

# BOARD OF PHARMACY

## Final Statement of Reasons

Subject Matter of Proposed Regulations: Self Assessment Form

Sections Affected: Title 16, Section 1715

Hearing Date: None.

Updated Information The proposed regulation was modified by the board during its January 24, 2001 meeting. Those changes were subject to a 15-day notice. The board altered the instructions on page three of both forms to include a board request that any waiver permitting the off-site storage of records pursuant to Title 16, Section 1707 of the California Code of Regulations be attached to the self assessment form.

The board received no comments on the change proposed in the 15-day comment period.

### Summary of Comments Received During the 45-Day Comment Period (May 12, 2000 to June 26, 2000)

One comment was received during the comment period.

In a letter dated January 5, 2001, John Cronin representing the California Pharmacists Association (CPhA) offered general support for the board's proposal. Dr. Cronin stated that the CPhA would prefer that the renaming of the "Comments" sections on the self-assessment forms read "Comments or Action" rather than "Corrective Action or Action Plan" as proposed in the notice. He stated that "Corrective Action" could be interpreted to mean that the pharmacy's operations need correction. In light of possible access to this document by board inspectors or others, the CPhA made its request for a modification of the proposed language.

The board responded that the purpose of the "Corrective Action or Action Plan" section is to provide the pharmacy an opportunity to note how the pharmacy has or plans to come into compliance with the relevant requirement. Each requirement on the form is based on a requirement in either federal or California law and the pharmacist-in-charge is only required to use the field when the self-assessment indicates that the pharmacy is not in compliance with a requirement. The concern expressed that the field would be interpreted to indicate a violation of law by board inspectors and generate a disciplinary action against a pharmacy is misplaced. The existence of a comment on a self assessment form is not of sufficient particularity to substantiate disciplinary action. Furthermore, the board made it clear during public meetings that the self assessment form is an educational tool, not a means to ferret out violations of law for prosecution by the board. The regulation states, "The primary purpose of the self-assessment is to promote compliance through self-examination and education."

Local Mandate: None.

Business Impact: The board has determined that the proposed regulatory action would have no significant adverse impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states.

Consideration of Alternatives: The Board of Pharmacy determined that no alternative presented would be more effective than or as effective as and less burdensome on affected private persons than the proposal described.