Changes in Regulation of Compounding in Minnesota

Cody Wiberg, Pharm.D., M.S., R.Ph.  
Executive Director  
Minnesota Board of Pharmacy
Sale of drugs by pharmacies for office use

- Board frequently received questions about the sale of drug products to health practitioners and clinics for office use.
- Most common question:
  
  Can pharmacy fill a prescription that is not written for a specific patient but is instead written out for “office use”? 

Sale of drugs by pharmacies for office use

- Short answer – “no”.
- **MN Rules 6800.0100, Subp. 11:**
  - “Prescription drug order” – a lawful written, oral, or electronic order of a practitioner for a drug *for a specific patient*. A prescription drug order *must contain the information specified in* this chapter and in *Minnesota Statutes, section 151.01, subdivision 16*.

- **MN Stat. 151.01, subd 16:** "prescription" means a signed written order, or an oral order reduced to writing *issued for an individual patient* and containing the following: *name and address of the patient*. . .
Sale of drugs by pharmacies for office use

- Pharmacy allowed to sell drugs to health practitioner or clinic at wholesale, but only if it is licensed by the Board of Pharmacy as a wholesaler.
  - See MN Stat. 151.44 (a) – definition of “wholesale drug distribution”; (b) definition of “wholesale drug distributor” and MN Stat. 151.47 and 151.48 – requiring wholesalers to be licensed.
  - Note definition of wholesale drug distributor includes pharmacy.
Can practitioners or hospitals purchase prescription drugs from pharmacies not licensed as wholesalers?

- MN Stat. 151.46 – unlawful . . . to knowingly purchase or receive prescription drug from a source other than person or entity licensed under the laws of the state . . . A person violating the provisions of this section is guilty of a misdemeanor.
Purchase of compounded drugs by practitioners or hospitals from pharmacies

- Can a practitioner or hospital buy compounded drugs from a pharmacy?
- Can a practitioner or hospital buy compounded drugs from a pharmacy that is also licensed as a wholesaler?

- Short answer to both questions – “no”.
Purchase of compounded drugs by practitioners or hospitals from pharmacies

- M.S. §151.01, subd. 14:

  “manufacturing” except in the case of bulk compounding, prepackaging or extemporaneous compounding within a pharmacy, means and includes the production, quality control and standardization by mechanical, physical, chemical, or pharmaceutical means, packing, repacking, tableting, encapsulating, labeling, relabeling, filling or by any other process, of all drugs, medicines, chemicals, or poisons, without exception, for medicinal purposes”. 
Purchase of compounded drugs by practitioners or hospitals from pharmacies

- **Extemporaneous** compounding – the preparation of a drug product upon receipt of a prescription for a specific patient.
- **Bulk** compounding – preparation by a pharmacy of a supply of a compounded drug product that is sufficient to meet its short-term anticipated need for the filling of prescriptions. Also called “anticipatory compounding”
Purchase of compounded drugs by practitioners or hospitals from pharmacies

- Minnesota Rules 6800.3300 requires compounding to be done pursuant to United States Pharmacopeia (USP) Chapters 795 or 797 standards.
  - USP Chapter 795 notes that compounding is differentiated from manufacturing by the existence of a “practitioner–patient–compounder relationship”.
  - When a drug product is prepared for office-use and a specific patient is not named, no such relationship exists – since the pharmacist has no idea who the drug will be administered to at the time he or she is preparing it.
Purchase of compounded drugs by practitioners or hospitals from pharmacies

- So, preparing a drug for office use is not actually compounding – it is manufacturing
- MN Stat. 151.25 requires registration of anyone engaged in manufacturing
- Consequently, a pharmacy that prepares a drug and sells it to a practitioner or hospital for “office use” needs to be licensed not only as a wholesaler – but also as a manufacturer
Statutory Changes – Minnesota

- 2013 Session Law – Chapter 8, Article 10
  Apply to all facilities licensed by the Board
  - Non-residential facilities
    - Must be licensed by state in which located and registered, if required, by FDA
    - Must supply Board with an inspection report < 24 months old
    - Must supply Board with proof that any deficiencies noted in reports have been corrected
  - MN Pharmacy Board to engage in rule-making to set standards for licensing facilities not required to be licensed/registered by other state or FDA.
Statutory Changes – Minnesota

- 2014 Board of Pharmacy (BOP) – Proposed Legislation related to compounding
  - Requires businesses registered by FDA as outsourcing facilities to be licensed by BOP
  - Adds definitions of “compounding”, “extemporaneous compounding”, “anticipatory compounding” to the law.
  - Creates exemptions to the manufacturing licensing requirement when pharmacies and practitioners are engaging in compounding
  - Empowers the BOP to allow compounding for office use in certain situations
Contact Information

Cody Wiberg, Pharm.D., M.S., R.Ph.
Executive Director
Minnesota Board of Pharmacy
2829 University Avenue SE, #530
Minneapolis, MN 55414

(651)201–2825 phone
(651)201–2837 (fax)

cody.wiberg@state.mn.us