Prescriber Compounding

Cameron McNamee
Director of Policy and Communications

Board of Pharmacy Oversight

Terminal Distributors of Dangerous Drugs

- Engaged in the sale of dangerous drugs at retail, or any person who has possession, custody, or control of dangerous drugs for any purpose other than for that person's own use and consumption, and includes pharmacies, hospitals, nursing homes, and laboratories and ***all other persons*** who procure dangerous drugs for sale or other distribution by or under the supervision of a pharmacist or licensed health professional authorized to prescribe drugs.

Board of Pharmacy Oversight

- 18,128 TDDD licenses active.

- Few exceptions to licensure:
  - Solo-practice physicians (including single shareholder corporations where the sole shareholder is a healthcare providers).
  - Dental practices.

Board of Pharmacy Oversight

- In 2014, Board requested and received legislative change for narrowing of exception if the entity possessed dangerous drugs that are compounded or used for the purpose of compounding.

- "Compounding" means the preparation, mixing, assembling, packaging, and labeling of one or more drugs.

Board of Pharmacy Oversight

- Following passage of legislation, the Board implemented a new questionnaire on application to determine type of compounding.

- Allowed for identification of compounding practices at specific locations.

Board of Pharmacy Oversight

- Fining authority.
- Can suspend without a prior hearing if compounding practices (or any actions related to dangerous drugs) presents a danger of immediate and serious harm to others.
- Proactive & unannounced inspection authority for current and prospective licensees.

New Compounding Regulations

- In 2014, Board began new compounding regulations to update and consolidate all compounding rules into a single chapter.
- Included regulations for pharmacies (797/795), outsourcing facilities, limited in-office use (restricted to Ohio pharmacies only) and prescriber compounding.
- For prescribers, proposed regulations required adherence to USP 797 & 795.

Prescriber Compounding

- Initial issues:
  - o Hematology and oncology physicians as it related to hazardous drugs.
  - o Clean room requirements in USP 797. Limited office space / long-term lease concerns.
  - o Indicated preference for USP 800.

Prescriber Compounding

- Compromise Solution:
  - o Move towards best practices.
  - o Created hazardous drug compounding rule (USP 800 light) – OAC 4729-16-13.
  - o Primarily diverges from USP 800 as it relates to environmental controls.

Prescriber Compounding

- Compromise Solution:
  - For products with a BUD less than 12-hours:
    - Requires externally vented PEC (BSC / CACI) in a segregated area.
    - Environmental wipe sampling a should not a shall.
  - For anything with a BUD greater than 12-hours must meet USP 797 requirements.
  - **DOES <u>NOT</u> EXEMPT RECONSTITUTION.**

Prescriber Compounding

- Prescriber compounding rules effective 5/1/2016.
- Sent out multiple communications via medical board and professional associations.
- Specifically conducted trainings for oncology professionals on hazardous drug requirements.

Prescriber Compounding

- Issues 2.0
  - o Reconstitution vs. Compounding
    - ❑ Wait for new USP 797 chapter.
  - o Immediate-use provision not realistic
    - ❑ Buffering of lidocaine, tumescent anesthesia and fillers for in-office use. One-hour provision not realistic.
  - o Botox and single use.
    - ❑ Botox sold in 50 ml bottle but procedures only use 10-15 ml. Increased cost to patients.
  - o Bleomycin to inject into recalcitrant warts.
    - ❑ Did not want to adhere to hazardous drug rule.

Prescriber Compounding

...It has scientifically been proven that botox is safe and effective as far as one month after reconstitution. There are many days where I have only one patient come in for botox in a day. That would mean that I would lose close to 300-400 dollars per vial. There is no way to make up the cost of that in charging the patient. Many patients would be priced out of the procedure...

That would be acceptable if the board of pharmacy would reimburse the physicians for all of their botox. There are no reported injuries or death related to physician compounding in the state of Ohio.

Prescriber Compounding

- Compromise Solution 2.0
- Exempts reconstitution of **non-hazardous** drugs and preparation of drug devices from the definition of compounding. Uses proposed USP 797 verbiage.
- Exemption of hazardous drugs was a non-starter.
- Also addresses certain licensure concerns raised by prescribers.

Reconstitution

The reconstitution or dilution of a conventionally manufactured sterile dangerous drug product with no intervening steps in accordance with the manufacturer's labeling for administration and beyond use dating. If no such beyond use date exists, the dangerous drug product may only be used for up to 6-hours following preparation. These drug products shall be prepared using aseptic technique and procedures shall be in place to minimize the potential for contact with nonsterile surfaces and introduction of particulate matter or biological fluids. Any other reconstitution or dilution of a conventionally manufactured sterile product is considered compounding and shall be performed in accordance with this rule.

Immediate Use

- Board did not exempt the creation of a new drug from the definition of compounding (i.e. buffering of lidocaine and other drugs used for in-office procedures).
- Created immediate-use chapter for drugs administered by a prescriber.
- Only for low-risk compounding and cannot be dispensed. Medium or high-risk must adhere to USP 797.
- Similar to immediate-use provision in 797 but permits administration up to 6-hours.

Immediate Use

- Requires preparation using aseptic technique.
- Prohibits non-patient specific batch compounding.
- Preparation of the drug in a designated clean medication area (disinfection required daily and before and after compounding process).
- Labeling requirements.

Immediate Use

- Final check required by prescriber.
- Does not apply to hazardous drugs.
- A new sterile needle shall be used to administer the compounded drug product to the patient.

Prescriber Compounding

- OAC 4729-16-13 – Immediate Use
- OAC 4729-16-11 – Hazardous Drugs
- OAC 4729-16-04 – Drugs Compounded by a Prescriber
  - For non-hazardous drugs that do not meet the definition of immediate use. Requires adherence to USP 797 & 795.

Lessons Learned

- Knowledge base on preparation of drugs varies among prescriber community.
- Education of stakeholders is key. Confusion can cause delay.
- Don’t let the perfect be the enemy of the good. Move towards best practices.