

ARTICLE 4.6 STERILE COMPOUNDING: SUPPLEMENTAL STAFF RECOMMENDED RESPONSES TO COMMENTS RECEIVED DURING THE 45-DAY COMMENT PERIOD AND REGULATION HEARING

Section	Commenter	Comment	Response
1736.1(e)(1)(A)	Melanie Horn (Sutter Health) Wendy Waldman (Torrance Memorial Medical Center) Rita Shane (Cedars-Sinai) Tommy Mai (Huntington Health) CSHP UCSF	Several commenters expressed concern about the proposed language related to the ability of the provisions for compounding “essentially a copy” and the impact on hospital patients. Proposed solutions varied.	Board staff have reviewed the comments and considered comments from members related to this issue and are recommending changes to the proposed text to address the comments by establishing additional authority for a healthcare facility, licensed pursuant to HSC 1250, to compound essentially a copy of a commercially available product under specified conditions.
1736.1(e)(1)(B)	Melanie Horn (Sutter Health) Rheta Silvas (Kaweah Health)	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 requirements that could have potentially required two pharmacists to make independent determinations.
1736.2 (d)	Rita Shane (Cedars Sinai) Tommy Mai (Huntington Health) Rheta Silvas (Kaweah Health) Narinder Singh (Santa Clara Valley Healthcare) Melanie Horn (Sutter Health) Wendy Waldman (Torrance Memorial Medical Center) John Gray (Kaiser Permanente) NCPA Scott Brunner (Alliance for Pharmacy Compounding)	Several commenters expressed concern with proposed language surrounding the ability for an individual who has failed aspects of ongoing training to continue performing supervision and control of compounding personnel. The commenters offered different changes to the proposed text.	Board staff have reviewed the comments and considered feedback from members. Staff are recommending changes to the proposed text to extend the duration of time an individual can continue to provide such supervision and control.

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1736.6(a)	<p>John Gray (Kaiser Permanente)                  Maria Cottman (Pacific Compounding)                  NCPA                  Scott Brunner (Alliance for Pharmacy Compounding)                  Rita Shane (Cedars-Sinai)                  Tommy Mai (Huntington Health)                  CSHP                  Walgreens                  UCSF                  Narinder Singh (Santa Clara Valley Healthcare (SCVH))</p>	<p>Several commenters expressed concern about the proposed language related to air and surface sampling requirements. Differing solutions were offered by commenters.</p>	<p>Board staff have reviewed the comment and considered the feedback from members. Staff are recommending removal of the subdivision.</p>
1736.20	<p>John Gray (Kaiser Permanente)</p>	<p>Comments regarding documentation requirements for prior versions of documents.</p>	<p>Board staff have reviewed the comments related to this issue and are recommending changes to the proposed text to clarify the requirement.</p>