



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: Agenda Item III: Discussion and Consideration of Proposed Regulation to Amend
16 CCR Sections 1760, Related to Disciplinary Guidelines

Attachment 1

Relevant Sections:

Title 16, California Code of Regulations (CCR) section 1760 requires the board to consider disciplinary guidelines when reaching a decision on a disciplinary matter.

Business and Professions Code (BPC) section 315 established the Substance Abuse Coordination Committee (SACC) within the Department of Consumer Affairs. The committee was charged with formulating uniform and specific standards in several areas for dealing with substance-abusing licensees.

BPC sections 4300 – 4315 defines disciplinary proceedings for the board as well as the grounds for taking such discipline.

Summary of Regulation:

This regulation updates the board's disciplinary guidelines that are incorporated by reference in CCR section 1760. The updated disciplinary guidelines incorporate changes to pharmacy law that occurred since the last revision of the guidelines in 2007 and implement the Uniform Standards developed in response to SB 1441 (Ridley-Thomas, Chapter 5448, Statutes of 2008).

Regulation Timeline:

Approved by Board: July 29, 2015

Rulemaking Initiated: September 4, 2015

Adopted by Board: April 27, 2016

Submitted to DCA: August 4, 2016

Rejected by OAL: January 13, 2017 (Note: The board has 120 days from the date of disapproval to address the concerns by OAL and resubmit.)

Updated Language Approved by Board: February 17, 2017

15-Day Comment Period: March 15, 2017

Background:

The board was advised during the January 2017 Board Meeting that OAL disapproved the board's rulemaking on the basis that the board did not meet the clarity and necessity standard in some of the terms and conditions language. OAL's disapproval also indicated that the board did not follow the required APA procedures. More recently, during the February 2017 Board Meeting, the board approved amendments to the language and authorized release for another 15-day comment period.

Recent Update:

After conferring with the OAL reviewing attorney, board staff released the revised language and a supplemental Initial Statement of Reasons for the required 15-day comment period. Because the comment period will end on May 29, 2017, any comments received will be distributed during the board meeting for consideration.

Attachment 1 includes a copy of the recommendations considered and approved during the February 2017 meeting.

The full disciplinary guidelines can be found using the following link:

http://www.pharmacy.ca.gov/laws_regs/1760_mdg_2.pdf

Attachment 1

Below is a summary of the changes the board approved at the February 17, 2017, board meeting in response to OAL's disapproval of the rulemaking.

Note: In addition to the language below, the board also made nonsubstantive changes. For example, the revision date was updated to reflect the current date.

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 report is not required to use.

Board Approved Modification: Remove the term "in a form or format" to read as follows:

2. Report to the Board

Respondent shall report to the board quarterly, on a schedule ~~and in a form or format~~, as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

2. The disapproval noted that Term 24 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.

Board Approved Modification: Amend the term to read as follows:

~~22-24. Random Drug Screening~~ **Drug and Alcohol Testing** (If PRP provision is required, this term is also to be included to allow for continued fluid monitoring by the Board in cases where a respondent successfully completes the PRP before completion of the probation period; terms is also appropriate for those cases where the evidence demonstrates that the respondent may have a

problem with chemical dependency (drugs, alcohol) but where the PRP is not required (Appropriate for those cases where the evidence demonstrates substance use.)

~~Respondent, at his or her [his/her] own expense, shall participate in random testing, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other drug screening program as directed by the board or its designee. Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be determined by the board or its designee. At all times, respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples for the detection of alcohol, narcotics, hypnotics controlled substances, and dangerous drugs and/or dangerous devices. or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and shall result in the automatic suspension of practice of pharmacy by respondent. Respondent may not resume the practice of pharmacy until notified by the board in writing. Testing protocols may include biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other testing protocols as directed by the board or its designee. All testing must be pursuant to an observed testing protocol, unless respondent is informed otherwise in writing by the board or its designee. Respondent may be required to participate in testing for the entire probation period and frequency of testing will be determined by the board or its designee.~~

By no later than thirty (30) days after the effective date of this decision, respondent shall have completed all of the following tasks: enrolled and registered with an approved drug and alcohol testing vendor; provided that vendor with any necessary information and documentation, and any information necessary for payment by respondent; commenced testing protocols, including all required contacts with the testing vendor to determine testing date(s); and begun testing. At all times, respondent shall fully cooperate with the testing vendor, and with the board or its designee, with regard to enrollment, registration, and payment for, and compliance with, testing. Any failure to cooperate timely shall be considered a violation of probation.

Respondent may be required to test on any day, including weekends and holidays. Respondent is required to make daily contact with the testing vendor

to determine if a test is required, and if a test is required must submit to testing on the same day.

Prior to any vacation or other period of absence from the ~~geographic area of the~~ ~~where the~~ approved testing vendor ~~provide services~~, respondent shall seek and receive approval from the board or its designee of an alternate testing vendor ~~to ensure testing can occur in the geographic area to be visited or resided in by~~ ~~respondent~~. Upon approval, respondent shall enroll and register with the approved alternate drug testing vendor, provide ~~to~~ that alternate vendor ~~with~~ any ~~necessary~~ information and documentation ~~required by the vendor~~, including any necessary payment by respondent. During the period ~~of absence of the area of visitation or residence in the alternate geographic area~~, respondent shall commence testing protocols with the alternate vendor, including required daily contacts with the testing vendor to determine if testing is required, and required testing. Any failure to timely seek or receive approval from the board or its designee, or to timely enroll and register with, timely commence testing protocols with, or timely undergo testing with, the alternate testing vendor, shall be considered a violation of probation.

Upon detection of ~~a~~ an illicit drug, controlled substance or dangerous drug, the board or its designee may require respondent to timely provide documentation from a licensed practitioner authorized to prescribe the detected substance demonstrating that the substance was administered or ingested pursuant to a legitimate prescription issued as a necessary part of treatment. All such documentation shall be provided by respondent within ten (10) days of being requested.

Any of the following shall be considered a violation of probation and shall result in respondent being immediately suspended from practice as a [insert license type] until notified by the board in writing that [he/she] may resume practice: failure to timely complete all of the steps required for enrollment/registration with the drug testing vendor, including making arrangements for payment; failure to timely commence drug testing protocols; failure to contact the drug testing vendor as required to determine testing date(s); failure to test as required; 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 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, 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/her] to immediately leave work, and shall notify respondent's employer(s) and work site monitor(s) of the suspension.³

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party-logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices and controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a pharmacist [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation. Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

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.

Board Approved Modification: Amend the term to read as follows:

41.30. Work Site Monitor (Appropriate for those cases where the evidence demonstrates substance use.)⁴

Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board or its designee, who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the board monthly or on another schedule as directed by the board or its designee. Should the designated work site monitor suspect at any time during the probationary period that respondent has abused alcohol or drugs, he or she shall notify the board immediately.

In the event of suspected abuse, the monitor shall make at least oral notification within one (1) business day of the occurrence, and shall be followed by written notification within two (2) business days of the occurrence. If, for any reason, including change of employment, respondent is no longer able to be monitored by the approved work site monitor, within ten (10) days respondent shall designate a new work site monitor for approval by the board or its designee. Failure to timely identify an acceptable initial or replacement work site monitor, or to ensure monthly reports are submitted to the board by the monitor, shall be considered a violation of probation.

~~⁴This probationary term is not new, but is being moved from the previous section "Pharmacy Technician – Standard Terms and Conditions" for purposes of consolidation. The language of this term is also changing from the previous version.~~

Within thirty (30) days of being approved by the board or its designee, the work site monitor shall sign an affirmation that he or she has reviewed the terms and conditions of respondent's disciplinary order and agrees to monitor respondent. The work site monitor shall at least:

- 1) Have regular face-to-face contact with respondent in the work environment, at least once per week or with greater frequency if required by the board or its designee;
- 2) Interview other staff in the office regarding respondent's behavior, if applicable; and
- 3) Review respondent's work attendance.

The written reports submitted to the board or its designee by the work site monitor shall include at least the following information: respondent's name and license number; the monitor's name, license number (if applicable) and work site location; the date(s) the monitor had face-to-face contact with respondent; the staff interviewed, if applicable; an attendance report; notes on any changes in respondent's behavior or personal habits; notes on any indicators that may lead to substance abuse; and the work site monitor's signature.

Respondent shall complete ~~any~~ the required consent forms and sign ~~any~~ the required agreement with the work site 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.

Option (Alternate language that is appropriate for respondents enrolled in PRP or who are given the PRP enrollment term: It is a condition of respondent's enrollment in the Pharmacists Recovery Program (PRP) that [he/she] is required to have a work site monitor approved by the PRP who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the PRP monthly or on another schedule as directed by the PRP. Should the designated work site monitor suspect at any time during the probationary period that respondent has abused alcohol or drugs, he or she shall notify the PRP immediately. The initial notification shall be made orally within one (1) business day of the occurrence, which shall be followed by written notification within two (2) business days of the occurrence. If, for any reason, including change of employment, respondent is no longer able to be monitored by the approved work site monitor, within ten (10) days of commencing new employment for prior approval by the PRP. Failure to identify an acceptable initial or replacement work site monitor, or to ensure monthly reports are submitted to the PRP by the work site monitor, shall be considered a violation of probation.

Within thirty (30) days of being approved by the PRP, the work site monitor shall sign an affirmation that he or she has reviewed the terms and conditions of respondent's disciplinary order and agrees to monitor respondent. The work site monitor shall at least:

- 1) Have regular face-to-face contact with respondent in the work environment, at least once per week or with greater frequency if required by the board or its designee;
- 2) Interview other staff in the office regarding respondent's behavior, if applicable; and
- 3) Review respondent's work attendance.

The written reports submitted to the PRP by the work site monitor shall include at least the following information: respondent's name and license number; the monitor's name, license number (if applicable) and work site location; the date(s) the monitor had face-to-face contact with respondent; the staff interviewed, if applicable; an attendance report; notes on any changes in respondent's behavior or personal habits; notes on any indicators that may lead to substance abuse; and the work site monitor's signature.

Respondent shall complete any required consent forms and sign any required agreement with the work site monitor and/or the PRP to allow the PRP to communicate freely on the subject of respondent's work performance and sobriety with the work site monitor.

Necessity Concerns:

The disapproval from OAL noted that the board failed to articulate the necessity for each of the changes being made in the guidelines. Board staff along with DCA counsel addressed each of these by supplementing the Initial Statement of Reasons, which was included as part of the 15-day notice documents.

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: Staff has specifically included a statement that the board received, reviewed and considered all of the comments provided in response to the rulemaking and will provided additional detail to the basis for the rejection of the comment including that the statement submitted by the commenter was outside the scope of the regulation.
2. Documents Relied Upon: Staff updated the Final Statement of Reasons to clearly state that 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: Staff has, as part of the non-substantive changes, ensured that language that moved within the document is appropriately shown as deleted in one section and added in another section. For example, Term 23 (Pharmacists Recovery Program) shows where existing language was moved from the ninth paragraph of the term to now the third paragraph of the term.

21-23. Pharmacists Recovery Program (PRP) (Appropriate for those cases where evidence demonstrates substance abuse ~~chemical dependency~~ (alcohol, drugs), or psychiatric disorders (mental illness, emotional disturbance, gambling addiction) (Pharmacists and Pharmacist Interns Only)

By no later than ten (10) days after ~~Within thirty (30) days~~ of the effective date of this decision, respondent shall have completed all of the following: contacted the Pharmacists Recovery Program (PRP) for evaluation; enrolled in the PRP; completed, signed, and returned the treatment contract as well as any addendums required or suggested by the PRP; successfully completed registration for any drug or alcohol testing mandated by the treatment contract and/or by enrollment in the PRP; and begun compliance with the drug or alcohol testing protocol(s). ~~contact the Pharmacists Recovery Program (PRP) for evaluation, and shall immediately thereafter enroll, successfully participate in, and complete the treatment contract and any subsequent addendums as~~

~~recommended and provided by the PRP and as approved by the board or its designee. Respondent shall successfully participate in the PRP and complete the treatment contract and any addendums required or suggested by the PRP. The costs for PRP participation shall be borne by the respondent.~~

If respondent is currently enrolled in the PRP, said participation is now mandatory and as of the effective date of this decision is no longer considered a self-referral under Business and Professions Code section 4362(c) (a)(2). Respondent shall successfully participate in and complete his or her current contract and any subsequent addendums with the PRP.

~~Failure to timely contact or enroll in the PRP or successfully participate in and complete the treatment contract and/or any addendums, shall be considered a violation of probation.~~

Respondent shall pay administrative fees as invoiced by the PRP or its designee. Fees not timely paid to the PRP shall constitute a violation of probation. The board will collect unpaid administrative fees as part of the annual probation monitoring costs if not submitted to the 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;
- 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;
- Any report from the PRP of material non-compliance with the terms and conditions of the treatment contract and/or any addendum(s); or
- Termination by the PRP for non-compliance, failure to derive benefit, or as a public risk.

Respondent may not ~~result~~ resume the practice of pharmacy until notified by the board in writing.

Probation shall be automatically extended until respondent successfully completes the PRP. ~~Any person terminated from the PRP program shall be automatically suspended by the board. Respondent may not resume the~~

~~practice of pharmacy until notified by the board in writing. The board will provide notice of any such suspension or extension of probation.~~

~~Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall result in the automatic suspension of practice by respondent and shall be considered a violation of probation. Respondent may not resume the practice of pharmacy until notified by the board in writing.~~

During any suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice ~~pharmacy~~ as a [insert license type] nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a pharmacist [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with this suspension shall be considered a violation of probation. Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.~~

~~Respondent shall pay administrative fees as invoiced by the PRP or its designee. Fees not timely paid to the PRP shall constitute a violation of probation. The board will collect unpaid administrative fees as part of the annual probation monitoring costs if not submitted by the PRP.~~

(Option language to be used in addition to standard language when appropriate to ensure licensee works in an access position while being

monitored.)

Option: Respondent shall work in a pharmacy setting with access to controlled substances for six (6) consecutive months before successfully completing ~~probation~~ the PRP. If respondent fails to do so, probation shall be automatically extended until this condition has been met. Failure to satisfy this condition within six (6) months beyond the original date of expiration of the term of probation shall be considered a violation of probation.

The full disciplinary guidelines can be found using the following link:

http://www.pharmacy.ca.gov/laws_regs/1760_mdg_2.pdf