

**MINNESOTA BOARD OF PHARMACY
URGENT MEMORANDUM**

DATE: December 5, 2012

TO: Executive Directors of Health Licensing Boards that License Practitioners

FROM: Cody Wiberg, Executive Director, Minnesota Board of Pharmacy

RE: Compounding

Given the recent tragic events surrounding the distribution of contaminated products to Minnesota health care providers, I am sending this memo to the Boards that license practitioners (i.e. licensed healthcare professionals who are allowed to purchase, possess, prescribe, dispense and administer prescription drugs pursuant to Minnesota Statutes §151.37). On behalf of the Board of Pharmacy, I request that you take whatever steps you deem to be appropriate to share this information with your licensees.

The Minnesota Board of Pharmacy frequently receives questions and complaints about the sale of drug products to practitioners and clinics for office-use. The most common question is whether or not pharmacies can fill a prescription that is not written for a specific patient but is instead written out for "office use". The short answer is no, they can't.

Minnesota Statutes §151.01, subd. 16 defines "prescription" as: "a signed written order, or an oral order reduced to writing, given by a practitioner licensed to prescribe drugs for patients in the course of the practitioner's practice, issued for an individual patient and containing the following: the date of issue, ***name and address of the patient***, name and quantity of the drug prescribed, directions for use, and the name and address of the prescriber". (Emphasis added). Clearly, by law, a practitioner cannot issue a prescription without specifying an individual patient. Thus, if a physician writes out an order on a prescription pad (or as part of an electronic prescription or chart order) that is "for office use", ***the order is not a legally valid prescription.***

A pharmacy is allowed to sell prescription drugs to a practitioner or clinic pursuant to a wholesale transaction, but only if it is licensed by the Minnesota Board of Pharmacy as a wholesaler. In such cases, the pharmacy must follow all applicable state and federal laws and rules concerning the wholesaling of drug products. However, drugs prepared by a compounding pharmacy cannot be supplied to a physician or clinic as part of a wholesale transaction unless certain other conditions are met, as described below

Another question the Board receives is whether or not pharmacies can provide "compounded drugs" to physicians, clinics and other healthcare providers or facilities for office-use. The answer is, again, no. Minnesota Rules 6800.3300 requires compounding to be done pursuant to United States Pharmacopeia (USP) Chapters 795 or 797 standards, as appropriate. 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.

Preparing a drug for sale to a practitioner or clinic for office use, when a prescription has not been issued for a specific patient in advance of the distribution of the drug, is not compounding. Instead, the preparation of the product would be considered manufacturing and the sale would be a wholesale transaction. That being the case, the pharmacy would need to be licensed by the Board as a wholesaler and a manufacturer and would need to follow good manufacturing procedures. The pharmacy would also need to be registered by the Food and Drug Administration as a manufacturer or would have to supply the Board with a letter from the FDA stating that registration with that agency is not required. A non-residential pharmacy would also need to be licensed as a wholesaler and a manufacturer by the state in which it is located.

The definition of *manufacturing* in M.S. §151.01, subd. 14 is:

“The term 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”. (internal quotation marks omitted).

Bulk compounding is the 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. It is **not** the preparation of bulk amounts of a drug product that can be sold for office use.

Extemporaneous compounding is the preparation of a drug product upon receipt of a prescription for a specific patient. Note that the prescription must be received prior to the shipment of the drug product to the patient (or to a practitioner that will use it in the care of the patient). Shipping a drug to a practitioner for office use and having the practitioner send back a prescription right before or after the drug is used for a patient is not acceptable because no practitioner-patient-compounder relationship truly exists in those circumstances.

Unless certain conditions are met, pharmacies in other states cannot legally supply Minnesota patients or practitioners with compounded drugs. Minnesota Statutes §151.19, subd. 2 requires any non-residential pharmacy that dispenses medications for Minnesota residents and mails, ships, or delivers prescription medications into this state to be licensed by this Board. A pharmacy license issued to a nonresidential pharmacy would allow it to dispense drugs to Minnesota residents only pursuant to a prescription for an individual patient. The laws and rules mentioned above concerning compounding, wholesaling and manufacturing apply to nonresidential pharmacies licensed by the Board.

In addition to state laws and rules, there are federal considerations as well. The U.S. Food and Drug Administration has issued a Compliance Policy Guide for compounding. The Guide includes the following language: “when the scope and nature of a pharmacy's activities raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of the new drug, adulteration, or misbranding provisions of the Act, FDA has determined that it should seriously consider enforcement action. In determining whether to initiate such an action, the Agency will consider whether the pharmacy engages in any of the following acts . . . compounding drugs for third parties who resell to individual patients or offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale . . . and failing to operate in conformance with applicable state law regulating the practice of pharmacy”. The full CPG can be found at:

<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074398.htm>.

Before purchasing any drug products from a company, practitioners would be well advised to verify the company's licensure status. That can be done using the licensure verification page on the Board's Web site at:

<https://www.hlb.state.mn.us/mnbop/glsuiteweb/homeframe.aspx>

Purchasing drugs at wholesale from any entity that is not licensed by the Board as a drug wholesaler is illegal (see Minnesota Statutes §151.46) Purchasing “compounded” products at wholesale from any company that is not also licensed as a manufacturer is also illegal.