STATE BOARD OF PHARMACY

Regulation of wholesale and retail drug distributors

- Expressly requires the State Board of Pharmacy to license out-of-state business operations involved in the retail and wholesale sale of drugs: terminal distributors, wholesale distributors, outsourcing facilities, third-party logistics providers, repackagers, and manufacturers.
- Increases the fees for issuing and renewing licenses for in-state terminal distributors.
- Requires all licensed drug distributors to have a responsible person designated and available at all times, to notify the Board of the person designation, and to pay a fee of $15 to make a change.
- Increases the fees for issuing and renewing registration for pharmacy technicians.

Instruments to reduce drug poisoning

- Expands, beyond fentanyl testing strips, the items that may be lawfully possessed and used to test for the presence of drugs and to prevent drug poisoning, without being considered in violation of the prohibition against drug paraphernalia.
- Requires the Board to adopt rules for approving additional types of instruments that may be possessed and used because they demonstrate efficacy in reducing drug poisoning by determining the presence of specific compounds.

Regulation of retail and wholesale drug distributors

Nonresident operations – licensure and fees

(R.C. 4729.52, 4729.54, and 4729.551, repealed; conforming changes in R.C. 3719.04, 4729.56, 4729.561, and 4729.60)

The bill expressly requires the State Board of Pharmacy to license out-of-state business operations involved in the retail and wholesale drug supply chain: terminal distributors, wholesale distributors, outsourcing facilities, third-party logistics providers, repackagers, and manufacturers. The bill's requirement replaces existing provisions that indirectly require or only authorize the Board to license out-of-state operations.

The bill designates the licenses that are issued to out-of-state operations as "nonresident licenses," which corresponds with existing Board rules addressing out-of-state licensure of terminal distributors.[128] For the remaining types of drug distributors, the bill requires the nonresident license that is issued to include an appropriate subcategory designation, based on the type of business involved: wholesale distributor of dangerous drugs, outsourcing facility,

[128] See O.A.C. Chapter 4729:5-8.

third-party logistics provider, repackager of dangerous drugs, or manufacturer of dangerous drugs.

For a terminal distributor, the fee for issuing or renewing a nonresident license is $500. For the remaining types of drug distributors, the fee for issuing or renewing a nonresident license is $2,000.

Procedures for issuing and renewing a nonresident license are the same as those that the Board uses for licensing in-state operations. Where necessary, the bill makes distinctions between provisions that apply differently to in-state or out-of-state operations.

For terminal distributors, the bill clarifies that the Board's general confidentiality requirements apply when investigatory information is received through agreements with other regulatory agencies. This requirement currently exists under agreements involving investigations of the remaining types of drug distributors.

In-state terminal distributor fees

(R.C. 4729.54)

Regarding the various categories of terminal distributor licenses that the Board issues to in-state operations, the bill increases the fees for initial and renewed licenses as follows:

- $360 (from $320) for a Category II license, including a limited license. (Category II excludes controlled substances.)
- $460 (from $440) for a Category III license, including a limited license and a pain management clinic license. (Category III includes controlled substances.)
- $160 (from $120) for a terminal distributor license that must be obtained by an entity that typically is exempt from licensure, except for that fact that it possesses controlled substances, compounded drugs, or drugs used in compounding.[129]
- $160 (from $120) for a terminal distributor license obtained by a veterinary practice.
- $160 (from $120) for a terminal distributor license obtained by an emergency medical service organization satellite.

Responsible person

(R.C. 4729.52 and 4729.54; conforming changes in R.C. 4729.53 and 4729.80)

The bill requires each type of drug distributor licensed by the Board, both in-state and out-of-state, to designate a person to serve for the licensed location as its responsible person. To qualify, a person must meet the requirements established by the Board in rules. There must be a responsible person available at all times. Along with the license holder, the designated person accepts responsibility for the operation of the licensed location in accordance with state and federal laws and rules.

[129] See R.C. 4729.541.

Each licensed drug distributor must notify the Board of the designated responsible person and any subsequent change that is made. Notice is to be provided in accordance with Board rules. For any change of responsible person, the Board must assess a fee of $15.

To correspond with the statutory requirement to designate a responsible person, the bill modifies provisions of existing law that indirectly acknowledge that the Board has adopted rules establishing a responsible person requirement.[130]

Pharmacy technicians

(R.C. 4729.901, 4729.902, and 4729.921)

Regarding the Board's current regulation of pharmacy technicians in their various categories, the bill increases the fees that are charged as follows:

- $65 (from $50) for initial registration as a registered pharmacy technician or certified pharmacy technician;
- $65 (from $50) for the biennial renewal of registration as a registered pharmacy technician or certified pharmacy technician. (The bill reflects in statute the two-year registration period that is currently established by Board rule.[131])
- $40 (from $25) for registration as a pharmacy technician trainee. (By Board rule, a trainee's registration is valid for 18 months, which the bill reflects by adjusting the existing one-year statutory minimum accordingly.[132])

Instruments to reduce drug poisoning

(R.C. 4729.261 (primary) and 2925.14)

The bill expands the types of items that a person may possess and use to test for the presence of drugs, and thereby prevent drug poisoning, without being guilty of the crime of illegal use or possession of drug paraphernalia. As part of its expansion, the bill maintains the exemption that currently applies only to fentanyl testing strips, and it extends the exemption to other items if they have been approved by the Board.

For purposes of the bill, the Board must adopt rules establishing standards and procedures for its approval of types of instruments that demonstrate efficacy in reducing drug poisoning by determining the presence of a specific compound or group of compounds. The Board is not permitted to approve any type of instrument to the extent that it is intended to measure the purity of a mixture.

[130] See O.A.C. 4729:5-2-01 and 4729:6-2-01.

[131] O.A.C. 4729:3-2-03.

[132] O.A.C. 4729:3-2-01(D).