

247 CMR: BOARD OF REGISTRATION IN PHARMACY

247 CMR 14.00: PETITION FOR WAIVER

Section

14.01: Petition for Waiver

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- (1) Unless otherwise prohibited by law, the Board may waive compliance with one or more regulatory requirements set in 247 CMR, if the Board finds:
 - (a) that there is a compelling public interest which would be served by granting the waiver;
 - (b) that the petitioner's adherence to the waived regulatory requirement(s) would be impractical and unduly burdensome; and
 - (c) that there are sufficient safeguards to protect the public health, welfare and safety without the petitioner's compliance with the waive regulatory requirements.
- (2) A petition for waiver of a regulatory requirement set in 247 CMR must be submitted on a form supplied by the Board and must be completed and signed by:
 - (a) the proposed manager of record on behalf of an applicant for a pharmacy license; or
 - (b) the current manager of record on behalf of licensed pharmacy
- (3) 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.
- (4) Before acting upon any petition, the Board may require the applicant to personally appear before it to answer questions that would enable the Board to determine that the waiver meets the criteria in 247 CMR 14.01(1).
- (5) Expiration.
 - (a) All waivers granted by the Board on or before June 30, 2013 shall expire on June 30, 2018.
 - (b) All waivers granted by the Board after June 30, 2013, shall expire on the fifth anniversary of the date that it was granted.
 - (c) A pharmacy may submit a subsequent petition for waiver in anticipation of, or following, the expiration of a previously granted waiver. The subsequent petition for waiver must comply with, and meet the criteria in, 247 CMR 14.01(1) through (4).
 - (d) A pharmacy must comply with all regulatory requirements in 247 CMR after the expiration of the waiver, unless the Board has granted a subsequent waiver.

REGULATORY AUTHORITY

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