



# OHIO STATE BOARD OF PHARMACY

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## DRUG ADDENDUM/PROTOCOL INSTRUCTION SHEET For Limited Terminal Distributor License Holders

### I) Licensed Locations

If the address, business name, business owner, or category will be changing, please contact the Board office for the correct application. You will need to submit an application including a letter signed by the Medical Director and notarized with the name and address of the new location, the proposed date of opening and whether the new location will operate under the current protocols and drug list or if a different set of protocols and drug list will be used (include a signed, notarized list of drugs and protocols for the new site if different).

### II) Changing the Medical Director for a Limited Terminal Distributor License

New Medical Director, Same Protocol - Submit a **signed, notarized** letter from the new Medical Director stating that they are assuming responsibility for the current protocols and drug list.

New Medical Director, New Protocol - Submit a **signed, notarized** protocol as approved by the new Medical Director. Include a list of the drugs, signed by the Medical Director, following the "Protocol Instructions" listed below.

### III) Changing the Responsible Person for a Limited Terminal Distributor License

A Notification of Change of Responsible Person form must be completed for each location (form available on Board website). The new Responsible Person must answer the legal questions and sign the change form. A new license will NOT be issued unless specifically requested and a replacement fee is submitted. It is not required to have a new license when the Responsible Person (Medical Director) changes.

The new Responsible Person must be a prescriber or pharmacist except for selected locations such as laboratories, teaching institutions, animal shelters (for euthanasia) and oxygen vendors.

### IV) Changing the Drug Addendum

**To ADD drugs**, submit a **signed, notarized** letter from the Medical Director with a list of drugs and the protocols or statement as described in Protocol Instructions below and an addendum update fee of \$15.00 to the Board office. To delete drugs, submit a copy of the current addendum to the Board office with a line drawn through the drug name(s) and initial or sign the addendum.

V) **Protocol Instructions**

When the services of an Ohio licensed prescriber are not immediately available, Ohio Administrative Code rule 4729-5-01(L) allows for Protocols (Standing Orders) to be established for specific instances to authorize the administration of drugs.

Following are two instances where drugs may be administered pursuant to pre-approved protocols.

- A) **For drugs to be used in a true EMERGENCY**, a protocol is a definitive set of treatment guidelines that include definitive orders for drugs and their specified dosages. The protocol must specifically define the intended audience, list the drug name and strength and give specific instructions on how to administer the drug. Drugs may include epinephrine, diphenhydramine and medical oxygen.

(Ex. For an employee having a severe allergic reaction or anaphylactic shock, give 0.3ml SC of epinephrine 1:1000.)

Of course, the Medical Director may have a more detailed protocol or may word the protocol as he/she may desire as long as it contains the required details above.

- B) **For VACCINES or BIOLOGICALS** for the purpose of preventing disease, a protocol is a definitive set of treatment guidelines that include definitive orders for drugs and their specified dosages. The protocol must specifically define the intended audience, list the drug name and strength and give specific instructions on how to administer the drug. Drugs may include tetanus toxoid, hepatitis B and flu vaccine.

(Ex. All employees will be offered this year's Flu vaccine. If accepted, inject 0.5ml IM of the Flu vaccine in the deltoid muscle.)

- C) **For any other prescription drug, the prescriber must be contacted before drug administration** in order that a direct order may be obtained for a specific patient. Drugs in this section will include drugs that the prescriber wishes to have available for his/her use only or to have available for administration upon giving a direct order to a health care professional for a particular patient. Prescription drugs in this list may include such items as antibiotics, non-steroidal anti-inflammatory agents, and topical burn agents.

The list of drugs in this section will be preceded by a statement such as:

**The drugs listed below will be used by me or for use when I give a direct order to a health care professional to administer such drug to a specific patient.**

- D) In all cases, protocols (or standing orders) **MAY NOT** be issued for dispensing prescription drugs to be taken at a later date or time. The prescriber may personally supply prescription medications to their patients and this **requires** the prescriber to be on site to supervise the preparation and make the final check of the drugs and label prior to handing them to the patient.