

TITLE 16: BOARD OF PHARMACY

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Dangerous Drug Distributors

Section Affected: Amend Title 16 California Code of Regulations (CCR) section 1780
Amend Title 16 CCR section 1781
Amend Title 16 CCR section 1782
Amend Title 16 CCR section 1783

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the position of the Board of Pharmacy (Board) regarding the amendment of the above section. The Initial Statement of Reasons (ISR) is updated as follows:

The 45-day public comment period began on May 29, 2020 and ended on July 13, 2020. The Board's notice indicated that the Board did not intend to hold a hearing on the matter, unless requested. No request for a hearing was received by the Board during the 45-day comment period.

During the 45-day comment period no comments were received. At its July 29-30, 2020 Board meeting, the Board adopted the regulation text as noticed on May 29, 2020.

The ISR incorrectly listed the page numbers for underlying data item 15 as "Pages 1 and 10 plus Attachment 6." The correct page numbers are "Pages 1 and 5 plus Attachment 6."

Local Mandate

A mandate is not imposed on local agencies or school districts.

Small Business Impact

While the Board does not have, nor does it maintain, data to define if any of its licensees (pharmacies) are a "small business" as defined in Government Code section 11342.610, the Board has made the determination that this proposal will not have a significant adverse impact directly affecting small businesses. The board believes that manufacturers, wholesalers and 3PLs are, by their nature, rather large businesses. Additionally, this proposal establishes that the regulatory requirements that apply to wholesalers also apply to 3PLs. Prior to 2014, these entities were considered and licensed as "wholesalers" in California and subject to the same rules; however, as

the result of the Federal Food, Drug, and Cosmetic Act, the board can no longer license these entities as wholesalers.

The updated reference standard is also not expected to have a cost impact. Despite the existing regulation's current reference, the board believes that dangerous drug distributors (manufacturers, wholesalers, and 3PLs) already apply the most recent standards established by USP.

Consideration of Alternatives

No reasonable alternative considered by the agency would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. The Board considered not amending the regulations to include this new licensing category. The board determined that this alternative was unacceptable because the board's regulations would not provide clear and consistent requirements to the regulated public.

Objections or Recommendations/Responses to Comments

During the 45-day public comment period from May 29, 2020 to July 13, 2020, the Board received zero comments.

At its July 29-30, 2020 meeting, the Board voted to adopt the regulation text as it was noticed on May 29, 2020.

Fiscal Impact Statement

The Board currently ensures compliance with Pharmacy Law and regulations through its inspection and enforcement programs. The Board indicates the proposed regulations are not anticipated to increase workload or costs to the state.