



Guidance: Split Certification and Unique ID

Pursuant to Minnesota Statutes 214.108, the Board of Pharmacy can 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 areas addressed below contain recommendations that do not have the force of law. Other areas concern issues that are addressed in statutes or rules. For those areas, the requirements in the law control. This document has been approved by the Minnesota Board of Pharmacy to offer guidance to pharmacies and other interested parties that are seeking to write policies and secure variances in compliance with Minnesota Rules 6800.3100. Please note other Rules and Statutes may apply. While each policy review or variance request is considered on its own merits, the Board seeks to handle these reviews and requests so that the individuals and businesses that are regulated by the Board are treated in a fair and consistent manner.

Definitions:

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pharmacist, pharmacist intern or practitioner shall check the original labeled container from which the medication was withdrawn, check the labeling on the medication container, check the contents of the medication container, review the patient’s profile for purposes of conducting a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 unique identifier on the prescription drug order or other permanently maintained record.

Minnesota Rule 6800.3100 Subp. 3a. **Accountability.** “Accountability” means that 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, pharmacy-intern or pharmacy technician completed.

Minnesota Rule 6800.9900 Subp. 1. **Right to request variance.** The pharmacist-in-charge of a pharmacy may request that the board grant a variance from any rule of the Board of Pharmacy.

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.

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.

***Note:** The Board of Pharmacy considers “dispensing” to include 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 dispense drugs for Minnesota residents, whether entirely on its own or when working with a resident Minnesota pharmacy through a central service pharmacy arrangement, must be licensed by the Minnesota Board of Pharmacy pursuant to Minnesota Statutes §151.19.

***Note:** 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. Note that Minnesota Statutes 151.15, subds. 5 & 6 do allow portions of the dispensing process to be completed outside of a licensed space in certain emergency situations and for certain patients.*

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 a non-resident pharmacy and a resident 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 **technician** working in Minnesota or working in a non-resident pharmacy, on prescriptions for Minnesota residents, must be registered by the Minnesota Board of Pharmacy and be working under direct supervision by a Minnesota licensed pharmacist. The supervising pharmacist must be stationed within the same work area as the technician, have the ability to control the technicians work, and is responsible for the action of the pharmacy technician.

***Note:** 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.*

Variance Requirements:

Minnesota Rule 6800.3100 Subpart 3 requires one individual pharmacist to perform all the final checks of a prescription.

- A **split certification variance** seeks permission to have more than one pharmacist involved in the certification process. When these variances are granted, each step of the dispensing process is certified by a pharmacist, but no single pharmacist certifies the accuracy of the entire dispensing process. It is important to specify when requesting a variance for split certification if the request is for pharmacists working within the same pharmacy or between pharmacies.

Policy Requirements:

Most of the requirements for a split certification variance are taken from Minnesota Rule 6800.3100. For variances of this nature, it is reasonable for the Board to ask for submission of policies that address the split certification process. To make a determination on the variance request, as required by Minnesota Rules 6800.9900, the Board does need a sufficient amount of information. Policies should address the following:

For split certification within a pharmacy

- System security
 - What software is used
 - How are access and permissions within the software granted
 - Who is responsible for access
 - Are there auto log off's
 - Password generation and frequency of updates
 - Unique identifiers (if the process does not meet the Rule, then Board approval is needed)
 - A unique ID policy approval seeks permission to use an identifier other than that defined by Minnesota Rule 6800.0100 Subp. 17 (see definitions above). Each step in the dispensing process must be accountable using a unique identifier.
- The maintenance of appropriate records and an audit trail to identify the responsible pharmacist and technician during each step of the dispensing process. Describe who is responsible for each step of the dispensing process and how accountability is documented for each step for the following:
 - Data entry
 - What identifiers are used to verify that the correct patient has been selected.
 - Verification process – what does this pharmacist review
 - Data entry
 - Profile review
 - Drug utilization review (DUR)

- Drug interactions
 - Therapeutic Duplication
 - Allergies
 - Procedures for handling the override of alerts and the corresponding documentation
- Filling
- Certification
 - Explain what the certification step entails
 - Explain the documentation that is maintained
- 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.
- Adequate and ongoing training of all staff
- Compliance with DEA requirements
 - Pharmacist corresponding responsibility for controlled substance prescriptions, whereby the verification of validity and propriety of the prescription is of the Original Prescription (i.e. remove CII prescriptions from remote verification).
 - Explain how transfers for controlled substances are handled
- Error reporting process
- Record retention (what documents are retained and for how long)
- Consultation
 - What is the process and who is responsible for determining if counseling is required
 - Who is responsible to provide consultation
 - Who initiates offer to consult on new prescriptions
 - Who initiates offer to consult on refills
 - How are refusals and reasons for refusal documented

For split certification between pharmacies

- You will need to specify on your variance request that the request is for split certification between more than one pharmacy.
- You will need to address staffing at all involved pharmacies as being reasonable and not adversely affecting patient care. To substantiate adequate staffing it is suggested that you provide your current staffing levels and workload.
- You will need to review and submit a separate additional policy for central services.
 - See separate Board Guidance on Centralized Prescription Processing and Filling
 - Review the centralized prescription processing and filling requirements found in Minnesota Rule 6800.4075

References:

Minnesota Rule 6800.0100 Subp. 17
Minnesota Rule 6800.0910
Minnesota Rule 6800.3100
Minnesota Rule 6800.3100 Subp. 3a.
Minnesota Rule 6800.3110 Subp. 4
Minnesota Rule 6800.3850 Subp. 5
Minnesota Rule 6800.3950 Subd. 4
Minnesota Rule 6800.4075
Minnesota Rule 6800.9900
Minnesota Statute 151.01 Subd. 30
Minnesota Statute 151.01 Subd. 31
Minnesota Statute 151.102
Minnesota Statute 151.15
Minnesota Statute 151.19
Minnesota Statute 151.215

Approval: May 20, 2020