Common Sense Initiative

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Business Impact Analysis

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

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

Outpatient Pharmacy Delivery Services

Rule Number(s): 4729:5-5-26, 4729:5-8-03

Date of Submission for CSI Review: 8/19/2024

Public Comment Period End Date: 9/13/2024

Rule Type/Number of Rules:

New/ 1 rules

No Change/___ rules (FYR? __)

Amended/ 1 rules (FYR? _)

Rescinded/____ rules (FYR?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.

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.

   - 4279:5-5-26 (NEW) – Requires outpatient pharmacies to adhere to certain standards when delivering medications to patients. Requires special packaging and notification for drugs that are considered temperature sensitive. Also requires the pharmacy to notify the patient of the specifics of the delivery and to assist patients in securing medication if there is a delivery delay.
   - 4729:5-8-03 (AMEND) – Requires adherence to the delivery requirements in OAC 4729:5-5-26 for non-resident pharmacies.

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, 3719.28, and 3719.13 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.

This rule does 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.

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 3719.28 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules establishing the manner of keeping and the form and content of records to be kept by persons authorized to manufacture, distribute, dispense, conduct research in, prescribe, administer, or otherwise deal with controlled substances.

   Section 3719.13 of the Ohio Revised Code authorizes employees of the Board of Pharmacy to inspect prescriptions, orders, records, and stocks of dangerous drugs and 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.

The delivery rule in this package was distributed for public comment to all licensees and registrants of the Board.

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?

The Board received several comments during the initial comment period and made the following changes to rule 4729:5-5-26:

- Added definition of temperature sensitive drug;
- Provided specific information on what must be provided to a patient who will be receiving a drug via delivery;
- Requires the pharmacy to take all steps to ensure temperature integrity;
- Clarified that proof of delivery may be a signature of receiving party;
- Changed the notification requirements for drugs experiencing a delay from 24 hours to 48 hours;
- Removed common carriers from the contract requirements in paragraph (F);
- Clarified that lost or stolen shipments should be reported in accordance with the Board's standard reporting rule (OAC 4729:5-3-02).

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 delivery of medications to patients in this state, 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.

Board of Pharmacy staff receive regular updates on rules via a monthly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, email updates, webinars from the Director of Policy and Communications, and feedback from the Board's legal department for every citation submitted.

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 that deliver medications to patients

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.

In general, violation of these rules may result in administrative licensure discipline for a licensee. Discipline might include reprimand, suspension of a license, monetary fine and/or revocation of a license.

- 4279:5-5-26 (NEW) – Requires outpatient pharmacies to adhere to certain standards when delivering medications to patients. Requires special packaging and notification

for drugs that are considered temperature sensitive. Also requires the pharmacy to notify the patient of the specifics of the delivery and to assist patients in securing medication if there is a delivery delay. This will increase administrative costs on pharmacies engaged in drug delivery. The costs of the rule are based on the modifications a pharmacy will need to make to its current delivery processes to meet the requirements of the rule. Pharmacies that offer delivery services will also be responsible for replacing any drug or device which is compromised or lost as part of the delivery process.

- 4729:5-8-03 (AMEND) – Requires adherence to the delivery requirements in OAC 4729:5-5-26 for non-resident pharmacies. The amendment to this rule seeks compliance with OAC 4729:5-5-26. The estimated costs associated with this amendment are outlined in the paragraph immediately above.

16. Are there any proposed changes to the rules that will <u>reduce</u> 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 delivery of medications to patients in this state. Additionally, more and more Ohioans will be relying on delivery services for medication access with the contraction of the retail pharmacy sector in this state.

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.

    Furthermore, the Board also developed external inspection guides available to all licensees to ensure compliance with our regulations.

Rule 4729:5-5-26 | Outpatient Pharmacy Delivery Services (NEW)

(A) As used in this rule,

(1) “Pharmacy delivery agent” means the United States postal service or common carrier, contract carrier, or employee of the pharmacy who delivers dangerous drugs that have been dispensed to a patient or agent of the patient.

(2) “Temperature sensitive drug” means any drug that is required to be stored at temperatures outside of controlled room temperature (59 degrees Fahrenheit to 86 degrees Fahrenheit).

(B) An outpatient pharmacy licensed as a terminal distributor of dangerous drugs providing delivery services of dispensed drugs and devices in this state shall comply with the following:

(1) Contact the patient or patient’s caregiver for approval prior to any billing or delivery of a drug or device, except if the patient has provided general consent for delivery services.

(2) Notify the patient or patient’s caregiver of the date shipped, method of delivery (e.g., mail, courier, etc.), and expected arrival.

(3) Take all appropriate measures to ensure that temperature sensitive drugs, will be maintained within the temperature ranges recommended by the manufacturer until the delivery has been completed.

(4) Provide notification to the patient, if the patient's prescription is a temperature sensitive drug, of the timeliness in addressing proper storage of the medication.

(5) Arrange for any controlled substances to require proof of delivery, which may include the signature of the receiving party.

(6) Assist patients with arranging access to medication from a local pharmacy if unable to delivery medications in the expected timeframe.

(7) Provide a method by which the patient or patient's caregiver can notify the pharmacy as to any irregularity in the delivery of the drug or device, including all of the following:

(a) Timeliness of delivery.

(b) Condition of the drug or device upon delivery.

(c) Failure to receive the proper drug or device.

(8) Ensure there is a process to inform the patient or patient's caregiver within forty-eight hours of being notified of the delay if the scheduled delivery of the patient's prescription will be interrupted or late.

(C) Any drug or device which is compromised or lost shall be replaced by the pharmacy at no additional cost to the patient. If the timeliness of the replacement will lead to an interruption in therapy, the outpatient pharmacy shall take all available steps to mitigate patient harm.

(D) Any drug or device that has been delivered to a patient or is no longer in the possession of a pharmacy delivery agent shall not be returned to stock in accordance with rule 4729:5-5-22 of the Administrative Code.

(E) An outpatient pharmacy shall maintain the following records for all drugs and devices delivered in accordance with this rule:

(1) Patient name;

(2) Patient address;

(3) Prescription number of drug or device being delivered;

(4) Name (brand name or generic) and dosage of each drug or device being delivered;

(5) Name and contact information of the pharmacy delivery agent who performed, or attempted to perform, the delivery.

(F) Except for deliveries performed by the United States Postal Service or common carrier, an outpatient pharmacy that utilizes a third-party to deliver drugs and devices shall enter into a contract with the third-party to ensure the following:

(1) The required records in paragraph (E) of this rule are provided to the contracting pharmacy; and

(2) The third-party entity agrees to cooperate with all investigations regarding the theft or loss of drugs and devices and produce required records listed in paragraph (E) of this rule within three business days of a request by an agent, officer, or inspector of the board.

(G) Theft or significant loss of any dangerous drugs shall be reported to the board in accordance with rule 4729:5-3-02 of the Administrative Code.

Rule 4729:5-8-03 | Compliance. (AMEND)

A nonresident terminal distributor of dangerous drugs shall:

(A) Maintain the following records of all dangerous drugs dispensed or personally furnished to persons in this state:

(1) Name, strength, dosage form, the serial number of the prescription, and quantity of the dangerous drug dispensed or personally furnished;

(2) Full name and date of birth of the patient for whom the drug is intended; or, if the patient is an animal, the last name of the owner, name of animal (if applicable), and species of the animal or animals; and

(3) Residential address, including the physical street address and, if provided, the telephone number of the patient or owner.

(B) Maintain the following records of transfer or sale conducted in accordance with rule 4729:5-3-09 of the Administrative Code for drugs sold or transferred into this state: name, strength, dosage form, national drug code, and quantity of the dangerous drug transferred or sold, the address of the location where the drugs were transferred or sold, and the date of transfer or sale.

(C) Maintain all records and documents required by this chapter for a period of three years in a readily retrievable manner.

(D) Label all drugs dispensed or personally furnished into this state with the following minimum information:

(1) The name or "doing business as" (DBA) name, or other legal or contractually affiliated name and address of the terminal distributor.

(2) The full name of the patient for whom the drug is prescribed; or, if the patient is an animal, the last name of the owner, name of animal (if applicable), and species of the animal or animals.

(3) The full name of the prescriber or the first initial of the prescriber's first name and the full last name of the prescriber.

(4) Directions for use of the drug.

(5) The date of dispensing.

(6) Any cautions which may be required by federal or state law.

(7) The serial number of the prescription.

(8) The proprietary name, if any, or the generic name and the name of the distributor or national drug code of the drug dispensed, and the strength, if more than one strength of the drug is marketed.

(9) The quantity of drug dispensed.

(10) If the licensee is an institutional central fill pharmacy as defined in rule 4729:5-9-02.13 of the Administrative Code, the prescription label attached to the container shall contain the name and address of the originating pharmacy and the name of the central fill pharmacy. If applicable, the date on which the medication order was dispensed shall be the date on which the central fill pharmacy filled the order.

(11) If the licensee is a central fill pharmacy as defined in rule 4729:5-5-19 of the Administrative Code, the prescription label attached to the container shall contain the name and address of the originating pharmacy. The date on which the prescription was dispensed shall be the date on which the central fill pharmacy filled the prescription.

(a) If the originating pharmacy and the central fill pharmacy are not under common ownership, either of the following shall apply:

(i) The name of the central fill pharmacy shall be included on the prescription label or an auxiliary label; or

(ii) A statement is included on the prescription information accompanying the dangerous drug that indicates a central fill pharmacy was used to fill the prescription and includes the name of the central fill pharmacy.

(b) The originating pharmacy shall provide, upon the request of a patient or caregiver, the name and address of the central fill pharmacy and a contact phone number where the patient or caregiver can receive further assistance regarding prescriptions filled by a central fill pharmacy.

(E) Comply with all the statutory requirements of the state of Ohio set forth in Chapters 4729., 3719., 3715., and 2925. of the Revised Code for all drugs sold, dispensed or personally

furnished into this state, unless the licensee can demonstrate that such compliance would cause the nonresident terminal distributor of dangerous drugs to violate either the statutory or regulatory requirements of the state in which it is located or federal statutory or regulatory requirements.

(F) Comply with the following regulatory requirements of the state of Ohio, unless the licensee can demonstrate that such compliance would cause the nonresident terminal distributor of dangerous drugs to violate either the statutory or regulatory requirements of the state in which it is located or federal statutory or regulatory requirements:

(1) The requirements set forth in this chapter;

(2) The requirements in Chapters 4729:5-1 and 4729:5-2 of the Administrative Code;

(3) Theft or significant loss reporting requirements in rule 4729:5-3-02 of the Administrative Code for all drugs sold, dispensed or personally furnished into this state;

(4) Inspection and corrective action requirements in rule 4729:5-3-03 of the Administrative Code;

(5) Licensure verification requirements in rule 4729:5-3-04 of the Administrative Code for all drugs sold, dispensed or personally furnished into this state;

(6) Patient confidentiality requirements in rule 4729:5-3-05 of the Administrative Code;

(7) Internet sales requirements in rule 4729:5-3-08 of the Administrative Code for all drugs sold, dispensed or personally furnished into this state;

(8) Occasional sale and drug transfer requirements in rule 4729:5-3-09 of the Administrative Code for all drugs sold, dispensed or personally furnished into this state;

(9) Remote medication order processing requirements in rule 4729:5-9-02.14 of the Administrative Code and remote outpatient prescription processing requirements in rule 4729:5-5-20 of the Administrative Code.

(10) The following central fill pharmacy requirements set forth in Chapters 4729:5-5 and 4729:5-9 of the Administrative Code:

(a) If the central fill pharmacy does not have the same owner as the originating pharmacy, the central fill pharmacy shall have a written contract with the originating pharmacy outlining the

services to be provided and the responsibilities of each pharmacy in fulfilling the terms of the contract in compliance with federal and state law, rules and regulations. For central fill pharmacies dispensing outpatient prescriptions, the contract shall also expressly state who is responsible for performing the patient counseling requirements in accordance with paragraph (L) of this rule.

(b) The central fill pharmacy shall maintain a record of all originating pharmacies, including name, address, terminal distributor number, and, if applicable, drug enforcement administration registration number, for which it processes a request for the filling or refilling of a medication order or prescription received by the originating pharmacy.

(c) The central fill pharmacy and originating pharmacy shall have access to common electronic files as part of a real time, online database or have appropriate technology to allow secure access to sufficient information necessary or required to dispense or process the medication order or prescription.

(d) The central fill pharmacy and originating pharmacy shall adopt a written quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, resolve identified problems, and ensure compliance with this rule. The quality assurance plan shall be reviewed and updated annually.

(11) If engaged in the provision of medication therapy management, as defined in rule 4729:5-12-01 of the Administrative Code, for patients residing in this state the requirements set forth in Chapter 4729:5-12 of the Administrative Code.

(12) The delivery requirements in rule 4729:5-5-26 of the Administrative Code.

(G) Submit to the applicable disciplinary actions set forth in section 4729.57 of the Revised Code and rule 4729:5-4-01 of the Administrative Code.

(H) Operate in compliance with all applicable laws, regulations and standards set forth by the United States food and drug administration and the United States drug enforcement administration.

(I) Nonresident terminal distributors of dangerous drugs who are pharmacies shall dispense prescriptions into this state issued by either:

(1) An Ohio prescriber who is authorized pursuant rule 4729:5-1-02 of the Administrative Code; or

(2) A nonresident prescriber whose license is current and in good standing and who is authorized to issue prescriptions for dangerous drugs in the course of the prescriber's professional practice in a state other than Ohio.

(J) Supply, within three business days of a request, all information needed by the board of pharmacy to carry out its responsibilities as a licensing, regulatory, and drug law enforcement agency of the state of Ohio.

(K) Supply, within three business days of a request, all information needed by the board of pharmacy and any local, state, or federal agency to carry out its responsibilities in enforcing the federal and state laws governing the distribution of drugs in the state of Ohio.

(L) If the nonresident terminal distributor is a pharmacy, there must be an offer to counsel the patient issued with every prescription dispensed. The offer shall be made by telephone or in writing on a separate document and shall accompany the prescription. A written offer to counsel shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service must be available at no cost to the pharmacy's primary patient population. The pharmacy shall have sufficient telephone service to provide access to incoming callers.

(M) Nonresident terminal distributors shall permit properly identified and authorized state board of pharmacy agents and federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles. A nonresident terminal distributor of dangerous drugs shall be responsible for all costs incurred by board of pharmacy agents in conducting an inspection. Upon completion of the inspection, the nonresident terminal distributor of dangerous drugs shall have ninety days to reimburse all inspection costs incurred after being notified, electronically or in writing, by the board.

In lieu of an inspection by the board, a nonresident terminal distributor of dangerous drugs may submit any of the following:

(1) Inspection reports by a state licensing agency demonstrating compliance with the requirements of this rule.

(2) Inspection reports demonstrating compliance with the requirements of this rule by one of the following organizations:

(a) The national association of boards of pharmacy's verified pharmacy program (VIPP);

(b) An organization approved by the board.

(N) Comply with all drug database reporting requirements pursuant to Chapter 4729. of the Revised Code and division 4729:8 of the Administrative Code.

(O) Unless approved by the board's executive director, a nonresident terminal distributor of dangerous drugs that is not a pharmacy shall not be permitted to sell or personally furnish controlled substances to patients residing in this state.