OHIO LEGISLATIVE SERVICE COMMISSION

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Office of Research and Drafting

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H.B. 558
134th General Assembly

Bill Analysis

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Version: As Passed by the House

Primary Sponsors: Reps. Roemer and Jordan

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SUMMARY

Drug repository program

- Revises the laws governing the State Board of Pharmacy's Drug Repository Program, including by exempting charitable pharmacies, hospitals, and nonprofit clinics from current law's general prohibition on accepting or distributing drugs not in their original sealed and tamper-evident unit dose packaging.
- Excludes from the program any drug for which the federal Food and Drug Administration requires, as a risk evaluation and mitigation strategy, that the patient be registered with the drug's manufacturer.
- Exempts charitable pharmacies, hospitals, and nonprofit clinics from the existing law prohibition on reselling drugs donated to the program, by authorizing those entities to make occasional sales of donated drugs at wholesale.
- Exempts charitable pharmacies participating in the program from the licensure and renewal fees that otherwise must be paid to operate as a pharmacy.
- Extends the authority to distribute drugs under the program to licensed health professionals authorized to prescribe drugs.
- Eliminates the requirement that the Board consult with the Director of Health when adopting rules.
- Makes other changes to the program's laws, including several conforming changes.

Temporary changes regarding certificates of need

- For a certificate of need (CON) granted during the period of the COVID-19 state of emergency:
  - Requires the Director of Health to grant a CON holder a 24-month extension to obligate capital expenditures and commence construction for a proposed project;

- Provides that the transfer of a CON, or transfer of the controlling interest in an entity that holds a CON, does not void the CON, so long as recognizing the transfer would not result in a violation of existing law that prohibits a CON application from being approved in various circumstances.

DETAILED ANALYSIS

Drug repository program

The bill modifies the laws governing the State Board of Pharmacy's Drug Repository Program, a program for the collection and redistribution of drugs donated or given by pharmacies, drug manufacturers, health care facilities, and others to Ohio residents who meet eligibility standards established by the Board in rules.[1]

Charitable pharmacies, hospitals, and nonprofit clinics

Two of the bill's substantive changes relate to charitable pharmacies, hospitals, and nonprofit clinics participating in the Drug Repository Program. Each is described briefly below.

Original sealed and tamper-evident unit dose packaging

In general under current law, only drugs in their original sealed and tamper-evident unit dose packaging may be accepted and distributed under the Drug Repository Program. The bill, however, authorizes drugs that are not in their original sealed and tamper-evident unit dose packaging to be accepted and distributed if done so by a charitable pharmacy, hospital, or nonprofit clinic. This authority is subject to rules that are to be adopted by the Board of Pharmacy. The existing law exclusion of controlled substances is retained.

The bill specifies that the authority being granted to a charitable pharmacy, hospital, or nonprofit clinic extends to both (1) orally administered cancer drugs and (2) drugs that may require storage at a special temperature. For other participating pharmacies, the bill retains a provision that permits drugs not in their original sealed and tamper-evident unit dose packaging to be accepted and distributed only if they are orally administered cancer drugs that do not require refrigeration, freezing, or storage at a special temperature.[2]

Occasional sales of donated drugs at wholesale

The bill establishes an exemption to the current law prohibition on reselling drugs that are donated or given to the Drug Repository Program, by authorizing – in Board rules – charitable pharmacies, hospitals, and nonprofit clinics to make occasional sales of donated drugs at wholesale.[3]

[1] R.C. 3715.87 to 3715.873.

[2] R.C. 3715.871.

[3] R.C. 3715.871 and 3715.873.

Definitions

Under the bill, "**charitable pharmacy**" is defined as a pharmacy that meets all of the following requirements:

- Holds a terminal distributor license issued by the Board of Pharmacy;
- Is exempt from federal taxation;
- Is not a hospital.[4]

The bill expands the definition of "**nonprofit clinic**" to include those that provide health care services to underinsured persons, as defined in Board rules. At present, for purposes of the Drug Repository Program, a nonprofit clinic is one that provides health care services only to indigent and uninsured persons.[5]

Drugs under certain risk evaluation and mitigation strategies

The bill excludes from the Drug Repository Program a drug, as determined in accordance with Board of Pharmacy rules, for which the federal Food and Drug Administration (FDA) requires, as a risk evaluation and mitigation strategy, or REMS, that the patient be registered with the drug's manufacturer.[6] For more information on the FDA's REMS drug safety program, see the following: Risk Evaluation and Mitigation Strategies and What's in a REMS?

Distribution by prescribers

Under existing law, when an entity participating in the Drug Repository Program distributes a drug to an eligible individual, the distribution must be pursuant to a prescription. The bill clarifies this provision by referring to a pharmacist as the health professional who performs the action of dispensing a drug. In addition, the provision is broadened by authorizing a drug to be distributed by being personally furnished by a licensed health professional authorized to prescribe, often referred to as a prescriber.[7] The bill makes a conforming change to include prescribers in the immunity from civil liability provisions that currently apply under the program.[8]

Facilitating the donation or gift of drugs

At present, any pharmacy, drug manufacturer, health care facility, or other person or government entity may donate or give prescription drugs to the Drug Repository Program. The bill maintains this authority, but also permits any person or government entity to facilitate the

[4] R.C. 3715.87 and 3719.811, not in the bill.

[5] R.C. 3715.87.

[6] R.C. 3715.87(C)(2)(b) and 3715.873(J).

[7] R.C. 3715.871.

[8] R.C. 3715.872.

donation or gift of drugs. The bill neither defines nor describes the act of facilitating a donation or gift.[9]

Rules on eligible drugs and forms for making donations

Existing law requires the Board of Pharmacy to adopt rules governing the program, including rules that establish lists of drugs that the program can and cannot accept. Separate lists must be established regarding drugs that may be donated by individuals and drugs that may be donated by health care facilities. Rather than requiring separate lists outlining the drugs that can and cannot be accepted, with distinctions based on the type of donor, the bill instead requires just one: a list of the drugs or drug types ineligible for donation.

Current law also directs the Board to establish in rule a form that must be signed when a donation is made to the program directly by an individual. Under the bill, the Board also must establish a form to be signed by an individual who represents a person or government entity that is donating drugs to the program. The form must allow for the individual representative to state that the person or entity being represented is the drugs' owner and intends to voluntarily donate them to the program.[10]

Handling fees

Current law authorizes an entity participating in the Drug Repository Program to charge individuals receiving donated or given drugs a handling fee, with the fee to be set by the Board of Pharmacy according to a formula established in rules. Under existing Board rules, a participating entity may charge a handling fee up to $20.[11] The bill maintains a provision specifying that the handling fee is to cover restocking and distribution costs, but also specifies that the fee is to be nominal.[12]

Consultation with the Director of Health

The bill eliminates the requirement that the Board of Pharmacy consult with the Director of Health when adopting rules governing the Drug Repository Program. In a corresponding change, the bill removes the Director from the current law provisions describing the persons and entities that receive immunity from civil liability under the program.[13]

Fee exemption for participating charitable pharmacies

Current law requires a pharmacy, including a charitable pharmacy, to hold a terminal distributor license issued by the Board of Pharmacy in order to operate in the state.[14] As part of

[9] R.C. 3715.871.

[10] R.C. 3715.873. *See also* Ohio Administrative Code (O.A.C.) 4729:5-10-06(A)(2).

[11] O.A.C. 4729:5-10-07(G).

[12] R.C. 3715.871 and 3715.873.

[13] R.C. 3715.872 and 3715.873.

[14] R.C. 4729.54.

the process of applying for an initial license and later renewing that license every two years, the pharmacy must submit to the Board a licensure or renewal fee, which may range from $320 to $440 depending on the type of terminal distributor license the pharmacy holds.[15] The bill exempts a charitable pharmacy participating in the Drug Repository Program from the requirement to pay such fees.[16]

Temporary changes regarding certificates of need

Under current law, certain activities involving long-term care facilities, such as constructing a new facility or increasing bed capacity, may be conducted only if a certificate of need (CON) has been granted by the Director of Health.[17] The bill makes the following two changes regarding certificates of need that were granted during the COVID-19 state of emergency (from March 9, 2020 through June 18, 2021):

- First, it grants a CON holder a 24-month extension to obligate capital expenditures and commence construction for a proposed project.[18]
- Second, it provides that the transfer of a CON, or the transfer of a controlling interest in an entity that holds a CON, prior to completion of the reviewable activity for which the CON was granted, does not void the CON.

In the event of such a transfer, the Director must recognize the transfer of ownership of the entity granted the CON to the new owner, but only on receipt of written notice from the transferee that provides sufficient evidence to enable the Director to determine that recognizing the new owner and operator would not result in a violation of existing law that prohibits a CON application from being approved.[19]

[15] At present, a pharmacy may hold a category II, limited category II, category III, or limited category III terminal distributor license. Under a category III license, a pharmacy may possess and distribute drugs, including schedule I, II, III, IV, and V controlled substances, while a category II license authorizes a pharmacy to possess and distribute drugs other than controlled substances. Under a limited category II or III license, a pharmacy may possess and dispense only the drugs listed in the application for licensure. *See* R.C. 4729.54(E).

[16] R.C. 4729.54(G) and (I). *See also* O.A.C. 4729:5-2-02(B).

[17] R.C. 3702.51 to 3702.62, not in the bill.

[18] Section 3(A).

[19] Section 3(B); reasons for which a CON must be denied under current law can be found in R.C. 3702.59, not in the bill.

HISTORY

Action	Date
Introduced	02-01-22
Reported, H Health	03-30-22
Passed House (96-0)	04-06-22

ANHB0558PH-134/ar