Common Sense Initiative

Mike DeWine, *Governor*
Jon Husted, *Lt. Governor*
Joseph Baker, *Director*

Comments on the proposed rules will be accepted until close of business on November 1, 2024. Please send all comments to the following email address: RuleComments@pharmacy.ohio.gov

In addition, please copy your comments to: CSIPublicComments@governor.ohio.gov

Business Impact Analysis

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

Rule Contact Name and Contact Information: Summer Reyburn

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

FYR 2024 Controlled Substances

Rule Number(s): 4729:9-3-01, 4729:9-3-02, 4729:9-3-03, 4729:9-3-04, 4729:9-3-05, 4729:9-3-06, 4729:9-3-07, 4729:9-3-08

Date of Submission for CSI Review: 10/15/2024

Public Comment Period End Date: 11/1/2024

Rule Type/Number of Rules:

New/_1_ rules **No Change/____ rules (FYR? __)**

Amended/____ rules (FYR? ___) **Rescinded/__8__ rules (FYR? _Y__)**

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.
   - 4729:9-3-01: Combines all ephedrine-related rules into a single rule. Rescinds the following rules that are now incorporated into this proposed rule: 4729:9-3-01, 4729:9-3-02, 4729:9-3-03, 4729:9-3-04, 4729:9-3-06, 4729:9-3-07, 4729:9-3-08.

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 3715.69 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 controlled substances by the Ohio Board of Pharmacy is required under chapter 3719. of the Revised Code.

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 state board of pharmacy to adopt rules governing the practice of pharmacy and distribution of dangerous drugs, including controlled substances.

   Section 3719.28 of the Ohio Revised Code authorizes the Board prescribing 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 3719.44 requires the Board to exempt ephedrine products that do not contain any other controlled substance. The standards by which the Board may grant an exemption must be adopted in rule.

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.
   N/A.

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 rules were published for public comment. Prior to filing with CSI, these 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?**

    Stakeholders did not provide any comments on the proposed rules in this package.

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 these rules.

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 regulation of controlled substances, 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 and quarterly 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**
       Entities that purchase and possess ephedrine products.
    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.

- 4729:9-3-01: Provides the registration and licensure for entities selling or manufacturing ephedrine or ephedrine products. Licensure as a terminal distributor of dangerous drugs category III costs $220 annually. The initial application for a terminal distributor license takes about one hour to complete, renewal takes about 10 minutes. There may also be administrative costs to maintain records and apply for an exemption request. The estimated timeframe to prepare an exemption request is approximately 1-2 hours.

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).*

    N/A

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 are intended to protect and promote public safety. In particular, they ensure uniform regulations that allow for the monitoring of pharmacy professionals who suffer from substance abuse or mental illness to ensure that they comply with all requirements of their treatment plan.

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.

Rule 4729:9-3-01 | Sale of Distribution of Ephedrine-Containing Products (NEW)

(A) As used in this rule, “ephedrine” is α -[-(Methylamino)ethyl]benzene-methanol; α-[1-(methylamino) ethyl]benzyl alcohol; 2-methylamino-1-phenyl-1-propanol; 1-phenyl-1-hydroxy-2-methylaminopropane; 1-phenyl-2- methylaminopropanol; α - hydroxy-β-methylaminopropylbenzene; a product which occurs in the Chinese herb Ma Huang (*Ephedra vulgaris, Ephedra sinica Stapf., Ephedra equisetina Bunge, Gnetaceae*) and in several other Ephedra spp. Isomeric forms include *d*- and *l*-ephedrine as well as *d*-and *l*-pseudoephedrine with *l*-ephedrine and *d*-pseudoephedrine as the naturally occurring isomers.

(B) Each of the following products containing ephedrine, its salts, its isomers, or the salts of its isomers is excepted from classification as a schedule V controlled substance:

(1) All products that contain the isomer known as pseudoephedrine or its salts, but do not also contain any of the isomer known as ephedrine or its salts.

(2) "Breathe Easy" herb tea.

(3) "Bronkaid Dual Action" caplets.

(4) "Hydrosal" hemorrhoidal ointment.

(5) "Primatene Dual Action Formula" tablets.

(6) "Primatene" tablets.

(7) "SnoreStop" tablets.

(8) Drug products listed in division (K)(1) of section 3719.44 of the Revised Code.

(C) Except as provided in paragraph (H) of this rule, any person who manufactures, sells at wholesale or retail, dispenses, imports or exports products containing ephedrine, its salts or isomers, or who proposes to engage in such activities, shall submit an application for the appropriate category III license in accordance with section 4729.52 of the Revised Code or 4729.54 of the Revised Code to conduct such activities in accordance with Chapters 3719. and 4729. of the Revised Code.

(D) Except as provided in paragraph (H) of this rule, schedule V products containing ephedrine may be sold at wholesale or retail, and must be maintained in accordance with Chapters 3719. and 4729. of the Revised Code and agency 4729 of the Administrative Code.

(E) Except as provided in paragraph (H) of this rule, a licensee who possesses any quantity of ephedrine or schedule V dangerous drug products containing ephedrine shall take an inventory pursuant to rule 4729:5-3-07 or 4729:6-3-06 of the Administrative Code.

(F) Except as provided in paragraph (H) of this rule, all licensees are required to keep records pursuant to Chapter 3719. of the Revised Code and agency 4729 of the Administrative Code shall maintain such records for ephedrine and schedule V drug products containing ephedrine.

(G) This requirements listed in paragraphs (C), (D), (E), and (F) do not apply if the ephedrine product is a food product or a dietary supplement that is specifically excepted in division (K)(1) of section 3719.44 of the Revised Code or paragraph (B) of this rule.

(H) A petition requesting that a drug product containing ephedrine be excepted by the board of pharmacy from being legally classified as a schedule V controlled substance stimulant may be submitted by any person engaged in the legitimate manufacture or wholesale sale of such products in the United States. The petition shall include the following information:

(1) Full name, address, and telephone number of the manufacturer.

(a) If incorporated, the petition must include copies of the incorporation papers and the names, dates of birth, addresses, and social security numbers of the officers of the corporation and all stockholders holding more than ten percent of the corporation's stock.

(b) If a proprietorship, the petition must include the name, address, date of birth, and social security number of the owner(s).

(c) If a partnership, the petition must include the names, addresses, dates of birth, and social security numbers of the partners.

(2) A description of the package sizes and the manner of packaging of the drug product.

(3) A limited number of samples of each dosage form marketed in the final marketed packages.

(4) The manner of distribution, advertising, and promotion of the product including the following:

(a) The full name and address of all accounts located in Ohio to which the products have been or will be distributed at wholesale based on other products marketed by the petitioner.

(b) Copies of all advertisements used to promote the product within the last twelve months shall be included with the petition. A list of the publications in which the advertisements appeared or will appear if not presently marketed. If the product has not yet been marketed, copies of other products marketed by the petitioner shall be submitted with the petition.

(5) A listing of all ingredients in the product, indicating the quantity of each ingredient, whether or not it has any therapeutic value, and its purpose for being included in the product. Documentation of the therapeutic value of all active ingredients in the product shall be included with the petition.

(6) A list of all names the product is marketed or will be marketed under in the United States or any other country.

(7) Any information regarding the product's abuse or potential for abuse in the United States or other countries where the product is marketed or will be marketed under any of the names listed in paragraph (H)(6) of this rule.

(I) The board shall consider the following factors in determining whether a particular over-the-counter (OTC) drug product containing the schedule V controlled substance ephedrine is manufactured and distributed for legitimate use in a manner consistent with the pertinent OTC tentative or final monograph issued by the United States food and drug administration and in a manner that reduces the likelihood of inappropriate use and/or abuse:

(1) The package size and the manner of packaging;

(2) Distribution, advertising, and promotion of the product;

(3) Labeling and the name of the product;

(4) The potential, duration, scope, and significance of inappropriate use and/or abuse;

(5) Other facts as may be relevant to and consistent with public health and safety.

(J) The board shall remove a drug product exception for a particular drug product if it determines that the drug product is not manufactured and distributed for legitimate use and in a manner that reduces the likelihood of abuse.

Rule 4729:9-3-01 | Definition of ephedrine. (RESCIND)

Ephedrine is α -[-(Methylamino)ethyl]benzene-methanol; α-[1-(methylamino) ethyl]benzyl alcohol; 2-methylamino-1-phenyl-1-propanol; 1-phenyl-1-hydroxy-2-methylaminopropane; 1-phenyl-2- methylaminopropanol; α - hydroxy-β-methylaminopropylbenzene; a product which occurs in the Chinese herb Ma Huang (Ephedra vulgaris, Ephedra sinica Stapf., Ephedra equisetina Bunge, Gnetaceae) and in several other Ephedra spp. Isomeric forms include d- and l-ephedrine as well as dand l-pseudoephedrine with l-ephedrine and d-pseudoephedrine as the naturally occurring isomers.

Rule 4729:9-3-02 | Licensure. (RESCIND)

(A) Any person who manufactures, sells at wholesale or retail, dispenses, imports or exports products containing ephedrine, its salts or isomers, or who proposes to engage in such activities, shall submit an application for the appropriate category III license in accordance with section 4729.52 of the Revised Code or 4729.54 of the Revised Code to conduct such activities in accordance with Chapters 3719. and 4729. of the Revised Code.

(B) This rule does not apply if the ephedrine product is a food product or a dietary supplement that is specifically excepted in division (K)(2) of section 3719.44 of the Revised Code or agency 4729 of the Administrative Code.

Rule 4729:9-3-03 | Security, storage, and sale. (RESCIND)

(A) Schedule V products containing ephedrine may be sold at wholesale or retail, and must be maintained in accordance with Chapters 3719. and 4729. of the Revised Code and agency 4729 of the Administrative Code.

(B) This rule does not apply if the ephedrine product is a food product or a dietary supplement that is specifically excepted in division (K)(2) of section 3719.44 of the Revised Code or agency 4729 of the Administrative Code.

Rule 4729:9-3-04 | Inventory. (RESCIND)

(A) A licensee who possesses any quantity of ephedrine or schedule V dangerous drug products containing ephedrine shall take an inventory pursuant to rule 4729:5-3-07 or 4729:6-3-06 of the Administrative Code.

(B) This rule does not apply if the ephedrine product is a food product or a dietary supplement that is specifically excepted in division (K)(2) of section 3719.44 of the Revised Code or agency 4729 of the Administrative Code.

Rule 4729:9-3-05 | Records. (RESCIND)

(A) All licensees required to keep records pursuant to Chapter 3719. of the Revised Code and agency 4729 of the Administrative Code shall maintain such records for ephedrine and schedule V drug products containing ephedrine.

(B) This rule does not apply if the ephedrine product is a food product or a dietary supplement that is specifically excepted in division (K)(2) of section 3719.44 of the Revised Code or agency 4729 of the Administrative Code.

Rule 4729:9-3-06 | Petitions for exception of ephedrine-containing products. (RESCIND)

(A) A petition requesting that a drug product containing ephedrine be excepted by the board of pharmacy from being legally classified as a schedule V controlled substance stimulant may be submitted by any person engaged in the legitimate manufacture or wholesale sale of such products in the United States. The petition shall include the following information:

(1) Full name, address, and telephone number of the manufacturer.

(a) If incorporated, the petition must include copies of the incorporation papers and the names, dates of birth, addresses, and social security numbers of the officers of the corporation and all stockholders holding more than ten percent of the corporation's stock.

(b) If a proprietorship, the petition must include the name, address, date of birth, and social security number of the owner(s).

(c) If a partnership, the petition must include the names, addresses, dates of birth, and social security numbers of the partners.

(2) A description of the package sizes and the manner of packaging of the drug product.

(3) A limited number of samples of each dosage form marketed in the final marketed packages.

(4) The manner of distribution, advertising, and promotion of the product including the following:

(a) The full name and address of all accounts located in Ohio to which the products have been or will be distributed at wholesale based on other products marketed by the petitioner.

(b) Copies of all advertisements used to promote the product within the last twelve months shall be included with the petition. A list of the publications in which the advertisements appeared or will appear if not presently marketed. If the product has not yet been marketed, copies of other products marketed by the petitioner shall be submitted with the petition.

(5) A listing of all ingredients in the product, indicating the quantity of each ingredient, whether or not it has any therapeutic value, and its purpose for being included in the product.

Documentation of the therapeutic value of all active ingredients in the product shall be included with the petition.

(6) A list of all names the product is marketed or will be marketed under in the United States or any other country.

(7) Any information regarding the product's abuse or potential for abuse in the United States or other countries where the product is marketed or will be marketed under any of the names listed in paragraph (A)(6) of this rule.

(B) This rule does not apply if the ephedrine product is a food product or a dietary supplement that is specifically excepted in division (K)(2) of section 3719.44 of the Revised Code or agency 4729 of the Administrative Code.

Rule 4729:9-3-07 | Exceptions. (RESCIND)

Each of the following products containing ephedrine, its salts, its isomers, or the salts of its isomers is excepted from classification as a schedule V controlled substance:

(A) All products that contain the isomer known as pseudoephedrine or its salts, but do not also contain any of the isomer known as ephedrine or its salts.

(B) "Breathe Easy" herb tea.

(C) "Bronkaid Dual Action" caplets.

(D) "Hydrosal" hemorrhoidal ointment.

(E) "Primatene Dual Action Formula" tablets.

(F) "Primatene" tablets.

(G) "SnoreStop" tablets.

Rule 4729:9-3-08 | Criteria to be considered in denying a petition for exception or removing a drug product exception. (RESCIND)

(A) The board shall consider the following factors in determining whether a particular over-the-counter (OTC) drug product containing the schedule V controlled substance ephedrine is manufactured and distributed for legitimate use in a manner consistent with the pertinent OTC tentative or final monograph issued by the United States food and drug administration and in a manner that reduces the likelihood of inappropriate use and/or abuse:

(1) The package size and the manner of packaging;

(2) Distribution, advertising, and promotion of the product;

(3) Labeling and the name of the product;

(4) The potential, duration, scope, and significance of inappropriate use and/or abuse;

(5) Other facts as may be relevant to and consistent with public health and safety.

(B) The board shall remove a drug product exception for a particular drug product if it determines that the drug product is not manufactured and distributed for legitimate use and in a manner that reduces the likelihood of abuse.