

Minnesota Board of Pharmacy

Guidance Concerning Approval of Telepharmacies

Minnesota Rules 6800.2150 requires a licensed pharmacist to be on duty in a licensed Minnesota pharmacy at all times when it is open for business. In addition, technicians are required to be under the direct supervision of a pharmacist per Minn. R. 6800.3850, Subp. 5. A pharmacist must perform the final certification of the prescription and provide counseling to the patient per Minn. R. 6800.3100 and Minn. R. 6800.0910. An individual or business that wants to operate a telepharmacy must submit variance requests to applicable rules. Some common variance requests are to the following Rules: 1. 6800.3850 for technician supervision whereby both sites (central and remote) should request, 2. 6800.2150 for pharmacist on duty whereby the remote site should request, 3. 6800.2400 for Pharmacist-In-Charge at two places, if applicable, whereby both affected sites should request.

Minn. R. 6800.9900 governs the manner in which the Board handles variance requests. The Board cannot grant a variance request unless: the variance will not adversely affect the health, safety or well-being of the public; the alternative measures proposed by the requestor are equivalent or superior to those found in the rule; and compliance to the rule in question would cause an undue hardship to the requestor.

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 telepharmacies. 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 telepharmacies 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 telepharmacies 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 telepharmacy requests. However, individuals or businesses requesting a telepharmacy variance are **not** required to submit proposals that incorporate these provisions.

1. The Board has considered the proximity of traditional, “bricks-and-mortar” pharmacies when considering telepharmacy variance requests. In doing so, the

Board has relied on the federal definition of medically underserved communities. The Board has *generally* not approved a telepharmacy variance unless the proposed remote site was located in a medically underserved community. However, the Board has approved telepharmacy variance requests even when the remote site has been located in closer proximity to a traditional pharmacy than would be allowed by these federal standards. "Community" is defined as:

- a) The census tract in which the remote site is located, if the remote site is located in a Metropolitan Statistical Area (MSA) as defined in the United States Census Bureau in the most recent Census; or
 - b) That area within 30 minutes travel time of the remote site, if the remote site is not located in a MSA. This generally corresponds to a distance of twenty (20) miles (official mileage as reported by the Minnesota Department of Transportation) from the remote site. This travel time/distance requirement is consistent with federal standards for medically underserved areas.
2. The remote site has been considered an extension of the central pharmacy. This applies even though the remote site must also be licensed as pharmacies.
 3. The Board has required a continual, two-way audiovisual link between the central pharmacy and each remote site. While the Board has not required pharmacies to use a particular type or brand of camera, the Board has required the camera used for the certification of prescriptions to be of sufficient quality and resolution so that the certifying pharmacist can visually identify the markings on tablets and capsules. Unless the camera used to certify prescriptions could also be used to monitor activities in other parts of the remote site, the Board has required a second camera to be used. A security camera trained on the entire dispensing area is an example of a second camera that the Board has found acceptable.
 4. The Board has established the condition on previous telepharmacy requests that all pharmacists performing services in support of the remote sites, whether those services are performed at the central pharmacy, the remote sites or elsewhere, must be licensed as a pharmacist by the Minnesota Board of Pharmacy. The Board has required that a copy of their licenses be posted in any remote site to which they provide any services.
 5. The Board has *recommended* (but not required) that a pharmacist working at the central pharmacy not certify more than an *average* of 8 prescriptions per hour, assuming that all prescriptions are for patients of the remote site(s). If some of the prescriptions are for patients of the remote site(s) and some are for patients of the central pharmacy, the pharmacist may certify additional prescriptions.
 6. The Board has approved previous telepharmacy variance requests on condition that each remote site display a sign, easily viewable by customers, that states:
 - This store is a telepharmacy supervised by a pharmacist located in (insert city);
 - The pharmacist is required to talk to you, over an audiovisual link, each time you pick a prescription up.

7. The Board has approved previous telepharmacy variance requests on condition that a pharmacist verifies daily that the computer and two-way audiovisual links are functioning between the central site and remote site. If the links are not functioning properly the remote site must be closed unless a pharmacist is at the remote site.
8. The Board has approved previous telepharmacy variance requests on condition that all remote sites are staffed with Minnesota registered pharmacy technicians. The Board has further required that pharmacy technicians working at a remote site have a minimum of one year (2080 hours) of experience as a registered technician and be certified through one of the certification programs recognized by the Board.
9. The provisions of Minnesota Statutes 151.102 and Minnesota Rules 6800.3850, subp. 6 apply to telepharmacies. Consequently, each pharmacist may supervise three technicians who are either working at or supervised from the central pharmacy. Given that all technicians must be certified, one additional technician may be working at or supervised from the central pharmacy. Examples - if one pharmacist is on duty at the central pharmacy, he/she may supervise no more than a total of four technicians. If two pharmacist are on duty at the central pharmacy, they may jointly supervise nor more than seven technicians. The total number of allowed technicians may be divided between the central and remote sites in any manner, provided that each remote site has a least one technician on duty when it is open. A telepharmacy variance request may ask for the Board to approve a different ratio.
10. Since a remote site is a licensed pharmacy, there must be restricted access at the remote site so that only those employees directly involved in processing prescriptions are permitted in the dispensing area.
11. In accordance with Minnesota Rules, non-pharmacist staff at the remote site(s) is not allowed to accept verbal orders for new prescriptions. Verbal orders may only be taken by a licensed pharmacist working at the central pharmacy. The Board has approved previous telepharmacy variance requests on condition that data entry of verbal orders takes place at the central pharmacy and the data entry is checked by the pharmacist before the prescription is filled at the remote site. The Board has further required that written orders for new prescriptions be entered at the central pharmacy unless the remote site uses pharmacy software that requires a pharmacist to review and act on all DUR/override alerts.
12. The Board has approved previous telepharmacy variance requests on condition that the remote site not be open when the central pharmacy is closed. In accordance with Minnesota Rules, with the exception of a licensed pharmacist serving as the pharmacist-in-charge, no employees are allowed access to the remote site when the central pharmacy is closed. The Board has approved previous telepharmacy variance requests on condition that each remote distribution site have a security system in place that requires any pharmacist entering the facility after hours to enter in a code unique to the pharmacist. The security system must allow for tracking of all entries into the pharmacy. The

pharmacist-in-charge must review the log of entries when conducting weekly inspections.

13. The Board has approved previous telepharmacy variance requests on condition that all prescriptions be profiled, reviewed, and interpreted *by a pharmacist*, using appropriate professional judgment, at the central pharmacy before dispensing and distribution can take place. In accordance with Minnesota Rules, all prescriptions must be certified by a pharmacist before they can be dispensed to the patient. The Board has approved previous telepharmacy variance requests on condition that the certification process be done using a real-time, two-way audiovisual link. (e.g. - a technician can't take a photograph of the finished product and fax it to the central pharmacy). All remotely distributed medications must have a label, properly prepared in accordance with Minnesota Rules 6800.3400, attached to the final drug containers before the pharmacist certifies the dispensing process. All certification must be documented.
14. Dispensing is considered to be done by the pharmacist, at the central pharmacy.
15. The Board has approved previous telepharmacy variance requests on condition that, when the patient receives their medications, the pharmacist must, through private audiovisual communication, counsel the patient concerning the medications being dispensed. An offer of counseling made by anyone other than the pharmacist is not sufficient to meet this requirement. The remote site must maintain a log, signed by the patient, which documents a patient's refusal of counseling.
16. The Board has approved previous telepharmacy variance requests on condition that a toll-free telephone number that patients can use to contact the central pharmacy be printed on the label of each prescription container. The toll-free number should also be made available to any prescriber attempting to phone a prescription order into a remote site. (Since the prescriber will have to phone new orders in to the central pharmacy).
17. Policies and procedures must be submitted to the Board of Pharmacy for consideration. The Board has approved previous telepharmacy variance requests on condition that the policies and procedures include a plan to conduct Failure Mode and Effect Analysis (FMEA)¹ and include policies, specific to each remote and central site that details all of the functions that technicians will perform. If approved, these policies and procedures must be available at both the central pharmacy and the remote sites. All staff must be fully trained and show adequate knowledge of the policies and procedures governing the remote distribution. This training must be documented with periodic follow-ups at least annually or more often as necessary.

The policies and procedures must be signed by all technicians and pharmacists, to indicate that they have reviewed and understand them. These policies and procedures must be updated as necessary and the updates must be submitted to the Board for consideration. No revisions or updates of policies and procedures shall be implemented without prior approval of the Board.

18. The Board has approved previous telepharmacy variance requests on condition that quality assurance be conducted in accordance with Minnesota Rules 6800.3950, subpart 4. The Board has required that a quality assurance check of controlled substance prescriptions, to verify both the accuracy and legitimacy of the original prescriptions, be conducted by the pharmacist-in-charge at the remote site, during the weekly inspection visits.
19. The Board has approved previous telepharmacy variance requests on condition that, if the remote site uses an automated pre-packaged distribution system, then the stocking and loading of this system must either be checked by a pharmacist, prior to use, or employ a fail-safe bar-coding system or its equivalent. Policies and procedures regarding the operation of the distribution system must be submitted to the Board for consideration. If approved, these policies and procedures must be available at both the main pharmacy and the remote distribution site.
20. The Board has approved previous telepharmacy variance requests on condition that a pharmacist conduct an on-site inspection at the remote distribution site at weekly intervals or more often as deemed necessary by the pharmacist-in-charge. Inspections must be documented and copies must be kept on file at the remote site, and be available for Board review, for a period of not less than three years.
21. The remote distribution site should be checked for at least the following: drug and record security; storage requirements for drugs; inventory; outdated drugs; integrity of the video-link; patient privacy; policy and procedures.
22. There should be an on-going review of incident reports and outcomes, with appropriate corrective action taken when necessary.
23. The Board has approved previous telepharmacy variance requests on condition that there be a process in place to review, analyze and reconcile the records and controls that exists between the remote distribution site(s) and the pharmacy.
24. The Board has approved previous telepharmacy variance requests on condition that the pharmacist-in-charge conduct a monthly perpetual inventory on all controlled substances. CII controlled substances shall only be ordered by a pharmacist, who shall also maintain the required records.

¹ Failure Mode and Effect Analysis (FMEA) – Error analysis may involve retrospective investigations (as in Root Cause Analysis) or prospective attempts to predict "error modes." Different frameworks exist for predicting possible errors. One commonly used approach is failure mode and effect analysis (FMEA), in which the likelihood of a particular process failure is combined with an estimate of the relative impact of that error to produce a "criticality index." By combining the probability of failure with the consequences of failure, this index allows for the prioritization of specific processes as quality improvement targets. For instance, an FMEA analysis of the medication dispensing process on a general hospital ward might break down all steps from receipt of orders in the central pharmacy to filling automated dispensing machines by pharmacy

technicians. Each step in this process would be assigned a probability of failure and an impact score, so that all steps could be ranked according to the product of these two numbers. Steps ranked at the top (i.e., those with the highest "criticality indices") would be prioritized for error proofing. (From the Agency for HealthCare Research and Quality).