STATE BOARD OF PHARMACY

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 criminal prohibition against drug paraphernalia.
- Requires the State Board of Pharmacy 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 wholesale and retail drug distributors

- Expressly requires the Board to license out-of-state business operations involved in retail and wholesale drug sales: 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 licensed drug distributors to have a responsible person designated and available at all times, to notify the Board of the person designated, and to pay a fee to make a change.
- Increases the fees for issuing and renewing registration for pharmacy technicians.

Instruments to reduce drug poisoning

(R.C. 2925.14 and 4729.261)

The act 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. Specifically, the items comprise any equipment, products, or material approved in rules adopted by the State Board of Pharmacy as demonstrating efficacy in reducing drug poisoning by determining the presence of a specific compound or group of compounds. The act maintains the criminal law exemption that applies to fentanyl testing strips.

The Board must adopt rules establishing standards and procedures for its approval of additional items. The Board may not approve any type of instrument that is intended to measure the purity of a mixture.

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(R.C. 4729.52, 4729.54, and 4729.551, repealed; conforming changes in R.C. 3719.04, 4729.56, 4729.561, and 4729.60)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 act expressly requires the Board 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 requirement replaces law that indirectly required or only authorized the Board to license out-of-state operations.

The act designates the licenses for out-of-state operations as "nonresident licenses," which corresponds with Board rules addressing out-of-state licensure of terminal distributors.[122] For the remaining types of drug distributors, the act requires a nonresident license to include an appropriate subcategory designation, based on the type of business involved: wholesale distributor of dangerous drugs, outsourcing facility, 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 for licensing in-state operations. Where necessary, the act distinguishes between provisions that apply differently to in-state or out-of-state operations.

For terminal distributors, the act clarifies that the Board's general confidentiality requirements apply when investigatory information is received through agreements with other regulatory agencies. This corresponds with continuing law that applies to 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 act 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.)

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

- $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.[123]
- $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 act requires each type of licensed drug distributor, both in-state and out-of-state, to designate a person to serve as the licensed location's responsible person. To qualify, a person must meet requirements established by Board rule. A responsible person must be 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.

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 act modifies law that indirectly acknowledged that the Board had adopted rules establishing a responsible person requirement.[124]

Pharmacy technicians

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

Regarding the Board's regulation of pharmacy technicians in their various categories, the act increases the fees 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 act reflects in statute the two-year registration period established by Board rule.[125])
    - $40 (from $25) for registration as a pharmacy technician trainee. (By Board rule, a trainee's registration is valid for 18 months, which the act reflects by adjusting the existing one-year statutory minimum accordingly.[126])

[123] See R.C. 4729.541.

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

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

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