

ARTICLE 4.5 NONSTERILE COMPOUNDING: SUPPLEMENTAL STAFF RECOMMENDED RESPONSES TO COMMENTS RECEIVED DURING THE 45-DAY COMMENT PERIOD AND REGULATION HEARING

Section	Commenter	Comment	Response
1735.1(f)(1)(B)	A VanOstrand (Hims and Hers) Walgreens Marci Bencomo (Pacific Compounding) Marie Cottman (Pacific Compounding) National Community Pharmacists Association (NCPA) Scott Brunner (Alliance for Pharmacy Compounding) Rheta Silvas (Kaweah Health)	Several commenters expressed concern with the proposed language cited requiring the prescribing practitioner, the compounding pharmacist and the dispensing pharmacist to determine that the compounded preparation produces a clinically significant difference in the patient. The different commenters offered varying proposed text to address their respective comments.	Board staff have reviewed the comments and considered feedback from members. Staff are recommending changes to the proposed text to remove the requirement that could have potentially required two pharmacists to make independent determinations.
1735.3(a)	John Gray (Kaiser Permanente) NCPA Marie Cottman (Pacific Compounding) Rheta Silvas (Kaweah Health) Melanie Horn (Sutter Health)	Several commenters expressed concern with the proposed language related to “potentially contaminated conditions.” The different commenters offered varying proposed text to address their respective comments.	Board staff have reviewed the comments related to this issue and are recommending changes to the proposed text to address the comments and some of the confusion that appears to be stemming from the provisions of Chapter 795 requirements and the Board’s proposed regulation text.
1735.8	Marie Cottman (Pacific Compounding)	Comment received suggesting changes to the language to reword the text.	Board staff have reviewed the comment and are recommending changes to the proposed text.
1735.12 (b)	Lauren Honda (Valor Compounding) Melanie Horn (Sutter Health) Wendy Waldman (Torrance Memorial Center) Marie Cottman (Pacific Compounding) CSHP NCPA Scott Brunner (Alliance for Pharmacy Compounding) Rita Shane (Cedars-Sinai)	Several commenters requested a change in the proposed text related to the timeframe to submit a notification to the Board in writing of the facility’s receipt of a potential quality problem. The different commenters offered varying proposed text to address their respective comments.	Board staff have reviewed the comments related to this issue and are recommending changes to the proposed text to address the comments to extend the time frame to make such a report to the Board to 96 hours.

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	Tommy Mai (Huntington Health) Keck Medicine of USC		
1735.12 (c)	Rita Shane (Cedars-Sinai) Tommy Mai (Huntington Health) Wendy Waldman (Torrance Memorial Care) CSHP	Several commenters requested a change in the proposed text related to the timeframe within which the PIC must review a complaint received.	Board staff have reviewed the comments related to this issue and are recommending changes to the proposed text to address the comments to extend the time frame within which the PIC must review a complaint received by the facility.
1735.14(b)	K. Scott Guess John Gray (Kaiser) Maria Cottman (Pacific Compounding)	Comments were received regarding the requirements to maintain records. Proposed changes varied among the comments received.	Board staff have reviewed the comments related to this issue and are recommending changes to the proposed text to clarify the requirement.