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Bill Analysis

Version: As Reported by Senate Health

Primary Sponsor: Sen. Reynolds

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SUMMARY

Remote dispensing pharmacies

- Authorizes the operation of remote dispensing pharmacies and requires the State Board of Pharmacy to regulate them.
- 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.

Mailing drugs to patients

- Prohibits health plan issuers, pharmacy benefit managers, and other administrators from prohibiting a pharmacy from mailing or delivering drugs to patients as ancillary services.

Pharmacist administration of injectable drugs

- Authorizes a pharmacist to administer by injection the following drugs if prescribed by a physician and if other conditions specified in current law are met: HIV treatment drugs in long-acting or extended-release forms and any other drug specified in rules adopted by the Board.

Pharmacy technician trainees

- Authorizes the Board to register as a pharmacy technician trainee an applicant who is age 17 and possesses a high school diploma or certificate of high school equivalence.

DETAILED ANALYSIS

Remote dispensing pharmacies

The bill requires the State Board of Pharmacy to regulate remote dispensing pharmacies.¹ The bill defines “remote dispensing pharmacy” as one where the dispensing of drugs, counseling of patients, and other pharmacist care is provided through a telepharmacy system. Dispensing of drugs at the pharmacy may include the dispensing of drug therapy related devices.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

Eligibility conditions

To operate as a remote dispensing pharmacy, the pharmacy must satisfy all of the following:

- Be licensed by the Board as a terminal distributor of dangerous drugs;
- Use only a telepharmacy system that meets standards established by the Board in rules;
- Be staffed by two or more pharmacy interns or certified pharmacy technicians;
- Have a supervising pharmacy and supervising pharmacist;
- Be located in Ohio, in a building that is zoned for commercial use;
- In general, not be located within a ten-mile radius of an outpatient pharmacy.⁴

Exceptions to the exclusion area surrounding an outpatient pharmacy

The bill establishes circumstances when a remote dispensing pharmacy’s proximity to an outpatient pharmacy may be closer than ten miles. Specifically, the ten-mile radius around an outpatient pharmacy that otherwise constitutes an area of exclusion does not apply in relation to (1) federally qualified health centers (FQHCs) and (2) locations approved by the Board based on a demonstration of need.⁵

Regarding FQHCs, the bill permits a remote dispensing pharmacy to be within the ten-mile radius of an outpatient pharmacy if the remote pharmacy is part of an FQHC or an FQHC look-alike, which is a facility that meets the eligibility requirements for federal FQHC

¹ R.C. 4729.554(B).

² R.C. 4729.554(A)(1).

³ R.C. 4729.554(A)(2).

⁴ R.C. 4729.554(B) and (C).

⁵ R.C. 4729.554(C)(2)(b).

funding but does not receive it. The remote pharmacy must be located on the same property as, or a campus contiguous to, the FQHC or look-alike.

Regarding location approvals based on a demonstration of need, the bill requires a remote dispensing pharmacy to meet standards established by the Board in rules for demonstrating the need. Further, as part of the Board's approval process, the bill requires the Board to establish a method by which persons may register to receive notice from the Board of requests for location approvals. The Board also must establish a system for accepting public comments regarding the requests. When the Board receives a request, it must electronically notify persons who register to be notified, and post notice on its website regarding a public comment period of 60 days. During that 60-day period, the Board must permit other pharmacies to submit requests for location approvals. After that period ends, the Board, in determining whether any of the location requests should be approved, must consider public comments, supervising pharmacy location in relation to the proposed remote dispensing pharmacy, and any other standards specified in rules. The determination must be made at the Board's next regularly scheduled meeting that occurs on or after the date that is 90 days after the electronic notices described above were sent.⁶

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 Board.
- The pharmacy must implement a quality assurance plan to ensure that there is a planned and systematic process for (1) monitoring and evaluating the quality and appropriateness of the pharmacy services and (2) identifying and resolving problems.
- 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.⁷

Pharmacy interns and technicians

The bill sets limits on the practice of pharmacy interns and certified pharmacy technicians when assisting in the process of dispensing drugs.⁸ When staffing a remote dispensing pharmacy, these practitioners are prohibited from doing any of the following:

- Counseling an individual regarding drugs that are dispensed, recommending drugs and drug therapy related devices or otherwise providing advice, or assisting with the

⁶ R.C. 4729.554(C)(2)(c).

⁷ R.C. 4729.554(F).

⁸ R.C. 4729.554(G).

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;
- Performing any other activities prohibited in Board rules.

Supervising pharmacies

The bill establishes requirements to be met by the pharmacies that supervise remote dispensing pharmacies.⁹ First, it requires a supervising pharmacy to be both licensed by the Board as a terminal distributor of dangerous drugs and located in Ohio. Second, the supervising pharmacy must either (1) be under common ownership and control with the remote dispensing pharmacy or (2) operate under a contract that meets requirements specified in Board rules. Third, it requires the supervising pharmacy to control the telepharmacy system used by the remote dispensing pharmacy and to employ or contract with the supervising pharmacist of the remote dispensing pharmacy.

Supervising pharmacists

The bill sets a number of conditions and limitations on the pharmacist who serves as the supervising pharmacist of a remote dispensing pharmacy.¹⁰ The supervising pharmacist must be licensed by the Board, physically located in Ohio, and employed by or under contract with the supervising pharmacy. In serving in this position, the supervising pharmacist must be in full and actual charge of the pharmacy by using its telepharmacy system and surveillance system. The pharmacist is prohibited from simultaneously overseeing the activities of more than one remote dispensing pharmacy, 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 must provide that oversight through the pharmacy's 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.

⁹ R.C. 4729.554(D).

¹⁰ R.C. 4729.554(E).

Rulemaking

The bill requires the Board to adopt rules governing the regulation of remote dispensing pharmacies.¹¹ 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.¹²

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, 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 any contract between a supervising pharmacy and remote dispensing pharmacy;
- Standards for making a demonstration 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;
- 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;

¹¹ R.C. 4729.554(H).

¹² Section 3.

- 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;
- Standards by which a supervising pharmacist may be approved to oversee more than one remote dispensing pharmacy simultaneously;
- Requirements for a remote dispensing pharmacy's responsible person;
- Any other standards or procedures the Board considers necessary to implement the bill's provisions on remote dispensing pharmacies.

Telehealth

Regarding existing law that generally authorizes health care professionals to provide telehealth services, the bill makes adjustments to account for the authority being granted to pharmacists to practice through remote dispensing pharmacies.¹³ Currently, a pharmacist may use telehealth to perform an action involved in dispensing a prescription drug only if the action is authorized through Board rules. The bill specifies that a pharmacist's telehealth authority also applies to drug dispensing actions performed through remote dispensing pharmacies.¹⁴

Mailing drugs to patients

The bill prohibits health plan issuers, pharmacy benefit managers, and other administrators from prohibiting a pharmacy from mailing or delivering drugs to patients as ancillary services.¹⁵

Pharmacist administration of injectable drugs

The bill adds drugs to existing law that authorizes pharmacists to administer by injection certain drugs prescribed by a physician. The additional drugs are (1) HIV treatment drugs in long-acting or extended-release forms and (2) any other drugs specified in rules adopted by the Board. The bill maintains other drugs authorized under current law, which include addiction treatment and antipsychotic drugs administered in long-acting or extended-release forms. The

¹³ R.C. 4743.09, not in the bill.

¹⁴ R.C. 4729.285.

¹⁵ R.C. 3959.22.

bill maintains pharmacist training, protocol, and other requirements in current law that apply to pharmacist administration of injectable drugs.¹⁶

Pharmacy technician trainees

The bill authorizes the Board to register as a pharmacy technician trainee an applicant who is age 17 and possesses a high school diploma or certificate of high school equivalence. Current law provides a pathway for a 17-year-old to be registered, but only if the individual is enrolled in certain career-technical school programs that are approved by the Board. By permitting the Board to accept the completion of high school education, the bill creates an additional pathway for 17-year-olds to be registered.¹⁷

HISTORY

Action	Date
Introduced	03-23-23
Reported, S. Health	05-08-24

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¹⁶ R.C. 4729.45.

¹⁷ R.C. 4729.921(B).