

TITLE 16: BOARD OF PHARMACY

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Renewal Requirements

Section Affected: Amend Title 16 California Code of Regulations (CCR) section 1702
Amend Title 16 CCR section 1702.1
Repeal Title 16 CCR section 1702.2
Amend Title 16 CCR section 1702.5

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 February 7, 2020 and ended on March 23, 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 May 7, 2020 Board meeting, the Board adopted the regulation text as noticed on February 7, 2020.

A technical, non-substantive change was made to the Note of section 1702.5 to add additional statutes to the reference section to refer to different premises or facility licenses.

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 proposed regulation simplifies the regulatory language, thereby providing clarity and consistency to the regulated public with respect to the requirements and criteria used by the Board to deem an application of renewal complete. The proposal requires all premises or facility licensees to report discipline by another government agency at the time of the license renewal; however, this is done by marking an indicator on the application for renewal and will not impose an economic or fiscal impact on the licensee.

Fiscal Impact

The Board anticipates a minor and absorbable increase in workload for staff to process notifications of discipline as follows:

Workload Costs	
Office Technician (\$59 per hour - 24 hours per year)	\$1,416
Staff Services Analyst (\$66 per hour - 144 hours per year)	\$9,504
Total Costs:	\$10,920

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 the following alternatives:

1. The Board considered not amending the regulation. The Board determined that this alternative was unacceptable because it is necessary to provide clarity to the regulated public so that they may be aware of the requirements to renew their individual or premises/facility license. This alternative would also not reduce the burden on the Board in having to undertake a regular rulemaking action each time a license type is established. Additionally, the Board would not be notified of disciplinary action taken against licensees other than nonresident pharmacies and nonresident wholesalers. This would not meet the Board's statutory mandate of consumer protection.
2. The Board considered amending the regulation text to include a list of license types. This alternative was unacceptable because the regulation would require frequent amendments as the Board's regulatory authority increases and a large list within the body of the text would reduce clarity within the regulation.

Objections or Recommendations/Responses to Comments

During the 45-day public comment period from February 7, 2020 to March 23, 2020, the Board received zero comments.

At its May 7, 2020 meeting, the Board voted to adopt the regulation text as it was noticed on February 7, 2020.