

Guidelines For The Use Of Pharmaceuticals In Physical Therapy

The Physical Therapy Section of the Ohio Occupational Therapy, Physical Therapy and Athletic Trainers Board received questions about the use and storage of drugs in a physical therapy clinic. The Section met with the Ohio State Board of Pharmacy and this information sheet was developed to share the information received from the Pharmacy Board with physical therapy practitioners in Ohio (also occupational therapy practitioners and athletic trainers, if applicable).

The Ohio Revised Code section 4729.01 defines a “dangerous drug” as:

- Any substance labeled “Caution: Federal law prohibits dispensing without prescription”, “Rx Only”, or any other similar restrictive statement;
- The drug may be dispensed only upon a prescription; or
- Any drug intended for administration into the human body other than through a natural orifice of the human body (e.g.: injectables).

“Dangerous drugs” include, but are not limited to:

- Flouri-Methane
- Dexamethasone
- Lidocaine (prescription strength)
- Hydrocortisone (prescription strength)

The approval to market drugs:

- All drugs commercially marketed must be approved by the Food and Drug Administration (FDA).

The purchase of “dangerous drugs”:

- Physical therapy sites that have a current license as a Terminal Distributor of Dangerous Drugs (issued by the Pharmacy Board) may only purchase “dangerous drugs” from: (1) a vendor who possesses a Wholesale Distributor of Dangerous Drugs license, or (2) a licensed pharmacy in Ohio. It is the responsibility of the physical therapy practitioner to verify that the vendor has a license as a wholesale distributor of dangerous drugs or a pharmacy licensed as a Terminal Distributor of Dangerous Drugs.

Storage of “dangerous drugs”:

- For physical therapy sites located within a hospital, “dangerous drugs” must be stored in accordance with policies and procedures established by the Director of the Hospital Pharmacy under the hospital’s license as a Terminal Distributor of Dangerous Drugs. (A separate Terminal Distributor of Dangerous Drugs license is not required if there is common ownership and control.)
- For physical therapy sites located outside of a hospital setting (even if owned by a hospital), “dangerous drugs” must be stored in an area secured by either a physical barrier with suitable locks and/or an electronic barrier to deter and detect unauthorized access.

Manufactured drugs are:

- Drugs approved by the FDA as commercially available products.

Compounded drugs are:

- Drugs that are not available in a commercially prepared dosage form approved by the FDA, but are compounded by a pharmacist pursuant to a prescription for a specific patient.

Compounded drugs include:

- Eurcerin or Aquaphor with Hydrocortisone
- Aquasonic gel and Dexamethasone (ex: phonogel or other trade names) products.

Purchase of compounded drugs:

- Only a patient, for whom a compounded drug has been prescribed and in such a quantity for that patient, may purchase compounded drugs from a licensed pharmacist.
- A physical therapy practitioner may not purchase compounded drugs.

Use of compounded (non-approved) drugs:

- Compounded drugs dispensed by a pharmacist are the patient's property and as such can be stored in a secure place with the patient's permission.

Storage of patients' compounded drugs:

- Drugs, once dispensed by a pharmacist, are the patient's property and as such can be stored in a secure place with the patient's permission.
- It is **STRONGLY** recommended that the physical therapy practitioner request a signed release from the patient to securely and properly store the patients' compounded drugs.
- It is **STRONGLY** recommended that included on the form for the patient to sign is the information about what will happen to the drug(s) following the end of treatment. (ex: On the patient's last day of treatment, any leftover compound will be destroyed (wasted) in the patient's presence with the patient's permission, or if the patient cancels or does not show up for the last treatment or is unable to be present for any reason, the physical therapy practitioner will hold the drug for 30 days. At the end of that time, the drug will be destroyed by the physical therapy practitioner and witnessed by another licensed individual.)
- **EITHER** situation must be completely documented.
- Under no circumstances can a stored drug be used on any other person than the one to whom it was dispensed.

Applying for a Limited Category Two Terminal Distributor of Dangerous Drugs license:

- A Terminal Distributor of Dangerous Drugs license (Limited Category Two) is required only if the physical therapy site desires to purchase and possess "*dangerous drugs*" for administration directly to patients pursuant to a prescriber's order.
- A Terminal Distributor of Dangerous Drugs license is not required if the physical therapy site only stores "*dangerous drugs*" that were dispensed by a pharmacy to a specific patient.

- An application packet for a Terminal Distributor of Dangerous Drugs license may be obtained from the Ohio State Board of Pharmacy by calling (614) 466-4143 or sending an email request to licensing@bop.ohio.gov.
- A completed application consists of:
 1. Completely filling out the two-page application;
 2. The signature of a pharmacist or physician licensed in Ohio to serve as the Responsible Person pursuant to Ohio Revised Code section 4729.55;
 3. A list of personnel having access to and administering “*dangerous drugs*” (name & SSN or professional license number and expiration date);
 4. A signed and notarized letter (by the Medical Advisory) specifying a list of “*dangerous drugs*” and their intended use. The list of “*dangerous drugs*” must include the name, strength, and dosage form of the drug;
 5. A check for \$112.50 for the original application (made payable to “Treasurer, State of Ohio”); and
 6. A copy of the corporation or LLC papers.
- A new application must be completed and submitted with the required fee each time there is a change of business name, change of ownership, or change of address.
- Delivery of a new license will be done by an inspector of the Ohio State Board of Pharmacy will check for:
 1. Security (including sharps disposable, if applicable);
 2. Accountability (documentation of receipt, administration, use, and disposal of “*dangerous drugs*”); and
 3. Control (storage conditions, including temperature control and sanitary conditions).
- Terminal Distributor of Dangerous Drugs licenses are issued on a calendar year basis and expire on December 31 of each year. A renewal application is sent each year at the end of September. The renewal application must be completed and returned to the State Board of Pharmacy along with a list of current personnel and a check for \$112.50.

Questions regarding licensure should be directed to:

Licensing Administrator
 Ohio State Board of Pharmacy
 77 South High Street, Room 1702
 Columbus, Ohio 43215-6126
 (614) 466-4143
licensing@bop.ohio.gov