

# Changes in Regulation of Compounding in Minnesota

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## ▶ 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

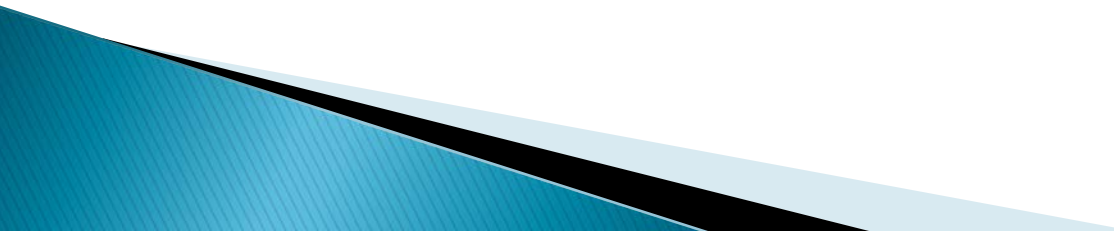
- Short answer – “no”.
- MN Rules 6800.0100, Subp. 11:
  - “Prescription drug order” – a lawful written, oral, or electronic order of a practitioner for a drug *for a specific patient*. A prescription drug order *must contain the information specified in this chapter and in Minnesota Statutes, section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

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- ▶ 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”.
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## ▶ 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**

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