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 <u>of the following:person authorized by the Revised Code to prescribe dangerous drugs as part of their professional practice.</u>
 - (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.

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

Promulgated Under: 119.03 Statutory Authority: Rule Amplifies: 4729.26

 $4729.01,\,4729.27,\,4729.28,\,4729.54$

Prior Effective Dates: 9/10/76, 5/15/87, 7/1/92, 7/1/93, 9/1/96, 1/17/97,

2/1/98, 3/1/99, 2/1/03, 1/1/04, 2/1/05, 1/1/06,

10/19/07, 10/27/11, 05/22/2014