HOUSE BILL NO. 679

INTRODUCED BY J. KARJALA

A BILL FOR AN ACT ENTITLED: “AN ACT CREATING A WHOLESALE DRUG IMPORTATION PROGRAM; PROVIDING PROGRAM DESIGN AND IMPLEMENTATION REQUIREMENTS; PROVIDING FOR AN ANNUAL REPORT; PROVIDING RULEMAKING AUTHORITY; PROVIDING DEFINITIONS; PROVIDING AN APPROPRIATION; AMENDING SECTION 37-7-201, MCA; AND PROVIDING AN IMMEDIATE EFFECTIVE DATE.”

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

NEW SECTION. **Section 1. Definitions.** As used in [sections 1 through 5], the following definitions apply:

(1) "340B covered entity" and "340B drug pricing program" have the same meaning provided in 33-22-170.

(2) "Licensed drug wholesaler" 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.

(3) "Program" means the wholesale prescription drug importation program.

(4) "Wholesale distribution" has the meaning provided in 37-7-602.

NEW SECTION. **Section 2. Importation of prescription drugs -- program design -- funding design -- submittal.** (1) The department and board, in consultation with appropriate federal and state agencies and other interested parties, shall design a wholesale prescription drug importation program that complies with the applicable requirements of 21 U.S.C. 384, including the requirements regarding safety and cost savings. The program design must:

(a) designate a state agency that shall either become a licensed drug wholesaler or contract with a licensed drug wholesaler in order to seek federal certification and approval to import safe, life-saving, or health-

maintaining prescription drugs and provide significant prescription drug cost savings to consumers;

(b) use prescription drug suppliers located in Canada who are regulated under the laws of Canada or of one or more Canadian provinces, or both;

(c) ensure that only prescription drugs meeting the United States food and drug administration's safety, effectiveness, and other standards are imported by or on behalf of the state;

(d) import only those prescription drugs that are:

(i) necessary for sustaining life or maintaining a healthy standard of living; and

(ii) expected to generate substantial savings for consumers;

(e) ensure that the program complies with the tracking and tracing requirements of 21 U.S.C. 360eee and 360eee-1 to the extent feasible and practical prior to imported drugs coming into the possession of the licensed drug wholesaler and ensure that the program complies fully after imported drugs are in the possession of the licensed drug wholesaler;

(f) prohibit the distribution, dispensing, or sale of imported products outside the state;

(g) recommend a charge for each prescription to ensure that the program is adequately funded in a manner that:

(i) does not jeopardize significant consumer savings; and

(ii) creates a net neutral budget for the department; and

(h) include a robust audit function to be performed by the office of budget and program planning.

(2) The department and board shall consult with the office of the attorney general to identify the potential for and to monitor for anticompetitive behavior in industries that would be affected by the program.

(3) The department and board shall:

(a) submit a request for approval and certification of the program to the United States department of health and human services no later than May 1, 2022; and

(b) seek the appropriate federal approvals, waivers, exemptions, or agreements, or a combination of these, as needed to enable all covered entities enrolled in or eligible for the federal 340B drug pricing program to participate in the state's program to the fullest extent possible without jeopardizing their eligibility for the 340B program.

NEW SECTION. **Section 3. Rulemaking authority.** The board shall adopt rules and regulations necessary to carry out the purpose and enforce the provisions of [sections 1 through 5] to include developing a list of eligible prescription drugs for the program no later than January 1, 2022.

NEW SECTION. **Section 4. Program implementation -- timing of implementation -- requirements.** (1) On receipt of federal approval and certification under 21 U.S.C. 384, the state agency designated to oversee the program pursuant to this chapter shall implement the program as required in [section 2].

(2) The program must begin operating no later than 6 months following receipt of federal approval and certification.

(3) Prior to operating the program, the state agency designated to oversee the program pursuant to [sections 1 through 5] shall:

(a) become a licensed drug wholesaler or enter a contract with a licensed drug wholesaler in the state;

(b) contract with one or more wholesale distributors licensed in the state;

(c) contract with one or more licensed and regulated prescription drug suppliers in Canada;

(d) engage with health insurance carriers or plans, employers, pharmacies, health care providers, and consumers;

(e) develop a registration process for health insurance carriers, pharmacies, pharmacists, and health care providers authorized to prescribe and administer prescription drugs who are willing to participate in the program;

(f) create a publicly accessible website for listing the prices of prescription drugs imported under the program;

(g) create an outreach and marketing plan to generate program awareness;

(h) provide a telephone hotline to answer questions and address the needs of consumers, employers, health insurance carriers or plans, pharmacies, health care providers, and others affected by the program;

(i) coordinate the audit function and a 2-year audit work-plan cycle with the office of budget and program planning; and

(j) conduct any other activities the department determines are necessary to successfully implement and operate the program.

NEW SECTION. **Section 5. Annual report.** Beginning in August 2022 and each year afterward, the state agency designated to oversee the program pursuant to this chapter shall report, in accordance with 5-11-210, to the legislature, appropriate interim committees, governor, attorney general, department of health and human services, department of labor and industry, and board of pharmacy regarding the implementation and operation of the program during the previous calendar year, including:

(1) the prescription drugs included in the program;

(2) the number of participating health insurance carriers or plans, pharmacies, and health care providers;

(3) the number of prescriptions dispensed through the program;

(4) the estimated cost savings to health insurance carriers or plans, employers, consumers, and the state during the previous calendar year and to date;

(5) information regarding implementation of the audit work plan and audit findings; and

(6) any other information the state agency considers relevant.

Section 6. 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 distributors;

(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) overseeing the wholesale drug importation program;

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

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

~~(l)~~(m) 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."

NEW SECTION. **Section 7. Appropriation.** There is appropriated $300,000 from the general fund to the department of labor and industry for the wholesale drug importation program for the biennium beginning July 1, 2021. If federal funds under the American Rescue Plan Act are appropriate for funding the program, there is appropriated $300,000 in federal funds. The appropriation of general fund is reduced by an amount equal to the amount for federal funds appropriated under this section.

NEW SECTION. **Section 8. Codification instruction.** [Sections 1 through 5] are intended to be codified as an integral part of Title 37, chapter 7, and the provisions of Title 37, chapter 7, apply to [sections 1 through 5].

NEW SECTION. **Section 9. Effective date.** [This act] is effective on passage and approval.

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