

247 CMR: BOARD OF REGISTRATION IN PHARMACY

247 CMR 14.00: PETITION FOR WAIVER

Section

14.01: Petition to the Board to Grant a Waiver to the Provisions of 247 CMR for Licensure of a Pharmacy/Pharmacy Department

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(1) The Board may grant a waiver to the provisions of 247 CMR, pertaining to the licensure of a pharmacy or pharmacy department, if the Board finds:

- (a) that there is a compelling public interest which would be served by the granting of such a waiver;
- (b) that adherence to a particular provision of 247 CMR would be impractical and unduly burdensome; and
- (c) that sufficient safeguards are in place to protect the public health, welfare and safety.

(2) Unless otherwise prohibited by law, when the Board finds that a provision of 247 CMR, may be waived, it may issue a special or limited-use pharmacy or pharmacy department permit. Such permit shall be issued when the scope, degree or type of pharmacy practice is of a special, limited or unusual nature as compared to a regular pharmacy service. In order to request a waiver of a Board regulation, the registered pharmacist who shall be responsible for the management and operation of a pharmacy or pharmacy department shall submit to the Board a Petition for Waiver of Board Regulations, upon a form supplied by the Board. A completed petition shall:

- (a) list the regulatory requirement(s) for which a waiver is requested and a brief explanation as to why each regulation should not apply to that pharmacy or pharmacy department;
- (b) explain why there is a compelling public interest which would be served by granting the waiver;
- (c) explain why adherence to the regulation(s) would be impractical and unduly burdensome to the petitioner;
- (d) include a comprehensive statement of the policies and procedures of the proposed operation, including safeguards to protect the public health, welfare and safety; and
- (e) be accompanied by any additional information as determined by the Board.

(3) Before acting upon any petition, the Board may require the applicant to personally appear before the Board to answer questions that would enable the Board to determine that the issuance of a permit would be in the best interest of the public health, welfare and safety and adherence to 247 CMR would be unreasonable.

(4) Upon the granting of a waiver and issuance of a special or limited-use permit, the Board shall issue a written finding that recites the specific Board regulation(s) which are being waived, the reasons the Board is waiving the regulation(s) at issue, and lists any contingent restrictions under which the pharmacy or pharmacy department may operate.

REGULATORY AUTHORITY

247 CMR 14.00: M.G.L. c. 112, §§ 36A through 42A.