



Guidance on Applying for Compliance Delays During Construction In Hospital 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 non-hospitals, please see [Guidance on Applying for Compliance Delays During Construction in 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 form is available at www.pharmacy.ca.gov.

Hospital Pharmacy Name:

License Number: HSP/HPE

Provide all sterile compounding license numbers associated with the above license that require modification as part of this request:

LSC LSC LSC LSC LSC LSC

Name of the Individual Submitting this Request:

Title:

Email:

Phone Number:

OSHPD Project Number for this modification (if applicable):

OSHPD Facility Identification (if applicable):

OSHPD Hospital Building Number (if applicable):

Please attach a copy of the Project Completion Timeline, including a specific timeline for construction for EACH compounding pharmacy location that needs modification and is included under this Project 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

Please provide the timeframe for construction to completion:

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

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. Identify how compounding will take place after 1/1/17 until construction starts, during construction, and the transition into the newly remodeled location. (Please note if a new or temporary location is needed, a new permit may be required with the Board of Pharmacy and notification may be required to the California Department of Public Health. Additionally inspections are likely to be required before the use of any sterile compounding location begins operation. Please plan and communicate accordingly.)

Reviewed by:

Hospital Chief Executive Officer, Hospital Chief Operating Officer or Executive Director:

Please Print Name and Title

Signature: _____ Date: _____

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