

Variance Renewals - Instructions for Renewal Requests

Renewal requests require inclusion of a complete copy of any previously approved policies and procedures with proposed changes highlighted for board's consideration.

Denied/Deferred Variance Requests

Use a New Variance Request form if you are requesting a variance for the first time or resubmitting a new variance that was previously denied or deferred. **Do not use this form.**

Use this form if you are requesting to renew an existing variance or your previous renewal request for an existing variance was denied or deferred and you are resubmitting the request. **Renewal variance requests need to be submitted in their entirety.**

Variance Request and Policy Review Committee Meeting Dates

All meetings begin at 9:00 am, please see the Board's website for current dates and submission deadlines.

Variance and appointment requests will only be accepted until **12:00 PM** on the submission deadline. If the variance request form is incomplete and/or if the form and supporting documents are not submitted by the submission deadline date and time, the submission will not be considered a valid variance request and will be either postponed to the next meeting or returned to the requestor. Plan your submissions accordingly to avoid any delays.

A Board meeting will usually occur two weeks after the variance committee meets. You will receive a letter after the Board meeting to notify you of the Board's decision.

Appointments

If you would like to be present for the Variance and Policy review meeting to discuss your submission, you must request an appointment on the variance request form. Appointment times are 30 minutes and must be requested at the time of the variance submittal.

Due to the large number of variance requests, meeting appointments are 30 minutes and will be granted to new variances first and then to renewed variances that are proposing significant changes in the policy and procedures. Appointment times will not be assigned until all required documents are received.

If you wish to request an appointment, complete the appointment section on the form. Staff will reach out to you if an appointment is available.

All documents should be sent via email **in a PDF format** or mailed to the Board. If the request is sent to any other board or email address, the request may not be included on the agenda for the Variance and Policy Review Committee meeting in question.

The Pharmacist-In-Charge (PIC) that is requesting the variance must be the signer of the request form for the request to be considered valid. If anyone else signs the form for a pharmacy, the request will not be considered valid.

Contact the Board Surveyors at 651.201.2839 with questions.

Note: If this form is incomplete and/or documents required for review of the variance are not submitted by the cutoff date, the Board will not consider this to be a valid request and may return the document to the requester.

Minnesota Board of Pharmacy

335 Randolph Ave, Suite 230 | Saint Paul, MN 55102

Fax: (651) 215-0951 | E-mail: pharmacy.board@state.mn.us

Review the rule below for an explanation on considerations that the Board must follow regarding variance requests.

BOARD OF PHARMACY RULE 6800.9900 VARIANCES

Subpart 1. **Right to request variance.** The pharmacist-In-Charge of a pharmacy requesting a variance, or in the case of manufacturers, wholesalers or gas distributors, a person responsible for the operation, may request that the board grant a variance from any rule of the Board of Pharmacy.

Subp. 2. **Submission and contents of request.** A request for a variance must be submitted to the board in writing. Each request must contain the following information:

- A. the specific rule for which the variance is requested;
- B. the reason for the request;
- C. the alternative measures that will be taken if a variance is granted;
- D. the length of time for which a variance is requested; and
- E. any other relevant information necessary to properly evaluate the request for the variance.

Subp. 3. **Decision on variance.** The board shall grant a variance if it determines that:

- A. the variance will not adversely affect directly or indirectly, the health, safety, or well-being of the public;
- B. 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
- C. 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 item A, B, or C has not been met.

Subp. 4. **Notification.** The board shall notify the applicant in writing within 60 days of the board's decision. If a variance is granted, the notification shall specify the period of time for which the variance will be effective and the alternative measures or conditions, if any, to be met by the applicant.

Subp. 5. **Renewal.** Any request for the renewal of a variance shall be submitted in writing prior to the expiration date of the existing waiver. Renewal requests shall contain the information specified in subpart 2. A variance shall be renewed by the board if the applicant continues to satisfy the criteria contained in subpart 3 and demonstrates compliance with the alternative measures or conditions imposed at the time the original variance was granted.

Subp. 5a. **Successor Pharmacist-In-Charge duties for active variances.** After termination of the services of a Pharmacist-In-Charge, the successor Pharmacist-In-Charge shall submit, on the approved form, an acknowledgment of an awareness and understanding of any active variances that the pharmacy has been granted according to this part. The successor Pharmacist-In-Charge shall be responsible for ensuring that any conditions imposed by the board on any active variances continue to be met. Existing active variances shall remain in effect until the successor Pharmacist-In-Charge successfully submits the forms required in this subpart, for 90 days from the naming of a successor Pharmacist-In-Charge, or until the expiration date of the existing variance, whichever is sooner.

Subp. 6. **Research projects.** Pharmacists desiring to participate in research or studies not presently allowed by or addressed by rules of the board may apply for approval of the projects through waivers or variances in accordance with subparts 1 to 4.

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Variance Request Form – Renewal

Variance number that you are requesting to renew (only one renewal per form) _____

I request an appointment

An appointment is not necessary for this request

Due to the large number of variance requests, meeting appointments are 30 minutes and will be granted to new variances first and then to renewed variances that are proposing significant changes in the policy and procedures.

Contact Information

This is the authorized individual that can answer questions on the variance request.

First, Last Name

Phone Number

Email Address

Person subject to the rules of the Board of Pharmacy requesting this variance

Pharmacist-In-Charge Name _____ License # _____

List the specific rule for which the variance is requested (MN Rules start with 6800) _____

Site affected

Site Name _____

License # _____

Address _____

City, State, Zip _____

Provide a brief summary of your request explaining what you are proposing, including new any modifications.

Explain how the request will not adversely affect the health, safety, or well-being of the public.

Explain any additions or modifications you are proposing to the existing variance.

Describe the methodology and standards for monitoring the outcomes if variance is approved with changes and explain how you will conduct ongoing monitoring to ensure that there are no adverse effects.

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