12/19/18

The following information is being provided pursuant to the requirements of Executive Order 2011-01K and Senate Bill 2 of the 129th General Assembly, which require state agencies, including the State of Ohio Board of Pharmacy, to draft rules in collaboration with stakeholders, assess and justify an adverse impact on the business community (as defined by S.B. 2), and provide an opportunity for the affected public to provide input on the following rules.

New

- 4729:1-4-02 – Establishes the requirements for when and how pharmacists should notify the Board of Pharmacy of violations of Ohio laws and rules.

Amends:

- 4729:1-6-01 – Establishes the definition section for consult agreement rule chapter. Amended to include definition for positive identification and reordered definitions alphabetically.
- 4729:1-6-02 – Provides general requirements for a consult agreement. Specifies the actions a pharmacist must record for a patient's drug therapy under a consult agreement, when a pharmacist can prescribe a drug order for drug therapy under a consult agreement, and when a pharmacist can issue a prescription. Requires pharmacist to submit a valid consult agreement to receive a controlled substance prescriber registration issued by the Board of Pharmacy. Requires a pharmacist who obtains a valid D.E.A. registration to submit registration information to the board within 30 days, and submit any changes to the registration within 30 days. Amended to include cross references for inpatient and outpatient prescription requirements. Language was added that specific tests or categories of testing may be ordered to manage the diagnoses and diseases under the agreement.
- 4729:1-6-03 – Provides the general requirements for managing drug therapy. Amended to correct cross references with appropriate sections of the Ohio Administrative Code.

Comments on the proposed rules will be accepted until close of business on **January 18, 2019**. Please send all comments to the following email address: **Ali.Simon@pharmacy.ohio.gov**

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

CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: State of Ohio Board of Pharmacy

Regulation/Package Title: Duty to Report, Consult Agreements

Rule Number(s):

New:

- 4729:1-4-02

Amends:

- 4729:1-6-01
- 4729:1-6-02
- 4729:1-6-03

Date: 12/19/2018

Rule Type:

New	5-Year Review
Amended	Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

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

New

- 4729:1-4-02 – Establishes the requirements for when and how pharmacists should notify the Board of Pharmacy of violations of Ohio laws and rules.

Amends:

- 4729:1-6-01 – Establishes the definition section for consult agreement rule chapter. Amended to include definition for positive identification and reordered definitions alphabetically.
- 4729:1-6-02 – Provides general requirements for a consult agreement. Specifies the actions a pharmacist must record for a patient's drug therapy under a consult agreement, when a pharmacist can prescribe a drug order for drug therapy under a consult agreement, and when a pharmacist can issue a prescription. Requires pharmacist to submit a valid consult agreement to receive a controlled substance prescriber registration issued by the Board of Pharmacy. Requires a pharmacist who obtains a valid D.E.A. registration to submit registration information to the board within 30 days, and submit any changes to the registration within 30 days. Amended to include cross references for inpatient and outpatient prescription requirements. Language was added that specific tests or categories of testing may be ordered to manage the diagnoses and diseases under the agreement.
- 4729:1-6-03 – Provides the general requirements for managing drug therapy. Amended to correct cross references with appropriate sections of the Ohio Administrative Code.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

The proposed rule is authorized by sections 4729.10, 4729.26, 4729.39 and 3719.28 of the Ohio Revised Code.

3. 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?

The rules do not implement a federal requirement.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

These rules exceed federal requirements because the regulation of the pharmacy profession has traditionally been done at the state level by legislatively created state boards of pharmacy.

5. **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 4729.10 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules requiring a licensee or registrant to report to the board a violation of state or federal law.

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

Section 4729.39 of the Ohio Revised Code authorizes the state board of pharmacy to adopt rules regarding pharmacist consult agreements.

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

The success of the regulation 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 rule.

Development of the Regulation

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

Chapter 4729:1-6 was reviewed by the Board's Rules Review Committee. The Committee, composed of pharmacists from a number of practice settings, is responsible for reviewing and approving all rules prior to their legislatively mandated five-year date.

Rule 4729:1-4-02 was reviewed by a stakeholder group of pharmacy professionals convened by the Board to specifically discuss the issue of duty to report.

Prior to filing with CSI, the rule package was reviewed and approved by the Board of Pharmacy.

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

For Chapter 4729:1-6, the Board of Pharmacy Rules Review Committee recommended the inclusion of language that broadens the testing that may be conduct when managing a patient's drug therapy.

For rule 4729:1-4-02, the stakeholder group proposed modifications to the reporting requirements for errors in dispensing. It was determined that errors resulting from recklessness or unprofessional conduct should be reported to the Board.

9. 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.

10. 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?

As the regulations are essential to protecting the public's safety by ensuring uniform standards for the practice of pharmacy and the reporting of violations, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

11. Did the Agency specifically consider a performance-based regulation? Please explain. ***Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.***

The agency did not consider a performance-based regulation for this rule package. It is the Board's responsibility to ensure uniform procedures for licensure and the practice of pharmacy.

12. 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 rule to ensure that the regulations do not duplicate another State of Ohio Board of Pharmacy regulation.

13. 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 feedback from the Board's legal department for every citation submitted.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;

The rule package impacts the following:

- Pharmacists

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

Violation of this rule may result in administrative licensure discipline for a pharmacist. Discipline might include reprimand, continuing education, suspension of a license, monetary fine and/or revocation of a license.

c. Quantify the expected adverse impact from the regulation.

New

- 4729:1-4-02 – Establishes the requirements for when and how pharmacists should notify the Board of Pharmacy of violations of Ohio laws and rules. This rule will require the reporting of suspected violations to the Board. The suspected violations may be reported using the Board's online complaint form, which takes approximately 10-15 minutes per submission.

Amends:

- 4729:1-6-01 – Establishes the definition section for consult agreement rule chapter. Amended to include definition for positive identification and reordered definitions alphabetically. The consent requirement may add additional administrative costs to entities operating under a consult agreement, however, such consent may be incorporated as part of the patient's overall consent to treatment.
- 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 $731.00

every three years, while the application takes approximate 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 30 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.

- 4729:1-6-03 – Provides the general requirements for managing drug therapy. Amended to correct cross references with appropriate sections of the Ohio Administrative Code. Facilities may experience administrative costs to comply with requirements for managing drug therapy, including annual patient follow-ups.

15. 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. They ensure uniform regulations that allow for:

- The protection of the health and safety of patients receiving drug therapy under a consult agreement;
- The Board has the most up-to-date information on licensees prescribing controlled substances;
- The Board is made aware of violations of Ohio laws and rules on the part of its licensees.

Regulatory Flexibility

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

This rule package does 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.

17. 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 State of 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 failure to report violations of Ohio law are not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

18. 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.

4729:1-4-02 Duty to Report. (New)

(A) As used in this rule:

(1) "Error in dispensing" or "prescription error" means an act or omission of clinical

significance relating to the dispensing of a drug. An error in dispensing may be considered a violation of division (A)(2) of section 3715.52 and section 3715.64 of the Revised Code.

(2)"Harm" means impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting there from.

(3)"Intervention" means a change in therapy or active medical/surgical treatment.

(4) "Intervention necessary to sustain life" means cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.).

(5) “Reckless behavior” means a person who acts recklessly or who is reckless. A person acts recklessly when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that the person's conduct is likely to cause a certain result or is likely to be of a certain nature. A person is reckless with respect to circumstances when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that such circumstances are likely to exist.

(6) “Unprofessional conduct” has the same meaning as defined in paragraph (A) of rule 4729:1-4-01 of the Administrative Code.

(B) Pursuant to section 4729.10 of the Revised Code, a pharmacist who has knowledge, from direct observation or objective evidence, of violations described in paragraph (C) of this rule shall report such conduct to the state board of pharmacy.

(C) The following shall be reported to the board:

(1) Except as provided in paragraph (C)(1)(a) of this rule, conduct indicating an individual licensed or registered by the board is addicted to or is suspected to be abusing alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.

(a) A pharmacist shall not be required to report in accordance with this rule if the pharmacist becomes aware of any condition described in paragraph (C)(1) of this rule as a result of either:

(i) The pharmacist's treatment of the individual for the condition; or

(ii) The pharmacist having access to the individual's protected health information.

(2) Except as provided in paragraph (H) of this rule, violations, attempts to violate or aid and abet in the violation of any of the provisions of Chapters 4729., 3715., 3719., 3796., 2925. and 2913.

of the Revised Code, or any rule adopted by the board under those provisions by an individual or entity licensed or registered by the board.

(3) Conduct by a pharmacy technician trainee, registered pharmacy technician, certified pharmacy technician, pharmacy intern or pharmacist that constitutes unprofessional conduct or dishonesty as defined in rule 4729:1-4-01 of the Administrative Code.

(D)

(1) Pursuant to section 4729.23 of the Revised Code, the identity of the pharmacist making a report in accordance with this rule shall remain confidential.

(2) Notwithstanding the confidentiality provided in accordance with paragraph (D)(1) of this rule, a pharmacist may be required to testify in a disciplinary proceeding as to the conduct or violations listed in paragraph (C) of this rule without disclosing the pharmacist was the reporting individual.

(E) Reporting required in accordance with this rule shall be made in writing, either by mail, using the board's online complaint form (available on the board's web site: www.pharmacy.ohio.gov), or by telephone and shall include the following information:

(1) The name of the licensee, registrant or other individual who may have committed a violation listed in paragraph (C) of this rule;

(2) The violation which is believed to have occurred; and (3) The date(s) of and place(s) of occurrence(s), if known.

(F) A licensed pharmacist shall notify the board of any of the following:

(1) Any criminal conviction within ten days after the date of conviction, except for minor traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or expired registration.

(2) The pharmacist is convicted of, plead guilty to, is subject to a judicial finding of eligibility for intervention in lieu of conviction in this state under section 2951.041 of the Revised Code or the equivalent thereof in another jurisdiction within ten days after the individual is deemed eligible.

(3) The pharmacist is granted entry into a diversion program, deferred prosecution program, or the equivalent thereof within ten days after the individual is granted entry into a program.

(4) Any arrest for a felony within ten days after the arrest.

(G) A pharmacist shall notify the board of any disciplinary licensing or registration action taken by another state against the licensee within ten days of the notice action. This includes, but is not limited to, a disciplinary action that is stayed pending appeal.

(H) An error in dispensing shall not be required to be reported pursuant to paragraph (C) of this rule except when the error is the result of reckless behavior or unprofessional conduct and meets any of the following per the National Coordinating Council for Medication Error Reporting and Prevention's Index for Categorizing Medication Errors (2/20/2001):

(1) An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention;

(2) An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization;

(3) An error occurred that may have contributed to or resulted in permanent patient harm;

(4) An error occurred that required intervention necessary to sustain life; or

(5) An error occurred that may have contributed to or resulted in the patient's death.

(J) Pursuant to rule 4729.10 of the Revised Code, in the absence of fraud or bad faith, a person who reports in accordance with this rule or testifies in any adjudication conducted under Chapter 119. of the Revised Code is not liable to any person for damages in a civil action as a result of the report or testimony.

Chapter 4729:1-6 Consult Agreements with Physicians

4729:1-6-01 Definitions - consult agreements.

(A) "Communication between a pharmacist and physician acting under a consult agreement", as used in division (B)(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 physician.

(B) "Comorbid disease," as used in division (B)(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.

(C)

(1) "Communicated" as used in division (B)(4) of section 4729.39, 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 ~~as defined in rule 4729-17-01 of the Administrative Code~~, 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 (C)(1) of this rule may be obtained as a part of the patient's initial consent to treatment.

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

(~~C~~E) "Institutional facility" has the same meaning as defined in agency 4729 ~~rule 4729-17-01~~ of the Administrative Code.

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

(G)

(1) "Positive identification" means a method of identifying a person that does not rely solely on the use of a private personal identifier such as a password, but must also include a secure means of identification such as 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 prescribed, administered, or dispensed the dangerous drug or controlled substance. The printout must be maintained for three years and made available on request to those individuals authorized by law to review such records; 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.

(~~D~~H) "Primary disease," as used in division (B)(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.

(~~E~~I) "Training and experience related to the particular diagnosis for which drug therapy is prescribed," as used in division (A)(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.

(~~F~~J) "Written notice," as used in division (B)(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.

~~(H) "Communicated" as used in division (B)(4) of section 4729.39, 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 as defined in rule 4729-17-01 of the Administrative Code, consent shall be obtained prior to a pharmacist managing a patient's drug therapy and shall communicate all of the following:~~

~~(1) A pharmacist may be utilized in the management of the patient's care; and~~

~~(2) 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.~~

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

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

4729:1-6-02 Consult agreements.

(A) Requirements of a consult agreement.

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

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

(i) Individual names of physicians and pharmacists;

(ii) Physician 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, decision criteria, and plan the 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 managing pharmacist is allowed to perform under a consult agreement.

(e) A description of the types of blood, urine or other tests permitted pursuant to section 4729.39 of the Revised Code that may be ordered and evaluated by the managing pharmacist as long as the tests relate ~~directly~~ 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 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. ~~pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code.~~

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

(h) A provision that allows a physician to override a decision made by the managing pharmacist when appropriate.

(i) An appropriate quality assurance mechanism to ensure that 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 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 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 managing pharmacists meet the specified criteria.

(l) An effective date and expiration date.

(2) Institutional or ambulatory outpatient 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 available to an agent of the board upon request.

(3) The agreement shall be signed by the primary physician, 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 Chapter 4729. of the Revised Code; or

(b) A managing pharmacist licensed pursuant to Chapter 4729. of the Revised Code if that pharmacist is not practicing at a pharmacy or institutional facility licensed as a terminal distributor of dangerous drugs.

(4) All amendments to a consult agreement shall be signed and dated by the primary physician, 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 Chapter 4729. of the Revised Code; or

(b) A managing pharmacist licensed pursuant to Chapter 4729. of the Revised Code if that pharmacist is not practicing at a pharmacy or institutional facility licensed as a terminal distributor of dangerous drugs.

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

(6) Only Ohio licensed physicians and Ohio licensed pharmacists may participate in a consult agreement pursuant to section 4729.39 of the Revised Code.

(B) Recordkeeping. As required by section 4729.39 of the Revised Code, a 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 (B)(1) of section 4729.39 of the Revised Code, the 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 ~~by a pharmacist pursuant to this paragraph~~, the pharmacist shall comply with rules 4729:5-5-16 ~~4729-5-30~~ and 4729:5-5-05 ~~4729-5-13~~ 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 of the Administrative Code.

(b) With respect to non-controlled dangerous drugs only, an agent of the consulting physician(s). As an agent of the consulting physician(s), a pharmacist is authorized to issue a drug order, on behalf of the consulting physician(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 physician shall comply with ~~all of~~all the following:

(i) For all outpatient prescriptions, the pharmacist shall comply with rules 4729:5-5-16 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 of the Administrative Code.

(~~i~~iii) ~~All requirements pursuant to rules 4729-5-30 and 4729-5-13 of the Administrative Code for non-controlled dangerous drugs.~~ Except as provided in paragraphs (C)(1)(b)(~~ii~~vi) and (C)(1)(b)(~~i~~v) of this rule, the prescription shall include the required information of the consulting physician(s).

(~~ii~~vi) The prescription shall also include the name of the managing pharmacist acting as the agent of the consulting physician.

(~~iii~~v) The telephone number where the 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 as required by rule ~~4729-5-30 of the Administrative Code~~.

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

(2) If the 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 managing pharmacist to act in this manner.

(3) A managing pharmacist shall request and review an OARRS report covering at least a one-year time period, including a border state's information when the pharmacist is practicing in a county bordering another state if that state's information is available, prior to any of the following:

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

(b) Adjusting a controlled substance drug's strength, dose, dosage form, frequency of administration or route of administration.

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

(5) A 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 managing pharmacist's order.

(6) A managing pharmacist authorized to prescribe controlled substances pursuant to paragraph (C)(1)(a) of this rule shall comply with ~~all of~~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 authorizing the pharmacist to prescribe controlled substances in a manner prescribed by the board.

(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 D.E.A. registration, which includes either:

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

(ii) If permitted by D.E.A., 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, failure to obtain or maintain a valid D.E.A. registration prohibits a managing pharmacist from prescribing controlled substances.

(d) A 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 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.

(1) The requirements of this chapter and section 4729.39 of the Revised Code do not apply within an institutional ~~facility as defined in rule 4729-17-01 of the Administrative Code~~ 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 (B)(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 division of the Administrative Code; or

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

4729:1-6-03 Standards for managing drug therapy.

(A) A 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) Conducting an initial consultation with the patient via in-person meeting, video conference or by telephone;

(3) Ordering tests 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 physician on 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 managing pharmacist shall comply with the same requirements of a physician pursuant to chapter 4731-11 ~~rules 4731-11-02, 4731-11-03, 4731-11-04, 4731-11-04.1, 4731-11-08 and 4731-11-09~~ 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.

(E) A 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 a patient's drug therapy pursuant to a consult agreement in an institutional facility. ~~as defined in rule 4729-17-01 of the Administrative Code.~~

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117
CSIOhio@governor.ohio.gov