

4729:5-3-12**Protocols and pre-printed orders for medication administration.**

(A) A terminal distributor of dangerous drugs may distribute or dispense dangerous drugs pursuant to a protocol. As used in this rule, "protocol" means a definitive set of written treatment guidelines with orders for drugs and their specified dosages for administration to individuals under the following circumstances:

- (1) The provision of medical services to individuals in an emergency situation when the services of a prescriber authorized by the revised code to prescribe dangerous drugs as part of their professional practice are not immediately available. An emergency situation may manifest itself by acute symptoms of sufficient severity that an authorized individual providing medical services under this paragraph could reasonably expect the absence of immediate medical attention to result in placing the health of the individual or, with respect to a pregnant woman, the health of the woman or her unborn child, in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part. Examples of emergency situations includes cases such as heart attacks, severe burns, extravasation, overdoses, cyanide poisonings, electrocutions, or severe asthmatic attacks;
- (2) The administration of biologicals or vaccines to individuals for the purpose of preventing diseases;
- (3) The administration of vitamin K for prevention of vitamin K deficient bleeding in newborns;
- (4) The administration of erythromycin for prevention of ophthalmia neonatorum; and
- (5) The administration of influenza antiviral treatment and chemoprophylaxis to residents and health care personnel at an institutional facility, as defined in agency 4729 of the Administrative Code, according to current guidance issued by the United States center for disease control and prevention.

(B) A protocol described in paragraph (A) of this rule shall:

- (1) Include a description of the intended recipients to whom the drugs are to be administered; drug name and strength; instructions of how to administer the drug, dosage, and frequency; signature of a prescriber or some other form of positive identification of the prescriber as defined in agency 4729 of the Administrative Code; and date of signature;
- (2) Be administered by an individual authorized by law to administer the drugs;

- (3) Be made readily retrievable;
 - (4) Be reviewed as necessary to ensure patient safety and practice in accordance with acceptable and prevailing standards of care; and
 - (5) Be maintained by the terminal distributor of dangerous drugs for a period of three years from the date of authorization or reauthorization following any modification or amendment.
- (C) A terminal distributor of dangerous drugs may distribute or dispense dangerous drugs for administration pursuant to a pre-printed order. As used in this rule, "pre-printed order" means a patient specific and dose specific order for the administration of a specific drug or drugs prescribed by a licensed health care professional authorized to prescribe drugs. The prescriber must complete an assessment and make a diagnosis prior to initiating a pre-printed order in accordance with the prescriber's scope of practice. The pre-printed order may only be initiated upon the order of a prescriber authorized by law to prescribe the drugs listed in the pre-printed orders. The drugs shall be administered by an individual authorized by law to administer the drugs.
- (D) A pre-printed order described in paragraph (C) of this rule shall:
- (1) Include the name of the patient; drug name and strength; specific instructions of how to administer the drug, dosage, and frequency; instructions of any patient specified dosage range based on objective measures such as calculations and patient physiologic data; signature of the prescriber or some other form of positive identification of the prescriber as defined in agency 4729 of the Administrative Code; and date of signature;
 - (2) Apply only to those drugs for which the therapeutic dose is significantly lower than the dose expected to cause detrimental adverse effects;
 - (3) Can be performed without requiring the exercise of medical judgment;
 - (4) Will lead to results that are reasonably predictable and safe;
 - (5) Can be performed safely by the individual authorized to administer the drugs and without the need for repeated medical assessments;
 - (6) Be maintained by the terminal distributor of dangerous drugs for a period of three years from the date of initiation. A pre-printed order which becomes a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph;
 - (7) Be made readily retrievable;

(8) If performed improperly, would not present a danger of immediate and serious harm to the patient; and

(9) Be reviewed as necessary to ensure patient safety and practice in accordance with acceptable and prevailing standards of care.

(E) Nothing in this rule shall be construed to otherwise prohibit the dispensing or administration of dangerous drugs pursuant to a protocol that is specifically authorized in the Revised Code or agency 4729 of the Administrative Code.

(F) For purposes of this rule, a terminal distributor of dangerous drugs may distribute or dispense dangerous drugs for administration to animals pursuant to a protocol in accordance with the provisions of paragraphs (A) and (B) of this rule or a pre-printed order in accordance with the provisions of paragraphs (C) and (D) of this rule.

Replaces: 4729-5-01
Effective: 3/1/2020
Five Year Review (FYR) Dates: 03/01/2025

CERTIFIED ELECTRONICALLY

Certification

02/04/2020

Date

Promulgated Under: 119.03
Statutory Authority: 4729.26, 3719.28
Rule Amplifies: 3719.01, 4729.01, 4729.54, 4729.55, 4729.57
Prior Effective Dates: 09/10/1976, 05/15/1987, 07/01/1992, 07/01/1993,
01/17/1997, 02/01/1998, 03/01/1999, 02/01/2003,
01/01/2004, 02/01/2005, 01/01/2006, 10/19/2007,
10/27/2011, 05/22/2014