OTHER DEFINITIONS; PROVIDING FOR CRIMINAL BACKGROUND CHECKS FOR WHOLESALE DISTRIBUTORS AND THIRD-PARTY LOGISTICS PROVIDERS; AND AMENDING SECTIONS 37-7-101, 37-7-201, 37-7-601, 37-7-602, 37-7-603, 37-7-604, 37-7-605, 37-7-606, 37-7-609, AND 37-7-610, MCA.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

Section 1. Section 37-7-101, MCA, is amended to read:

"37-7-101. Definitions. As used in this chapter, the following definitions apply:

(1) (a) "Administer" means the direct application of a drug to the body of a patient by injection, inhalation, ingestion, or any other means.

(b) Except as provided in 37-7-105, the term does not include immunization by injection for children under 18 years of age.

(2) "Board" means the board of pharmacy provided for in 2-15-1733.

(3) "Cancer drug" means a prescription drug used to treat:

(a) cancer or its side effects; or

(b) the side effects of a prescription drug used to treat cancer or its side effects.

(4) "Chemical" means medicinal or industrial substances, whether simple, compound, or obtained through the process of the science and art of chemistry, whether of organic or inorganic origin.

(5) "Clinical pharmacist practitioner" means a licensed pharmacist in good standing who meets the requirements specified in 37-7-306.

(6) "Collaborative pharmacy practice" means the practice of pharmacy by a pharmacist who has agreed to work in conjunction with one or more prescribers, on a voluntary basis and under protocol, and who may

perform certain patient care functions under certain specified conditions or limitations authorized by the prescriber.

(7) "Collaborative pharmacy practice agreement" means a written and signed agreement between one or more pharmacists and one or more prescribers that provides for collaborative pharmacy practice for the purpose of drug therapy management of patients.

(8) "Commercial purposes" means the ordinary purposes of trade, agriculture, industry, and commerce, exclusive of the practices of medicine and pharmacy.

(9) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device based on:

(a) a practitioner's prescription drug order;

(b) a professional practice relationship between a practitioner, pharmacist, and patient;

(c) research, instruction, or chemical analysis, but not for sale or dispensing; or

(d) the preparation of drugs or devices based on routine, regularly observed prescribing patterns.

(10) "Confidential patient information" means privileged information accessed by, maintained by, or transmitted to a pharmacist in patient records or that is communicated to the patient as part of patient counseling.

(11) "Controlled substance" means a substance designated in Schedules II through V of Title 50, chapter 32, part 2.

(12) "Department" means the department of labor and industry provided for in Title 2, chapter 15, part 17.

(13) "Device" has the same meaning as defined in 37-2-101.

(14) "Dispense" or "dispensing" means the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for administration to or use by a patient.

~~(15) "Distribute" means the delivery of a drug or device by means other than administering or dispensing.~~

(15) "Distribute" or "distribution" means the sale, purchase, trade, delivery, handling, storage, or receipt of a drug or device and does not include administering or dispensing a prescription drug, pursuant to section 353(b)(1), or a new animal drug, pursuant to section 360b(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, et seq.

(16) "Drug" means a substance:

(a) recognized as a drug in any official compendium or supplement;

(b) intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(c) other than food, intended to affect the structure or function of the body of humans or animals; and

(d) intended for use as a component of a substance specified in subsection (16)(a), (16)(b), or (16)(c).

(17) "Drug utilization review" means an evaluation of a prescription drug order and patient records for duplication of therapy, interactions, proper utilization, and optimum therapeutic outcomes. The term includes but is not limited to the following evaluations:

(a) known allergies;

(b) rational therapy contraindications;

(c) reasonable dose and route administration;

(d) reasonable directions for use;

(e) drug-drug interactions;

(f) drug-food interactions;

(g) drug-disease interactions; and

(h) adverse drug reactions.

(18) "Equivalent drug product" means a drug product that has the same established name, active ingredient or ingredients, strength or concentration, dosage form, and route of administration and meets the same standards as another drug product as determined by any official compendium or supplement. Equivalent drug products may differ in shape, scoring, configuration, packaging, excipients, and expiration time.

(19) "FDA" means the United States food and drug administration.

~~(19)~~(20) "Health care facility" has the meaning provided in 50-5-101.

~~(20)~~(21) (a) "Health clinic" means a facility in which advice, counseling, diagnosis, treatment, surgery, care, or services relating to preserving or maintaining health are provided on an outpatient basis for a period of less than 24 consecutive hours to a person not residing at or confined to the facility.

(b) The term includes an outpatient center for primary care and an outpatient center for surgical services, as those terms are defined in 50-5-101, and a local public health agency as defined in 50-1-101.

(c) The term does not include a facility that provides routine health screenings, health education, or immunizations.

~~(21)~~(22) "Hospital" has the meaning provided in 50-5-101.

~~(22)~~(23) "Intern" means:

(a) a person who is licensed by the state to engage in the practice of pharmacy while under the personal supervision of a preceptor and who is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist;

(b) a graduate of an accredited college of pharmacy who is licensed by the state for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;

(c) a qualified applicant awaiting examination for licensure; or

(d) a person participating in a residency or fellowship program.

~~(23)~~(24) "Long-term care facility" has the meaning provided in 50-5-101.

~~(24)~~(25) ~~(a)~~ "Manufacturing" means the production, preparation, propagation, conversion, 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.

~~(b) Manufacturing includes:~~

~~(i) any packaging or repackaging;~~

~~(ii) labeling or relabeling;~~

~~(iii) promoting or marketing; and~~

~~(iv) preparing and promoting commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons.~~

~~(25)~~(26) "Medicine" means a remedial agent that has the property of curing, preventing, treating, or mitigating diseases or which is used for this purpose.

(27) "Outsourcing facility" means a facility at one geographic location or address that:

(a) engages in compounding of sterile drugs;

(b) has elected to register as an outsourcing facility with FDA; and

(c) complies with all the requirements of section 353b of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq.

~~(26)~~(28) "Participant" means a physician's office, pharmacy, hospital, or health clinic that has elected to voluntarily participate in the cancer drug repository program provided for in 37-7-1403 and that accepts donated cancer drugs or devices under rules adopted by the board.

~~(27)~~(29) "Patient counseling" means the communication by the pharmacist of information, as defined by the rules of the board, to the patient or caregiver in order to ensure the proper use of drugs or devices.

~~(28)~~(30) "Person" includes an individual, partnership, corporation, association, or other legal entity.

~~(29)~~(31) "Pharmaceutical care" means the provision of drug therapy and other patient care services 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.

~~(30)~~(32) "Pharmacist" means a person licensed by the state to engage in the practice of pharmacy and who may affix to the person's name the term "R.Ph.".

~~(31)~~(33) "Pharmacy" means an established location, either physical or electronic, registered by the board where drugs or devices are dispensed with pharmaceutical care or where pharmaceutical care is provided.

~~(32)~~(34) "Pharmacy technician" means an individual who assists a pharmacist in the practice of pharmacy.

~~(33)~~(35) "Poison" means a substance that, when introduced into the system, either directly or by absorption, produces violent, morbid, or fatal changes or that destroys living tissue with which it comes in contact.

~~(34)~~(36) "Practice of pharmacy" means:

(a) interpreting, evaluating, and implementing prescriber orders;

(b) administering drugs and devices pursuant to a collaborative practice agreement, except as provided in 37-7-105, and compounding, labeling, dispensing, and distributing drugs and devices, including patient counseling;

(c) properly and safely procuring, storing, distributing, and disposing of drugs and devices and maintaining proper records;

(d) monitoring drug therapy and use;

(e) initiating or modifying drug therapy in accordance with collaborative pharmacy practice agreements established and approved by health care facilities or voluntary agreements with prescribers;

(f) participating in quality assurance and performance improvement activities;

(g) providing information on drugs, dietary supplements, and devices to patients, the public, and other health care providers; and

(h) participating in scientific or clinical research as an investigator or in collaboration with other investigators.

~~(35)~~(37) "Practice telepharmacy" means to provide pharmaceutical care through the use of information technology to patients at a distance.

~~(36)~~(38) "Preceptor" means an individual who is registered by the board and participates in the instructional training of a pharmacy intern.

~~(37)~~(39) "Prescriber" has the same meaning as provided in 37-7-502.

~~(38)~~(40) "Prescription drug" means any drug that is required by federal law or regulation to be dispensed only by a prescription subject to section ~~503(b)~~ 353(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ~~353~~ 301 et seq.

~~(39)~~(41) "Prescription drug order" means an order from a prescriber for a drug or device that is communicated directly or indirectly by the prescriber to the furnisher by means of a signed order, by electronic transmission, in person, or by telephone. The order must include the name and address of the prescriber, the prescriber's license classification, the name and address of the patient, the name, strength, and quantity of the drug, drugs, or device prescribed, the directions for use, and the date of its issue. These stipulations apply to written, oral, electronically transmitted, and telephoned prescriptions and orders derived from collaborative pharmacy practice.

~~(40)~~(42) "Provisional community pharmacy" means a pharmacy that has been approved by the board, including but not limited to federally qualified health centers, as defined in 42 CFR 405.2401, where prescription drugs are dispensed to appropriately screened, qualified patients.

~~(41)~~(43) "Qualified patient" means a person who is uninsured, indigent, or has insufficient funds to obtain needed prescription drugs or cancer drugs.

~~(42)~~(44) "Registry" means the prescription drug registry provided for in 37-7-1502.

~~(43)~~(45) "Utilization plan" means a plan under which a pharmacist may use the services of a pharmacy technician in the practice of pharmacy to perform tasks that:

(a) do not require the exercise of the pharmacist's independent professional judgment; and

(b) are verified by the pharmacist.

~~(44)~~(46) "Wholesale" means a sale for the purpose of resale."

Section 2. Section 37-7-201, MCA, is amended to read:

"37-7-201. Organization -- powers and duties. (1) The board shall meet at least once a year to

transact its business. The board shall annually elect from its members a president, vice president, and secretary.

(2) The board shall regulate the practice of pharmacy in this state, including but not limited to:

(a) establishing minimum standards for:

(i) equipment necessary in and for a pharmacy;

(ii) the purity and quality of drugs, devices, and other materials dispensed within the state through the practice of pharmacy, using an official compendium recognized by the board or current practical standards;

(iii) specifications for the facilities, including outsourcing facilities, as well as for the environment, supplies, technical equipment, personnel, and procedures for the storage, compounding, or dispensing of drugs and devices;

(iv) monitoring drug therapy; and

(v) maintaining the integrity and confidentiality of prescription information and other confidential patient information;

(b) requesting the department to inspect, at reasonable times:

(i) places where drugs, medicines, chemicals, or poisons are sold, vended, given away, compounded, dispensed, or manufactured; and

(ii) the appropriate records and the license of any person engaged in the practice of pharmacy for the purpose of determining whether any laws governing the legal distribution of drugs or devices or the practice of pharmacy are being violated. The board shall cooperate with all agencies charged with the enforcement of the laws of the United States, other states, or this state relating to drugs, devices, and the practice of pharmacy. It is a misdemeanor for a person to refuse to permit or otherwise prevent the department from entering these places and making an inspection.

(c) regulating:

(i) the training, qualifications, employment, licensure, and practice of interns;

(ii) the training, qualifications, employment, and registration of pharmacy technicians; and

(iii) under therapeutic classification, the sale and labeling of drugs, devices, medicines, chemicals, and poisons;

(d) examining applicants and issuing and renewing licenses of:

(i) applicants whom the board considers qualified under this chapter to practice pharmacy;

(ii) pharmacies and certain stores under this chapter;

(iii) wholesale ~~drug~~ distributors; ~~and~~

(iv) third-party logistics providers as defined in 37-7-602; and

(v) persons engaged in the manufacture and distribution of drugs or devices;

(e) in concurrence with the board of medical examiners, defining the additional education, experience, or certification required of a licensed pharmacist to become a certified clinical pharmacist practitioner;

(f) issuing certificates of "certified pharmacy" under this chapter;

(g) establishing and collecting license and registration fees;

(h) approving pharmacy practice initiatives that improve the quality of, or access to, pharmaceutical care but that fall outside the scope of this chapter. This subsection (2)(h) may not be construed to expand on the definition of the practice of pharmacy.

(i) establishing a medical assistance program to assist and rehabilitate licensees who are subject to the jurisdiction of the board and who are found to be physically or mentally impaired by habitual intemperance or the excessive use of addictive drugs, alcohol, or any other drug or substance or by mental illness or chronic physical illness. The board shall ensure that a licensee who is required or volunteers to participate in the medical assistance program as a condition of continued licensure or reinstatement of licensure must be allowed to enroll in a qualified medical assistance program within this state and may not require a licensee to enroll in a qualified treatment program outside the state unless the board finds that there is no qualified treatment program in this state.

(j) making rules for the conduct of its business;

(k) performing other duties and exercising other powers as this chapter requires; and

(l) adopting and authorizing the department to publish rules for carrying out and enforcing parts 1 through 7 of this chapter, including but not limited to:

(i) requirements and qualifications for the transfer of board-issued licenses;

(ii) minimum standards for pharmacy internship programs and qualifications for licensing pharmacy interns;

(iii) qualifications and procedures for registering pharmacy technicians; and

(iv) requirements and procedures necessary to allow a pharmacy licensed in another jurisdiction to be registered to practice telepharmacy across state lines.

(3) The board may:

(a) join professional organizations and associations organized exclusively to promote the improvement of standards of the practice of pharmacy for the protection of the health and welfare of the public and whose activities assist and facilitate the work of the board; and

(b) establish standards of care for patients concerning health care services that a patient may expect with regard to pharmaceutical care."

Section 3. Section 37-7-601, MCA, is amended to read:

"37-7-601. Scope and purpose. This part applies to ~~a person or entity engaged in~~ the wholesale distribution, third-party logistics, manufacturing, or repackaging of prescription drugs in this state. The purpose of this part is to implement the federal Prescription Drug Marketing Act of 1987 and the Drug Quality and Security Act of 2013, which includes but is not limited to the Drug Supply Chain Security Act, by providing minimum standards, terms, and conditions for licensing by the department of persons or entities engaged in the wholesale ~~distributions~~ distribution, third-party logistics, manufacturing, or repackaging of prescription drugs."

Section 4. Section 37-7-602, MCA, is amended to read:

"37-7-602. Definitions. As used in this part, the following definitions apply:

~~(1) "Blood" means whole blood collected from a single donor and processed either for transfusion or for further manufacturing.~~

~~(2) "Blood component" means that part of blood separated by physical or mechanical means.~~

(1) (a) "Dispenser" means a retail pharmacy, a hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of the entities listed in this subsection (1)(a), if they are under common ownership and control and do not act as a wholesale distributor.

(b) The term does not include a person who dispenses only products used in animals in accordance with FDA laws and regulations.

~~(3) "Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.~~

~~(4)~~(2) "Manufacturer" means ~~a person or entity engaged in the manufacturing, preparing, propagating,~~

~~compounding, processing, packaging, repackaging, or labeling of a prescription drug or device.~~:

(a) a person approved by application to the FDA to manufacture a product as defined in section 360eee of the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq., or a biologic pursuant to 42 U.S.C. 262;

(b) a person who manufactures a product as defined in section 360eee of the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq., or a biologic pursuant to 42 U.S.C. 262 that is not the subject of an approved application or license by the FDA;

(c) a colicensed partner of a person described in subsection (2)(a) or (2)(b) that obtains the product directly from a person described in subsection (2)(a), (2)(b), or (2)(d); or

(d) an affiliate of a person described in subsection (2)(a), (2)(b), or (2)(c) that receives the product directly from a person described in subsection (2)(a), (2)(b), or (2)(c).

~~(5)~~(3) "Prescription drug" has the same meaning as provided in 37-7-101.

(4) "Repackager" means a person who owns or operates an establishment that repacks and relabels a product or a package for:

(a) further sale; or

(b) distribution without a further transaction.

(5) "Third-party logistics provider" or "3PL" means an entity that provides or coordinates warehousing or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product but does not take ownership of the product or have responsibility to direct the sale or disposition of the product.

(6) "Transaction" has the same meaning as provided in section 360eee of the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq.

~~(6)~~(7) (a) "Wholesale ~~drug~~ distribution" means distribution of prescription drugs to persons other than a consumer or patient.

(b) The term does not include~~:~~

~~(i) intracompany sales;~~

~~(ii) 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 group purchasing organizations;~~

~~(iii) 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 Internal Revenue Code, 26 U.S.C. 501(c)(3), as amended, to a nonprofit affiliate of the organization to the extent otherwise permitted by law;~~

~~(iv) 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 subsection (6)(b)(iv), "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, contract, or otherwise.~~

~~(v) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons. For the purposes of this subsection (6)(b)(v), "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.~~

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

~~(vii) the distribution of drug samples by manufacturers' representatives or distributors' representatives; or~~

~~(viii) the sale, purchase, or trade of blood and blood components intended for transfusion~~ the exclusions listed in section 353(e)(4) of the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq.

~~(7)~~(8) "Wholesale ~~drug~~ distributor" means a person or entity, other than a manufacturer, a manufacturer's colicensed partner, a third-party logistics provider, or a repackager, who is engaged in wholesale distribution of prescription drugs~~, including but not limited to manufacturers, repackers, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail pharmacies that conduct wholesale distributions~~."

Section 5. Section 37-7-603, MCA, is amended to read:

"37-7-603. Prohibited purchase or receipt of drugs -- dispensing and distribution restrictions ~~on wholesale drug distributors~~ -- penalty. (1) Except as otherwise provided, it is unlawful for a person to knowingly purchase or receive a prescription drug from a source other than a person or entity licensed under this part.

(2) Licensed wholesale ~~drug~~ distributors, third-party logistics providers, manufacturers, and repackagers ~~other than pharmacies~~ may not dispense or distribute prescription drugs directly to patients, except when the licensed wholesale distributor is also a licensed pharmacy.

(3) A person who violates the provisions of this section is guilty of a misdemeanor."

Section 6. Section 37-7-604, MCA, is amended to read:

"37-7-604. Wholesale ~~drug~~ distributor, third-party logistics provider, manufacturer, and repackager licensing requirements -- fee -- federal compliance. (1) A person or distribution outlet may not act as a wholesale ~~drug~~ distributor, third-party logistics provider, manufacturer, or repackager without first obtaining a license from the board and paying the license fee.

(2) A license may not be issued or renewed for a wholesale ~~drug~~ distributor, third-party logistics provider, manufacturer, or repackager to operate in this state unless the applicant:

(a) agrees to abide by federal and state law and to comply with the rules adopted by FDA and the board; and

(b) pays the license fee set by the board.

(3) The board in its discretion may require that a separate license be obtained for:

(a) each facility directly or indirectly owned or operated by the same business entity within the state; or

(b) a parent entity with divisions, subsidiaries, or affiliates within the state if operations are conducted at more than one location and joint ownership and control exists among all entities.

(4) ~~In order to obtain and maintain a wholesale drug distributorship in this state, an~~ An applicant for a license under this section or for a license renewal shall provide written documentation to the board attesting that the applicant has maintained and will continue to maintain:

(a) adequate storage conditions and facilities;

(b) minimum liability and other insurance that may be required by applicable federal or state law;

(c) a functioning security system that includes:

(i) an after hours central alarm or comparable entry detection system;

(ii) restricted access to the premises;

(iii) comprehensive employee applicant screening; and

(iv) safeguards against employee theft;

(d) a system of records setting forth all activities of wholesale ~~drug~~ distribution, third-party logistics, manufacturing, or repackaging ~~as defined in 37-7-602~~ for at least a period of the 2 previous years. The system of records must be accessible, as defined by board regulations, for inspections authorized by the board.

(e) a list of active entity principals, including officers, directors, primary shareholders, and management executives, who shall at all times demonstrate and maintain their responsibility for conducting the business in conformity with sound financial practices as well as state and federal law;

(f) complete, updated information, to be provided to the board as a condition for obtaining and ~~retaining~~ renewing a license, pertaining to each wholesale ~~drug~~ distributor, third-party logistics provider, manufacturer, or repackager to be licensed, including but not limited to:

(i) all pertinent corporate license information, if applicable; and

(ii) other information regarding ownership, principals, key personnel, and facilities;

(g) a written protocol of procedures and policies that ~~assures~~ ensures preparation by the ~~wholesale drug distributor~~ applicant or licensee under this section for the handling of security or operational problems, including but not limited to those caused by:

(i) natural disaster or government emergency;

(ii) inventory inaccuracies or product shipping and receiving;

(iii) insufficient inspections for all incoming and outgoing product shipments;

(iv) lack of control of outdated or other unauthorized products;

(v) inappropriate disposition of returned goods; and

(vi) failure to promptly comply with product recalls; and

(h) operations in compliance with all federal requirements applicable to a wholesale ~~drug distribution~~ distributor, third-party logistics provider, manufacturer, or repackager.

(5) An agent or employee of a licensed wholesale ~~drug~~ distributor, third-party logistics provider, manufacturer, or repackager need not be licensed as a wholesale ~~drug~~ distributor, third-party logistics provider, manufacturer, or repackager.

(6) For purposes of this section, all rules and regulations promulgated by the board must conform to the wholesale ~~drug~~ distributor, third-party logistics provider, manufacturer, and repackager licensing guidelines and rules formally adopted by the ~~United States food and drug administration~~ FDA. If a conflict arises between ~~a food and drug administration~~ an FDA guideline or rule and a rule or regulation of the board, the former controls.

(7) Wholesale distributors, third-party logistics providers, manufacturers, and repackagers licensed by the board shall comply with the tracing requirements defined in sections 353 and 360eee of the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq., and all corresponding guidelines and rules."

Section 7. Section 37-7-605, MCA, is amended to read:

"37-7-605. Out-of-state ~~wholesale drug distributor~~ licensing requirements. (1) An out-of-state wholesale ~~drug~~ distributor, third-party logistics provider, manufacturer, or repackager may not conduct business in this state without first obtaining a license from the board and paying the license fee established by the board.

(2) Application for a license under this section must be made on an approved form.

(3) The issuance of a license may not affect tax liability imposed by the department of revenue on any out-of-state ~~wholesale drug distributor~~ license.

(4) A person acting as principal or agent for an out-of-state ~~wholesale drug distributor~~ licensee may not sell or distribute prescription drugs in this state unless the wholesale distributor, third-party logistics provider, manufacturer, or repackager has obtained a license."

Section 8. Section 37-7-606, MCA, is amended to read:

"37-7-606. Licenses. ~~The~~ A license for a wholesale ~~drug distributors~~ distributor, third-party logistics provider, manufacturer, or repackager is effective during the period specified by department rule."

Section 9. Section 37-7-609, MCA, is amended to read:

"37-7-609. Board access to ~~wholesale drug~~ records. Wholesale ~~drug~~ distributors, third-party logistics providers, manufacturers, and repackagers may keep records at a central location apart from the principal office of the wholesale ~~drug~~ distributor, third-party logistics provider, manufacturer, and repackager or the location where the drugs are stored and from where they are shipped, ~~provided that~~ if the records ~~must be~~ are available for inspection within 2 working days of a request by the board. The records may be kept in any form permissible under federal law applicable to prescription drug recordkeeping."

Section 10. Section 37-7-610, MCA, is amended to read:

"37-7-610. Rulemaking authority. (1) The board shall adopt rules and regulations necessary to carry out the purpose and enforce the provisions of this part, including FDA guidelines and rules pursuant to the Drug Quality and Security Act of 2013, which includes the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq., to implement:

(a) product tracing, reporting, and other requirements compliant with FDA uniform national policy; or

(b) national standards for the licensing of wholesale distributors, third-party logistics providers, manufacturers, and repackagers.

(2) If the rules and regulations conflict with the wholesale ~~drug distribution~~ distributor, third-party logistics provider, manufacturer, or repackager guidelines or rules promulgated by the ~~United States food and drug administration~~ FDA, the latter control."

Section 11. Criminal background check for wholesale distributors and third-party logistics providers. (1) Each applicant for licensure as a wholesale distributor or a third-party logistics provider shall submit a full set of the applicant's fingerprints to the board for the purpose of obtaining a state and federal criminal history background check.

(2) Each license applicant is responsible to pay all fees charged in relation to obtaining the state and federal criminal history background check.

(3) The board may require a licensee renewing a license to submit a full set of the licensee's fingerprints to the board for the purpose of obtaining a state and federal criminal history background check.

(4) The Montana department of justice may share the fingerprint data obtained under subsection (1) or (3) with the federal bureau of investigation.

Section 12. Bond requirements for wholesale distributors. An applicant for licensure as a wholesale distributor and all wholesale distributors renewing licenses shall comply with the surety bond requirements as provided in rule.

Section 13. Codification instruction. [Sections 11 and 12] are intended to be codified as an integral part of Title 37, chapter 7, part 6, and the provisions of Title 37, chapter 7, part 6, apply to [sections 11 and 12].

Section 14. Severability. If a part of [this act] is invalid, all valid parts that are severable from the invalid part remain in effect. If a part of [this act] is invalid in one or more of its applications, the part remains in effect in all valid applications that are severable from the invalid applications.

- END -

I hereby certify that the within bill,

SB 0068, originated in the Senate.

President of the Senate

Signed this _____ day

of _____, 2017.

Secretary of the Senate

Speaker of the House

Signed this _____ day

of _____, 2017.

SENATE BILL NO. 68

INTRODUCED BY D. BARRETT

BY REQUEST OF THE BOARD OF PHARMACY

AN ACT REVISING LICENSING AND REGULATIONS FOR WHOLESALE DISTRIBUTORS, THIRD-PARTY LOGISTICS PROVIDERS, MANUFACTURERS, AND REPACKAGERS OF PRESCRIPTION DRUGS; INCORPORATING REFERENCES TO FEDERAL DRUG SUPPLY CHAIN AND OTHER FEDERAL LAWS; DEFINING "OUTSOURCING FACILITY" AND PROVIDING OTHER DEFINITIONS; PROVIDING FOR CRIMINAL BACKGROUND CHECKS FOR WHOLESALE DISTRIBUTORS AND THIRD-PARTY LOGISTICS PROVIDERS; AND AMENDING SECTIONS 37-7-101, 37-7-201, 37-7-601, 37-7-602, 37-7-603, 37-7-604, 37-7-605, 37-7-606, 37-7-609, AND 37-7-610, MCA.