OHIO STATE BOARD OF PHARMACY

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-Equal Opportunity Employer and Service Provider-

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COMPOUNDING IN OHIO

We recognize and enforce Federal law that compounding is performed by a pharmacist in a pharmacy and pursuant to a patient specific prescription. Refer to 21 USCA 353a

- You may not compound FDA approved drugs that are commercially available.
- On July 9, 2012, President Obama signed into law the FDA Safety and Innovation Act which in part grants permission for hospitals and health systems to repack and share drugs, not controlled substances, in short supply during an FDA published shortage plus 60 days after the drug is taken off the list. Caveat: only within the same health system
  http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm313121.htm

Our state law defines compounding in ORC 4729.01(C)

(C) "Compounding" means the preparation, mixing, assembling, packaging, and labeling of one or more drugs in any of the following circumstances:

(1) **Pursuant to a prescription** issued by a licensed health professional authorized to prescribe drugs;

(2) Pursuant to the modification of a prescription made in accordance with a consult agreement;

(3) As an incident to research, teaching activities, or chemical analysis;

(4) In anticipation of orders for drugs pursuant to prescriptions, based on routine, regularly observed dispensing patterns;

(5) Pursuant to a request made by a licensed health professional authorized to prescribe drugs for a drug that is to be used by the professional for the purpose of direct administration to patients in the course of the professional's practice, if all of the following apply:

(a) At the time the request is made, the drug is not commercially available regardless of the reason that the drug is not available, including the absence of a manufacturer for the drug or the lack of a readily available supply of the drug from a manufacturer.

(b) A limited quantity of the drug is compounded and provided to the professional.

(c) The drug is compounded and provided to the professional as an occasional exception to the normal practice of dispensing drugs pursuant to patient-specific prescriptions.

Note: also refer to OAC 4729-9-25 below for specifics relating to (5)

We further regulate compounding in the following rules:

DRUGS COMPOUNDED IN A PHARMACY **OAC Rule 4729-9-21**
Please review particularly:

(F) A prescription shall be compounded and dispensed only **pursuant to a specific order for an individual patient issued by a prescriber**. A limited quantity may be compounded in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(G) A compounded prescription that is dispensed to a patient must be labeled according to rule 4729-5-16 of the Administrative Code.

DRUGS COMPOUNDED FOR DIRECT ADMINISTRATION BY A PRESCRIBER
OAC Rule 4729-9-25
Please review particularly:

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 4729.01of 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 controlled room temperature at twenty to twenty-five degrees celsius, or fourteen days when refrigerated at two to eight degrees celsius, or forty-five days in solid frozen state at minus twenty-five to minus ten 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 controlled room temperature at twenty to twenty-five degrees celsius, or nine days when refrigerated at two to eight

degrees celsius, or forty-five days in solid frozen state at minus twenty-five to minus ten 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 controlled room temperature at, twenty to twenty-five degrees celsius, or three days when refrigerated at two to eight degrees celsius, or forty-five days in solid frozen state at minus twenty-five to minus ten 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.**

In addition, all controlled substance prescriptions must be sent to the PATIENT

If you want to ship NON-CONTROLLED patient specific medications to the prescriber rather than the patient, you must have Board approval (specific to each prescriber office/pharmacy) prior to any such shipment pursuant to

PRESCRIPTION PICK-UP STATION OAC Rule 4729-5-10
Please review particularly:

(B) No pharmacist shall dispense dangerous drugs to a place which offers, in any manner, its services as a "pick-up station" or intermediary for the purpose of having prescriptions filled or delivered unless such place is a pharmacy as defined in section 4729.01 of the Revised Code, has received board approval to function in such a manner, and paragraphs (B)(1) to (B)(4) of this rule apply or, if not a pharmacy, unless all of the following apply:

(1) The site is appropriately licensed pursuant to Chapter 4729. of the Revised Code.
(2) The receipt, storage, control, and distribution of prescriptions or drugs are in the full and actual charge of a health care professional licensed pursuant to Chapter 4715., 4723., 4729., 4730., 4731., or 4741. of the Revised Code.
(3) An appropriate recordkeeping system is in place that will provide accountability for proper receipt, delivery, and return of all prescription medications.
(4) There is a documented method in place to ensure compliance with rule 4729-5-22 of the Administrative Code.
(5) The state board of pharmacy has approved the site for such activity due to clear and convincing evidence that delivery of prescription medication directly to the patient would result in:
(a) Danger to public health or safety, or
(b) Danger to the patient without increased involvement by a health care professional in the patient's drug therapy.

If your special circumstance meets these criteria, you must request approval to ship to a pick-up station rather than to the patient using the request form that is available on our website.