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

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

FYR Pharmacists

Rule Number(s): 4729:1-2-04, 4729:1-3-04, 4729:1-3-06, 4729:1-3-07, 4729:1-6-01, 4729:1-6-02, 4729:1-6-03

Date of Submission for CSI Review: 1/12/2026

Public Comment Period End Date: 2/10/2026

Rule Type/Number of Rules:

New/___ rules

No Change/____ rules (FYR? ___)

Amended/__7__ rules (FYR? _Y_)

Rescinded/____ rules (FYR? ___)

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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.***

4729:1-2-04: Provides the passing scores for the Test of English as a Foreign Language, Internet-based Test. Updates the passing scores for writing to twenty-two, speaking to twenty-five, listening to twenty-two, and reading to twenty-one. This reflects national changes by the National Association of Boards of Pharmacy: https://nabp.pharmacy/programs/foreign-pharmacy/

4729:1-3-04: Specifies the protocols and other requirements under which a pharmacist may dispense naloxone without a prescription. Updates instances of "naloxone" to "overdose reversal drug" as defined in rule 4729-8-02 of the Administrative Code. Updates instances of "physician-established protocol" to "prescriber-established protocol." Removes training requirements. Adds definition of "prescriber."

4729:1-3-06: Specifies the protocols and other requirements under which a pharmacist may dispense epinephrine without a prescription. Clarifies the epinephrine a pharmacist may dispense is an epinephrine autoinjector or other formulation authorized in chapter 4729. of the Revised Code and removes further instances of "autoinjector" from the rule. Adds definitions for "epinephrine" and "pharmacy affiliated with the pharmacist."

4729:1-3-07: Provides the standards for dispensing nicotine replacement therapy by pharmacists as authorized by HB 110 (134th General Assembly) – ORC 4729.284. Adds a definition for "prescriber" and updates instances of "physician-established protocol" to "prescriber-established protocol." Makes small grammatical changes.

4729:1-6-01: Establishes the definition section for consult agreement rule chapter. Changes "managing pharmacist" to "collaborating pharmacist" to reflect national terminology. Updates positive identification definition to align with other Board of Pharmacy rules.

4729:1-6-02: Establishes the requirements of a consult agreement. Changes "managing pharmacist" to "collaborating pharmacist" to reflect national terminology. Removes allowance that a pharmacist can prescribe controlled substances under a hospital's DEA registration as it conflicts with federal rules. Clarifies that testing ordered must related specifically to the management of a patient's drug therapy. Requires pharmacists who prescribe gabapentin to check OARRS.

4729:1-6-03: Provides the standards of care for a pharmacist under a consult agreement. Expands the ability of the pharmacist to administer controlled substances to treatment opioid use disorder outside of an opioid treatment program. Specifies that all telehealth be conducted in accordance with all applicable federal and state laws and rules. Prohibits the use of consult agreements for the administration of intravenous drugs and for performing cosmetic procedures.

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, 4729.39, 3715.502, 4729.47, 4729.284, 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 the operation of pharmacies 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 4729.39 of the Ohio Revised Code authorizes the state board of pharmacy to adopt rules regarding pharmacist consult agreements.

Section 3715.502 of the Ohio Revised Code requires the Board of Pharmacy to adopt rules pertaining to the dispensing of naloxone by pharmacists and pharmacy interns pursuant to a prescriber-approved protocol.

Section 4729.47 of the Ohio Revised Code requires the Board of Pharmacy to adopt rules pertaining to the dispensing of epinephrine autoinjectors by pharmacists and pharmacy interns pursuant to a prescriber-approved protocol.

Section 4729.284 of the Ohio Revised Code requires the Board of Pharmacy to adopt rules to implement nicotine replacement therapy dispensing by pharmacists via prescriber protocol.

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.

Changes to rule 4729:1-2-04 were put out for stakeholder comment between the dates of 10/23-11/14/2025.

This rule package was also reviewed by the Board's Rules Review Committee. The Committee, composed of pharmacists and pharmacy technicians from a number of practice settings, is responsible for reviewing and approving rules prior to their legislatively mandated five-year date. Prior to filing with CSI, the rules were 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, the Board of Pharmacy Rules Review Committee reviewed the proposed changes. The Committee recommended and the Board approved updating instances of "managing pharmacist" to "collaborating pharmacist" throughout the rules to avoid confusion or misinterpretation. The committee also recommended a number of other changes including the requirement for pharmacists prescribing gabapentin to be required to check OARRS.

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 package.

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 practice of pharmacy, 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

- Pharmacists
- Pharmacies

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 discipline for a Board of Pharmacy licensee. Discipline might include reprimand, denial of a license, suspension of a license, monetary fine, and/or revocation of a license.

4729:1-2-04: Those who do not meet these updated scores will be required to retake the examination. In the US, the examination costs a total of $270.

4729:1-3-04: This rule reduces the overall burden on the pharmacist by streamlining the training requirements for pharmacists who distribute overdose reversal medications. This will result in overall reduction in time for pharmacists dispensing these medications. The other costs of compliance include the educational training program for staff on the availability of overdose reversal medications. It should be noted that this provision is to ensure compliance with division (G) of section 3715.502 of the Revised Code.

4729:1-3-06: The parts of the rule that are not included in the law that may pose an adverse impact include the following:

- Components of the prescriber-established protocol and the requirements that such protocols be reviewed every two years. A pharmacy that opts to offer this service will experience administrative costs associated with implementing this requirement. However, it should be noted that these requirements mirror the requirements for immunization protocols, which are offered by a majority of pharmacies in the state. Therefore, the burden of this requirement may be minimal if the pharmacies opt to use the same authorizing prescriber.
- The rule requires pharmacists or pharmacy interns to conduct patient training on the proper method of administering epinephrine. It is estimated that this required training may take between 2-5 minutes per dispensing.

4729:1-3-07: A pharmacy may experience increased administrative costs to develop and implement a prescriber authorized protocol and follow-up care plan. Pharmacists may also experience increased demands to meet the training requirements, the requirements of the protocol, and provide notice to a patient's primary care provider (**NOTE:** These requirements are mandated by the statute).

4729:1-6-01: The rule outlines a consent requirement which may add additional administrative costs to entities operating under a consult agreement, however this requirement is in the current rule. Please be advised that patient consent is a requirement of ORC 4729.39 and of the existing rule.

4729:1-6-02: This rule requires a pharmacist authorized to prescribe controlled substances to obtain a valid registration from the D.E.A. The registration fee is $888.00 every three years, while the application takes approximately one hour to complete. It also requires a pharmacist to obtain a controlled substances registration from the Board of Pharmacy. This registration is provided at no-cost and will take an estimated 20 minutes to complete. The rule also requires additional information to identify a pharmacist issuing a prescription as an agent of a physician. Those facilities using electronic prescribing may have to make modifications to meet the requirements of this rule. Further, the rule requires that a pharmacist check a patient's OARRS report prior to prescribing gabapentin. Depending on the pharmacy's integration status, it may take anywhere from 20 seconds – 3 minutes to query a patient's OARRS report.

4729:1-6-03: Facilities may experience administrative costs to comply with requirements for managing drug therapy, including annual patient follow-ups. These requirements are unchanged from current rule.

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).***

4729:1-3-04: Removes requirement that pharmacies must conduct an initial and annual patient training if the pharmacy is offering naloxone without a prescription. Removing this requirement may save pharmacies an estimated 2-5 minutes per patient.

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 requirements for pharmacists entering into consult agreements, pharmacists dispensing nicotine replacement therapy in accordance with the provisions of ORC 4729.284, and providing uniform epinephrine dispensing. Additionally, some of these rules are required by Ohio law.

Regulatory Flexibility

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

The 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 regulations are 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 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 are 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. Staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

Additionally, to assist our licensees, including those representing small businesses, the Board developed inspection guides. 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. The guides may be accessed by visiting: www.pharmacy.ohio.gov/inspection. The Board also has a number of resources on its licensing and continuing education websites to educate our licensees.

Rule 4729:1-2-04 - Successful completion of the Test of English as a Foreign Language, Internet-based Test. (AMEND)

Successful completion of the "Test of English as a Foreign Language, Internet-based test" (TOEFL iBT) shall be the following minimum scores or higher:

(A) Writing: **twenty-two** ~~**twenty-four**~~;

(B) Speaking: **twenty-five** ~~**twenty-six**~~;

(C) Listening: **twenty-two** ~~**twenty-one**~~; and

(D) Reading: **twenty-one** ~~**twenty-two**~~.

Rule 4729:1-3-04 | Dispensing of ~~naloxone~~ overdose reversal drugs by pharmacists. (AMEND)

(A) A pharmacist may dispense ~~**naloxone**~~ **an overdose reversal drugs as defined in rule 4729-8-02 of the Administrative Code** without a prescription to either of the following in accordance with a protocol specified in paragraph (B) of this rule:

(1) An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose;

(2) A family member, friend, or other ~~**person**~~ **individual** in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

(B) A ~~**physician**~~ **prescriber-**established protocol for the dispensing of ~~**naloxone**~~ **an overdose reversal drug** by a pharmacist or pharmacy intern under the direct supervision of a pharmacist shall include, but is not limited to, the following:

(1) A description of the clinical pharmacology of ~~**naloxone**~~ **the overdose reversal drug being dispensed**.

(2) Indications for use of ~~**naloxone**~~ **an overdose reversal drug** as rescue therapy, including criteria for identifying persons eligible to receive ~~**naloxone**~~ **an overdose reversal drug** under the protocol.

(3) Precautions and contraindications concerning dispensing ~~**naloxone**~~ **an overdose reversal drug**.

(4) ~~**Naloxone products**~~ **The overdose reversal drugs** authorized to be dispensed, including all of the following information:

(a) Name of product;

(b) Dose;

(c) Route of administration and required delivery device; and

(d) Directions for use.

(5) Any patient instructions **or training requirements.** ~~**in addition to the patient training specified in this rule and rule 4729:2-3-04 of the Administrative Code.**~~

(C) A pharmacist who dispenses ~~**naloxone**~~ **an overdose reversal drug** pursuant to this rule shall**:**

(1) Instruct the individual to whom ~~**naloxone**~~ **an overdose reversal drug** is dispensed verbally or in writing to summon emergency services as soon as practicable either before or after administering ~~**naloxone**~~ **an overdose reversal drug; and**

(2) Offer to counsel the patient in accordance with rule 4729:5-5-09 of the Administrative Code.

(D) All overdose reversal drugs dispensed pursuant to this rule shall be in packaging that contains the manufacturer's instructions for use.

~~**(D) Except as provided in paragraph (E) this rule, a pharmacist or a pharmacist's designee that is appropriately trained shall provide in-person training, unless the in-person training requirement is waived by the board, and written educational materials to the individual to whom naloxone is dispensed that includes all the following:**~~

~~**(1) Risk factors of opioid overdose;**~~

~~**(2) Strategies to prevent opioid overdose;**~~

~~**(3) Signs of opioid overdose;**~~

~~**(4) Steps in responding to an overdose;**~~

~~**(5) Information on the naloxone dispensed;**~~

~~**(6) Procedures for administering the naloxone dispensed;**~~

~~**(7) Proper storage and expiration of the naloxone dispensed; and**~~

~~**(8) Information on where to obtain a referral for substance abuse treatment.**~~

~~**(E) Patient training as required by paragraph (D) of this rule is not required if the patient has previously received training and all the following apply:**~~

~~**(1) The patient is offered training and refuses;**~~

~~**(2) The pharmacist or pharmacist designee has documentation confirming training pursuant to this rule has been provided within the previous twelve months;**~~

~~**(3) A pharmacist who dispenses naloxone pursuant to this rule shall still instruct the individual to whom naloxone is dispensed verbally or in writing to summon emergency services as soon as practicable either before or after administering naloxone.**~~

~~**(F) If training conducted pursuant to paragraph (D) of this rule is offered by a pharmacist's designee, the pharmacist shall not be required to counsel a patient or caregiver pursuant to rule 4729:5-5-09 of the Administrative Code if the patient or caregiver refuses the offer of counseling or does not respond to the written offer to counsel.**~~

~~**(G) A terminal distributor of dangerous drugs shall ensure that all pharmacists that dispense naloxone pursuant to this rule are trained on the use of naloxone and can meet the training requirements listed in paragraphs (C) and (D) of this rule.**~~

~~**(H) A terminal distributor of dangerous drugs shall ensure that all pharmacist designees are trained on the use of naloxone and can meet the training requirements listed in paragraph (D) of this rule.**~~

(**E** ~~**I**~~) A pharmacist may document on a prescription form the dispensing of ~~**naloxone**~~ **an overdose reversal drug** by the pharmacist or a pharmacy intern supervised by the pharmacist. The form may be assigned a number for record-keeping purposes.

(**F** ~~**J**~~) All ~~**physician**~~ **prescriber**-established protocols must be signed and dated by the ~~**physician**~~ **prescriber** prior to implementation and maintained by the terminal distributor of dangerous drugs. The protocols shall be renewed by a ~~**physician**~~ **prescriber** on a biennial basis.

(1) A ~~**physician**~~ **prescriber** may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs.

(2) Each location licensed as a terminal distributor of dangerous drugs shall maintain a copy of the protocol on-site for inspection by an agent, inspector or employee of the state board of pharmacy.

(**G** ~~**K**~~) Any pharmacy that dispenses ~~**naloxone**~~ **overdose reversal drugs** pursuant to section ~~4729.44~~ **3715.502** of the Revised Code shall notify the board, in a manner determined by the board, within thirty days of establishing a protocol. A pharmacy that no longer dispenses ~~**naloxone**~~ **overdose reversal drugs** pursuant to section ~~4729.44~~ **3715.502** of the Revised Code shall notify the board, in a manner determined by the board, within thirty days of discontinuation.

(1) Except in the event of a drug shortage, a pharmacy submitting notification of ~~**naloxone**~~ **overdose reversal drug** dispensing shall ensure ~~**naloxone**~~ **such drugs** ~~**is**~~ **are** made available in accordance with this rule.

(2) A pharmacy that has submitted notification of ~~**naloxone**~~ **overdose reversal drug** dispensing shall provide initial training to all new employees and annual training to existing employees on the availability of ~~**naloxone**~~ **overdose reversal drugs** ~~**dispensing**~~ pursuant to a protocol. Employees requiring training in accordance with this paragraph shall include: pharmacists, pharmacy interns, certified pharmacy technicians, registered pharmacy technicians, pharmacy technician trainees, and support personnel, as defined in rule 4729:3-1-01 of the Administrative Code, that have direct contact with the public. Training documentation records shall be maintained for a period of three years and shall be made readily retrievable.

(**H** ~~**L**~~) Paragraph (**G** ~~**K**~~) of this rule does not apply to institutional pharmacies that provide ~~**naloxone**~~ **overdose reversal drugs** to inpatients or patients upon discharge.

(I) As used in this rule, "prescriber" means any of the following:

(1) A physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery;

(2) A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner who holds a current, valid license issued under Chapter 4723. of the Revised Code to practice nursing as an advanced practice registered nurse;

(3) A physician assistant who holds a license to practice as a physician assistant issued under Chapter 4730. of the Revised Code, holds a valid prescriber number issued by the state medical board, and has been granted physician-delegated prescriptive authority; or

(4) A certified mental health assistant licensed under Chapter 4772. of the Revised Code who has been granted physician-delegated prescriptive authority by the physician supervising the certified mental health assistant.

(J) Nothing in this rule shall prohibit the sale or distribution of an overdose reversal drug by pharmacy personnel in accordance with section 3715.50 of the Revised Code.

Rule 4729:1-3-06 | Dispensing of epinephrine ~~autoinjectors~~ by pharmacists. (AMEND)

(A) A pharmacist may dispense ~~**an**~~ epinephrine**, which shall be an epinephrine autoinjector or any other formulation authorized pursuant to Chapter 4729. of the Revised Code,** ~~**autoinjector**~~ without a prescription to either of the following in accordance with a protocol specified in paragraph (B) of this rule:

(1) An individual who there is reason to believe is experiencing or at risk of experiencing anaphylaxis if the pharmacy affiliated with the pharmacist has a record of previously dispensing epinephrine to the individual in accordance with a prescription issued by a licensed health professional authorized to prescribe drugs; or

(2) An individual acting on behalf of a qualified entity, as defined in section 3728.01 of the Revised Code.

(B) A physician-established protocol for the dispensing of epinephrine ~~**autoinjectors**~~ by a pharmacist or pharmacy intern under the direct supervision of a pharmacist shall include, but is not limited to, the following:

(1) Indications for use of epinephrine ~~**autoinjectors**~~, including criteria for identifying persons eligible to receive an autoinjector under the protocol.

(2) Precautions and contraindications related to the dispensing of epinephrine ~~**autoinjectors**~~.

(3) Epinephrine ~~**autoinjectors**~~ **formulations** authorized to be dispensed, including all the following information:

(a) Name of product;

(b) Dose;

(c) Quantity to be dispensed; and

(d) Directions for use.

(4) Any patient instructions in addition to the training specified in this rule and rule 4729:2-3-06 of the Administrative Code.

(C)

(1) A pharmacist who dispenses ~~**an**~~ epinephrine ~~**autoinjector**~~ pursuant to this rule shall instruct the individual to whom the epinephrine ~~**autoinjector**~~ is dispensed, either verbally or in writing, to summon emergency services as soon as practicable either before or after administering epinephrine.

(2) A pharmacist who dispenses ~~**an**~~ epinephrine ~~**autoinjector**~~ to an individual identified in paragraph (A) of this rule shall provide notification of the dispensing to the individual's primary care provider, if known, or to the prescriber who issued the individual the initial prescription for ~~**an**~~ epinephrine ~~**autoinjector**~~. Notification shall be conducted using one of the following methods that is capable of confirming delivery of the required notification:

(a) Electronic mail;

(b) Interoperable electronic medical records system;

(c) Facsimile;

(d) Electronic prescribing system;

(e) Electronic pharmacy record system;

(f) Documented verbal communication;

(g) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

(D) When a pharmacist dispenses ~~**an**~~ epinephrine ~~**autoinjector**~~ pursuant to this rule, the pharmacist, or pharmacy intern under the direct supervision of a pharmacist, shall provide to the person receiving the ~~**device**~~ **medication** instruction on the proper method of administering epinephrine ~~**with the device**~~.

(E) A terminal distributor of dangerous drugs shall ensure that all pharmacists that dispense epinephrine ~~**autoinjectors**~~ pursuant to this rule are trained on the use of epinephrine and can meet the training requirements listed in paragraphs (C) and (D) of this rule.

(F) A pharmacist may document the dispensing of ~~an~~ epinephrine ~~autoinjector~~ by the pharmacist or pharmacy intern under the direct supervision of the pharmacist on a prescription form. The form may be assigned a number for record-keeping purposes.

(G) This rule does not affect the authority of a pharmacist to:

(1) Dispense a new prescription or refill for epinephrine; or

(2) Contact a prescriber to obtain a new oral prescription for ~~an~~ epinephrine ~~autoinjector~~ in accordance with the applicable provisions of division 4729:5 of the Administrative Code.

(H) All physician-established protocols must be signed and dated by the physician prior to implementation and maintained by the terminal distributor of dangerous drugs. The protocols shall be renewed by a physician on a biennial basis.

(1) A physician may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs.

(2) Each location licensed as a terminal distributor of dangerous drugs shall maintain a copy of the protocol on-site for inspection by an agent, inspector, or employee of the state board of pharmacy.

(I) As used in this rule:

(1) "Epinephrine" means an epinephrine autoinjector or any other formulation authorized pursuant to Chapter 4729. of the Revised Code.

(2) "Pharmacy affiliated with the pharmacist" as used in paragraph (A)(1) of this rule means the pharmacy that dispensed the epinephrine autoinjector or another pharmacy under common ownership of the pharmacy that dispensed the epinephrine autoinjector.

Rule 4729:1-3-07 | Dispensing nicotine replacement therapy by pharmacists. (AMEND)

(A) As used in this rule: ~~,~~

(**1**) "Nicotine replacement therapy" means a drug, including a dangerous drug, that delivers small doses of nicotine to an individual for the purpose of aiding in tobacco cessation or smoking cessation including for the cessation of alternative nicotine delivery systems, such as e-cigarettes.

(2) "Prescriber" means any of the following:

(a) Physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery; or

(b) Certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner licensed under Chapter 4723. of the Revised Code.

(B) A pharmacist may dispense nicotine replacement therapy to individuals who are eighteen years old or older and seeking to quit using tobacco-containing products in accordance with paragraph (C) of this rule.

(C) For a pharmacist to be authorized to dispense nicotine replacement therapy under this rule, the pharmacist shall do both of the following:

(1) Successfully complete a course on nicotine replacement therapy that is taught by a provider that is accredited by the accreditation council for pharmacy education, or another provider approved by the state board of pharmacy, and that meets requirements established in paragraph (H) of this rule; and

(2) Practice in accordance with a ~~**physician**~~ **prescriber**-authorized protocol that meets the requirements of paragraph (D) of this rule.

(D) All of the following apply with respect to the protocol required by this rule:

(1) The protocol shall be established by a **prescriber defined in paragraph (A) of this rule.** ~~**physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.**~~

(2) The protocol shall specify a definitive set of treatment guidelines and the locations at which a pharmacist may dispense nicotine replacement therapy under this rule.

(3) The protocol shall specify the types of nicotine replacement therapy that may be dispensed.

(4) The protocol shall include provisions for implementation of the following requirements:

(a) Use by the pharmacist of a screening procedure, recommended by the United States centers for disease control and prevention or another organization approved by the board, to determine if an individual is a good candidate to receive nicotine replacement therapy dispensed as authorized by this rule;

(b) A requirement that the pharmacist refer high-risk individuals, as defined in the protocol, or individuals with contraindications to a primary care provider or, as appropriate, to another type of provider;

(c) A requirement that the pharmacist develop and implement a follow-up care plan in accordance with paragraph (D)(5) of this rule, including a recommendation by the pharmacist that the individual seek additional assistance with behavior change, including assistance from the Ohio tobacco quit line made available by the department of health.

(5) A follow-up care plan shall include all the following:

(a) A recommendation that the individual notify their provider that they have initiated a quit attempt;

(b) A plan to deal with the psychological aspects of tobacco addiction, including information regarding how to seek services from the Ohio tobacco quit line;

(c) A plan for how to deal with possible side effects;

(d) Instructions regarding how, when, and how many times to refill the medication;

(e) Follow-up with patient should occur within a clinically appropriate length of time after the initiation of the nicotine replacement therapy as deemed appropriate by the pharmacist;

(f) How and when to stop using nicotine replacement therapy;

(g) Instructions to seek assistance from the pharmacist or provider before continuing to use the medication if a relapse occurs and tobacco use is reinitiated;

(h) If a patient returns to the pharmacy to report a relapse, the follow-up care plan should include efforts to identify smoking cues and triggers and decide upon alternative coping strategies before a follow-up attempt to quit tobacco;

(i) If dual therapy is indicated for the patient, instructions to seek assistance from a prescribing provider to add prescription-only smoking cessation medication to the pharmacist-initiated nicotine replacement therapy.

(6) All ~~**physician**~~ **prescriber**-established protocols must be signed and dated by the ~~**physician**~~ **prescriber** prior to implementation and maintained by the terminal distributor of dangerous drugs. The protocols shall be renewed by a ~~**physician**~~ **prescriber** on a biennial basis.

(a) A ~~**physician**~~ **prescriber** may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs.

(b) Each location licensed as a terminal distributor of dangerous drugs shall maintain a copy of the protocol on-site for inspection by an agent, inspector, or employee of the state board of pharmacy.

(E)

(1) Documentation related to screening, dispensing, and follow-up care plans shall be maintained in the records of the terminal distributor of dangerous drugs where the pharmacist practices for at least three years. Dispensing of nicotine replacement therapy may be documented on a prescription form, and the form may be assigned a number for recordkeeping purposes.

(2) Not later than seventy-two hours after a screening is conducted under this rule and the patient has been identified as a candidate for smoking cessation therapy, the pharmacist shall provide notice to the individual's primary care provider, if known, or to the individual if the primary care provider is unknown. The notice shall include results of the screening, and if applicable, the dispensing record and follow-up care plan. Notification shall be conducted

using one of the following methods that is capable of confirming delivery of the required notification:

(a) Electronic mail;

(b) Interoperable electronic medical records system;

(c) Facsimile;

(d) Electronic prescribing system;

(e) Electronic pharmacy record system;

(f) Documented verbal communication; or

(g) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

(3) A copy of the documentation identified in paragraph (E)(1) of this rule shall also be provided to the individual or the individual's primary care provider on request.

(F) This rule does not affect the authority of a pharmacist to do any of the following:

(1) Fill or refill prescriptions for nicotine replacement therapy;

(2) Sell nicotine replacement therapy that does not require a prescription.

(G) A provider who is not accredited by the accreditation council for pharmacy education may petition the board for approval of a course in accordance with division (C) of section 4729.284 of the Revised Code. The board shall develop and post a petition application on its website providing the criteria for approval.

(H) No pharmacist shall do either of the following:

(1) Dispense nicotine replacement therapy in accordance with a protocol unless the requirements of paragraph (C) of this rule have been met;

(2) Delegate to any person the pharmacist's authority to engage in or supervise the dispensing of nicotine replacement therapy.

(I) A terminal distributor of dangerous drugs shall ensure that all pharmacists that dispense nicotine replacement therapy pursuant to this rule have completed the requirements set forth in paragraph (C) of this rule.

(J) A terminal distributor of dangerous drugs dispensing nicotine replacement therapy in accordance with this rule shall also comply with the applicable record keeping provisions of Chapter 4729:5-5, 4729:5-8, or 4729:5-9 of the Administrative Code.

Rule 4729:1-6-01 | Definitions - consult agreements. (AMEND)

(A) "Certified nurse practitioner," "certified nurse-midwife," "clinical nurse specialist," and "standard care arrangement" have the same meanings as in section 4723.01 of the Revised Code.

(B) "Collaborating physician" means a physician who has entered into a standard care arrangement with a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner.

(C) "Communication between a pharmacist and practitioner acting under a consult agreement," as used in division (D)(6) of section 4729.39 of the Revised Code, means any of the following:

(1) Electronic mail that confirms delivery;

(2) Interoperable electronic medical records system;

(3) Facsimile that confirms delivery;

(4) Electronic prescribing system;

(5) Electronic pharmacy record system;

(6) Documented verbal communication; or

(7) Any other method of documented notification as outlined in the consult agreement between the pharmacist and practitioner.

(D) "Comorbid disease," as used in division (D)(3)(a) of section 4729.39 of the Revised Code, means an additional disease that co-occurs with a primary disease. A comorbid disease may be related to or occur independently of the primary disease.

(E)

(1) "Communicated" as used in division (D)(4) of section 4729.39 of the Revised Code, means consent shall be obtained from each individual patient participating in a consult agreement. With the exception of inpatient management of patient care at an institutional facility,

consent shall be obtained prior to a pharmacist managing a patient's drug therapy and shall communicate all of the following:

(a) A pharmacist may be utilized in the management of the patient's care; and

(b) The patient's or an individual authorized to act on behalf of a patient's right to elect to participate in and withdraw from the consult agreement.

(2) Consent as required in paragraph (E)(1) of this rule may be obtained as a part of the patient's initial consent to treatment.

(F) "Consult agreement" means an agreement that has been entered into pursuant to section 4729.39 of the Revised Code.

(G) “Collaborating pharmacist” means a pharmacist managing a patient's drug therapy pursuant to a consult agreement.

(**H** ~~**G**~~) "Institutional facility" has the same meaning as defined in ~~**agency 4729**~~ **chapter 4729:5-9** of the Administrative Code.

~~**(H) "Managing pharmacist" means a pharmacist managing a patient's drug therapy pursuant to a consult agreement.**~~

(I) "Physician" means an individual authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.

(J) "Physician assistant" means an individual who is licensed to practice as a physician assistant under Chapter 4730. of the Revised Code, holds a valid prescriber number issued by the state medical board, and has been granted physician-delegated prescriptive authority.

(K)

(1) "Positive identification" means a method of identifying a person that does not rely on the use of a private personal identifier such as a password, but must use a secure means of identification that includes any of the following:

(a) A manual signature on a hard copy record;

(b) A magnetic card reader;

(c) A bar code reader;

(d) A biometric method;

(e) A proximity badge reader;

(f) A board approved system of randomly generated personal questions;

(g) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who performed the action requiring positive identification. The printout must be maintained for three years and made readily retrievable; or

(h) Other effective methods for identifying individuals that have been approved by the board.

(2) **~~A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.~~** **A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier.**

(L) "Practitioner" means any of the following:

(1) Physician;

(2) Physician assistant;

(3) Clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner.

(M) "Primary disease," as used in division (D)(3)(a) of section 4729.39 of the Revised Code, means a disease that arises spontaneously and is not associated with or caused by a previous disease, injury, or event, but that may lead to a comorbid disease.

(N) "OARRS report" means a report of information related to a specific person generated by the drug database established and maintained pursuant to section 4729.75 of the Revised Code.

(O) "Readily retrievable" means that records maintained in accordance with this chapter shall be kept in such a manner that, upon request, they can be produced for review no later than three business days to an agent, officer, or inspector of the board.

(P) "Supervising physician" means a physician who has entered into a supervision agreement with a physician assistant under section 4730.19 of the Revised Code.

(Q) "Training and experience related to the particular diagnosis for which drug therapy is prescribed," as used in division (C)(3) of section 4729.39 of the Revised Code, means an Ohio licensed pharmacist whose license is in good standing and who meets the training and experience criteria specified in paragraph (A)(1)(k) of rule 4729:1-6-02 of the Administrative Code.

(R) "Written notice," as used in division (D)(2)(b) of section 4729.39 of the Revised Code, means one of the following methods that is capable of confirming delivery of the required written notice:

(1) Electronic mail;

(2) Interoperable electronic medical records system;

(3) Facsimile;

(4) Electronic prescribing system;

(5) Electronic pharmacy record system;

(6) Any other method in writing that provides notice in a timely manner; or

(7) Any other method of notification as outlined in the consult agreement that might reasonably be expected to allow for the confirmed transmission of the written notification required.

Rule 4729:1-6-02 | Consult agreements. (AMEND)

(A) Requirements of a consult agreement.

(1) A consult agreement shall include all of the following:

(a) Identification of the practitioner(s) and pharmacist(s) authorized to enter into the agreement. This may include:

(i) Individual names of practitioners and pharmacists;

(ii) Practitioner or pharmacist practice groups; or

(iii) Identification based on institutional credentialing or privileging.

(b) The specific diagnoses and diseases being managed under the agreement, including whether each disease is primary or comorbid.

(c) A description of the drugs or drug categories managed as part of the agreement.

(d) A description of the procedures **(i.e., processes)**, decision criteria, and plan the **collaborating ~~managing~~** pharmacist is to follow in acting under a consult agreement. Such a description should provide a reasonable set of parameters of the activities a **collaborating ~~managing~~** pharmacist is allowed to perform under a consult agreement.

(e) A description of the types of tests permitted pursuant to section 4729.39 of the Revised Code that may be ordered and evaluated by the **collaborating ~~managing~~** pharmacist**. Tests may only be ordered and evaluated if the tests relate specifically to the management of a patient's drug therapy.** ~~**as long as the tests relate to the management of drug therapy. This may include specific tests or categories of testing that may be ordered and evaluated to manage the diagnoses and diseases under the agreement.**~~

(f) A description of how the **collaborating ~~managing~~** pharmacist shall maintain a record of each action taken for each patient whose drug therapy is managed under the agreement. All prescribing, administering, and dispensing of drugs shall be documented using positive identification.

(g) A description of how communication between a **collaborating ~~managing~~** pharmacist and practitioner acting under a consult agreement shall take place at regular intervals specified by the practitioner who authorized the agreement. The agreement may include a requirement that a **collaborating ~~managing~~** pharmacist send a consult report to each consulting practitioner.

(h) A provision that allows a practitioner to override a decision made by the **collaborating ~~managing~~** pharmacist when appropriate.

(i) A quality assurance mechanism to ensure that **collaborating ~~managing~~** pharmacists only act within the scope authorized by the consult agreement.

(j) A description of a continuous quality improvement (CQI) program used to evaluate the effectiveness of patient care and ensure positive patient outcomes. The CQI program shall be implemented pursuant to the agreement.

(k) The training and experience criteria for **collaborating ~~managing~~** pharmacists. The criteria may include privileging or credentialing, board certification, continuing education**,** or any other training requirements. The agreement shall include a process to verify that the **collaborating ~~managing~~** pharmacists meet the specified criteria.

(l) An effective date and expiration date.

(2) Institutional **facilities as defined in Chapter 4729:5-9 of the Administrative Code** or **~~ambulatory~~** outpatient facilities **owned and operated by institutional facilities** may implement a consult agreement and meet the requirements of paragraphs (A)(1)(b) to (A)(1)(e) of this rule through institutional credentialing standards or policies. Such standards or policies shall be referenced as part of the consult agreement and made readily retrievable.

(3) The agreement shall be signed by the primary practitioner, which may include a medical director or designee if the designee is licensed pursuant to Chapter 4731. of the Revised Code, and one of the following:

(a) The terminal distributor's responsible person, which may include the responsible person's designee if the designee meets the qualifications of the responsible person pursuant to rule 4729:5-2-01 of the Administrative Code; or

(b) A **collaborating ~~managing~~** pharmacist licensed pursuant to Chapter 4729. of the Revised Code.

(4) All amendments to a consult agreement shall be signed and dated by the primary practitioner, which may include a medical director or designee if the designee is licensed pursuant to Chapter 4731. of the Revised Code, and one of the following:

(a) The terminal distributor's responsible person, which may include the responsible person's designee if the designee meets the qualifications of the responsible person pursuant to rule 4729:5-2-01 of the Administrative Code; or

(b) A **collaborating ~~managing~~** pharmacist licensed pursuant to Chapter 4729. of the Revised Code.

(5) A consult agreement shall be valid for a period not to exceed two years.

(6) Only Ohio licensed practitioners and Ohio licensed pharmacists **physically located in the United States** may participate in a consult agreement pursuant to section 4729.39 of the Revised Code.

(B) Record keeping. As required by section 4729.39 of the Revised Code, a **collaborating ~~managing~~** pharmacist shall maintain a record of each action taken for each patient whose drug therapy is managed under the agreement. These records shall be maintained in such a manner that they are readily retrievable for at least three years from the date of the last action taken under the agreement. Such consult agreements shall be considered confidential patient records and are subject to the confidentiality requirements of rule 4729:5-3-05 of the Administrative Code.

(C) Managing drug therapy.

(1) For the purpose of implementing any actions related to the management of drug therapy listed in division (D)(1) of section 4729.39 of the Revised Code, the **collaborating ~~managing~~** pharmacist may be authorized as one or both of the following, as specified in the consult agreement:

(a) A prescriber authorized to issue a drug order in writing, orally, by a manually signed drug order sent via facsimile**,** or by an electronic prescribing system for drugs or combinations or mixtures of drugs to be used by a particular patient as authorized by the consult agreement.

(i) For all outpatient prescriptions issued, the pharmacist shall comply with rules 4729:5-5-15 and 4729:5-5-05 of the Administrative Code.

(ii) For all inpatient prescriptions or orders issued at an institutional facility, the pharmacist shall comply with the requirements of **~~agency 4729~~** **chapter 4729:5-9** of the Administrative Code.

(b) With respect to non-controlled dangerous drugs only, an agent of the consulting practitioner(s). As an agent of the consulting practitioner(s), a pharmacist is authorized to issue a drug order, on behalf of the consulting practitioner(s), in writing, orally, by a manually signed drug order sent via facsimile**,** or by an electronic prescribing system for drugs or combinations or mixtures of drugs to be used by a particular patient as authorized by the consult agreement. A pharmacist issuing a prescription as an agent of a practitioner shall comply with all the following:

(i) For all outpatient prescriptions, the pharmacist shall comply with rules 4729:5-5-15 and 4729:5-5-05 of the Administrative Code.

(ii) For all inpatient prescriptions or orders issued at an institutional facility, the pharmacist shall comply with the prescription requirements of **~~agency 4729~~** **chapter 4729:5-9** of the Administrative Code.

(iii) Except as provided in paragraphs (C)(1)(b)(v) and (C)(1)(b)(vi) of this rule, the prescription shall include the required information of the consulting practitioner(s).

(iv) The prescription shall also include the name of the **collaborating ~~managing~~** pharmacist acting as the agent of the consulting practitioner.

(v) The telephone number where the **collaborating ~~managing~~** pharmacist can be personally contacted during normal business hours. The telephone number may be in addition to or in place of the telephone number required by rule 4729:5-5-15 of the Administrative Code.

(vi) Pursuant to the consult agreement, all required positive identification (including a manual signature) on a prescription shall be of the **collaborating ~~managing~~** pharmacist on behalf of the consulting practitioner(s).

(2) If the **collaborating ~~managing~~** pharmacist is not the dispensing pharmacist or the person administering the dosage ordered, a copy of the consult agreement or privileging documentation shall be made available to the dispensing pharmacist or the person administering the dosage ordered if it is requested in order to prove the right of the **collaborating ~~managing~~** pharmacist to act in this manner.

(3) A **collaborating ~~managing~~** pharmacist shall request and review an OARRS report covering at least a one-year time period prior to any of the following:

(a) Adding a controlled substance drug **or a drug containing gabapentin** to a patient's drug therapy; or

(b) Adjusting a**ny of the following for a** controlled substance drug**~~'s~~ or a drug containing gabapentin:** strength, dose, dosage form, frequency of administration, or route of administration.

(4) Except as provided in paragraph (C)(5) of this rule, a **collaborating ~~managing~~** pharmacist shall not delegate drug therapy management to anyone other than another authorized pharmacist practicing under the consult agreement.

(5) A **collaborating ~~managing~~** pharmacist may delegate the administration of a drug to a licensed healthcare professional in accordance with their applicable scope of practice pursuant to the **collaborating ~~managing~~** pharmacist's order.

(6) A **collaborating ~~managing~~** pharmacist authorized to prescribe controlled substances pursuant to paragraph (C)(1)(a) of this rule shall comply with all the following:

(a) Maintain a valid controlled substance prescriber registration issued by the state board of pharmacy by submitting an application and a valid consult agreement, in a manner determined by the board, authorizing the pharmacist to prescribe controlled substances.

(i) A pharmacist shall be required to renew their controlled substance prescriber registration in accordance with a renewal schedule adopted by the board. A controlled substance prescriber registration shall be deemed void if a pharmacist does not renew their registration in accordance with the renewal schedule adopted by the board.

(ii) A pharmacist shall be required to notify the board, in a manner determined by the board, if they are no longer authorized to prescribe controlled substances pursuant to a consult agreement. Notification shall occur within five business days. A controlled substance prescriber registration shall be deemed void if the pharmacist no longer has a valid consult agreement authorizing the prescribing of a controlled substance. Failure to obtain or maintain a valid controlled substance prescriber registration prohibits a pharmacist from prescribing controlled substances.

(iii) A pharmacist applying for a controlled substance registration shall be an Ohio licensed pharmacist in good standing. The pharmacist shall not be the subject of any current board disciplinary action or have a restricted license. In determining whether to grant a registration, the board may consider any previous disciplinary action.

(iv) The board may deny a registration if the applicant fails to meet any of the required qualifications or if the board finds that issuing a controlled substance registration presents a danger to public safety.

(b) Subject to approval by the United States drug enforcement administration (D.E.A.), prescribe utilizing a valid **mid-level** D.E.A. registration**.~~, which includes either:~~**

~~(i) Obtaining and maintaining a valid registration with the D.E.A.; or~~

~~(ii) If authorized by federal law or regulation, a pharmacist who is employed as a staff prescriber of a hospital pursuant to a consult agreement who is not individually registered under the provisions of the controlled substances act and, therefore, does not possess a D.E.A. registration, may administer, dispense, and prescribe controlled substances, as specified in a consult agreement, under the registration of the hospital. A hospital that authorizes a pharmacist to dispense or prescribe under its registration~~

~~**shall assign a specific internal code number for each managing pharmacist so authorized.**~~

(c) ~~**Unless a pharmacist utilizes a hospital's D.E.A. registration,**~~ **F**ailure to obtain or maintain a valid D.E.A. registration shall prohibit a **collaborating** ~~**managing**~~ pharmacist from prescribing controlled substances.

(d) A **collaborating** pharmacist that obtains a valid registration with the D.E.A. pursuant to paragraph (C)(6)(b)~~**(i)**~~ of this rule shall:

(i) Submit the pharmacist's registration information, in a manner determined by the board, within thirty days of issuance.

(ii) Submit any changes to a pharmacist's registration, in a manner determined by the board, within thirty days of any change to the registration.

(7) A prescription, to be valid, must be issued for a legitimate medical purpose by a pharmacist authorized pursuant to a consult agreement. The responsibility for the proper prescribing is upon the **collaborating** ~~**managing**~~ pharmacist, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be considered a violation of this rule and may be subject to disciplinary action in accordance with Chapter 4729. of the Revised Code or any rule promulgated thereunder.

(D) Therapy management by formulary. The requirements of this chapter and section 4729.39 of the Revised Code do not apply within an institutional facility when the pharmacists are following the requirements of a formulary system that was developed pursuant to section 4729.381 of the Revised Code.

(E) Review of consult agreements. Upon the request of the state board of pharmacy, a pharmacist shall immediately provide a consult agreement and any relating policies or documentation pursuant to this rule and division (D)(3) of section 4729.39 of the Revised

Code. The state board of pharmacy may prohibit the execution of a consult agreement if the board finds any of the following:

(1) The agreement does not meet the requirements set forth in section 4729.39 of the Revised Code or this chapter of the Administrative Code; or

(2) The agreement, if executed, would present a danger to patient safety.

Rule 4729:1-6-03 | Standards for managing drug therapy. (AMEND)

(A) A **collaborating ~~managing~~** pharmacist shall prescribe in accordance with a valid prescriber-patient relationship. This includes, but is not limited to, the following:

(1) Reviewing a thorough history of the patient;

(2) Except as provided in paragraphs (F) and (G)(2) of this rule, conducting an initial consultation with the patient via in-person meeting, video conference, or by telephone **in accordance with all state and federal laws, rules, and regulations**;

(3) Ordering tests **that are related to the drug therapy being managed** and evaluation of test results in accordance with section 4729.39 of the Revised Code;

(4) Prescribing medication in accordance this division of the Administrative Code, ruling out the existence of any recognized contraindications;

(5) Consulting with the **~~authorizing~~** practitioner **or practitioners ~~on~~ who authorized** the consult agreement when necessary; and

(6) Documenting these steps in the patient's medical record.

(B) The pharmacist's prescriptive authority shall not exceed what is specified in the consult agreement.

(C) A **collaborating ~~managing~~** pharmacist shall comply with the same requirements for the prescribing dangerous drugs pursuant to Chapter 4731 of the Administrative Code.

(D) A pharmacist**~~, as part of an opioid treatment program licensed by the state,~~** may administer controlled substance narcotics pursuant to a consult agreement in accordance with this division of the Administrative Code for the maintenance or detoxification treatment of **~~opioid addiction~~ opioid-use disorder**.

(E) Except as provided in paragraphs (F) and (G)(1) of this rule, a **collaborating ~~managing~~** pharmacist shall, at a minimum, conduct a follow-up consultation with the patient on an annual basis. The review shall be conducted via in-person meeting, video conference**,** or by telephone and shall be documented in the patient's medical record.

(F) Paragraphs (A)(2) and (E) of this rule do not apply to the inpatient management **of** a patient's drug therapy pursuant to a consult agreement in an institutional facility.

(G) A hospital, clinic, or other healthcare facility that utilizes **collaborating** ~~**managing**~~ pharmacists for the purposes of authorizing prescriptions that were originally issued by a consulting practitioner shall comply with the following:

(1)

(a) A **collaborating** ~~**managing**~~ pharmacist, consulting practitioner, or agent of the consulting practitioner shall, at a minimum, conduct a follow-up consultation with the patient on an annual basis. The review shall be conducted via in-person meeting, video conference, or by telephone and shall be documented in the patient's medical record.

(b) The required follow-up consultation with patients pursuant to paragraph (G)(1)(a) of this rule does not apply if the patient, or an individual authorized to act on behalf of a patient, elects to opt-out of the follow-up consultation.

(2) The initial consultation requirement by a **collaborating** ~~**managing**~~ pharmacist is not required if the **collaborating** ~~**managing**~~ pharmacist is only engaged in the authorization of prescriptions.

(3) In addition to the communication requirements in paragraph (C) of rule 4729:1-6-01 of the Administrative Code, the hospital, clinic, or healthcare facility shall:

(a) Obtain patient consent specifically authorizing the use of **collaborating** ~~**managing**~~ pharmacists to authorize prescriptions pursuant to a consult agreement.

(b) Provide contact information, either electronically or in writing, of the person or persons at the hospital, clinic, or other healthcare facility who are responsible for answering questions regarding the patient's drug therapy.

(4) Notwithstanding any other provision of the Administrative Code, all prescriptions authorized pursuant to this paragraph shall include the name of the **collaborating** ~~**managing**~~ pharmacist authorizing the prescription and the telephone number where the **collaborating** ~~**managing**~~ pharmacist can be personally contacted during normal business hours.

(5) **Collaborating ~~managing~~** pharmacists authorizing prescription refills in accordance with this paragraph shall utilize an electronic health records system that complies with the following:

(a) The system shall provide **collaborating ~~managing~~** pharmacists and consulting practitioner with real-time access to the patient's complete medical record maintained by the consulting practitioner, including patient lab results and prescriber and pharmacist notes.

(b) The electronic health records system shall have the capability to allow communication between **collaborating ~~managing~~** pharmacists and consulting practitioner.

(6) The consult agreement shall include an algorithm that is specific to refill authorizations. The algorithm must include, but is not limited to, the following decision criteria for **collaborating ~~managing~~** pharmacists to follow when conducting prescription refill authorizations:

(a) Required lab results;

(b) Any restrictions or limitations; and

(c) The maximum amount of time between prescriber visits a refill may be authorized based upon prevailing standards of care.

(H) Consult agreements shall not be utilized for the following:

(1) Administration of intravenous dangerous drugs; and

(2) The performance of cosmetic procedures, such as the injection of botulinum toxin or dermal fillers.