

**DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16: BOARD OF PHARMACY**

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Disciplinary Guidelines

Sections Affected: Title 16, California Code of Regulations (CCR) section 1760

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 23, 2024, and ended on April 12, 2024. The Board's notice stated that the Board did not intend to hold a hearing on the matter unless requested. The Board did not receive a request for a hearing during the comment period and one was not held.

During the 45-day comment period, the Board received no comments. At the April 24-25, 2024 Board meeting, the Board reviewed staff recommended amendments, accepted the recommendations, and voted to initiate a 15-day public comment period. The 15-day comment period commenced on April 29, 2024, and concluded on May 14, 2024.

During the 15-day comment period, the Board received no comments. On May 17, 2024, per the delegated authority granted to the Executive Officer (EO) at the April 24-25, 2024 Board meeting, the EO adopted the regulation as noticed for public comment on April 29, 2024.

The changes for the modified text comment period are as follows:

Term 23 - Pharmacists Recovery Program (PRP)

[...] Any of the following shall result in the automatic suspension of practice by respondent and shall be considered a violation of probation:

- Failure to contact, complete enrollment, and execute and return the treatment contract with the PRP, including any addendum(s), within ten (10) days of the effective date of the decision as directed by the PRP;
- Deemed unsafe to practice by an assessor in the PRP or medical evaluation.
- Failure to complete registration for any drug or alcohol testing mandated by the treatment contract and/or by the PRP, and begin compliance with the testing protocol(s), within ten (10) days of the effective date of the decision as directed by the PRP;
- Failure to comply with testing protocols regarding daily check-in and/or failure to complete a mandated test as directed by the PRP; [...]

The purpose of this addition is to add the provision for suspension of a license should the licensee be deemed unsafe to practice following a medical evaluation or by a PRP assessor. Currently, when a licensee is deemed unsafe to practice as part of PRP or via a medical evaluation, a cease practice notice is issued consistent with the terms of the PRP; however, the Board is unable to automatically suspend the license. The addition of this language is necessary to enable the Board to automatically suspend the license and reflect the suspension on the Board's website, which serves to better protect California consumers.

Term 24 – Drug and Alcohol Testing

“...failure to test as required; failure to refrain from alcohol; failure to timely supply documentation demonstrating that a detected substance was taken pursuant to a legitimate prescription issued as a necessary part of treatment; and/or detection through testing of alcohol, or drug that contains alcohol, without a prescription, or of an illicit drug, or of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment. In the event of a suspension ordered after detection through testing of alcohol, or drug that contains alcohol, without a prescription, an illicit drug, or of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment, the board or its designee shall inform Respondent of the suspension and inform him to immediately leave work, and shall notify Respondent's employer(s) and work site monitor(s) of the suspension...”

The purpose of this addition is to specify that a probationer does not violate a term of their probation if they test positive for alcohol, or a drug containing alcohol, when they have a valid prescription. This addition is necessary to further clarify that probationers, subject to drug and alcohol testing, must refrain from alcohol as a condition of probation and that detection of alcohol without a prescription is a violation of the term of probation. Currently, the disciplinary guidelines do not include the clarifying phrase “or drug that contains alcohol, without a prescription.” This specification is needed as there are some prescription medications that may contain alcohol, which could result in a positive test. Without this additional language, the licensee would be in violation of this term of their probation, even if the positive test is the result of a prescription medication.

Following adoption by the board, staff made non-substantive changes to the proposed text to ensure all statutes and regulations identified within the authority and reference are consistent and are appropriately referenced. Specifically, to break out the each reference section between 4300 and 4313 that applies instead of listing the range. Additionally, section 4314 is added as it provides authority for issuing an administrative fine. These edits were non-substantive as they did not have any regulatory effect.

Finally, the disciplinary guidelines were amended on page 1 of the guidelines to add “and/or dangerous devices” to the first sentence of the last paragraph. The phrase is existing text and was inadvertently deleted from the noticed guidelines. The first

paragraph on page 2 was amended to add “and the provisions contained in Sections 1771-1774” as the phrase is existing text and was inadvertently deleted from the noticed guidelines. The phrase “board licensees” was added to the first paragraph as the phrase is existing text and was inadvertently deleted from the noticed guidelines. The phrase “Petitioner shall take and pass the [North American Pharmacist Licensure” was added and stricken as the phrase is existing text and was inadvertently deleted instead of stricken from the noticed guidelines. Additionally, minor typographical and grammar edits were made. These edits were all non-substantive as they did not have any regulatory effect.

Incorporation by Reference

The existing regulation incorporates the Disciplinary Guidelines by reference. This rulemaking continues the incorporation by reference of the guidelines. Continued incorporation is appropriate because the 60-plus page guidelines are cumbersome and contain formatting that would not be publishable in the CCR.

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 determine if any of its licensees are “small businesses”, as defined in Government Code section 11342.610, the Board determined that the proposed regulatory action will not have a significant adverse economic impact on small businesses. Although the proposed regulation will directly affect businesses statewide that are licensed by the Board and placed on probation, which may include small businesses, the Board does not anticipate any adverse economic impact. Licensees on probation are required to comply with numerous terms and conditions of probation.

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, as effective and less burdensome to affected private persons than the adopted regulation, or more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Board considered not updating the disciplinary guidelines; however, the Board determined that was not acceptable given the requirements of the uniform and specific standards, and the knowledge that not updating and clarifying the regulations would be contrary to the Board’s public protection mandate, as the proposed changes assist the Board in better monitoring licensees on probation.

No comments were received during the 45-day or 15-day comment periods.

On May 17, 2024, per the delegated authority granted to the Executive Officer (EO) at the April 24-25, 2024 Board meeting, the EO adopted the regulation as noticed for public comment on April 29, 2024.