Agency Proposal for Legislation for the 2017 Legislative Session

AGENCY NAME: Department of Labor and Industry

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1. What is the problem or issue?

In order to comply with changes in federal law, Board of Pharmacy needs to amend wholesale drug distribution licensing.

2. What do you want the legislation to do?

In 2013 Congress passed legislation changing the way the Food and Drug Administration (FDA) and states will regulate wholesale drug distribution. The FDA is now implementing some of these changes, have released guidelines to states on federal and state implementation of these new laws, and is drafting rules for national licensing standards.

The essence of these changes is that wholesale drug distribution is being redefined, while other acts related to drug distribution are now being classified separately. The FDA has informed states they may retain regulatory authority over wholesale drug distribution and the newly-created classifications if the states adopt statutes and rules consistent with federal requirements. The Board's current statutes regarding wholesale drug distribution are inconsistent with the new federal requirements, which means the Board will lose its regulatory authority over current licensees unless the statutes are updated.

Presently, the Board issues 1 license type, wholesale drug distributor, for all acts related to drug distribution. The new federal requirements limit who is defined as a wholesale drug distributor, and establish new license types for those related acts of distribution that the Board currently licenses under its 1 license type. Therefore, to comply with the new federal requirements, the Board will need to propose the following:

Redefine wholesale drug distribution in Title 37, chapter 7, part 6, MCA, to comply with new federal requirements. This will result in narrowing the Board's definitions of wholesale drug distribution/distributor and revise the statutory scope of wholesale drug distribution to reference new federal laws.

Require fingerprinting/background checks for wholesale drug distributor applicants – new federal requirements include fingerprinting/background checks for the person-in-charge of the wholesale drug distributor. The Board does not currently require fingerprinting/background checks for wholesale drug distributor applications, and therefore needs to include this requirement to comply with federal law.

The FDA is creating new national licensing standards for wholesale drug distributor applicants which are not known at this time. The Board will provide notice if these standards are published shortly requiring the Board's statute on license requirements to be modified. Otherwise, 37-7-604(6), MCA provides that FDA guidelines control when they conflict with the Board's statutes or rules.

Create new license type for Third-Party Logistics Providers (3PL) – presently, the Board's statutory definition of wholesale drug distribution is so broad that it includes acts related to distribution, including 3PLs who coordinate the shipping and warehousing of the drugs from manufactures to wholesalers to pharmacies, but do not take ownership of the drugs. Because of the new federal requirements, the Board will no longer be able to license 3PLs as wholesale drug distributors, and will therefore have to create a new license type for 3PLs.

Additionally, the Board will need to add a similar provision to 37-7-604(6), MCA for 3PLs, as the FDA is creating new national licensing standards which are not known at this time. As explained above, 37-7-604(6), MCA provides that FDA guidelines control when they conflict with the Board's statutes or rules.

Create new (catch-all) license type for all other acts of drug distribution – similar to 3PLs, the new federal requirements prohibit all other actors involved in the drug distribution process (i.e. manufacturer, repackage, etc.) from being included in the definition and licensure of wholesale drug distributors or 3PLs. Therefore, the Board must create a new license type for all of these remaining actors who participate in the wholesale drug distribution process and are currently licensed by the Board as wholesale drug distributors.

Define "outsourcing facilities" – the new federal requirements now define outsourcing facilities, which are involved in the sterile compounding process. The Board will need to add a similar definition to the FDA one, and make sure it has the rulemaking authority to issue an outsourcing facility endorsement on existing license types

(mail-order pharmacy and wholesale drug distributor).

3. If possible, please list the MCA (Montana Code Annotated) sections that would need to be amended.

See above and 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, 37-7-610 AND 37-7-1511, MCA.

4. If the proposed change requires additional funding, what funding sources do you propose (e.g., an increase in or both)?

Fiscal Impact estimated to be: $24,000 per year

5. Has similar legislation been requested in the past, been introduced in another state, or provided as a model act? If so, please provide a citation, reference, or point of contact.

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