

TITLE 16: BOARD OF PHARMACY
FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Renewal Requirements

Sections Affected: Amend section 1702 of Article 1 of Division 17 of Title 16 California Code of Regulations (CCR).

Add sections 1702.1, 1702.2, and 1702.5 of Article 1 of Division 17 of Title 16 California Code of Regulations (CCR).

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 adoption of the above sections, and is updated to include the following information. The Board's notice indicated that the Board did not intend to hold a hearing on the matter, unless requested.

The 45-day public comment period began on August 12, 2016 and ended on September 26, 2016. No request for a hearing was received by the Board during the 45-day comment period, and no hearing was held.

During the 45-day comment period, the Board received comments from two individuals. The Board considered these comments at its meeting held October 26, 2016. In response to the comments received, the Board voted to modify the text and initiate a 15-day public comment period.

The modified text was noticed for a 15-day comment period that began on October 27, 2016 and ended on November 11, 2016. During that time, no comments were received.

After having considered all comments in the record, the Board adopted the regulation, as noticed on October 27, 2016.

The Final Statement of Reasons contains a summary of all comments received during all public comment periods, as well as the Board's responses.

The regulation was modified from the original proposed text as follows:

The reference section was updated to appropriately identify all the proper references. This update included adding section 141, 4300, 4302, 4303, 4303.1, and 4316 as needed and removing 4301.5 where appropriate.

1702 – Pharmacist Renewal Requirements

Subdivision (b) was amended to remove "under \$500" from the regulation text in response to comments received. The Board determined that the dollar threshold was not necessary given that traffic infractions for alcohol, dangerous drugs, or a controlled substance must still be reported.

Additionally, this section was amended to ensure that the Board receives notification of disciplinary action taken against a licensee by another state at minimum of each renewal cycle. The disclosure of disciplinary action will provide the Board with more information in order to protect the public from incompetent, unethical and unprofessional practitioners.

1702. 1 – Pharmacy Technician Renewal Requirements and 1702. 2 – Designated Representative Renewal Requirements

Subdivision (a) was amended to change that effective date from July 1, 2014 to July 1, 2017. These regulation changes were originally approved by the Board in 2013. As they were not promulgated until 2016, it was necessary to update the effective date to a future date.

Subdivision (b) was amended to remove “under \$500” from the regulation text in response to comments received. The Board determined that the dollar threshold was not necessary given that traffic infractions for alcohol, dangerous drugs, or a controlled substance must still be reported.

Non-Substantive Changes

The phrase “or registrants” was added to 1702(a). Business and Professions Code section 4032 defines a license and includes “any license, permit, registration, certification, or exemption issued by the Board. Additionally, the term “licensee or registrant” is used together within other Board regulations and for Board purposes, the terms have similar meaning.

Section 1702(a)(1) was amended to change “electronic fingerprint system” to “electronic fingerprinting system” for clarity. This is the proper way to refer to the system, however, it does not change what the system is or does, as such, the Board determined this to be a non-substantive change.

Local Mandate

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

Small Business Impact

The Board has determined that the proposed regulations would not affect small businesses. This proposed regulation would only affect individuals for whom an electronic record of his or her fingerprints does not exist in the DOJ criminal offender record identification database and those licensees that do not comply with the proposed regulation.

There are approximately 1380 vendors statewide who provide fingerprinting services. There should be no initial or ongoing cost impact upon the vendors because they are already equipped to provide the service and the fingerprinting requirement will be staggered and extended over the licensees' renewal periods.

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Board would be more effective in carrying out the purpose for which it was proposed or 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.

Objections or Recommendations/Responses to Comments

45-Day Public Comment Period

During the 45-day public comment period from August 12, 2016 to September 26, 2016, the Board received two written comments. The comments were provided to the Board in the Meeting Materials for the October 26-27, 2016 Board meeting, and were reviewed and considered by the Board at that meeting.

Written Comments from Ray Vrabel

Comment #1: Mr. Vrabel requested that the \$500 limit be removed. He indicated that traffic infractions should not be reported unless they involve alcohol, dangerous drugs, or controlled substances. He explained that a red light infraction could be over \$500 and are not a crime so they should not be investigated. Additionally, Mr. Vrabel expressed concern about the unnecessary reporting and staff workload.

Response to Comment #1: The Board accepted Mr. Vrabel's comment. In response to the comment the Board modified the text in the three regulation sections to remove the reporting dollar figure of \$500.

Written Comments from Robert Stein, Pharm.D.

Comment #1: Dr. Stein requested that the language in (b) be modified to specify "traffic fine." He indicated that different court jurisdictions charge varying fees and taxed and could make a traffic violation total over \$500 when the actual fine was less.

Response to Comment #1: The Board appreciates Dr. Stein's comment. Based on the totality of the comments from Dr. Stein and Mr. Vrabel, the Board modified the text in the three regulation sections to remove the reporting dollar figure of \$500.

First Modified Text – Response to Comments

During the 15-day public comment period from October 27, 2016 to November 11, 2016, the Board received no comments.

At its December 14, 2016 meeting, the Board, after having considered all of the comments, voted to adopt the renewal requirements regulation text as it was noticed on October 27, 2016.