

## **DRUGS COMPOUNDED FOR DIRECT ADMINISTRATION BY A PRESCRIBER**

### **Rule 4729-9-25 [Update effective 01/01/2006]**

The following requirements do not apply to the compounding of radiopharmaceuticals by a nuclear pharmacy. Radiopharmaceuticals must be prepared pursuant to Chapter 4729-15 of the Administrative Code.

A pharmacist may compound a drug pursuant to a request made by a prescriber, or by an agent of the prescriber, for a drug to be used by the prescriber for the purpose of the direct administration to patients in the course of the prescriber's practice pursuant to division (C)(5) of section 4729.01 of the Revised Code and the following:

- (A) The drug is compounded and provided to a prescriber as an occasional exception to the normal practice of dispensing drugs pursuant to patient specific prescriptions:
  - (1) A pharmacy may provide compounded drug preparations to prescribers for direct administration to patients as long as the total value of those compounded preparations does not exceed five percent of the pharmacy's total dollar amount of sales of patient specific compounded prescriptions within the past twelve months.
  - (2) The pharmacy shall only provide those compounded drugs that are not commercially available to a prescriber which are needed:
    - (a) To treat an emergency situation;
    - (b) For an unanticipated procedure for which a time delay would negatively affect a patient outcome;
    - (c) For diagnostic purposes.
- (B) A pharmacy shall not supply more than a seventy-two hour supply of a compounded drug to a prescriber. A prescriber shall not have more than a seventy-two hour supply of a compounded drug on hand at any given time. The seventy-two hour supply provided to the prescriber shall be determined by previous administration patterns provided by a prescriber to the pharmacist. The limitation of a seventy-two hour supply shall not apply to either of the following:
  - (1) Compounded non-sterile drug preparations for topical administration, pursuant to paragraphs (A)(2)(b) and (A)(2)(c) of this rule, shall be supplied to a prescriber in a single container in which the quantity does not exceed sixty grams or sixty milliliters. A prescriber shall not have more than one full container of sixty grams or sixty milliliters of a compounded drug on hand at any given time; or
  - (2) Compounded non-sterile drug preparations intended to treat an emergency situation, pursuant to paragraph (A)(2)(a) of this rule, may be provided to a prescriber in a quantity required to sufficiently treat individuals in the event of an emergency situation.
- (C) A pharmacy shall not sell a compounded drug to another pharmacy or wholesaler.
- (D) Prescribers shall only administer a requested compounded drug directly to their own patients. Prescribers shall not:

- (1) Dispense a compounded drug to a patient;
  - (2) Sell a compounded drug to another prescriber;
  - (3) Sell a compounded drug to a pharmacy; or
  - (4) Return a compounded drug to the supplying pharmacy.
- (E) Compounded drug preparations shall be assigned beyond use dates that are based on stability and sterility for sterile compounded drug preparations and stability for non-sterile compounded drug preparations pursuant to the following:
- (1) Beyond use dates for non-sterile compounded preparations shall be determined by the compounding pharmacy through drug product testing pursuant to acceptable practice standards; by published peer reviewed pharmaceutical literature that have been critically reviewed by unbiased independent experts; or in compliance with requirements in the current edition of an official compendium, such as the "United States Pharmacopoeia/National Formulary".
  - (2) Beyond use dates for sterile compounded preparations shall be determined by the compounding pharmacy through drug product testing pursuant to acceptable practice standards or shall be based on the following "United States Pharmacopoeia/National Formulary" standards:
    - (a) Low risk level compounded drug preparations shall be assigned a beyond use date of not more than forty-eight hours when stored at room temperature, or fourteen days when refrigerated at two to eight degrees celsius.
    - (b) Medium risk level compounded drug preparations shall be assigned a beyond use date of not more than thirty hours when stored at room temperature, or seven days when refrigerated at two to eight degrees celsius.
    - (c) High risk level compounded drug preparations shall be assigned a beyond use date of not more than twenty-four hours when stored at room temperature, or three days when refrigerated at two to eight degrees celsius.
- (F) The labeling of a compounded drug preparation must contain the following:
- (1) The statement "For direct patient administration only" displayed prominently;
  - (2) The statement "Not for resale" displayed prominently;
  - (3) Proper storage conditions;
  - (4) Beyond use dates pursuant to paragraph (E) of this rule;
  - (5) The name(s) of the active and inactive ingredients;
  - (6) The amount or percentage of active drug ingredients;
  - (7) The quantity of compounded drug provided;
  - (8) The route of administration;
  - (9) The pharmacy name, address, and telephone number;

- (10) The pharmacy control number assigned to the compounded drug preparation.
- (G) Compounded drug preparation containers that are too small to bear a complete label pursuant to paragraph (F) of this rule must bear a label that contains at least the following information:
- (1) "Not for resale";
  - (2) The storage conditions if other than room temperature;
  - (3) The beyond use date;
  - (4) The drug name(s);
  - (5) The drug strength;
  - (6) The route of administration;
  - (7) The pharmacy control number;
  - (8) The pharmacy name.

In all cases, a complete label meeting the requirements of paragraph (F) of this rule must be applied to the outside container in which such compounded preparation is supplied.

- (H) The sale of a compounded drug preparation to a prescriber is considered a wholesale sale as defined in section 4729.01 of the Revised Code. A pharmacy is required to follow the record keeping requirements for wholesale sales listed in paragraph (H) of rule 4729-9-16 of the Administrative Code.
- (I) A pharmacy must follow the compounding requirements pursuant to rules 4729-5-25 and 4729-9-21 of the Administrative Code, Chapter 4729-19 of the Administrative Code, current professional compounding standards, and all applicable federal and state laws, rules, and regulations.

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