

MINNESOTA BOARD OF PHARMACY

GUIDANCE CONCERNING VARIANCE REQUESTS FOR OFF-SITE, AFTER REGULAR HOURS, HOSPITAL PHARMACY SERVICES

Pursuant to Minn. Stats. § 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 variances related to off-site, after regular hours, hospital pharmacy services. 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 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 and consistent manner.

All variance requests related to off-site, after regular hours, hospital pharmacy services are reviewed by the full Board of Pharmacy at one of its regularly scheduled business meetings. All variance requests are considered on a case-by-case basis. Per Minnesota Statutes Chapter 14, the Board may place conditions on any variance request before granting approval. Establishing conditions is also done on a case-by-case basis. Below are some of the conditions that the Board has imposed when it has considered past requests. However, individuals or businesses requesting a variance are **not** required to submit proposals that incorporate these provisions.

INTRODUCTION

If a hospital has a pharmacy that is not open 24 hours a day and if that hospital wants a pharmacist to provide pharmacy services from any remote location, an agreement must be made with an outside service (Hub pharmacy) to provide after-hours pharmacy services. A copy of this agreement must be provided to the Board for review at least 30 days prior to service being implemented.

(Important note: Nothing in state laws, rules or even this guideline **requires** a hospital pharmacy that is not open 24 hours per day to enter into a contract with a hub pharmacy for the provision of after-hour pharmacy services. However, if a pharmacy wants to have a pharmacist provide pharmacy services from a remote location, the Board will use these guidelines when it decides whether or not to approve the required variance requests).

Definitions:

Hub Pharmacy – an off-site licensed facility staffed by licensed Minnesota pharmacists providing service to a hospital pharmacy site after its normal business hours.

Receiving Pharmacy - A hospital pharmacy that has contracted with an off-site, Hub Pharmacy Service to provide pharmacist services after its normal business hours.

After-hours Service – Pharmacy coverage by the hub pharmacy for all hours not covered by the receiving pharmacy

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Implementation of an after-hours service by an off-site Hub pharmacy to a receiving pharmacy must be approved by the Board of Pharmacy via variance. Each receiving pharmacy and Hub pharmacy must apply for a variance to use the Hub pharmacy's services. The suggested variances are:

- The receiving pharmacy should request a variance to **MN Rule 6800.7950** to extend pharmacy services to the off-site Hub Pharmacy.
- The Hub Pharmacy should request a variance to **MN Rule 6800.7520** for consideration of the off-site coverage.

Both the sites' pharmacists-in-charge must present policies and procedures per these guidelines and MN Rule 6800.4075, and must meet both Minnesota and federal regulations. The hospital pharmacist-in-charge of the receiving pharmacy is responsible for the after regular hours pharmacy services according to MN Rule 6800.7400 Span of Control.

RECOMMENDATIONS

1. Policies and procedures should be presented to and approved by the Pharmacy & Therapeutics Committees of all facilities. Submit documentation of the approval to the Board of Pharmacy along with the variance request.
2. There should be documentation of Risk Management and/or legal approval at all sites.
3. All facilities must address HIPAA requirements.
4. The provided after-hours service cannot be used to reduce the present hours or staff of the pharmacy that is being serviced, or to prevent needed expansion of hours. Provide the current level of staffing of the receiving pharmacy, including pharmacist full time equivalents, with the variance request. Include the anticipated or estimated number of prescriptions that will be serviced by the Hub Pharmacy.
5. The Hub pharmacy should have reasonable and appropriate pharmacist staffing to not adversely affect patient care at the Hub and/or receiving pharmacy. A system should be in place within the Hub facility to track workload units to determine adequate, safe staffing. Provide the current level of staffing and coverage provided to remote sites from the Hub pharmacy, with the variance request. Include the anticipated or estimated number of prescriptions that will be serviced for the Receiving Pharmacy.
6. There must be adequate initial training of the Hub pharmacists at the receiving pharmacy to demonstrate competency and qualifications for the Hub pharmacy services. There must also be ongoing training and communication of changes in policies, procedures or medication-use systems occurring within the receiving pharmacy that impact the Hub Pharmacists' actions.
7. The Hub pharmacist must receive a copy of the prescriber's original patient medication order via facsimile or electronic transmission.

8. The Hub pharmacist must be able to review the inpatient and/or ambulatory patient's electronic or hard copy current profile and/or Medication Administration Record (MAR) for:
 - a. Medication history
 - b. Diagnosis
 - c. Allergies
 - d. Height, weight, age, sex
 - e. Duplications of drug therapies
 - f. Potential drug interactions
 - g. Adverse drug reactions (ADR's)
 - h. Pertinent lab data or
 - i. Any other needed information
9. The Hub pharmacists should either verify that they entered the medication order themselves or that they have reviewed and approved the order entered by other staff before the medication order is released and available for staff to administer to the patient, unless an emergent need requires the override function. This must be documented either electronically or by initials of the Hub pharmacist and these records must be kept for two years
10. The electronic patient profile or MAR should be interfaced with an automated distribution machine to limit the staff's removal to medication orders reviewed by a pharmacist.
11. The Hub pharmacist should have the ability to contact the prescriber to discuss any concerns identified during the pharmacist's review of the patient's information.
12. The Hub pharmacy must have adequate references to answer questions in a timely manner including, but not limited to:
 - a. The receiving pharmacy's Policy and Procedure Manuals
 - i. Standard drip concentrations or drug protocols
 - ii. High risk policies
 - b. The pharmacy's formulary information
 - c. Clinical reference materials including those required by the Board of Pharmacy
 - d. A 24-hour contact number at the receiving facility
13. The receiving pharmacy must provide their nursing supervisor with a telephone number to contact the Hub pharmacy when needed. The Hub pharmacy should provide pharmacy service at all non-regular pharmacy hours to ensure the site has continuous 24 hour pharmacist service.
14. Policies and Procedure should address a standard time requirement for release of stat and routine medications.
15. Policies should address an ongoing Quality Assurance/Continuing Quality Improvement/Failure Mode Effects Analysis (FMEA) on all aspects of the after-hours pharmacy service including, but not limited to:
 - a. Evaluation of the standards and policies on a regular basis
 - b. Equipment, computers, etc.
 - c. Identity of high-risk medications and/or high-risk patients

- d. Over-ride medications limited to medications needed for emergent use prior to a pharmacist's review of the order.
 - e. Competency Assessment/Education needs
16. The receiving site's pharmacist should develop a continuous quality improvement program to monitor and evaluate the quality and appropriateness of the offsite pharmacist's actions and document any follow-up actions or resolved problems.
- 17.. The receiving pharmacy should have an independent check policy for high-risk drugs or high-risk patients, for example; a pediatric dose has an independent dose calculation check, which is verified, by the Hub pharmacist and the nurse before giving the medication.
18. There should be a system/policy in place for non-pharmacy personnel (nurse or nurse supervisor) to enter the closed receiving pharmacy after hours. The ideal example would be with the use of an audio/visual camera for the Hub pharmacist to:
- a. identify and verify the medication a patient may use from home,
 - b. verify and certify the compounding of a non-sterile product,
 - c. verify and certify the compounding of a sterile product, and
 - d. verify and certify the removal of a medication from the off-site pharmacy by a nurse or nursing supervisor.
19. A Hub pharmacy service located out of state must be licensed as a pharmacy in the state of Minnesota.
- a. The Hub staff pharmacists located out of state must be licensed as a pharmacist in the state of Minnesota and follow the more stringent state law.
20. The Hub pharmacists should have at least 3 years of direct hospital pharmacy experience.