BOARD OF PHARMACY

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Disciplinary Guidelines

Section Affected: Amend Title16 of the California Code of Regulations (CCR) Section 1760.

Updated Information

The Initial Statement of Reasons (ISR) is included in this rulemaking file. The information contained therein accurately reflects the board's position regarding the adoption of the above section. As indicated in the ISR, the board is pursuing changes to its Disciplinary Guidelines (guidelines) to facilitate three types of changes:

1. Consolidation of license types within the guidelines to improve ease of use.
2. Revisions to implementation of/or modifications to conform with uniform standards established pursuant to Business and Professions Code Section 315.
3. Revisions to improve our ability to monitor licensees on probation with the board.

Specific to the changes referenced in item 2 above, the board is working to implement the provisions of the Uniform Standards for Substance Abusing Licensees (Standards). These standards impose requirements on three different types of entities/individuals. Specifically, the standards provide direction to the board in how to handle aspects of the implementation of the standards, direction to contractors that are responsible for aspects of the standards as well as requirements for individual licensees subject to the standards themselves. The proposed changes to the discpilinary guidelines reference the Standards themselves, but also incorporate the requirements specific to licensees subject to the standards as part of the terms and conditions of probation.

Further, the board has updated this rulemaking to include the following information:

The 45-day comment period began on September 4, 2015, and ended on October 19, 2015. The Board's notice indicated that the Board did not intend to hold a hearing on the matter, unless requested. No request for hearing was received by the Board. The Board received comments from two individuals during the 45-day comment period. In addition, staff and counsel provided comments for board consideration as well. These comments were considered by the board during its October 2015 Board Meeting. Based on its review of the comments, the board voted to further amend the section and guidelines, which are incorporated by reference into the regulation text. Specifically, the board made the following changes:

1. Updated the revision date to the guidelines being incorporated by reference.
2. Revised the model cost terms of probation (Term 9 of the Individual and Term 6 of the Premises sections of the guideline) to incorporate optional payment plan language into a standard language of the term.

3. Revised the pharmacist exam term (Term 19) to establish separate time frames to comply with the provisions and the triggering compliance time frames for noncompliance resulting in suspension versus noncompliance resulting in a violation of probation.
4. Revised the remedial education term (Term 33) to modify the noncompliance outcomes from a violation of probation outcome to rather a requirement that a course that is not applicable will not count towards satisfaction of the term requirements.
5. Removed the intern pharmacist experience requirement (Term 34).
6. Added optional language to the supervised practice provision (Term 35) to create the ability of the board to approve the supervisor of a pharmacy technician subject to the term of probation.
7. Modified the model language used for revocation and surrender of a premises license to specify the requirements to arrange for the continuity of patient care.
8. Removed the notification of departure provisions as a stand alone term (proposed term 14) and incorporated them into the drug and alcohol testing provisions (term 24).
9. Included additional references to pharmacy law sections.

The 15-day comment period began on December 22, 2015, and ended on January 6, 2015. The Board received comments from three individuals. These comments were considered by the during its February 2016 Board meeting. No changes were made to the modified text based on the comment received.

A second 15-day comment period began on April 6, 2016 and ended on April 21, 2016. This comment period was necessary to add a legal opinion previously considered by the board to the rulemaking file as well as relevant background materials that while publically available on the board's website, were not specifically referenced in the underlying data section of the rulemaking documents. Specifically, the following documents were added and made available for inspection:

1. Opinion No. 13-202 issued by the State of California, Department of Justice relating to Uniform Standards Regarding Substance-Abusing Healing Arts Licensees, Senate Bill 1441 (Ridley-Thomas).

2. Relevant Meeting Material and Minutes from April 21-22, 2015 Board Meeting.

3. Relevant Meeting Material and Minutes of the Board's SB 1441 Uniform Standards Implementation Committee Meeting held on June 19, 2015.

4. Relevant Meeting Material and Minutes of the Board's SB 1441 Uniform Standards Implementation Committee Meeting held on July 27, 2015.

5. Relevant Meeting Minutes of July 27-28, 2015 Board Meeting minutes.

No comments were received during the comment period. During its April 2016 meeting, the board voted to adopt section 1760 and the modified guidelines and to delegate authority to the executive officer to make any technical or non-substantive changes required to complete the rulemaking file.

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

1. The document was formatted to ensure appropriate page breaks, section breaks and consistent formatting.
2. The page numbers detailed on the table of content have been updated to reflect the final document page numbers.
3. A typo graphical error was corrected to replace the phrase "not longer" with "no longer."
4. Cross reference to specific Standards contained within the terms and conditions were removed. These references were not intended to be included in guidelines, but were inadvertently included in the document. These cross references neither created requirements nor mandates on any stakeholders and were provided to the board as a quick and efficient manner to demonstrate the board's compliance with implementation of the Standards themselves. (Note: The substance of the Standards themselves were incorporated as appropriate into the relevant terms and remain in the guidelines. Further the Standards were provided in the rulemaking file and referenced as underlying data.)

Local Mandate

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

Small Business Impact

This action will not have a significant adverse economic impact on small businesses. The Board has determined, based on the absence of substantive comments and the lack of any requests for a hearing during this rulemaking process, that this regulation will not have a significant adverse economic impact on businesses.

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and bought 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

During the intial 45-day comment period the board received comments from two individuals. The comment was presented to the Board in the meeting materials provided for the October 2015 Board meeting.

Below is a summary of the comments submitted by Ronald S. Marks as well as the board's response.

1. Mr. Marks commented that it is an error to fail to address the economic impact and merely assert that the revisions will not eliminate jobs. Mr. Marks continued to discuss his experience as a pharmacist and indicated that it is very difficult for probationers to find employment. Mr. Marks concluded these comments by indicating that a study should be done on how many probationers are unemployed and what the likely impediments would be to newly graduated interns before the board makes such a determination.

   The board rejects this comment for several reasons. The board notes that over 90% of all pharmacists on probation that are currently eligible to work are employed. Further, 82% of pharmacy technicians eligible to work are employed.The board's mandate is public protection. When a licensee violates the law to such a degree that the license is restricted in some fashion, the board must have the ability to thoroughly and appropriately monitor the licensee to ensure additional or future harm does not come to the pubilc. The board's public protection mandate cannot be compromised by allowing a licensee to work in an unrestricted fashion because it may result in an inability to work.

2. Mr. Marks commented that the board should eliminate other license history from the Factors to be Considered in Determining Penalty and indicated that he believes it is vague.

   The board rejects this comment. The history of a licensee is an important factor to consider in determing rehabiliation and the appropriate penalty. The board can look at license history to determine whether a licensee knew or should have know that an act violated pharmacy law. If a licensee was previously advised that a act violated pharmacy law, a subsequent violation of the act must be considered by the board when determing the appropriate discipline consistent with its consumer protection mandate. Further, this information is detailed in the pleading document under disciplinary considerations. Respondents are fully aware of the information being considered by the board because it is incorporated into the pleading document.

3. Mr. Marks comments that the board should allow more than 10 days to replace a practice supervisor and notes that in his experience finding a practice supervisor is extremely difficult. Mr. Marks continues to assert that the consequence of suspension is too hard and could impact the operation of a pharmacy. <u>Mr. Marks quotes language in the term regarding the the requirement for a practice supervisor to timely report to the board in writing and questions how someone fails to cause someone to do something.</u>

   The board rejects this comment. The intent of the supervised requirement provision is to ensure at minimum daily monitoring of the licensee at the worksite. More than 10 days would allow a probationer to go too long without supervision, which is contrary to the intent of the guidelines as well as the Standards. During its October meeting, the board considered the term and made changes to the provisions, but did not make changes to the timeframe with which a probationer can identify a new practice supervisor. Rather, the board determined the timeframe to be appropriate and necessary to meet its mandate and ensure appropriate

monitoring at the worksite. In response to Mr. Marks' comment about suspensions being too hard, suspensions are also appropriate to ensure a licensee takes action seriously and, in some cases, to enable appropriate remedial efforts to occur. Further, in response to Mr. Marks's question about how someone can cause another person to do something, the board notes that this is current language in the guidelines. The board nonetheless reviewed the comment and did not make changes based on the question.

4. Mr. Marks commented that the board should not add the provision that probation will continue if the board staff requests the Office of the Attorney General to prepare an accusation or petition to revoke probation and noted that this provision should be eliminated.

   The board rejects this comment. The board must retain jurisdiction over a licensee when violations of probation are substantied and public protection requires the board to extend probation until the subsequent violations are resolved to both protect the public with probationary terms and notice of an ongoing concern. Further, the board works with the Office of the Attorney General to secure timely filings of such pleadings and requests that such pleadings be drafted within 30 days of receipt of the matter.

5. Mr. Marks commented that he does not believe it is workable to have a probationer notify the board every time he/she leaves the "probationary geographic area" and noted that there is not a definition of what constituted such area.

   After consideration of the comment, the board voted to remove this provision as a standard term but to make it an optional one. The board notes that these provisions were included in the prior version of the disciplinary guidelines and are still appropriate for inclusion with drug and alcohol testing provisions to ensure continuous testing/monitoring. The board must know where the probationer is located in some instances to ensure probationary compliance.

6. Mr. Marks commented that the proposed guidelines eliminate the qualification "unless the respondent can demonstrate satisfactory evidence of rehabilitation" under the criteria to be considered for revocation.

   The board rejects this comment. The board considers rehabilitation. It is detailed as one of the Factors to Be Considered in Determining Penalties.

7. Mr. Marks commented that adding knowingly or willfully violating law or regulation are not consistently defined in the law and that the phrase should either be modified to be more specific or eliminated altogether.

   The board rejects this comment. The terms "knowlingly" and "willfully" as used consistently throughout the code and are readily understandable in the disciplinary context.

Below is a summary of the comments submitted by Megan Harwood, PharmD as well as the board's response.

1. Dr. Harwood stated that she is in favor of less ambigious terms and further clarifying the specifics of what is expected of a probationee. Dr. Harwood noted that she has experienced difficulty with this and is favor of improved definitions and clarification on expectations. Dr. Harwood requested that the guidelines include a requirement for the board to provide confirmation of receipt of records submitted by probationers.

   The board rejects this comment. Dr. Harwood did not specify which term(s) and expectations she would like clarified. Further, the board does not believe there is a lack of specificity in either the guidelines as currently used, or in the proposed revised version. This is based on the absense of any other comments in this area in relation to the significant number of licensees currently on probation with the board that have demonstrated compliance with terms and conditions of probation and successfully returned to a full and unrestricted license.

   The board further rejects the request to include a requirement for the board to provide confirmation of receipt of records submitted by probationers. This would result in significant workload that cannot be absorbed within existing resources. Further, the board notes that a probationer could send items return receipt either via e-mail or regular mail to confirm that the board received the documents.

2. Dr. Harwood commented that the guidelines reference Business and Professions Code Section 315.2 and its authorization for the board to suspend a licensee on probation from practice if the licensee tests positive in a drug or alcohol screening. Dr. Harwood recommended that this term only be included for probationees who have been found to be substance abusing licensees. Dr. Harwood noted her belief that it is not within the best interest of the public or the licensee to suspend them without first giving timely notice.

   The board rejects this comment for several reasons. First, the authority to suspend a license and the conditions under which that can be done is already established in the current version of the guidelines. This authority is essential to ensure that the board's public protection mandate can be met quickly when a licensee violates specific terms and conditions of probation. Second, the board notes that a license is placed on probation after an investigation has been completed, violations identified and a determination is made that the extent of the violations is so eggregious, the license either needs to be removed or restricted. Reducing the board's authority to quickly respond to acts that constitute a violation of probation undermines not only the board's probation monitoring, but also its public protection mandate.

During the first 15-day comment period the board received comments from three individuals. The comments were presented to the Board in the meeting materials provided for the February 2016 Board meeting.

1. Ron Marks provided a copy of his previous comments submitted to the board originally during the 45-day comment period.

The board rejects these comments as the board previously considered the comments and either made modifications or rejected as stated earlier in this document.

2. Dr. Harwood referenced page 51 of the guidelines and recommended inclusion of all medication records be on file with the board, and updated at a regular and or specified/spelled out frequency. Dr. Harwood commented that it would be fair to the licensee to ensure more accurate and appropriate understanding on the part of the license.

   The board rejects this comment as it is outside the scope of the 15-day comment period. However, the board agrees that it is important for a licensee on probation to understand all of the terms and conditions of probation imposed in against them. The information Dr. Harwood is suggesting is however already contained in the term entitled Prescription Coordination and Monitoring of Prescription Use.

3. Lauren Berton, PharmD., Director, Pharmacy Regulatory Affairs for CVS Health referenced page 90 of the guidelines as ask the board to clarify how "serious violation of recordkeeping" is defined.

   The board rejects this comment as it was submitted outside the scope of the 15-day comment period. Further the board notes that these guidelines and general discriptions of the types of violations are just that, guidelines. The board makes an independent assessment of the gravity of each of the violations as part of its role as the decision maker in disciplinary matter.

4. Dr. Berton referenced page 103 under the Standard Conditions and suggested that the board only require reporting of crimes reasonably related to the practice or profession of pharmacy be included.

   The board rejects this comment as it is outside the scope of the proposed change. Further, the board notes that the board is required to determine if a substantial relationship exists between an action (arrest or conviction) as the duties for which the license is authorized. It can only do that if it is aware of each arrest or conviction.

The board did not receive any comments in response to the second 15-day comment period.

Incorporation by Reference

The incorporation by reference method was used because it would be impractical and cumbersome to publish the disciplinary guidelines in the California Code of Regulations (CCR). The guidelines are intended to assist administrative law judges, attorneys, licensees, and others involved in the disciplinary process. The guidelines were developed to establish consistency and impose the most appropriate penalty in administrative disciplinary actions for similar offenses on a statewide basis. They are extensive and have been printed booklet-style. If the guidelines were incorporated into the CCR, it

would increase the size of Division 17 and may cause confusion to the user. The guidelines were made available to the public and were posted on the board's website.