

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 of variance.** 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.

Statutory Authority: *MS s 151.06; 152.02*

History: *10 SR 2007; 18 SR 1145; 31 SR 1673; 36 SR 237*

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