**3/1/16**

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.

**Rescind Rules**

- 4729-29-01: Reasonable attempt to contact and confer.
- 4729-29-02: Pharmacist as agent.
- 4729-29-03: Records.
- 4729-29-04: Therapy management by formulary.
- 4729-29-06: Institutional policy for consult agreements.
- 4729-29-07: Board review of the institutional policy for consult agreements.

**New**

- 4729-29-01: Provides definition section for implementation of updates to ORC 4729.39.
- 4729-29-02: Sets forth the requirements for pharmacist consult agreements. Consult agreements permit pharmacists to manage a patient's drug therapy in collaboration with physicians.

**Amended**

- 4729-5-01: Amended to specify that pharmacists may initiate and modify drug therapy pursuant to a consult agreement.
- 4729-5-15: Amended to specify that pharmacists may initiate and modify drug therapy pursuant to a consult agreement.

Comments on the proposed rules will be accepted until close of business on March 15, 2016. Please send all comments to the following email address:
**Cameron.mcnamee@pharmacy.ohio.gov**

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

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# CSI - Ohio
The Common Sense Initiative

## Business Impact Analysis

**Agency Name:** State of Ohio Board of Pharmacy

**Regulation/Package Title:** Consult Agreements

**Rule Number(s):** New: 4729-29-01; 4729-29-02

Rescind: 4729-29-01, 02, 03, 04, 06 and 07

Amendment: 4729-5-15; 4729-5-01

**Date:** 03/01/2016

**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| Amended | Rescinded |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.**

**Rescind Rules**

The following rules are proposed to be rescinded because they pertain to the use of consult agreements prior the passage of Ohio HB 188 (131st General Assembly). New rules are being proposed in order comply with the recent changes to the law.

- 4729-29-01: Reasonable attempt to contact and confer.

- 4729-29-02: Pharmacist as agent.
- 4729-29-03: Records.
- 4729-29-04: Therapy management by formulary.
- 4729-29-06: Institutional policy for consult agreements.
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- 4729-29-01: Provides definition section for implementation of updates to ORC 4729.39.
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**Amended**

- 4729-5-01: Amended to specify that pharmacists may initiate and modify drug therapy pursuant to a consult agreement.
- 4729-5-15: Amended to specify that pharmacists may initiate and modify drug therapy pursuant to a consult agreement.

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

The proposed rules are authorized by sections 4729.26, 3719.28 and 4729.39 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 rule does 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 rule package exceeds federal requirements because the regulation of the pharmacy profession has traditionally been done at the state level by legislatively created state boards of pharmacy, such as the State of Ohio Board 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 4729.26 of the Ohio Revised Code authorizes the state board of pharmacy to adopt rules governing the practice of pharmacy and distribution of dangerous drugs.

Section 3719.28 of the Ohio Revised Code authorizes the state board of pharmacy to adopt rules prescribing the manner of keeping and the form and content of records to be kept by persons authorized to manufacture, distribute, dispense, conduct research in, prescribe, administer, or otherwise deal with controlled substances.

Section 4729.39 of the Ohio Revised Code requires the state board of pharmacy, in consultation with the state medical board, to adopt rules to be followed by pharmacists that establish standards and procedures for entering into a consult agreement and managing a patient's drug therapy under a consult agreement. The board is required specify in the rules any categories of drugs or types of diseases for which a consult agreement may not be established and may adopt any other rules it considers necessary for the implementation and administration of this section.

The rules proposed under this statutory authority are necessary to facilitate compliance with the provisions in the above referenced chapters of the Ohio Revised Code to promote the public's safety and uniformity of care throughout Ohio. Without these regulations, the Ohio State Board of Pharmacy would not be able to set uniform requirements for 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 regulations will be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees and prescribers 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.**

The rules in this package were posted for comment on the Board's web site. Stakeholders from the following organizations provided feedback on the initial draft regulation:

- St. Rita's Medical Center

- Ohio Health
- SUMMA Health System, Akron City Hospital
- Healthspan Partners and Integrated Care
- Meijer
- CeutiCare Inc.
- University Hospital Geriatrics Department
- Cleveland Clinic
- The Kroger Co. Columbus Division
- Mercy Health Select
- Ohio State University College of Pharmacy
- Ohio Society of Health-System Pharmacists
- Dublin Methodist Hospital
- ProMedica Health System
- Ohio Pain Initiative
- Ohio State Wexner Medical Center
- Ohio Pharmacists Association

Prior to filing with CSI, the rules are also reviewed and approved by the State of Ohio 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?**

The feedback provided by stakeholders resulted in the following changes to the draft rules:

- Training and experience requirements for pharmacists: Removal of specific training requirements for pharmacists who enter into consult agreements. Instead, the rules specify that the primary physician may determine the experience and training necessary for a pharmacist to manage a specific drug therapy.
- Signature requirements: Removal of the requirement that all participating pharmacists and physicians sign the agreement. Instead, the consult agreement must be signed by the primary physician (i.e. a medical director) and the responsible pharmacist.
- Notification requirements: Draft regulation was amended to allow for verbal communication between a consulting pharmacist and physician as long as such communication is documented.
- Laboratory testing: After comments from stakeholders, the Board required all consult agreements to specify the types or categories of laboratory testing that can be conducted by pharmacists.

- Identification of participating pharmacists and physicians: The Board clarified that such pharmacists and physicians may be identified in the agreement individually, by practice groups or by an institutional credentialing or privileging process.
- Controlled substance drug therapy management: The draft regulation was amended to allow the management of controlled substances by a pharmacist. The Board also adopted a recommendation provided by a stakeholder to require a managing pharmacist to run an OARRS report prior to making any addition or modification to a patient's outpatient controlled substance drug therapy.
- Management of therapy: The draft regulation was amended to specify that a pharmacist may act as the agent of the prescriber or may initiate a valid prescription drug order pursuant to the consult agreement.

**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 did not utilize scientific data to develop the rules in this package.

**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 health and safety by ensuring the safe and effective implementation of consult agreements, 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, bu*t don't dictate the process* the regulated stakeholders must use to achieve compliance.**

The Board did set forth performance based regulations to meet certain consult agreement requirements (i.e. training/education, quality improvement programs, etc.) in the rules. It also set performance-based requirements on methods of communications between pharmacists and prescribers.

**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 rules 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 Pharmacy Board's web site, information concerning the rule will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals and groups. Pharmacy Board staff are also available via phone or email to answer questions regarding implementation of the rule. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

Pharmacy Board 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, monthly email updates from the legislative affairs liaison and feedback from the Board's legal director 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 and physicians who enter into a consult agreement.
- Terminal distributors of dangerous drugs.

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

Violation of these rules may result in administrative licensure discipline for a pharmacist, terminal distributor of dangerous drugs and physician. Discipline might include reprimand, suspension of a license, required course work (pharmacists), monetary fine and/or revocation of a license.

**c. Quantify the expected adverse impact from the regulation.**

- 4729-29-01: This rule does require the use of certain methods of documented communication between pharmacists and physicians. This should have minimal

impact because there are a number of low cost options listed in the rule (i.e. documented telephone conversation or email).

- 4729-29-02: Sets forth the requirements for pharmacist consult agreements. Consult agreements permit pharmacists to manage a patient's drug therapy in collaboration with physicians. The rule may result in increased compliance costs for entities that implement consult agreements to ensure that all of the requirements are included in the agreement and are properly executed. Additionally, pharmacists who manage outpatient controlled substance medications would be required to query the Ohio Automated Rx Reporting System (OARRS). The time, per patient, for checking OARRS varies from 3-4 minutes (for those manually entering data into the web portal) to a few seconds if the system is integrated into the electronic medical record.
- 4729-5-01: Amended to specify that pharmacists may initiate and modify drug therapy pursuant to a consult agreement. This is a definitional section and should have no adverse impact.
- 4729-5-15: Amended to specify that pharmacists may initiate and modify drug therapy pursuant to a consult agreement. A pharmacist who violates this rule by prescribing or modifying a prescription not authorized in a consult agreement may be subject to administrative discipline by the Board of Pharmacy.

**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 patients deserve uniform standards to ensure that their drug therapy is appropriately managed. Without such quality standards and accountability by pharmacists and physicians, the Board is would not be fulfilling its mission to protect the health and safety of Ohioans.

## Regulatory Flexibility

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

These rules do 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 legal distribution of dangerous drugs is 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. Additionally, field staff (i.e. compliance officers) is trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

**4729-29-01 Definitions (NEW)**

(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.

**4729-29-02 Consult Agreements (NEW)**

(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.

(e) A description of the types of blood and urine tests 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 the 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) The agreement shall be signed by the primary physician and the pharmacy's responsible person using positive identification pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code. The primary physician may include a medical director or their designee.

(3) All amendments to a consult agreement shall be signed and dated by the primary physician and the pharmacy's responsible person using positive identification pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code. The primary physician may include a medical director or their designee.

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

(B) Recordkeeping.

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 consult. Such consult agreements shall be considered confidential patient records and are therefore 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 rule 4729-5-01 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; or

(b) 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) If the consulting pharmacist is not the dispensing pharmacist or the person administering the dosage ordered, a copy of the consult agreement 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.

(3) 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.

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

(D) Therapy management by formulary.

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) 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.

(2) A pharmacist, responsible person or terminal distributor of dangerous drugs who fails to properly execute the provisions of a consult agreement required by this rule, as determined by the state board of pharmacy, shall be considered in violation of this rule and subject to disciplinary actions pursuant to sections 4729.16 and 4729.57 of the Ohio Revised Code.

(F) Immunization administration.

Nothing in this chapter shall prohibit a pharmacist from administering immunizations, if done so in accordance with the requirements of section 4729.41 of the Revised Code and rules 4729-5-36 through 4729-5-38 of the Administrative Code.

**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:

(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.

**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., 4729., 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) Section 4729.39 of the Revised Code: 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.

(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 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.