

California State Board of Pharmacy 2720 Gateway Oaks Drive, Ste 100

Sacramento, CA 95833

Phone: (916) 518-3100 Fax: (916) 574-8618

www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



To: Board Members

Subject: Agenda Item V. Discussion and Possible Action Related to Proposed Amendment to California Code of Regulations, Title 16, Section 1711 Related to Quality Assurance Programs and Review of Comments Received during the 15-Day Comment Period

Background:

At the February 7, 2023, Board meeting, the Board approved the proposed regulation text to amend Section 1711 related to Quality Assurance Programs. This proposal amends the board's regulations regarding quality assurance programs.

As required by the Administrative Procedure Act, Board staff released the proposed text for the 45-day comment period on August 9, 2024, which ended on September 23, 2024. Several comments were received during the comment period. The Board reviewed the comments at the November 2024 Board meeting and voted to amend the text in response to the comments received.

Board staff released revised text for a 15-day comment period on November 15, 2024, which ended on December 2, 2024. One comment was received during this comment period, which includes comments on existing legal requirements as well as items previously considered by the Board following the 45-day comment period.

Attached to this memo are:

- 1. The modified text that was released for the 15-day public comment period.
- 2. Board staff prepared summarized comments with recommendations.
- 3. Comments received during the 15-day comment period.

At this Meeting:

The Board will have the opportunity to discuss the regulation and determine what course of action it wishes to pursue. Among its options:

- 1. Adopt the regulation text as noticed on November 15, 2024.
- 2. Amend the regulation and notice the modified text for an additional 15-day comment period.

Possible Adoption Language:

Accept the Board staff's recommended comment responses, adopt the regulation text as noticed on November 15, 2024, and authorize the Executive Officer to take all steps necessary to complete the rulemaking. Further, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.