

**BOARD OF PHARMACY
ADDENDUM TO THE FINAL STATEMENT OF REASONS**

Subject Matter of Proposed Regulations: Disciplinary Guidelines

Section Affected: Amend Title 16 of the California Code of Regulations (CCR) Section 1760

Updated Information

On January 12, 2017, the Office of Administrative Law (OAL) disapproved the proposed regulations amending section 1760 of Title 16 of the California Code of Regulations and the disciplinary guidelines that are incorporated by reference. The board received the opinion from OAL on January 20, 2017 followed by an amended opinion on January 23, 2017.

In the proposed regulation text for 16 CCR Section 1760 and incorporated document, the following changes were made in response to OAL's Decision of Disapproval. Provided below is a summary of issues discussed in the OAL decision and the changes and actions taken by the board to remedy the identified issues. As part of the remedies, the board proposed additional changes to the regulation section and document incorporated by reference as well as released a supplemental Initial Statement of Reasons that were released for a 15-day comment period on March 15 – 29, 2017. No comments were received during this third 15-day comment period.

Clarity Concerns:

1. The disapproval noted that Term 2 requires a respondent to "report to the board quarterly, on a schedule and in a form or format, as directed by the board or its designee." Although the term continues on to state that "the report shall be made either in person or in writing as directed" OAL's disapproval states that the term "in a form or format" does not specify what form or format the request is now required to use.

The board amended the term and noticed the proposed change for a 15-day comment period. No comments were received in response to the comment period. A similar term included in the premises (Term 3) portion of the guidelines was similarly amended during the comment period.

2. The disapproval noted that Term 24, which establishes the Drug and Alcohol Testing requirement, does not meet the clarity standard because the board uses the term "geographic area" but does not define the term. The disapproval further notes that the board specifies the necessary information and documentation must be provided to an alternate testing vendor, but the board does not detail what this necessary information and documentation is.

The board amended the term and noticed the proposed change for a 15-day comment period. No comments were received in response to the comment period.

3. The disapproval noted that Term 30 (Relating to worksite monitor requirements) specifies a respondent "shall complete **any** required consent forms and sign **any** required agreement with the worksite monitor and/or the board to allow the board or its designee to communicate **freely on the subject of respondent's work performance and sobriety** with the work site monitor." OAL concluded that this language is inconsistent with the uniform standards which requires

respondent “shall complete **the** required consent forms and sign **an** agreement...” and notes that the board’s current language also restricts the content of the communication between the board and the worksite monitor.

The board amended the term and noticed the proposed change for a 15-day comment period.

Necessity Concerns:

The disapproval from OAL notes that the board failed to articulate the necessity for each of the changes being made in the guidelines.

The board released a supplement to the Initial Statement of Reasons for a 15-day comment period. No comments were received in response to the comment period.

APA Procedures Concern:

OAL noted that the board did not fully respond to one of the comments received in the 45-day comment period, failed to make documents relied upon available for inspection and failed to properly display text.

1. 45-Day comment: The board received, reviewed and considered all of the comments provided in response to the rulemaking.

One commenter stated: [T]o penalize the pharmacist for failure to “cause the practice supervisor to timely report to the board in writing” etc. is too vague. How do you fail to cause someone to do something?

Board Response: This requirement is in the current version of the guidelines and is not a new requirement. An example of the language in the current guidelines is included in Term 5, but many more are present.

2. Documents Relied Upon: The licensing and enforcement statistics referenced in the underlying data portion of the Initial Statement of Reasons is the same as the licensing and enforcement statistics referenced in the Table of Contents of the rulemaking package.
3. Improperly displayed text: As part of the proposed changes released for a 15-day comment period, nonsubstantive changes were made to reflect existing language that moved within the guidelines document as deleted in one section and added in another section. For example, Term 23 (Pharmacists Recovery Program) clearly reflects where existing language was moved from the ninth paragraph of the term to now the third paragraph of the term.

Additional Changes Made and Included in the 15-day comment Period

In addition to the changes made to address the concerns of the OAL disapproval, the board also updated the revision date both in the regulation language as well as the revision date contained in the incorporated document. The board made nonsubstantive changes to correct grammar and include reference to the Drug Supply Chain Security Act requirements in lieu of the now repealed electronic pedigree requirements.

Again, the board received no comments in response to this 15-day comment period.

The following nonsubstantive changes were made to the Disciplinary Guidelines (guidelines) which is the document incorporated by reference.

1. On page 34, Term 14: The phrase “respondent practices as a [insert license type] in California for a minimum of” was added as underlined text and noticed for comment during the 45-day comment period. During the first 15-day comment period, the underline was inadvertently removed from the noticed text. During the third 15-day comment period, the underline was added back in to the noticed text. As it was properly noticed for the 45-day comment period, this is a nonsubstantive change.
2. On page 48, Term 26: The phrase “paraphernalia, except when” was inadvertently stricken from the proposed text that was noticed for comment during the 45-day comment period. The phrase was added back into the proposed text and notice for comment during the first 15-day comment period. The phrase is existing text and is necessary as the paragraph would be unclear and not grammatically correct if it is removed.
3. On pages 51 and 52, Term 30: The final paragraph of the initial term language and the optional term language was amended to be consistent with the Uniform Standards and now reads: “Respondent shall complete the required consent forms and sign an agreement with the work site monitor and the board to allow the board to communicate with the work site monitor.” Business and Professions Code section 315(c) states that the uniform standards shall be used in dealing with substance-abusing licensees. This is a nonsubstantive change as the language is specified in Uniform Standard 7, which is required to be used by statute.