



Common Sense Initiative

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Business Impact Analysis

Agency Name: State Medical Board of Ohio

Regulation/Package Title: Pharmacy Consult Agreements

Rule Number(s): 4731-35-01; 4731-35-02, Ohio Administrative Code

Date: 3/19/19

Rule Type:

New

Amended

5-Year Review

Rescinded

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 all regulations 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.

Regulatory Intent

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

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

The rules establish the requirements for physicians entering into consult agreements with pharmacists.

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

Section 4729.39 and 4731.05, 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? If yes, please briefly explain the source and substance of the federal requirement.

No. 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.

This section is not applicable.

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 4729.39 (C) of the Ohio Revised Code requires the State Medical Board and the State Board of Pharmacy to each adopt rules to be followed by physicians and pharmacists working under a consult agreement and to establish the standards and procedures for entering into a consult agreement and managing a patient's drug therapy under a consult agreement. Each Board is also required to consult with the other in the development of the rules.

6. 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, coordination with the Board of Pharmacy, and minimal questions from licensees, medical practices, pharmacies and medical facilities regarding the provisions of the rules.

Development of the Regulation

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

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

The rules were circulated to physicians, hospital systems and other interested parties on January 18, 2019. More than 200 comments were received from physicians, pharmacists and hospital systems around the state.

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

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The following is a summary of the comments received from the interested parties:

- Nearly all comments recommended the deletion of the following sections because they are too restrictive and essentially render the consult agreements useless:
 - (1) Rule 4731-35-01(A)(1)(i): requirement for physician approval prior to the adjustment to the dose of a controlled substance;
 - (2) Rule 4731-35-02(A)(2): requirement for physician to periodically assess the patient at least one time per year.
 - (3) Rule 4731-35-02(A)(7): requirement for physician to promptly review records of all services provided to the patient under the consult agreement.
 - (4) Rule 4731-35-02(C)(4): requirement for notification and consent of the physician prior to any adjustment in current drug therapy;
 - (5) Rule 4731-35-02(D)(1): requirement for regular meetings between the primary physician and managing pharmacist to review a written consult report.

- Many of the comments expressed concerns about the wording of the informed consent provisions of the rules and suggested that the rules be modified to reflect the consent provisions in the rules promulgated by the Board of Pharmacy, as follows:
 - (1) Rule 4731-35-01(A)(1)(b): Delete the word “informed” and indicate that the patient’s consent to drug therapy management is based on Rule 4729:1-6-01 (H) and (I) of the Administrative Code. The Pharmacy Board rule indicates that the patient consent must be obtained prior to the pharmacist managing the care and that the patient must be advised that a pharmacist may be utilized in the management of the patient’s care and that the patient or individual authorized to act on behalf of the patient have a right to elect to participate in and withdraw from the consent agreement. The rule also allows the consent to be obtained as part of the patient’s initial consent to treatment.
 - (2) Rule 4731-35-02(A)(3): Delete language in (a) through (d) regarding the details regarding the consent of the patient and adding language to reflect the requirements from the Board of Pharmacy’s rule at 4729:1-6-01(H) and (I) of the Administrative Code.

- Several commenters expressed concern with the language around the scope of the managing pharmacist in Rule 4731-35-02(B)(1) and (2). It was suggested that this section could be deleted since the language of Rule 4731-35-01(A)(1)(c)-(f) and Rule 4729:1-06-02(b)-(e) already require these items to be outlined in the consult agreement.

- Several sections were duplicative or required some clean-up to align with the language from the Board of Pharmacy:
 - (1) Rule 4731-35-01(A)(1)(h): language added to match the language in Rule 4729:1-6-02(A)(1)(g) which indicates that the agreement may include a requirement that a managing pharmacist send a consult report to each consulting physician.

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- (2) Rule 4731-35-02(A)(2): Modify
the references to the sections of the consult agreement dealing with the scope of the agreement for the institutional and ambulatory outpatient facility section.
- (3) Rule 4731-35-02(A)(5): Revise the situations where an amendment to consult agreement is required so it is limited to times when the scope of the permitted procedures expands past what was contemplated.
- (4) Rule 4731-35-01(B): For recordkeeping, add language to indicate that a physician group or institution may also be the entity maintaining the records.
- (5) Rule 4731-35-01(C)(1)(b)(i), (ii): Delete duplicative words at the beginning of each paragraph.
- (6) Rule 4731-35-01(C)(1)(d): Add some language to clarify the meaning of the section.
- (7) Rule 4731-35-02(A)(6): Add some language to indicate that pharmacist's training can be verified through the credentialing process for institutional facilities.
- (8) Rule 4731-35-02(D)(2)(a): Clarify that notification is required if the pharmacist's license is revoked, suspended or denied by the Board of Pharmacy;
- (9) Rule 4731-35-02(D)(2)(b) and (c): Clarify that these sections only apply if the pharmacist is prescribing controlled substances.

The Board agreed to make all of the suggested changes to the draft rule.

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?

The Board used its expertise in the regulation of medical practice to develop the rule, focusing on patient safety.

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?

The Board considered the alternatives provided by the interested parties and made significant changes to the draft.

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.*

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The Board did not propose performance-based regulations in this rule package due to the necessity of setting established processes and standards to achieve its public protection mandate.

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

The Board carefully reviewed the Pharmacy Board rules related to consult agreements to ensure that the rules were complementary and not in conflict.

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 Medical Board's website, information concerning the rules will be included in informational materials e-mailed to licensees, and notices will be sent to associations, individuals, and groups. Medical Board staff members are available by telephone and e-mail to answer questions. Medical Board staff members also give presentations to groups and associations who seek an update on physician practice regulations

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 scope of the impacted business community would be physician licensees of the Medical Board who are entering into consult agreements with pharmacists.

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

The Board has drafted the rules so that they are complementary to the Pharmacy Board rules so that there are not competing or inconsistent regulations related to consult agreements. Physicians who violate the rules are subject to discipline, which includes monetary fines.

c. Quantify the expected adverse impact from the regulation.

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.

Individuals who receive formal disciplinary action for violating these rules will be subject to civil penalties as set forth in 4731.225, Ohio Revised Code.

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

The Medical Board has a compelling interest in promoting safe prescribing practices and avoiding risks of harm to patients. The rules outline the specifics for safe practice for physicians practicing under a consult agreement with one or more pharmacists.

Regulatory Flexibility

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

Treatment of patients with prescription drugs is a complex matter which impacts the health and safety of patients. The public safety requirements relevant to these rules require consistency in their application to all licensees and are not amenable to exemptions or alternative means of compliance for small businesses.

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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?

Due process requires the Medical Board to consistently apply its rules regarding prescribing such that all prescriber licensees are equally treated.

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

Medical board staff members are available by telephone and e-mail to answer questions.

4731-35-01

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. They 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) A description of the patient's consent to drug therapy management pursuant to the consult agreement as set forth in paragraphs (H) and (I) of Rule 4729:1-06-01 of the Administrative Code.

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

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

(e) 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.

(f) 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.

(g) 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.

(h) 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 the managing pharmacist send a consult report to each consulting physician.

- (i) A provision that allows a physician to override a decision made by the managing pharmacist when appropriate.
- (j) An appropriate quality assurance mechanism to ensure that managing pharmacists only act within the scope authorized by the consult agreement.
- (k) A description of a continuous quality improvement (COI) program used to evaluate effectiveness of patient care and ensure positive patient outcomes. The COI program shall be implemented pursuant to the agreement.
- (l) 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.
- (m) A statement that the physicians and pharmacists shall meet minimal and prevailing standards of care at all times.
- (n) An effective date and expiration date.
- (o) Any other requirements contained in rules 4729:1-6-01, 4729:1-6-02 and 4729:1-6-03 of the administrative code.
- (2) Institutional or ambulatory outpatient facilities may implement a consult agreement and meet the requirements of paragraphs (A)(1)(c) to (A)(1)(f) 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.

(c) Amendments to the consult agreement are required when the scope of the managing pharmacist's permitted procedures expands past what was contemplated withing the agreement

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

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

(B) Recordkeeping. The primary physician, physician group or institution as defined in rule 4729-17-01 of the Administrative Code shall maintain a copy of the original consult agreement, and all amendments made thereafter, and a record of actions made in consultation with the managing pharmacist regarding each patient's drug therapy. 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.

(C) Managing Drug Therapy.

(1) For the purpose of implementing the management of a patient's drug therapy by an authorized managing pharmacist acting pursuant to a consult agreement, the primary physician must:

(a) Provide the managing pharmacist with access to the patient's medical record; and

(b) Establish the managing pharmacist's prescriptive authority as one or both of the following:

(i) 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. For all prescriptions issued by a pharmacist pursuant to this paragraph, the pharmacist shall comply with rules 4729-5-30 and 4729-5-13 of the Administrative Code; and or

(ii) 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, and

(c) Specifically authorize the managing pharmacist's ability to:

(i) Change the duration of treatment for the current drug therapy; adjust a drug's strength, dose, dosage form, frequency of administration, route of administration, discontinue a drug, or to prescribe new drugs; and or

(ii) Order blood, urine and other tests related to the drug therapy being managed and to evaluate those results, and

(d) Identify the extent to which, and to whom, the managing pharmacist may delegate drug therapy management to other authorized pharmacists under the agreement.

(D) Review of consult agreements. Upon the request of the state medical board, the primary physician shall immediately provide a copy of the consult agreement, amendments, and any relating policies or documentation pursuant to this rule and section 4729.39 of the revised code. The state medical board may prohibit the execution of a consult agreement, or subsequently void 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 consult agreement, if executed, would present a danger to patient safety.

4731-35-02

Standards for managing drug therapy.

(A) A physician may elect to manage the drug therapy of an established patient by entering into a consult agreement with a pharmacist. The agreement is subject, but not limited to, the following standards:

(1) The primary physician must ensure that the managing pharmacist has access to the patient's medical record, the medical record is accurate, and that while transferring the medical record, the primary physician ensures the confidentiality of the medical record.

(2) The physician must have an ongoing physician-patient relationship with the patient whose drug therapy is being managed, including an initial assessment and diagnosis by the physician prior to the commencement of the consult agreement.

(3) With the exception of inpatient management of patient care at an institutional facility as defined in rule 4729-17-01 of the Administrative Code, the physician, prior to a pharmacist managing the patient's drug therapy, shall communicate the content of the proposed consult agreement to each patient whose drug therapy is managed under the agreement, in such a manner that the patient or the patient's representative understands scope and role of the managing pharmacist, which includes the following:

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

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

(c) Consent may be obtained as part of the patient's initial consent to treatment.

(4) The diagnosis by the physician must be within the physician's scope of practice.

(5) The physician shall meet the minimal and prevailing standards of care.

(6) The physician must ensure that the pharmacist managing the patient's drug therapy has the requisite training, and experience related to the particular diagnosis for which the drug therapy is prescribed. Physicians practicing at institutional or ambulatory outpatient facilities may meet this requirement through institutional credentialing standards or policies.

(7) The physician shall review the records of all services provided to the patient under the consult agreement.

(B) Quality assurance mechanisms. The following quality assurance mechanisms shall be implemented to verify information contained within the consult agreement, and

ensure the managing pharmacist's actions are authorized and meet the standards listed in sections (A) and (B) of this rule:

(1) Verification of ongoing physician-patient relationship. A physician-patient relationship can be established by detailing criteria set forth in section (A)(2) of this rule, within the consult agreement.

(2) Verification that physician diagnosis is within the physician's scope of practice. Establishing that a diagnosis is within the physician's scope of practice may be established by detailing the criteria set forth in section (A)(4) of this rule, within the consult agreement.

(3) Verification that pharmacist's training and experience is related to the drug therapy. Establishing that a pharmacist's requisite training and experience with a particular drug therapy is related to the diagnosis for which the drug therapy is prescribed, may be established by detailing the criteria set forth in section (A)(6) of this rule, within the consult agreement.

(C) Continuous quality improvement program. The following should be included in the development of a continuous quality improvement program in order to evaluate the effectiveness of patient care and ensure positive patient outcomes:

(1) Notifications to primary physician. The managing pharmacist must notify the primary physician of the following situations regarding any pharmacist authorized to manage drug therapy under the agreement:

(a) A pharmacist has had their pharmacist license revoked, suspended, or denied by the state board of pharmacy;

(b) If prescribing controlled substances, a pharmacist has failed to renew their controlled substance prescriber registration;

(c) If prescribing controlled substances, a pharmacist fails to obtain or maintain a valid D.E.A. registration;

(D) Overriding decisions of managing pharmacist. Any authorized physician identified under the consult agreement may override any decision, change, modification, evaluation or other action by any pharmacist acting pursuant to consult agreement or under the direction of the managing pharmacist, that was made with respect to the management of the patient's drug therapy under the consult agreement.