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STATE OF OHIO BOARD OF PHARMACY

# Pharmacist Consult Agreements with Physicians

**Updated 8.9.2016**

On March 23, 2016, Ohio HB 188 (131st General Assembly) went into effect. This law makes the following modifications to pharmacist consult agreements with physicians (ORC 4729.39):

- Authorizes one or more pharmacists practicing under a consult agreement with one or more physicians to (1) manage a patient's drug therapy for specified diagnoses or diseases and (2) order and evaluate blood and urine tests.
- Creates a single process for establishing a consult agreement, in place of separate processes that were based on whether the patient's drug therapy was being managed within or outside a hospital or long-term care facility.
- Grants certain immunities from civil liability to pharmacists and physicians practicing under consult agreements.

New rules regarding consult agreements go into effect on **August 18, 2016**. A copy of the rules is included with this document.

**NOTE: The Board will not be issuing controlled substance registrations (see paragraph (C)(6) of rule 4729-29-02) until it receives approval by the United States Drug Enforcement Administration. Therefore, pharmacists will not be permitted to prescribe controlled substances pursuant to a consult agreement until such authorization is provided by the DEA. This document will be updated as additional information becomes available.**

## Additional Questions

If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: http://www.pharmacy.ohio.gov/contact.aspx.

4729-5-01 **Definitions.**

As used in Chapter 4729. of the Revised Code:

(A) "Practice of pharmacy" is as defined in division (B) of section 4729.01 of the Revised Code.

(B) The term "dispense" means the final association of a drug with a particular patient pursuant to the prescription, drug order, or other lawful order of a prescriber and the professional judgment of and the responsibility for: interpreting, preparing, compounding, labeling, and packaging a specific drug. In the case of an automated drug delivery system meeting the requirements of rule 4729-5-35 of the Administrative Code, the final association with the name of a particular patient will be deemed to have occurred when the pharmacist has given final approval to the patient specific prescription in the system.

(C) The term "compounding" has the same meaning as defined in division (C) of section 4729.01 of the Revised Code.

(D) "Interpret prescriptions" means the professional judgment of a pharmacist when reviewing a prescription order of a prescriber for a patient.

(E) "To participate in drug selection" means selecting and dispensing a drug product pursuant to sections 4729.38 and 4729.381 of the Revised Code.

(F) "To participate with prescribers in reviews of drug utilization" means monitoring the appropriate use of drugs through communication with the prescriber(s) involved.

(G) "Pharmacist" means an individual who holds a current pharmacist identification card pursuant to section 4729.08 or 4729.09 of the Revised Code; or, pursuant to section 4729.12 of the Revised Code.

(H) "Original prescription" means the prescription issued by the prescriber in writing, an oral or electronically transmitted prescription recorded in writing by the pharmacist, a prescription transmitted by use of a facsimile machine, or a prescription transmitted by a board approved electronic prescription transmission system, each of which is pursuant to rule 4729-5-30 of the Administrative Code.

(I) "Personal supervision" or "direct supervision" means a pharmacist shall be physically present in the pharmacy, or in the area where the practice of pharmacy is occurring, and provide personal review and approval of all professional activities.

(J) "Preprinted order" is defined as a patient specific, definitive set of drug treatment

directives to be administered to an individual patient who has been examined by a prescriber and for whom the prescriber has determined that the drug therapy is appropriate and safe when used pursuant to the conditions set forth in the preprinted order. Preprinted orders may be used only for inpatients in an institutional facility as defined in Chapter 4729-17 of the Administrative Code.

(K) "Standing order" will mean the same as the term "protocol".

(L) "Protocol" is defined as:

(1) A definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber and have been approved by the state board of pharmacy pursuant to section 4729.54 of the Revised Code. A protocol may be used only by licensed health care professionals when providing limited medical services to individuals in an emergency situation when the services of a prescriber are not immediately available; or

(2) A definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber and have been approved by the state board of pharmacy pursuant to section 4729.54 of the Revised Code. A protocol may be used only by licensed health care professionals when administering biologicals or vaccines to individuals for the purpose of preventing diseases; or

(3) A definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber and have been approved by the state board of pharmacy pursuant to section 4729.54 of the Revised Code. A protocol may be used only by licensed healthcare professionals when administering vitamin K for prevention of vitamin K deficient bleeding in newborns; or

(4) A definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber and have been approved by the state board of pharmacy pursuant to section 4729.54 of the Revised Code. A protocol may be used only by licensed healthcare professionals when administering erythromycin for prevention of ophthalmia neonatorum; or

(5) A definitive set of written treatment guidelines that include patient specific and dose specific orders for the administration of a specific drug that have been authorized by a prescriber to be used when the services of that prescriber are not immediately available. The state board of pharmacy must approve the

treatment guidelines prior to implementation. To be considered for approval by the board, the treatment guidelines must meet the following requirements:

(a) The drugs shall only be administered by an individual authorized by law to administer the drugs that are listed in the treatment guidelines.

(b) A prescriber must complete an assessment and make a diagnosis prior to ordering a set of treatment guidelines.

(c) The treatment guidelines:

(i) Can only be initiated upon the order of a prescriber, and the prescriber, utilizing positive identification, must create an order in the patient record to acknowledge and document an adjustment made pursuant to the treatment guidelines before another dose or frequency adjustment can be made;

(ii) Shall only apply to adjusting the dose or frequency of the administration of a specific drug that has been previously ordered by a prescriber;

(iii) Apply only to those drugs that may require calculations for specific dose and frequency adjustments which shall be based on objective measures;

(iv) Apply only to those drugs for which the therapeutic dose is significantly lower than the dose expected to cause detrimental adverse effects;

(v) Do not apply to those drugs for which a dosage change selected within the usual normal dose range could cause detrimental adverse effects;

(vi) Can be performed without requiring the exercise of medical judgment;

(vii) Will lead to results that are reasonably predictable and safe;

(viii) Can be performed safely without repeated medical assessments;

(ix) If performed improperly, would not present a danger of immediate

and serious harm to the patient.

A protocol may be used only by individuals authorized by law to administer the drugs and to perform the procedures included in the protocol.

Protocols submitted for approval by the state board of pharmacy may be reviewed with the appropriate health care related board prior to any approval by the state board of pharmacy.

(M) "Prescriber" means any of the following:~~person authorized by the Revised Code to prescribe dangerous drugs as part of their professional practice.~~

(1) A person authorized by the revised code to prescribe dangerous drugs as part of their professional practice; or

(2) A pharmacist authorized to manage drug therapy pursuant to a consult agreement but only if specifically authorized in the agreement and to the extent specified in the agreement.

(N) "Positive identification" means a method of identifying an individual who prescribes, administers, or dispenses a dangerous drug.

(1) A method may 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. 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.

(O) "Originating pharmacy", as it relates to central fill pharmacies, means the pharmacy that received the original prescription.

(P) "Personally furnish" means the distribution of drugs by a prescriber to the prescriber's patients for use outside the prescriber's practice setting.

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

(R) "Reported drugs" means all the drugs listed in rule 4729-37-02 of the Administrative Code that are required to be reported to the drug database established and maintained pursuant to section 4729.75 of the Revised Code.

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Five Year Review (FYR) Dates: 05/22/2019

CERTIFIED ELECTRONICALLY

Certification

08/08/2016

Date

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4729-5-15 **Prescriber.**

(A) For purposes of division (Y) of section 3719.01 and division (I) of section 4729.01 of the Revised Code, the following persons, maintaining current licenses and in good standing, licensed pursuant to Chapters 4715., 4725., 4731., and 4741. of the Revised Code, are authorized by law to write prescriptions for drugs or dangerous drugs in the course of their professional practice:

(1) Chapter 4715. of the Revised Code: dentist.

(2) Chapter 4725. of the Revised Code: optometrist, if that person holds a current "therapeutic pharmaceutical agents certificate" as defined in division (H) of section 4725.01 of the Revised Code.

(3) Chapter 4731. of the Revised Code: doctor of medicine, doctor of osteopathic medicine and surgery, and doctor of podiatry.

(4) Chapter 4741. of the Revised Code: doctor of veterinary medicine.

(5) Chapter 4723. of the Revised Code: advanced practice nurse in accordance with paragraph (D) of this rule.

(6) Chapter 4730. of the Revised Code: physician assistant in accordance with paragraph (E) of this rule.

(7) Chapter 4729. of the Revised Code: pharmacist in accordance with paragraph (F) of this rule.

(B) Those persons pursuing an approved internship, residency, or fellowship program in this state are authorized to write prescriptions only when acting within their scope of employment in the hospital(s) or institution(s). Approved internship and residency programs are those accredited by the "Accreditation Council for Graduate Medical Education (ACGME)" or the "American Osteopathic Association (AOA)". Approved clinical fellowships are those at institutions which have a residency program in the same or a related clinical field which is accredited by the ACGME or the AOA.

(C) A nonresident prescriber whose license is current and in good standing and who is authorized to issue prescriptions for drugs in the course of their professional practice in a state, as defined in division (G) of section 1.59 of the Revised Code, other than Ohio is authorized to write prescriptions in that state for drugs to be dispensed in the state of Ohio.

(D) An advanced practice nurse approved pursuant to section 4723.48 of the Revised

Code may prescribe those drugs which have been approved by the committee on prescriptive governance for advanced practice nurses and pursuant to the standard care agreement for that advanced practice nurse.

(E) A physician assistant who holds a valid prescriber number pursuant to section 4730.41 of the Revised Code issued by the state medical board is authorized to prescribe and personally furnish drugs and therapeutic devices in the exercise of physician-delegated prescriptive authority.

(F) A pharmacist who is authorized to manage drug therapy pursuant section 4729.39 of the Revised Code but only if specifically authorized by a consult agreement and to the extent specified in the agreement.

~~(E) A physician assistant approved pursuant to section 4730.44 of the Revised Code may prescribe those drugs approved in rule by the medical board and pursuant to the physician supervisory plan for that physician assistant.~~

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4729-29-01 **Definitions.**

(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;

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

(D) "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) "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 4729-29-02.

(F) "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.

(G) "Institutional facility" as used in rule 4729-29-02 of the Administrative Code has the same meaning as defined in rule 4729-17-01 of the Administrative Code.

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4729-29-02 **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 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 pharmacist is to follow in acting under a consult agreement. Such a description should provide a reasonable set of parameters of the activities a 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 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 pharmacist shall maintain a record of each action taken for each patient whose drug therapy is managed under the agreement using positive identification pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code.

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

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

(i) An appropriate quality assurance mechanism to ensure that pharmacists who act under a consult agreement do so only within the scope authorized by the 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 pharmacists to manage drug therapy pursuant to the consult agreement. 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 reference internal policies as part of a consult agreement in order to meet the requirements of paragraph (A)(1)(b) to (e) of this rule. Such policies shall be regularly reviewed and approved by the primary physician, which may include a medical director or their designee.

(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) an individual pharmacist 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 rule 4729-5-11 of the Administrative Code; or

(b) an individual pharmacist 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.

(1) As required by section 4729.39 of the Revised Code, a pharmacist acting under a consult agreement shall maintain a record of each action taken for each patient whose drug therapy is managed under the agreement using positive identification pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code. 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 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 consulting pharmacist may be authorized as one or both of the following as specified in the consult agreement:

(a) a prescriber, as defined in rules 4729-5-01 and 4729-5-15 of the administrative code, authorized to issue a new or refill drug order in writing, orally 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;

(b) with respect to non-controlled dangerous drugs only, an agent of the consulting physician(s) as the term agent as used in rules 4729-5-21 and 4729-5-30 of the Administrative Code.

(2) For all prescriptions issued by a pharmacist pursuant to this rule, the pharmacist shall comply with rule 4729-5-30 of the administrative code;

(3) If the consulting 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 pharmacist to act in this manner.

(4) A pharmacist managing a patient's outpatient drug therapy pursuant to a consult agreement 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.

(5) A pharmacist shall not delegate drug therapy management to anyone other than another authorized pharmacist practicing under the consult agreement.

(6) A 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 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) A pharmacist who is employed as a staff prescriber of a hospital pursuant to a consult agreement, 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 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 pharmacist from prescribing controlled substances.

(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.

(1) Upon the request of the state board of pharmacy, a pharmacist shall immediately provide a consult agreement(s) 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:

(a) The agreement does not meet the requirements set forth in section 4729.39 of the Revised Code or chapter 4729-29 of the Administrative Code; or

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

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