

**6800.3100 COMPOUNDING AND DISPENSING.**

Subpart 1. **Duties.** The practice of compounding and dispensing a prescription drug order includes, but is not limited to, the following acts, which shall be performed only by a pharmacist, practitioner, or pharmacist-intern under the immediate and direct supervision of a pharmacist:

- A. determination of brands and suppliers;
- B. receipt of verbal prescription drug orders which must include documentation of the individual communicating the order and the pharmacist or pharmacist intern receiving the order;
- C. verification of the prescription drug order;
- D. selection of the drug to be used in filling the prescription drug order;
- E. establishment and validation of the initial formulation record of all compounded preparations according to part 6800.3300;
- F. certification of the filled prescription drug order;
- G. ensuring that, when required by law or by the best professional practice, permission to refill is obtained from authorized practitioners or other individuals allowed to prescribe legend drugs according to Minnesota Statutes, section 151.37, subdivision 2, and then noting on the reverse side of the prescription drug order or in the electronically maintained record of the prescription drug order the following data: date refilled; name of practitioner or other authorized prescriber personally authorizing the refill, and the name of the practitioner's agent transmitting or communicating the refill authorization, if applicable; quantity of drug dispensed, if different from the original prescription; and the unique identifier of the pharmacist refilling the prescription;
- H. supervising clerical personnel in limited nonprofessional duties such as typing that does not involve prescription data entry, record keeping, filing, and completing sales transactions; and
- I. supervising pharmacy technicians utilized in the performance of certain pharmacy tasks not requiring professional judgment in accordance with part 6800.3850.

Subp. 2. **Verification.** Verification of validity and propriety under subpart 1, item C, must be of the original prescription drug order. A rewritten, verbal, or electronically produced copy is not acceptable except as provided in parts 6800.3000, subpart 2, 6800.3120, subpart 7, and 6800.3950, subpart 1a.

Subp. 3. **Certification.** In certifying and documenting the filled prescription under subpart 1, item F, an individual pharmacist, practitioner, or pharmacist-intern shall:

A. check the original labeled container from which the medication was withdrawn, except as provided in part 6800.2600, or when the pharmacy uses a computerized process to identify oral, solid drugs through the use of images;

B. check the labeling on the medication container that will be dispensed;

C. check the contents of the medication container that will be dispensed and the appearance of the total product to ensure that all of the doses that are dispensed are of the correct drug, strength, and dosage form prescribed;

D. review the patient's medication profile for purposes of conducting a prospective drug review and checking the accuracy of the addition to the profile of the medication dispensed; and

E. place the pharmacist's, practitioner's, or pharmacist-intern's unique identifier on the prescription drug order or other permanently maintained record. Those pharmacists using automated medication management dispensing systems must develop written policies and procedures which provide that all certification steps are performed and documented before the medication is dispensed to the patient. These policies and procedures must be made available for inspection by the board upon request.

Subp. 3a. **Accountability.** For prescriptions filled in a pharmacy, the unique identifier of each pharmacist, pharmacist-intern, or pharmacy technician who performs any portion of the prescription filling process must be documented, with the documentation maintained for a minimum of two years. The documentation must indicate which portion of the prescription filling process each pharmacist, pharmacist-intern, or pharmacy technician completed. For prescriptions filled by a practitioner, the unique identifier of each practitioner and each individual who assists the practitioner according to part 6800.9952 must be documented and the documentation maintained for a minimum of two years. This subpart does not waive the requirement for an individual pharmacist, practitioner, or pharmacist-intern to certify a filled prescription drug order according to subpart 3.

Subp. 3b. **Notice required.** A pharmacy utilizing a central service pharmacy to provide dispensing functions, drug utilization review, packaging, labeling, delivery of a filled prescription, or other services must notify the pharmacy's patients of that fact.

Subp. 4. **Exception.** This part applies to all pharmacies. Provided, however, that nothing in this part prevents pharmacists in hospitals from dispensing to hospital inpatients according to parts 6800.7100 to 6800.7950.

**Statutory Authority:** *MS s 151.06; 151.102; 152.02*

**History:** *9 SR 1656; 10 SR 2007; 18 SR 1145; 23 SR 1597; 31 SR 1673; 36 SR 237*

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