



## Guidance: Centralized Prescription Processing and Filling

Pursuant to Minnesota Statutes 214.108, the Board of Pharmacy is allowed to offer guidance to licensees about the application of the statutes and rules that the Board enforces. Such guidance is not binding in any court or other adjudicatory body. Some of the comments below are recommendations that do not have the force of law and that do not have to be followed. However, some of them do state the actual requirements of various statutes and rules. This document has been approved by the Minnesota Board of Pharmacy and offers guidance to pharmacies and other interested parties that are seeking to write policies in compliance with Minnesota Rules 6800.4075. Please note other Rules and Statutes may apply.

### Definitions:

Minnesota Statutes §151.01, Subd. 31. **Central service pharmacy.** "Central service pharmacy" means a pharmacy that performs those activities involved in the dispensing of a drug for another pharmacy pursuant to the requirements of this chapter and the rules of the Board.

Minnesota Rules 6800.0100, Subp. 17. **Unique Identifier.** "Unique identifier" means a manual signature or initials, a biometric identifier, or a board approved electronic means of identifying only one individual.

Minnesota Rules 6800.3100, Subp 3. **Certification.** "Certification" means a pharmacist, pharmacist intern or practitioner shall check the original labeled container from which the medication was withdrawn, check the labeling on the medication container, check the contents of the medication container, review the patient's profile for purposes of conducting a prospective drug review and place a unique identifier on the prescription drug order or other permanently maintained record.

Minnesota Statutes §151.01, Subd. 30. **Dispense or dispensing.** "Dispense or dispensing" means the interpretation, evaluation, and processing of a prescription drug order and includes those processes specified by the board in rule that are necessary for the preparation and provision of a drug to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

**Note:** The Minnesota Board of Pharmacy understands that the word "dispensing" includes the following activities: receipt of prescription, data entry, certification, filling, verification, counseling, delivery and a quality assurance double check of the prescription from 2 to 72 hours after completion.

### Licensure:

Any **pharmacy** located in this state must be licensed by the Minnesota Board of Pharmacy. Any pharmacy located in another state that dispenses drugs for Minnesota residents, whether entirely on its own or when working with a Minnesota located pharmacy through a central service pharmacy arrangement, must be licensed by the Minnesota Board of Pharmacy pursuant to Minnesota Statutes §151.19.

Prior to legislative changes in 2019, the Board had not approved policies or variance requests when any portion of the “dispensing process” for Minnesota residents would occur outside of licensed space (for example data entry by technicians working from home). Note that Minnesota Statutes §151.15, subds. 5 & 6 does allow portions of the dispensing process to be completed outside of a licensed space in certain emergency situations.

Any **pharmacist** working in Minnesota must be licensed by the Minnesota Board of Pharmacy. Any pharmacist working in another state who is performing dispensing functions involving Minnesota residents, as part of a central service arrangement between the non-resident pharmacy and a Minnesota located pharmacy, must be licensed by the Minnesota Board of Pharmacy. Pharmacists working in other states do not have to be licensed by the Minnesota Board of Pharmacy only if **all** dispensing functions, except for the delivery of filled prescriptions to patients and prescription counseling, are completed entirely outside of Minnesota.

Any **technicians** working in Minnesota or working in a pharmacy located in another state on prescriptions for Minnesota residents, must be registered by the Minnesota Board of Pharmacy and working under direct supervision by a Minnesota licensed pharmacist.

Minnesota law does not allow the Board to issue licenses for foreign pharmacies. Consequently, no portion of the dispensing process can be performed in any pharmacy located outside of the United States.

### **Policy Requirements:**

(Most of these requirements are taken from Minnesota Rules 6800.4075 and therefore have the force of law). A Minnesota licensed pharmacy may perform or outsource centralized prescription drug order filling or centralized prescription drug order processing services provided:

- The parties have the same owner or have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations.
  - Provide a business summary on how you intend to conduct the central service arraignment.
  - Explain if the pharmacies are under common ownership.
  - Explain the responsibilities and accountabilities of each party.
- The parties share a common electronic file or have appropriate technology such as an interface with a real time electronic database to allow access to sufficient information necessary or required to fill or refill a prescription drug order.
  - Identify the software and explain how it works.
  - Explain software and system security features including accountability, auto logoffs, unique identifiers, safe-guarding of protected health information, and any disciplinary action taken for violation of policies and procedures.

- Please note: pharmacies may need to obtain board approval for unique identifiers that are electronically retained other than by biometrics.
- The parties performing or contracting for centralized prescription order processing services shall maintain a policy and procedures manual with documentation that operations are occurring in a manner consistent with the manual. The Board recommends that the manual be updated on an annual basis (or sooner if any significant changes are made). ***The manual must be submitted to the Board at least 30 days before centralized prescription drug order processing services begin,*** and shall address at a minimum, the following:
  - A description of how the parties will comply with federal and state laws and regulations such as those involving;
    - Licensure and registration
    - Loss reporting for controlled substances
    - Perpetual inventories for controlled substances
    - DEA Central Fill requirements (and other applicable DEA requirements)
    - Transfers of prescriptions
    - Prescription Monitoring Program reporting
    - Minnesota requirement for pharmacists and technicians to work in licensed space
    - Supervision of pharmacy technicians as required in Minnesota Rules 6800.3850 Subp.5.
  - A listing of all participating pharmacies, locations, phone numbers, Minnesota license numbers and a detailed description of each pharmacy's specific responsibilities
  - The maintenance of appropriate records and an audit trail to identify the responsible pharmacists and technicians during each step of the dispensing process. Describe who is responsible for each step of the dispensing process and how accountability for each step is ensured for all of the following:
    - Data entry
    - Profile review including drug utilization review
      - Include procedures for handling the override of alerts and the corresponding documentation.
    - Filling
    - Certification
    - Verification
    - Counseling
    - Delivery
    - Quality Assurance (QA or double checks) as required in Minnesota Rules 6800.3950 Subp. 4
  - The maintenance of appropriate records to identify the responsible pharmacist in the counseling process, the documentation of refusals and the reasons for refusal.
  - Notification - the way you will identify all participating pharmacies in this central service arraignment to patients, including patients in long-term care facilities or other non-ambulatory patients, and to staff. Examples:
    - Signage or other means of informing patients of all participating pharmacies;
    - A listing of all pharmacies on the prescription label involved in this central service policy.
  - Adequate security measures to protect the integrity of protected health information and prevent its illegal use or disclosure.
  - The maintenance of a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and

appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

- Patient freedom of choice.
- That no returns are allowed back to the central pharmacy except when the prescription has not left the physical custody of the central fill pharmacy or its staff.
- Emergency operations for computer system downtimes, severe weather, power outages, etc.
- Training
  - Initial and ongoing
  - Documentation
  - Who is responsible
- Shipping and delivery
  - Adequate and secure tamper proof delivery
  - Storage and shipment containers
  - Accountability
  - Receiving process for deliveries
- A pharmacist or pharmacist intern at the pharmacy that dispenses, delivers, mails, or ships the completed prescription drug order to the patient is responsible for certifying the completed prescription drug order, except as provided for in Minnesota Statutes, section 151.215
- A pharmacist or pharmacist intern at the pharmacy that dispenses, delivers, mails, or ships the completed prescription drug order to the patient is responsible for counseling the patient according to Minnesota Rule 6800.0910.
  - How and when will counseling occur
  - Who is responsible
  - How are the counseling notes maintained, shared between sites and get to the patient?
  - Documentation of the pharmacist or pharmacist intern involved with providing consultation or accepted the consultation refusal when the prescription(s) are dispensed.
  - Documentation of the consultation refusals and the reasons for refusal.
- Explain record keeping requirements
  - How will prescription records be maintained
    - Hard copies and faxes
    - Electronic
  - How will originating pharmacy get the prescription

#### **Variations required:**

A variance may be required for split up of certification when more than one pharmacist is involved in the certification of a prescription (per MN Rule 6800.3100 Subp. 3). See also Minnesota Board of Pharmacy Guidance “Concerning Variance Requests for Split Certification”.

A variance may also be needed if certain services (i.e. like consultation) are only performed by other central service locations.

#### **Policy approvals needed for:**

Centralized prescription processing and filling (MN Rule 6800.4075)

Unique Identifier if accountability is retained electronically by a means other than biometrically. (MN Rule 6800.0100 Subp. 17)

**References:**

Minnesota Rule 6800.0100 Subp. 1c

Minnesota Rule 6800.0100 Subp. 17

Minnesota Rule 6800.0910

Minnesota Rule 6800.3100

Minnesota Rule 6800.3100 Subp. 1(l)

Minnesota Rule 6800.3110

Minnesota Rule 6800.3400

Minnesota Rule 6800.3850 Subp. 5

Minnesota Rule 6800.3950

Minnesota Rule 6800.4075

Minnesota Statute 151.01 Subd. 27

Minnesota Statute 151.01 Subd. 30

Minnesota Statute 151.01 Subd. 31

Minnesota Statute 151.102

Minnesota Statute 151.19

Minnesota Statute 151.215

FDA Guidance April 2016 "Hospital and Health System Compounding Under the Federal Food, Drug and Cosmetic Act"

**Approved 08/21/2019**