

Board of Pharmacy

Final Statement of Reasons

Subject Matter of Proposed Regulation: Disciplinary Guidelines

Title 16 Sections Affected: Amend 1760

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein is updated as follows:

The Board of Pharmacy issued a 15-day Notice of Modified Text on January 30, 2009, to remove the "Option" language related to automatic revocation when a probationer fails to submit cost recovery as mandated.

Summary of Comments Received During the 45-Day Comment Period:

The Board received comments from two individuals that were received during the 45-day comment period.

Comments from Donald Brown, Law Offices of Brown and Brown.

1. As regards to Term 8, page 31 of the proposed Disciplinary Guidelines Mr. Brown expressed concern about the automatic revocation of a license for failure to make any payment of board costs by the directed deadline. Mr. Brown was specifically concerned that this condition is a violation of due process, as it does not allow for notice and an opportunity to be heard.

Board's Response

Term 8 of the proposed Disciplinary Guidelines contains optional language that may be included in the Cost Recovery term by an administrative law judge (in a Proposed Decision), or by the board (in a settlement or in its own Decision). This language permits automatic revocation for failure(s) to make timely cost recovery payments as required, without further notice or opportunity to be heard. This optional language in Term 8 is consistent with the legal requirements of due process.

First, recall that this is a term of probation, to be applied to a respondent who has already been provided formal notice and the opportunity for a full hearing on the initial Accusation, Statement of Issues, or other underlying pleading. This respondent has already agreed to or had lawfully imposed

the requirement to pay cost recovery to the board. Indeed, the amount(s) that are due are costs incurred in investigating/prosecuting the prior case. Any due process rights that the respondent may have had as to deciding the amount of cost recovery, respondent's responsibility to pay, and/or the timeline for doing so, were duly considered in this first proceeding.

Second, recall also that the fact that the respondent is serving a probation means it has already been adjudicated (or agreed) that this respondent's license is subject to revocation for failures to comply with probation terms. The remedy for failure to pay cost recovery (revocation) is already set out.

Third, these first two factors make the collection of such costs as a term of probation and/or the imposition of a revocation as remedy in the event of non-payment purely ministerial acts. There is no judgment to be applied. The respondent either is or is not timely with cost recovery payment(s); in the event s/he is not, that failure can lead to only one remedy (revocation).

Fourth, for the foregoing reason(s) no formal notice or hearing is required to determine if there has been timely payment of costs, or to determine a remedy. These ministerial applications of the terms of probation may be accomplished by the board's enforcement staff, who are in any case the keepers of the board records that would be relied upon in any hearing.

Fifth, in the event that the board's records are somehow incorrect and/or a respondent would be able to demonstrate timely payment in spite of same, under this term such respondent is not without avenue(s) to challenge the conclusion(s) of the board and/or the imposition of the revocation remedy. Most likely, any respondent would have one or more informal opportunities to present such proof of payment before the board would initiate action(s) to revoke the license, in the normal give and take between the probationer and the monitoring individual(s). In addition, in most cases the respondent would first receive a letter of warning regarding non-payment before action was taken. However, even if neither of these opportunities was presented to a respondent, that respondent could challenge this allegedly erroneous conclusion of non-payment upon receipt of a Decision revoking his or her license, either or both through a Petition for Reconsideration to the board and/or a request for judicial review in a Superior Court, with his/her proof. These avenues preserve any due process rights that might attach, by the provision of a further opportunity to be heard and correct any error(s).

Sixth, the respondent is made aware at the time this optional language is agreed to (in settlement) or imposed (in Proposed Decision or Decision of the board) that s/he is expected to make timely cost recovery payment(s), and that the prescribed remedy for not doing so is automatic revocation. If respondent objects to this term, s/he may refuse to agree to a settlement, and/or challenge imposition of this term via a Petition for Reconsideration

or a request for judicial review. There is no facial due process defect, and the language itself is entirely appropriate for the Disciplinary Guidelines.

Seventh, note that the language in question is purely optional, available in cases where it is appropriate, e.g., where respondent has a history of non-payment or financial instability, or there is some reason to believe that this particular respondent would have difficulty complying with payment terms or probation generally, but not mandated for all cases. This may give the board a greater opportunity to offer probation and a chance at redemption to a licensee who might otherwise be deemed to great a financial risk.

Eighth, nothing in this term precludes a respondent from making a show of hardship, inability to pay, or other basis for reduction or adjustment of the cost recovery amount(s) or timeline(s) for repayment, either prospectively during the course of settlement negotiations, or after the term of probation has begun and the schedule for cost recovery payment has begun. There is no promise of adjustment, but this term will encourage communication.

To address the concerns of the administration with regard to the "option" language in Term 8 which provided for automatic revocation for failure to make agreed-upon cost recovery payment(s), the Board voted to strike that "option" language from Term 8 and issue a Notice of Availability of Modified Text (15-day comment period).

2. Mr. Brown similarly objects to Term 22, page 43 (random drug screening) and Term 24, page 44 (prescription coordination and monitoring of prescription use) in that these terms call for the automatic suspension of a probationer's license for confirmed positive random drug screening tests and if an approved practitioner determines that a probationer cannot practice safely or independently as a pharmacist. No provision for notice or opportunity to be heard is available to the probationer.

Board's Response

Many of the responses given to Mr. Brown's comments on the optional language in Term 8 of the proposed Disciplinary Guidelines (see above) would also apply to this comment, including that the respondent will have already been provided with notice and the opportunity to be heard on the initial Accusation, Statement of Issues, or other underlying pleading, all of the terms of his/her probation (including Terms 22 and 24) will have been adjudicated or agreed to in that hearing or settlement process, and there will be other avenues and means for respondent to challenge suspensions levied under the terms that are challenged by Mr. Brown.

Perhaps more importantly, however, for this review of *changes* to existing Disciplinary Guidelines, the remedy of an automatic suspension for either

a failed drug test or at the behest of a health care practitioner is not new. Indeed, this remedy for a failed drug test is already included in the extant version of Term 22 (previously numbered Term 8 of the Optional Terms and Conditions), and does not represent a change. And though Term 24 is a new term to the board's Disciplinary Guidelines, the very concept of a suspension initiated by an independent health care practitioner is not; this power appears in extant Terms 4 (now 18, Mental Health Examination), 5 (now 19, Psychotherapy), 6 (now 20, Medical Evaluation) and 7 (now 21, Pharmacist Recovery Program). Moreover, this remedy is consistent with the authority under Business and Professions Code section 822 to revoke or suspend a license for mental or physical impairment affecting practice.

The board's statutory mandate is the protection of the public and both of these probationary terms allow that protection to occur by the automatic suspension of a license and allow the board time to confirm when a licensee can safely resume the practice of pharmacy. A confirmed positive test for alcohol or any drug means that the "positive" test has been retested and may have been retested more than once through an appropriate and reliable process. When the board ascertains that the respondent can resume the practice of pharmacy safely and the protection of the public is not compromised, he or she is notified by the board in writing that he or she can resume practice.

When monitoring the prescription use of a probationer who has chemical dependency or psychiatric disorders, an approved practitioner (of the respondent's choice) who is aware of the respondent's history is designated to coordinate and monitor any prescriptions for respondent. If the practitioner determines that the respondent is unable to practice safely or independently as a pharmacist, the board is notified and the respondent is automatically suspended from practice until the board receives confirmation that the respondent can safely resume practice as a pharmacist. The automatic suspension provision of both of these probation terms are critical to protect and safeguard the public.

3. Likewise, as to Term 21, page 41, Pharmacist Recovery Program, which provides that "any confirmed positive test for alcohol or drugs will result in the automatic suspension of practice..." Mr. Brown complains that there is no definition of what is meant by "confirmed" and asserts that an automatic suspension should be changed to a Temporary Restraining Order procedure.

Board's Response

As stated above, a confirmed positive test for alcohol or any drug means that the "positive" test has been retested and may have been retested more than once through an appropriate and reliable process. The board's

statutory mandate is the protection of the public and this probationary term allows immediate protection by the automatic suspension of a license until such time as it is deemed that the probationer can return to practice.

4. With regard to Term 30, Supervised Practice, page 30, also provides for the automatic suspension of a license without notice and an opportunity to be heard.

Board's Response

Supervised practice of a respondent is an optional term and condition of probation that is appropriate in those cases where a probationer is also a participant in the Pharmacists Recovery Program and clearly requires supervision to ensure that he or she can practice safely and the protection of the public is not compromised. It is critical that the board is notified of the name of the supervisor to ensure that a supervisor is licensed and in good standing, and is clearly aware of the terms and conditions of probation imposed, including the condition of supervised practice. The board is required to assure that safeguards are in place and to not allow the probationer to work unless supervised appropriately.

Comments from Fred S. Mayer, R.Ph., Pharmacist Planning Service, Inc.

1. Mr. Mayer was concerned about the economic impact of the proposed regulations as they relate to patient consultation.

Board's Response

This concern is outside the scope of this proposal as the requirement for patient consultation is existing law.

2. There is a concern on the impact of the Model Disciplinary Language, page 23, of the Disciplinary Guidelines and how they impact managers' responsibility for these issues.

Board's Response

The Model Disciplinary Language is standardized, consistent, language for an administrative law judge to use or a deputy attorney general to use when crafting a proposed decision or stipulated settlement in rendering a disciplinary action on a board licensee. The language clarifies the disciplinary order.

3. Mr. Mayer made several comments concerning the regulatory process.

Board's Response

These comments are not responded to as they are outside the scope of this proposal and are procedural in nature. His questions concerning the regulatory process were responded to previously.

The board held a public meeting on April 23, 2008. No comments were made during this public hearing.

Summary of Comments Received During the 15-Day Comment Period:

The Board received the following comments during the 15-day comment period.

Comments from John Gallegos, R.Ph.

1. Mr. Gallegos offered comments related to factors to be considered in determining penalties within section 1760 of Division 17, Title 18 of the California Code of Regulations in that language does not appear to offer sufficient due process protections of a pharmacist-in-charge. Mr. Gallegos asks that the regulations be reconsidered by the Board to maintain due process protections provided by the Federal Constitution.

Board's Response

Term 8 of the proposed Disciplinary Guidelines previously contained optional language that may have been included in the Cost Recovery term by an administrative law judge (in a Proposed Decision), or by the board (in a settlement or in its own Decision). The language would have permitted automatic revocation for failure(s) to make timely cost recovery payments as required, without further notice or opportunity to be heard. While that (previous) optional language in Term 8 is consistent with the legal requirements of due process, that "optional" language was stricken in the text provided during the 15-day comment period. The board believes that the striking of the optional language adequately addresses Mr. Gallegos' comments.

Comments from Mr. John Sang, Pharm.D., FCSHP, Regional Center for Compounding and Repackaging

1. That a chain of accountability to which the disciplinary guidelines apply be expanded to include a CEO or direct supervisor of a pharmacist-in-charge.

Board's Response

While the Board appreciates the comment of Mr. Sang, it is outside of the scope of the modified text provided in the 15-day comment period.

2. Mr. Sang recommends that whenever a change in pharmacist-in-charge occurs or when the license is renewed, that the organizational personnel disclosure is updated for all personals *[sic]* of the organization so that the state board and the pharmacy have an updated record of accountable personnel.

Board's Response

While the Board appreciates the comment of Mr. Sang, it is outside of the scope of the modified text provided in the 15-day comment period.

Comments from Richard I. Sakai, Pharm.D., Director of Pharmacy Services, Children's Hospital Central California

1. Mr. Sakai comments that the term "drugs or alcohol" is redundant, because alcohol is a drug. He references the use of this term throughout the document.

Board's Response

While the Board appreciates the comment of Mr. Sakai, it is outside of the scope of the modified text provided in the 15-day comment period.

2. Mr. Sakai comments that he does not believe a pharmacist-in-charge should be held responsible for actions of an employee when the employee breaks established policies, breaks the law, or does not follow established regulations.

Board's Response

While the Board appreciates the comment of Mr. Sakai, it is outside of the scope of the modified text provided in the 15-day comment period.

3. With regard to "factors to be considered in determining penalties" (Introduction Section) Mr. Sakai believes that an additional factor should be included to address the presence of a policy and procedure, and whether they were followed or not.

Board's Response

While the Board appreciates the comment of Mr. Sakai, it is outside of the scope of the modified text provided in the 15-day comment period.

4. In the Introduction section, Mr. Sakai asks the board to clarify if a violation is a single episode with a single error or multiple violations for the same type of error.

Board's Response

While the Board appreciates the comment of Mr. Sakai, it is outside of the scope of the modified text provided in the 15-day comment period.

5. Mr. Sakai asks the board of clarify if the "entrance" to a pharmacy is that of the prescription area versus the general pharmacy area.

Board's Response

While the Board appreciates the comment of Mr. Sakai, it is outside of the scope of the modified text provided in the 15-day comment period.

6. Mr. Sakai asks that within the "Notice to Employers" section, the board to clarify if the 15-day response time for a respondent is 15 business days or 15 calendar days.

Board's Response

While the Board appreciates the comment of Mr. Sakai, it is outside of the scope of the modified text provided in the 15-day comment period.

7. With regard to the completion of probation, Mr. Sakai comments "Should not be Board be held to some standard for an "appropriate" timeframe in the processing and responding to the person upon completion of the probation. Don't know what is appropriate, but delays in processing seems to be not fair."

Board's Response

While the Board appreciates the comment of Mr. Sakai, it is outside of the scope of the modified text provided in the 15-day comment period.

8. With regard to the "No Access to Controlled Substances" provision, Mr. Sakai comments on the term "possess". "What if the individual has a medical condition requiring the use of controlled substances. Ie person requires surgery during probation and needs some narcotics for pain

relief? Maybe some language "unless the medication is prescribed by a licensed prescriber".

Board's Response

While the Board appreciates the comment of Mr. Sakai, it is outside of the scope of the modified text provided in the 15-day comment period. However, this issue was previously addressed as follows during the 45-day comment period:

When monitoring the prescription use of a probationer who has chemical dependency or psychiatric disorders, an approved practitioner (of the respondent's choice) who is aware of the respondent's history is designated to coordinate and monitor any prescriptions for respondent. If the practitioner determines that the respondent is unable to practice safely or independently as a pharmacist, the board is notified and the respondent is automatically suspended from practice until the board receives confirmation that the respondent can safely resume practice as a pharmacist. The automatic suspension provision of both of these probation terms are critical to protect and safeguard the public.

9. With regard to "Ethic Course." Mr. Sakai asks if there are sufficient number of course [sic] to make it reasonable for this person to fulfill the requirement.

Board's Response

While the Board appreciates the comment of Mr. Sakai, it is outside of the scope of the modified text provided in the 15-day comment period.

10. Mr. Sakai provides a multipart question, "Is there a section that deals with who sits on this group that determines what the penalty shall be based upon section 1760? Is there a minimum number of individuals? Could it be one? Do they need to be a Board Member, or staff or a pharmacist? Is the quality control or review of the penalties to ensure fairness in giving out the penalties?"

Board's Response

While the Board appreciates the comment of Mr. Sakai, it is outside of the scope of the modified text provided in the 15-day comment period.

Local Mandate:

None

Business Impact:

This regulation will not have a significant adverse economic impact on businesses. This determination was based on the absence of testimony indicating adverse economic impact regarding these rulemaking proposal during the regulation hearing held by the board and during the 45-day comment period.

Specific Technologies or Equipment:

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives:

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to the affected persons than the proposed regulation.