Minnesota Board of Pharmacy Variance Recommendations for Methadone Pharmacies

Under Minnesota Statutes § 214.108, the Board is allowed to offer guidance to licensees about the application of the statutes and rules that the Board enforces. Such guidance is not binding on any court or other adjudicatory body. This document has been approved by the Minnesota Board of Pharmacy and offers guidance to pharmacies and other interested parties that are seeking the required approval of variances related to pharmacies located within Opioid Treatment Programs (OTP). 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.** The Board strongly recommends that policies and procedures be developed with all of these issues in mind, even those that are not addressed in statutes and rules. 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 manner. To help the Board and its staff determine if your policies and procedures address the following areas, please provide a cross-reference that specifies the location in your P&Ps at which an area is addressed. Please address each area even if you believe that it does not apply to your request.

INTRODUCTION

OTP pharmacies must submit a new pharmacy application listing categories for which they will be providing services for; in most instances this will be "community/outpatient" and "limited service". Based on practices followed, the pharmacy may need variances to comply with Board rules. In order to grant any variance approval under **MN Rule 6800.9900** the Board must determine that the variance will not adversely affect directly or indirectly, the health, safety, or well-being of the public; the alternative measures to be taken, if any, are equivalent or superior to those prescribed in the part for which the variance is requested; and compliance with the part for which the variance is requested would impose an undue burden upon the applicant. The board shall deny, revoke, or refuse to renew a variance if the board determines that all items above have not been met. The following should be considered for all requested variances and should be addressed within the submitted P&P's provided with the requested variance(s):

1. The pharmacy space must be described and either meet **MN Rule 6800.0700** or request a variance explaining the deviation.

2. The pharmacy must either obtain the required references and equipment per **MN Rule 6800.1050** or request a variance explaining the reason they are not needed.

3. Pharmacies are required to have a pharmacist on duty per **MN Rule 6800.2150**. If you do not, request a variance and explain how the pharmacist will verify adequate practices.

4. If a pharmacist will be Pharmacist-in-charge at more than one location you will need to request a variance to **MN Rule 6800.2400**.

5. If a pharmacist is not verifying all prescription drug orders and certify that they are filled accurately you will need a variance to **MN Rule 6800.3100**. Policies and procedures must address:

   A) Hours of pharmacy.
   B) How often the pharmacist will visit the facility
   C) What will the pharmacist review during each visit
   D) How will the pharmacist be involved in the ordering and receiving process
   E) Which drugs will be stocked and dispensed
   F) How often will the pharmacist reconcile the drug inventory
   G) Access to the licensed pharmacy should be limited, must be defined and be trackable
   H) Audits should be completed - the policy should define what will be audited and how often the pharmacist will do these audits.
   I) How all prescription drug orders (including dose changes) will be received, entered, and verified by the pharmacist.
   J) How is a patient's drug history obtained, updated and reviewed by the pharmacist. This pharmacist profile review should be completed at intake and a minimum of monthly thereafter.
   K) How pharmacist certification will be documented including addressing **MN Rule 6800.0100 subp 17** "unique identifier" (see #6 below)
   L) Positive patient identification must be defined and achieved
   M) No doses may be dispensed without pharmacist certification or disciplinary action will occur. This must be clear within the P&P.

6. The records must show compliance with **MN Rule 6800.0100 subd 17** during each step of the filling and dispensing process.

7. Review **MS 152.11** and define within your policy how you will comply, paying particular attention to how the prescription is received (electronic, fax or signed hard copy) and Schedule II controlled substances regulations (methadone).

8. Review **MN Rule 6800.3400** and address labeling of dispensed prescriptions. Request a variance if there is deviation from this rule.

9. Address supervision of the licensed nurses functioning within the licensed pharmacy space. Within your P&P define all duties performed by the nursing staff and how this process will be monitored by the pharmacist.

10. Explain how you will meet **MN Rule 6800.3950 subp. 4** for all new prescriptions.

11. Training must be addressed for new employees and ongoing for existing staff, with documentation. You should explain who will train all staff.

12. Explain how discontinued orders will be handled when a patient leaves the program or is hospitalized.

13. Explain downtime procedures that will be followed.

14. Explain waste policies to meet Minnesota Pollution Control Agency (MPCA) regulations.

15. Explain incident reporting practices including how the pharmacist is involved, documentation, and corrective action.

16. If a pump is used in the dispensing process explain pump calibration, cleaning and tubing changes to show accuracy of the pump if all policies are followed.

17. If a pump is used, order entry cannot be done by a nurse unless the system will not allow dispensing until the order has been certified by the pharmacist (such as a hard stop in the software)

18. Prepacking should be avoided.

19. If suboxone is also dispensed provide specific policies addressing the above and detailed policies explaining how the pharmacist will certify all doses. Labeling must be accurate and contain specific dose directions.

****All Variance approvals from the Board will be specific with any listed conditions to be followed including all approved policies and procedures.****