



Guidance on Applying for Compliance Delays During Construction In Pharmacies that Compound

Title 16 of the California Code of Regulations (CCR) section 1735.6 (f) states where compliance with California's compounding regulations requires physical construction or alteration to a facility or physical environment, the board may grant a waiver of such compliance for a period of time to permit the required physical changes. See also related provisions in CCR section 1751.4.

Application for any waiver must be made in writing, identify the provisions requiring physical construction or alteration, and provide a timeline for any such changes. The board may grant the waiver for a specified period when, in its discretion, good cause is demonstrated for such waiver.

For hospitals, please see *Guidance on Applying for Compliance Delays During Construction in Hospital Pharmacies that Compound*, to request an exemption.

Please submit your request via email to: Compounding.waivers@dca.ca.gov

Or mail to: Compounding Construction Waiver Request
 CA State Board of Pharmacy
 1625 N Market Boulevard, Suite N-219
 Sacramento, CA 95834

Please retain a copy of your submitted request and make available for review at the licensed location.

Below is an example of the requested information in a format that you may submit to the board to request a waiver. It is in a fillable PDF format that you can complete online, printout, have signed and then return to the board along with any attachments. This document and form are available at www.pharmacy.ca.gov.

Pharmacy Name:

License Number: PHY/PHE

Please provide sterile compounding licenses associated with the above license: LSC/LSE

Name of the Individual Submitting this Request:

Title:

Email:

Phone Number:

The provisions of the regulation for which a compliance delay for construction is needed:

(Note: CA Code of Regulations section 1735.6(f) requires the identification of code sections requiring physical construction, alteration or improvement that are the reason for the waiver request)

1735.6, list subsections

1751.4 list subsections

Please list if other sections

A description of the physical changes that must be made for compliance *(Attach additional page if necessary):*

Please provide the timeframe for construction to completion:

Have building plans been developed? Yes _____ No _____

Has a building permit been secured? If yes, please provide number:

Please provide a written description of how the pharmacy will perform compounding while the compliance delay is in effect.

Reviewed by:

Pharmacy Pharmacist-in-Charge _____

Please Print

Signature: _____ Date: _____

Please do not send architectural drawings or structural plans as they will not be reviewed.