

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 agency 4729 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.

Effective: 10/31/2020

Five Year Review (FYR) Dates: 10/31/2025

CERTIFIED ELECTRONICALLY

Certification

10/19/2020

Date

Promulgated Under: 119.03
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Rule Amplifies: 4729.39

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 agency 4729 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.

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