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 the agreement involves.

(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.

(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, drug utilization review 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. These 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 pharmacists participating in the agreement 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 paragraph (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 their 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 4729-5-11 of the Administrative 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 their 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 Administrative 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 4729-5-29 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 approved 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 rule 4729-5-30 and 4729-5-13 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 approved 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 the following:

(i) All requirements pursuant to rule 4729-5-30 and 4729-5-13 of the Administrative Code for non-controlled dangerous drugs. Except as provided in paragraph (C)(1)(b)(iii) and (C)(1)(b)(iv) of this rule, the prescription shall include the required information of the

consulting physician(s).

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

(iii) 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 required by rule 4729-5-30 of the Administrative Code.

(iv) 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 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 prescribed by the board, if they are no longer authorized to prescribe controlled substances pursuant 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 prescribed by the board, within thirty days of issuance.

(ii) Submit any changes to a pharmacist's registration, in a manner prescribed 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.

Replaces: 4729-29-02

Effective:

Five Year Review (FYR) Dates:

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Certification

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Date

Promulgated Under:	119.03
Statutory Authority:	4729.26, 4729.39, 3719.28
Rule Amplifies:	4729.01, 4729.39
Prior Effective Dates:	8/18/2016