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H.B. 645
134th General Assembly

Bill Analysis

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Version: As Passed by the House

Primary Sponsors: Reps. Fraizer and Holmes

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SUMMARY

- Authorizes the operation of remote dispensing pharmacies and charges the State Board of Pharmacy with their regulation.
- Requires a remote dispensing pharmacy to be staffed by two or more pharmacy interns or certified pharmacy technicians and overseen and operated by both a supervising pharmacy and pharmacist through the use of a telepharmacy system.
- Requires the Board to adopt rules governing the operation of remote dispensing pharmacies within 18 months of the bill's effective date and, if the Board fails to do so, authorizes the Ohio Attorney General or a county prosecuting attorney to apply for a court order requiring their adoption.

DETAILED ANALYSIS

Remote dispensing pharmacies

The bill requires the State Board of Pharmacy to regulate remote dispensing pharmacies.¹ Under the bill, such a pharmacy is one where a supervising pharmacist – using a telepharmacy system – dispenses drugs and drug therapy related devices, counsels patients, and provides other pharmacist care.² A telepharmacy system is one that monitors the dispensing of drugs and provides for related drug utilization review and patient counseling services by an electronic method.³

¹ R.C. 4729.554(B).

² R.C. 4729.554(A)(1).

³ R.C. 4729.554(A)(2).

Eligibility conditions

In order to operate as a remote dispensing pharmacy, the pharmacy must satisfy all of the following:

- Be licensed by the Pharmacy Board as a terminal distributor of dangerous drugs;
- Be staffed by two or more pharmacy interns or certified pharmacy technicians who meet qualifications and training requirements established by the Board in rules;
- Be overseen and operated by a supervising pharmacy and have a supervising pharmacist who is in full and actual charge of the remote dispensing pharmacy through the use of a telepharmacy system and surveillance system, both of which must meet Board standards established in rules;
- Operate only by using a telepharmacy system that meets Board standards and is under the control of its supervising pharmacy;
- Be physically located in Ohio, in a building that is zoned for commercial use, and more than ten miles from an outpatient pharmacy.⁴

Note, however, that the bill authorizes a remote pharmacy to be within this ten-mile limitation if (1) it is part of a federally qualified health center or federally qualified health center look-alike or (2) the Pharmacy Board, based on a demonstration of need, approves the pharmacy's physical location.

Operational conditions

The bill establishes conditions on the operation of each remote dispensing pharmacy. These include all of the following:

- The pharmacy must not fill prescriptions at a rate that exceeds an average of 150 prescriptions per day during a 90-day period, unless otherwise approved by the Pharmacy Board.
- The pharmacy must implement a quality assurance plan to ensure that there is a planned and systematic process for monitoring and evaluating the quality and appropriateness of the pharmacy services.
- If the pharmacy holds a category III terminal distributor of dangerous drugs license, it must maintain a perpetual controlled substance inventory, as specified in Board rules.⁵

⁴ R.C. 4729.554(C).

⁵ R.C. 4729.554(F), (G), and (H).

Pharmacy interns and technicians

The bill also sets limits on the practice of pharmacy interns and certified pharmacy technicians.⁶ When staffing a remote dispensing pharmacy, these practitioners are prohibited from doing any of the following:

- Counseling an individual regarding the individual's drug therapy, recommending drugs and drug therapy related devices, or assisting with the selection of drugs and drug therapy related devices for treatment of common diseases and injuries or with providing instruction on their use;
- Performing sterile or nonsterile drug compounding, except for the reconstitution of prepackaged dangerous drugs;
- Engaging in the repackaging of dangerous drugs;
- Administering immunizations or performing diagnostic testing, unless a pharmacist is onsite to provide direct supervision;
- Any other activities prohibited in Pharmacy Board rules.

Supervising pharmacies

The bill establishes requirements and prohibitions on the pharmacies that supervise remote dispensing pharmacies.⁷ First, it requires a supervising pharmacy to be both licensed by the Pharmacy Board as a terminal distributor of dangerous drugs and located in Ohio. Second, the bill directs a supervising pharmacy to be either (1) under common ownership or control as the remote dispensing pharmacy or (2) under a contract that meets requirements specified in Pharmacy Board rules. Third, it prohibits a supervising pharmacy from overseeing or operating more than one remote dispensing pharmacy.

Supervising pharmacists

With respect to a pharmacist who is in full and actual charge of a remote dispensing pharmacy, the bill sets a number of conditions and limitations on the pharmacist's supervision.⁸ The supervising pharmacist must be licensed by the Pharmacy Board, physically located in Ohio, and employed by or under contract with the supervising pharmacy. In addition, the supervising pharmacist must not simultaneously oversee the activities of a remote dispensing pharmacy and a nonremote dispensing pharmacy or any other location licensed by the Pharmacy Board, unless otherwise approved by the Board.

The supervising pharmacist must oversee the pharmacy interns and certified pharmacy technicians who are assisting in the dispensing process at the remote dispensing pharmacy and

⁶ R.C. 4729.554(I).

⁷ R.C. 4729.554(D).

⁸ R.C. 4729.554(E).

must provide that oversight through a telepharmacy system and surveillance system. Next, the supervising pharmacist must verify each prescription and dispensed drug before the drug leaves the remote dispensing pharmacy. Such verification includes a visual review and the use of barcoding and any other technology required in Board rules. Finally, the supervising pharmacist must offer to provide patient counseling for each drug dispensed under a new prescription.

Rulemaking

The bill requires the Pharmacy Board to adopt rules governing the regulation of remote dispensing pharmacies.⁹ The Board must do so in accordance with Ohio's Administrative Procedure Act and not later than 18 months after the bill's effective date. If the Board fails to meet this deadline, the bill authorizes the Ohio Attorney General or a county prosecuting attorney to apply to a court of common pleas for a court order requiring the rules to be adopted.¹⁰

The Board must include all of the following in the required rules:

- Standards for a system of continuous video surveillance and recording of each remote dispensing pharmacy, including establishing an adequate number of views of the entire pharmacy and requiring the retention of each recording for at least 60 days;
- Standards for telepharmacy systems and surveillance systems used by remote dispensing pharmacies, including standards to ensure that the systems are capable of (a) facilitating a safe and secured method for appropriate pharmacist supervision, (b) allowing an appropriate exchange of visual, verbal, and written communications for patient counseling and other pharmacy services, and (c) being secure and compliant with the federal Health Insurance Portability and Accountability Act (HIPAA);
- Requirements for the contract between a supervising pharmacy and remote dispensing pharmacy;
- Standards for making a determination of need in the case of a remote dispensing pharmacy seeking to locate within ten miles of an outpatient pharmacy;
- Requirements for implementing a remote dispensing pharmacy's quality assurance plan;
- The qualifications and training necessary for pharmacy interns and certified pharmacy technicians who staff remote dispensing pharmacies, including the number of experiential hours required;
- Any additional activities that pharmacy interns and certified pharmacy technicians are prohibited from performing;

⁹ R.C. 4729.554(J).

¹⁰ Section 2.

- The number of pharmacy interns and certified pharmacy technicians that a supervising pharmacist may supervise at any given time;
- The maximum distance that a supervising pharmacist may be physically located from the remote dispensing pharmacy;
- Standards for remote patient counseling by a supervising pharmacist, including the counseling required to be offered for each drug dispensed under a new prescription;
- Standards for and frequency of remote dispensing pharmacy inspections by the supervising pharmacist;
- Requirements for the closure of a remote dispensing pharmacy if its telepharmacy system or surveillance system, or any related security system used by the pharmacy, is malfunctioning;
- Requirements related to perpetual controlled substance inventories;
- Security requirements for remote dispensing pharmacies that include methods for supervising pharmacists to determine who has accessed the pharmacy;
- Limits on the number of remote dispensing pharmacies that a supervising pharmacist may oversee at one time to ensure patient safety and sufficient staffing to meet the prescription workload;
- Requirements for a remote dispensing pharmacy's responsible person;
- Any other standards or procedures the Board considers necessary to implement the bill's provision.

Telehealth provisions of H.B. 122

Effective since March 23, 2022, H.B. 122 authorizes specified health care professionals, including pharmacists, to provide telehealth services, or health care services through the use of information and communication technology by a health care professional who is located at a site other than the site where the recipient is located.¹¹ However, in the case of a pharmacist, the pharmacist may not use telehealth mechanisms or other virtual means to perform any actions involved in dispensing a prescription drug, unless specifically authorized under State Board of Pharmacy rules.¹²

¹¹ R.C. 4743.09, not in the bill.

¹² R.C. 4729.285, not in the bill.

HISTORY

Action	Date
Introduced	05-11-22
Reported, H. Health	12-13-22
Passed House (90-2)	12-13-22
