



Common Sense Initiative

Mike DeWine, Governor
Jim Tressel, Lt. Governor

Joseph Baker, Director

Business Impact Analysis

Agency, Board, or Commission Name: Ohio Board of Pharmacy

Rule Contact Name and Contact Information: Summer Reyburn
summer.reyburn@pharmacy.ohio.gov

Regulation/Package Title (a general description of the rules' substantive content):

Remote Dispensing Pharmacies

Rule Number(s): 4729:5-18-01, 4729:5-18-02, 4729:5-18-03, 4729:5-18-04, 4729:5-18-05, 4729:5-18-06, 4729:5-18-07

Date of Submission for CSI Review: 6/12/2025

Public Comment Period End Date: 7/18/2025

Rule Type/Number of Rules:

New/ 7 rules

No Change/ 0 rules (FYR?)

Amended/ 0 rules (FYR?)

Rescinded/ 0 rules (FYR?)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIPublicComments@governor.ohio.gov

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- a. ☐ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**
- b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**
- c. ☐ **Requires specific expenditures or the report of information as a condition of compliance.**
- d. ☒ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **Please briefly describe the draft regulation in plain language.**

Please include the key provisions of the regulation as well as any proposed amendments.

4729:5-18-01 – Defines terms related to the operation of remote dispensing pharmacies.

4729:5-18-02 – Establishes requirements for the operation of remote dispensing pharmacies, including licensure.

4729:5-18-03 – Provides the exceptions to and process by which a remote dispensing pharmacy may be located within 10 miles of another outpatient pharmacy.

4729:5-18-04 – Establishes requirements for the operation of a remote dispensing pharmacy.

4729:5-18-05 – Provides the requirements pharmacy personnel must meet in order to work in a remote dispensing pharmacy.

4729:5-18-06 – Establishes the technology requirements for the telepharmacy system used in remote dispensing pharmacies.

4729:5-18-07 – Establishes the security requirements for a remote dispensing pharmacy.

- 3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

The proposed rules are authorized by sections 4729.26, 4729.554, and 3719.28 of the Ohio Revised Code.

- 4. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**
If yes, please briefly explain the source and substance of the federal requirement.

These rules do not implement a federal requirement.

- 5. If the regulation implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

This rule package exceeds federal requirements because the regulation of the practice of pharmacy and distribution of dangerous drugs has traditionally been done at the state level by legislatively created state boards of pharmacy. The regulation of the pharmacy practice and distribution of dangerous drugs includes the inspection of sites with dangerous drugs, valid requirements for the release of confidential patient records, the licensure of terminal distributors of dangerous drugs, and regulations for licensees providing medication therapy management (i.e. engaged in the practice of pharmacy). Section 4729.554 of the Ohio Revised Code requires the Board to adopt rules regarding the operation and regulation of remote dispensing pharmacies.

- 6. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the practice of pharmacy and distribution of dangerous drugs.

Section 4729.554 of the Ohio Revised Code requires the Board of Pharmacy to adopt rules regulating the operation of remote dispensing pharmacies.

Section 3719.28 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules for the administration and enforcement of Chapter 3719. of the Revised Code in order to prescribe the manner of keeping and the form and content of records to be kept by persons authorized to manufacture, distribute, dispense, prescribe, or administer controlled substances.

7. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

The success of the regulations will be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees regarding the provisions of the rules.

8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No.

Development of the Regulation

9. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

If applicable, please include the date and medium by which the stakeholders were initially contacted.

This rule package was distributed for initial public comment by posting the rule package to the Board's proposed rules website. Prior to filing with CSI, the rules were also reviewed and approved by the Board of Pharmacy.

10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

For the proposed rules, external stakeholders via public comment reviewed the proposed content of the rules. Any proposed feedback agreed to and approved by the Board was incorporated into the rule package.

The Board incorporated a comment to change the requirement for a sign designating the pharmacy as a remote dispensing pharmacy from being visible to the public (outward-facing) to being visible at the point of sale. Many of the comments received had to do with requirements of the law that cannot be changed in rule.

11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

Scientific data was not used to develop or review this rule.

- 12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**
Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.

As the regulations are essential to protecting the public's safety by ensuring uniform standards for the operation of remote dispensing pharmacies, requirements for pharmacy personnel to work in a remote dispensing pharmacy, and security of these dispensing sites, the Ohio Board of Pharmacy did not consider any regulatory alternatives.

- 13. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

The Board of Pharmacy's Director of Policy and Communications reviewed the proposed rules to ensure that the regulations do not duplicate another Ohio Board of Pharmacy regulation.

- 14. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

The rules will be posted on the Board of Pharmacy's web site, information concerning the rules will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals, and groups. Board of Pharmacy staff are also available via phone or email to answer questions regarding implementation of the rules. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

Adverse Impact to Business

- 15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:**

- a. Identify the scope of the impacted business community, and**

Terminal distributors of dangerous drugs planning to commence operations of a remote dispensing pharmacy

b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a representative business. Please include the source for your information/estimated impact.

Violation of this rule may result in administrative licensure discipline for a terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, monetary fine, and/or revocation of a license. Several components of the rules may also require money, time, and/or other resources for remote dispensing pharmacies to attain/maintain compliance with these rules.

- 4729:5-18-02: Requires remote dispensing pharmacies to obtain active licensure with the Board as a terminal distributor of dangerous drugs with a remote dispensing classification. Licensure as a terminal distributor of dangerous drugs costs between \$160 and \$220 annually. The application takes between 30-60 minutes to complete.
- 4729:5-18-04: Requires the responsible person designated for the remote dispensing pharmacy to conduct a controlled substances inventory on a quarterly basis. This may take several hours to complete.
- 4729:5-18-04: Requires remote dispensing pharmacies to implement a continuous quality improvement program. Creation of such a program may take several hours to complete and the pharmacy may experience increased administrative costs.
- 4729:5-18-04: Requires remote dispensing pharmacies to maintain a perpetual controlled substance inventory to provide accountability in all aspects of controlled substance distribution. Time of on-site staff will be required to maintain this inventory to ensure the security of controlled substances at a remote dispensing pharmacy.
- 4729:5-18-06: Requires remote dispensing pharmacies to utilize a telepharmacy system to ensure the safe and accurate dispensing and verification of dangerous drugs. The supervising pharmacy may or may not already have acquired this technology, which ranges in price and installation cost.
- 4729:5-18-07: Requires remote dispensing pharmacies to utilize a surveillance system to ensure the supervising pharmacist may appropriately oversee activities at the remote dispensing pharmacy. Costs associated with this requirement may include those for cameras, video monitors, alarm systems, locks, and keys.

16. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify. (*Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors*).

No.

17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The Board determined that the regulatory intent justifies the impact on business because the regulations protect and promote public safety by ensuring uniform standards for the operation of remote dispensing pharmacies.

Regulatory Flexibility

18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

These rules do not provide any exemptions or alternative means of compliance for small businesses. The law does not differentiate on the size of the business and therefore the regulation is uniform across Ohio.

19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure of a standard of care in the practice of pharmacy or the preparation/distribution of dangerous drugs is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

20. What resources are available to assist small businesses with compliance of the regulation?

Board of Pharmacy staff is available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek updates on current regulations and host regional meetings to discuss changes to Ohio laws and rules. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

The Board has also developed inspection guides that licensees can use to conduct self-inspections. These guides align with internal guidance used by Board inspectors and allow licensees to conduct self-inspections to maintain compliance. The guides also include links to the rules, important definitions, and reminders of when a licensee is required to submit notification or additional information to the Board.

Rule 4729:5-18-01 – Definitions – remote dispensing pharmacies.

As used in Chapter 4729:5-18 of the Administrative Code:

(A) "Remote dispensing pharmacy" means a pharmacy where the dispensing of drugs, patient counseling, and other pharmacist care is provided through a telepharmacy system. The dispensing of drugs at a remote dispensing pharmacy may include the dispensing of drug therapy-related devices.

(B) "Telepharmacy system" means a system that monitors the dispensing of drugs and provides for related drug utilization review and patient counseling services by an electronic method, that complies with the requirements of Chapter 4729: 5-18-06. The telepharmacy system shall include the following technologies:

(1) Audio and video;

(2) Still image capture; and

(3) Store and forward.

(C) "Surveillance system" means a system providing continuous video footage of the remote dispensing pharmacy that is recorded and stored for at least sixty days, and that complies with the requirements of Chapter 4729: 5-18-07.

(D) "Supervising pharmacy" means a pharmacy licensed as a terminal distributor of dangerous drugs that exclusively oversees the operations of a remote dispensing pharmacy.

(E) "Supervising pharmacist" means a pharmacist holding a current Ohio license to practice pharmacy who has met the requirements to supervise a remote dispensing pharmacy as described in this chapter.

(F) "Responsible person" means the same as in Chapter 4729:5-2-01 of the Administrative Code.

(G) "Social vulnerability" means the demographic and socioeconomic factors that contribute to communities being more adversely affected by external hazards and stressors that cause disease and injury.

(H) “Social vulnerability index” or “SVI” means a risk score assigned to communities using U.S. Census data. These data are grouped into four themes that cover four major areas of social vulnerability (household characteristics, house type & transportation, racial & ethnic minority status, and socioeconomic status) and then combined into a single measure of overall social vulnerability. The overall SVI score ranges from 0 (least vulnerable) to 1 (most vulnerable).

Rule 4729:5-18-02 – Licensure of remote dispensing pharmacies.

(A) A remote dispensing pharmacy shall apply for and obtain a terminal distributor of dangerous drugs license with a remote dispensing classification.

(B) The remote dispensing pharmacy shall comply with the licensing requirements of Chapter 4729:5-2 of the Administrative Code.

(C) Remote dispensing pharmacies shall have a pharmacist designated as the responsible person in accordance with Chapter 4729:5-2-01 of the Administrative Code.

(D) The responsible person designated for a remote dispensing pharmacy shall be the same responsible person as is designated for the supervising pharmacy. The responsible person may, but is not required to, act as a supervising pharmacist.

(E) If the supervising pharmacy and remote dispensing pharmacy are not under common ownership and control, the supervising pharmacy and remote dispensing pharmacy shall enter into a contract that specifies the services to be provided and the responsibilities and accountabilities of each party to the contract or agreement in compliance with federal and state statutes, rules, and regulations. The contract shall be maintained in a readily retrievable format.

Rule 4729:5-18-03 – Demonstration of need.

(A) Except as provided in this rule, a remote dispensing pharmacy shall not be located within a ten-mile radius of a pharmacy that serves the public as an outpatient pharmacy as defined in Chapter 4729:5-5 of the Administrative Code.

(B) A remote dispensing pharmacy may be located within the ten-mile radius of an outpatient pharmacy if either of the following apply:

(1) The remote dispensing pharmacy is part of a federally qualified health center or federally qualified health center look-alike, as defined in section 3701.047 of the Revised Code, and the remote dispensing pharmacy is located on the same property as, or on a campus contiguous to, the health center or look-alike.

(2) The board approves a request, based on a demonstration of need, that meets the standards established in paragraph (C) of this rule.

(C) A person may submit a request to the board, in a manner determined by board, to allow a remote dispensing pharmacy located within a ten-mile radius of an outpatient pharmacy if the proposed remote dispensing pharmacy is located in census block that is medium-high (0.5-0.75) or high (greater than 0.75) based upon the social vulnerability index (SVI) as designated by the board's Ohio Pharmacy Access Dashboard (accessible via www.pharmacy.ohio.gov).

(D) Persons may register to receive notice from the board (accessible via www.pharmacy.ohio.gov) of requests received pursuant to paragraph (C) of this rule. The board shall notify any person who has registered to be notified and allow for the submission of public comments on the proposed request.

(E) During the sixty-day period that begins on the date that the board sends the electronic notice, a pharmacy currently operating in the state may submit a request to the board for approval as a location for operation of a remote dispensing pharmacy.

(F) At the board's next regularly scheduled meeting that occurs on or after the date that is ninety days after the electronic notices are sent, the board shall review all the requests

received and make its determination of whether any should be approved. As part of the board's determination, the board shall consider the following:

- (1) Any comments received from the public;
- (2) The geographic proximity of a supervising pharmacy to a proposed remote dispensing pharmacy;
- (3) The supervising pharmacy has not been disciplined for violation of rule 4729:5-5-02 and all subsequent rules thereunder within the preceding twelve months;
- (4) The supervising pharmacy has not been disciplined for any significant theft or loss of dangerous drugs within the preceding twelve months; and
- (5) The supervising pharmacy is not currently on probation or has other restrictions placed upon its terminal distributor of dangerous drugs license pursuant to a settlement agreement or order of the board.

Rule 4729:5-18-04 – Operation of a remote dispensing pharmacy.

- (A) The remote dispensing pharmacy must be located within this state in a building that is zoned for commercial or industrial use and not out of a personal residence.
- (B) Remote dispensing pharmacies shall display a sign at the point of sale indicating that the facility is a remote dispensing pharmacy, that the facility is under continuous video surveillance, and that the video is recorded and retained.
- (C) The supervising pharmacy shall be exclusively responsible for the operation of the remote dispensing pharmacy and its employees.
- (D) There shall be one supervising pharmacist at all times when the remote dispensing pharmacy is operational, who shall be located in this state while serving as the supervising pharmacist.
- (E) A supervising pharmacist shall not be more than fifty miles from a remote dispensing pharmacy under that pharmacist's supervision.
- (F) To avoid disruption in pharmacy services, the supervising pharmacy shall have a process in place to ensure there is a pharmacist who meets the training requirements of this chapter if the regularly scheduled supervising pharmacist is unable to provide supervision in accordance with this chapter.
- (G) The remote dispensing pharmacy shall be staffed by at least two certified pharmacy technicians and/or pharmacy interns physically present in the remote dispensing pharmacy for the pharmacy to be open to the public.
- (H) There shall be no more than a total of three certified pharmacy technicians and/or pharmacy interns working within a remote dispensing pharmacy location unless a pharmacist is physically located on-site.
- (I) Unless approved by the board, a supervising pharmacist shall not simultaneously oversee the activities of more than one remote dispensing pharmacy. The board may consider expanding this limit to up to two remote dispensing pharmacies per one supervising pharmacist. For the board to consider a waiver of this limitation, the supervising pharmacy

shall submit documentation, in a manner determined by the Board, that sufficiently demonstrates the following:

- (1) The prescription volume and workload at the supervising pharmacy allows the supervising pharmacist to safely and effectively oversee more than one remote dispensing pharmacy;
- (2) The prescription volume and workload at the remote dispensing pharmacies allows the supervising pharmacist to safely and effectively oversee more than one remote dispensing pharmacy; and
- (3) Failure to grant this waiver may negatively impact patient health and access to pharmacy services.

(J) Certified pharmacy technicians, pharmacy interns, and pharmacists shall complete a training program to ensure that the telepharmacy system can be operated in a safe and effective manner. Training documentation shall be maintained and immediately retrievable at the remote dispensing pharmacy. Remote dispensing pharmacies must conduct additional training for their employees if any of the following occur:

- (1) The telepharmacy system used by the remote dispensing pharmacy has changed;
- (2) The existing telepharmacy system used by the remote dispensing pharmacy has undergone significant updates.

(K) Unless approved by the Board, a remote dispensing pharmacy shall not dispense drugs pursuant to Chapter 4729:5-5 of the Administrative Code more than an average of one hundred fifty prescriptions per day during a ninety-day period. For the board to consider a waiver of this limitation, a remote dispensing pharmacy shall submit documentation, in a manner determined by the Board, that sufficiently demonstrates the following:

- (1) The remote dispensing pharmacy is located in a census block that is medium-high (0.5-0.75) or high (greater than 0.75) based upon the social vulnerability index (SVI) as designated by the board's Ohio Pharmacy Access Dashboard (accessible via www.pharmacy.ohio.gov); and

(2) It is not economically feasible for the remote dispensing pharmacy to convert to an outpatient pharmacy as defined by Chapter 4729:5-5-01 of the Administrative Code.

(L) The responsible person shall perform on-site visits of the remote dispensing pharmacy at least once per quarter. The on-site visit shall be documented by the responsible person and such documentation shall be immediately retrievable at the location licensed as a remote dispensing pharmacy for three years from the date of the visit by the responsible person. As part of this site visit, the responsible person shall conduct a controlled substance inventory in accordance with rule 4729:5-3-07 of the Administrative Code.

(M) In the event that the telepharmacy system is not in operation, the supervising pharmacist must be physically located on-site to dispense prescriptions.

(N) A remote dispensing pharmacy shall implement a continuous quality improvement program in accordance with rule 4729:5-3-22 of the Administrative Code.

(O) A remote dispensing pharmacy shall comply with all applicable requirements for the operation of an outpatient pharmacy in accordance with Chapter 4729:5-5 of the Administrative Code.

(P) A remote dispensing pharmacy that holds a category III terminal distributor of dangerous drugs license shall maintain a perpetual controlled substance inventory for all controlled substances stocked by the remote dispensing pharmacy. The inventory shall be established in a manner that will provide total accountability in all aspects of controlled substance distribution.

Rule 4729:5-18-05 – Personnel requirements.

(A) The supervising pharmacy is solely responsible for ensuring that the requirements of this rule are met.

(B) Before a pharmacist may act as the supervising pharmacist for a remote dispensing pharmacy, a pharmacist shall:

- (1) Be licensed as a pharmacist under Chapter 4729. of the Revised Code;
- (2) Be physically located in this state when acting as the supervising pharmacist; and
- (3) Be employed by or under contract with the supervising pharmacy.

(C) In serving as a supervising pharmacist, the supervising pharmacist shall do all of the following:

- (1) Supervise no more than three certified pharmacy technicians and pharmacy interns per remote dispensing pharmacy.
- (2) Be in full and actual charge of the remote dispensing pharmacy by using the pharmacy's telepharmacy system and by using a surveillance system that meets standards established in this Chapter of the Administrative Code.
- (3) Through the telepharmacy system and surveillance system, oversee the pharmacy interns and certified pharmacy technicians who are staffing the remote dispensing pharmacy.
- (4) Verify each prescription and drug dispensed pursuant to the prescription before the drug leaves the remote dispensing pharmacy and provide the verification through visual review and the use of barcoding and any other technology as specified in rule 4729:5-18-06 of the Administrative Code. Barcodes shall be scanned, and not manually typed, into the system. Documentation of verification shall capture the positive identification of the supervising pharmacist.
- (5) Offer to provide the service of counseling for each drug dispensed pursuant to a new or refill prescription in accordance with rule 4729:5-5-09 of the Administrative Code.

(6) Have completed a training program on the proper use of the telepharmacy system used at the remote dispensing pharmacy.

(7) Have completed a training program on the proper use of the surveillance system used at the remote dispensing pharmacy.

(D) Before a certified pharmacy technician may work in a remote dispensing pharmacy, the certified pharmacy technician shall:

(1) Hold an active registration as a certified pharmacy technician under Chapter 4729. of the Revised Code;

(2) Hold a national certification as a pharmacy technician from an organization approved by the board, in accordance with rule 4729:3-1-01 of the Administrative Code.

(3) Have completed a training program on the proper use of the telepharmacy system used at the remote dispensing pharmacy.

(4) Have at least one thousand hours of practical experience working as a certified pharmacy technician in a pharmacy setting under the direct supervision of a pharmacist.

(5) Have worked at least one year in a pharmacy setting during the three years preceding the date the certified pharmacy technician begins working at the remote dispensing pharmacy.

(E) The supervising pharmacy must attest that all certified pharmacy technicians meet the requirements of paragraph (D) of this rule, and a record of such attestation must be immediately retrievable at the remote dispensing pharmacy.

(F) Before a pharmacy intern may work in a remote dispensing pharmacy, the pharmacy intern shall:

(1) Hold an active license as a pharmacy intern under Chapter 4729. of the Revised Code;

(2) Have at least one thousand hours of experience working as a certified pharmacy technician or pharmacy intern under the direct supervision of a pharmacist;

(3) Only five hundred hours of experience earned as part of the intern's introductory pharmacy practice experience or advanced pharmacy practice experience may count towards the one thousand hour requirement as described in paragraph (F)(2) of this rule.

(4) Have worked at least one thousand hours in a pharmacy setting during the three years preceding the date the pharmacy intern begins working at the remote dispensing pharmacy;

(5) Have completed a training program on the proper use of the telepharmacy system used at the remote dispensing pharmacy.

(G) The supervising pharmacy must attest that all working pharmacy interns meet the requirements of paragraph (F) of this rule, and a record of such attestation must be immediately retrievable at the remote dispensing pharmacy.

(H) Certified pharmacy technicians or pharmacy interns are not permitted to do any of the following while working at a remote dispensing pharmacy:

(1) Counsel an individual regarding drugs that are dispensed, recommend drugs and drug therapy-related devices or otherwise provide advice regarding drug therapy, or assist with selecting drugs and drug therapy related devices for treatment of common diseases and injuries or assist with providing instruction on their use;

(2) Perform compounding of sterile or nonsterile drugs, except for the reconstitution of prepackaged dangerous drugs;

(3) Engage in the repackaging of dangerous drugs;

(4) Administer immunizations or perform diagnostic testing, unless a pharmacist is physically onsite to provide direct supervision;

(I) Technicians-in-training, registered pharmacy technicians, or any other pharmacy personnel who do not meet the requirements of this chapter shall not engage in the practice of pharmacy or work at a remote dispensing pharmacy.

Rule 4729:5-18-06 – Technology requirements for a telepharmacy system.

(A) There shall be a fully functioning telepharmacy system in the remote dispensing pharmacy that is operational at all times that pharmacy personnel are working in the pharmacy.

(1) The telepharmacy system shall utilize positive identification and comply with the record keeping requirements for outpatient pharmacies in accordance with Chapter 4729:5-5 of the Administrative Code.

(2) All pharmacy personnel must complete a training program on proper use of the telepharmacy system and documentation of this completion must be maintained and immediately retrievable at the remote dispensing pharmacy.

(3) In the event that the telepharmacy system is not functional for more than one-business day, the supervising pharmacist or another pharmacist employed by the supervising pharmacy shall be required to be physically on-site to allow for prescriptions to be dispensed during normal business hours of the remote dispensing pharmacy.

(4) The supervising pharmacy shall have backup procedures to ensure prescriptions may be dispensed in the event of a telepharmacy system outage that is greater than one business day.

(5) In the event of a temporary telepharmacy system outage of less than the duration of one business day, the supervising pharmacist may direct the certified pharmacy technicians and/or pharmacy interns at the remote dispensing pharmacy to complete activities not requiring pharmacist verification or use of the telepharmacy system. Staff at the remote dispensing pharmacy may continue to sell prescriptions that have already been dispensed by the pharmacist. In this case, patients shall be provided with a phone number where they can obtain patient counseling in accordance with rule 4729:5-5-09 of the Administrative Code.

(6) The telepharmacy system shall comply with all the following:

(a) Chapter 3798. of the Revised Code;

(b) 42 U.S.C. 1320d et. seq.; and

(c) 45 C.F.R. parts 160, 162, and 164 for individually identifiable health information (HIPAA).

(C) The telepharmacy system shall, at a minimum, have high-definition image resolution with variable viewing options to accurately and safely dispense a dangerous drug or drug device, and sufficient data retention capabilities to investigate any quality-related events.

(1) The telepharmacy system must produce images that are high definition in that the image resolution is at least 300 pixels per inch.

(2) The images shall contain the following to ensure the pharmacist is able to appropriately verify the prescription prior to dispensing:

(a) A clear copy of the prescription label and the medication or device;

(b) The full quantity of the filled prescription;

(c) The medication stock bottle used to fill the prescription, if applicable; and

(d) Clear markings present on the pill or capsule, if applicable.

(3) Images associated with the verification of the prescription will be retained and become part of the patient's profile and maintained for one year.

(D) There shall be a working computer link, video link and audio link to the supervising pharmacist at a supervising pharmacy whenever the remote dispensing pharmacy is open to the public. The required technology must allow the supervising pharmacist to provide the personal assistance, direction, and approval needed to verify and ensure remote tasks are safely and properly performed.

(E) Written prescriptions presented to the remote dispensing pharmacy shall be scanned into the telepharmacy system to ensure initial dispensing and each refill and the original prescription may be viewed at both the remote dispensing pharmacy and the supervising pharmacy.

(1) All information in the prescription shall be scanned in full color (i.e. retains color information and/or color graphics in the document) via technology designed to capture

information in one form and reproduce it in an electronic medium presentable and usable to an end user.

(2) A prescription record or image once created shall be unalterable but may be annotated as necessary so long as the original record or image is still available for review and the individual that made the annotation is noted.

(F) Certified pharmacy technicians and/or pharmacy interns shall use barcoding technology when filling prescriptions at the remote dispensing pharmacy to ensure the accuracy of prescriptions dispensed in accordance with this chapter. Barcodes shall be scanned, and not manually typed, into the system.

(G) All records of prescriptions dispensed including the records of the actions performed through the telepharmacy system shall be maintained at the remote dispensing pharmacy and shall be maintained for three years after the filling of the prescription.

Rule 4729:5-18-07 – Security requirements for a remote dispensing pharmacy.

(A) There shall be a fully functioning surveillance system in the remote dispensing pharmacy that is operational at all times.

(1) No operations of the remote dispensing pharmacy shall commence if the surveillance system is not functional.

(2) The video produced by the surveillance system must be stored for sixty days in a readily retrievable manner.

(3) The surveillance system shall be capable of providing not less than four simultaneous camera views of the pharmacy operation at the remote dispensing pharmacy.

(B) The surveillance system must allow the supervising pharmacist to determine who has accessed the pharmacy. A supervising pharmacist shall complete a training program on proper use of the surveillance system and documentation of this completion must be maintained and immediately retrievable at the remote dispensing pharmacy.

(C) The supervising pharmacist shall supervise the remote dispensing pharmacy via the pharmacy surveillance system to deter and detect theft or diversion.

(D) The supervising pharmacist shall ensure that all dangerous drugs, drug devices, controlled substances, and hypodermics that are delivered onto the premises of the remote dispensing pharmacy are immediately placed and secured in the pharmacy.

(E) Pharmacy technicians and pharmacy interns who meet the qualifications of rule 4729:5-18-05 and are employed by the remote dispensing pharmacy may only access the pharmacy if the supervising pharmacist is providing regular supervision via the pharmacy's surveillance system.

(F) An unlicensed person is permitted to enter the remote dispensing pharmacy if all the following apply:

(1) The person is performing maintenance or repair of the pharmacy;

(2) The supervising pharmacist provides supervision of the unlicensed person via the pharmacy's surveillance system; and

(3) There are two certified pharmacy technicians or pharmacy interns present in the pharmacy to provide on-site supervision of the unlicensed person.

(G) All schedule II controlled substance dangerous drugs shall be stored in a securely locked, substantially constructed cabinet or safe and shall not be dispersed through the stock of dangerous drugs. The cabinet or safe shall remain locked and secured when not in use. Schedule III through V controlled substance dangerous drugs may be stored with Schedule II controlled substance dangerous drugs.

(H) A remote dispensing pharmacy shall be secured by both:

(1) A physical barrier (i.e. barricade) with suitable locks approved by the board. Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the board of any installation or modification to a physical barrier prior to implementation.

(2) An alarm system approved by the board that is monitored by a central station for control and can detect unauthorized access to the pharmacy. The alarm system shall be tested on a biannual basis. The pharmacy or the entity that manages security for the pharmacy shall maintain testing records for three years from the date of testing and shall make such records readily retrievable. The pharmacy shall be responsible for obtaining testing records if such records are maintained by a third-party. Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the board of any installation or modification to an alarm system prior to implementation.

(I) The remote dispensing pharmacy shall contain all dangerous drugs, hypodermics, and D.E.A. controlled substance order forms and every other item or product that requires the supervision or sale by a pharmacist.

(J) Only the supervising pharmacist, certified pharmacy technicians, and pharmacy interns employed by the remote dispensing pharmacy may have access to keys or other methods of gaining access to the pharmacy.

(K) All keys, combinations, or access codes, including alarm codes, shall be changed upon termination of employment of an employee having knowledge of the combination or access code.

(L) No prescription, dangerous drug, hypodermic, nor any other item or product that requires the supervision or sale by a pharmacist may be sold, given away, or disposed of at any time the pharmacy is closed or the surveillance system is inoperable.

(M) New or refill prescription orders may be deposited into a secure area within the building where the pharmacy is located when the pharmacy is closed.

(N) If a remote dispensing pharmacy provides services by means of a drive-through facility, the drive-through facility shall be constructed and maintained in a manner, and with materials, that secures the premises of the pharmacy from unauthorized access.