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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 V: Discussion and Consideration of Proposed Regulation to Amend 16 CCR Sections 1760, Related to Disciplinary Guidelines

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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.

Background:
As the board was advised during the January 2017 Board Meeting, OAL disapproved the board's rulemaking. OAL disapproval of the rulemaking was on the grounds that the board did not meet the clarity and necessity standard in some of the language included in the terms and conditions of the language. OAL's disapproval also indicated that the board did

not follow the required APA procedures. Board staff had the opportunity to discuss the disapproval with the assigned OAL attorney on February 9, 2017.

In addition to the proposed language below, the board also made nonsubstantive changes. For example, the revision date will be 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 request is not required to use.

   Staff Recommendation: 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.

   Staff Recommendation: 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.

   Staff Recommendation: 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.

~~4 This 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 notes that the board failed to articulate the necessity for each of the changes being made in the guidelines. Board staff along with DCA counsel will address each of these by supplementing the Initial Statement of Reasons, which will be 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 will specifically include 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 will update 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 will, as part of the non-substantive changes, ensure 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) will show 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.

At this Meeting:

The board will have the opportunity to review the information and recommended changed and provide staff will direction.

Requested Action:

The board is asked to review the recommendations and proposed revised language and to motion and move to initiate a 15-day notice period to incorporate the additional changes to the board's Disciplinary Guidelines. As part of its motion staff requests that the board delegate authority to the board's Executive Officer to make non-substantive changes and absent any negative comments, compile and resubmit the rulemaking.

Attachment 1 includes a copy of the disapproval from OAL. The relevant pages will be provided at the meeting. The proposed language is undergoing review by OAL. If there are subsequent changes are requested, board staff will advise the board at the board meeting. The full disciplinary guidelines can be found using the following link http://www.pharmacy.ca.gov/laws_regs/1760_mt.pdf.

Attachment 1

State of California
Office of Administrative Law

In re:
Board of Pharmacy

Regulatory Action:

Title 16, California Code of Regulations

Adopt sections:
Amend sections: 1760
Repeal sections:

AMENDED **DECISION OF DISAPPROVAL OF REGULATORY ACTION**

Government Code Section 11349.3

OAL Matter Number: 2016-1130-01

OAL Matter Type: Regular (S)

SUMMARY OF REGULATORY ACTION

On November 30, 2016, the Board of Pharmacy (Board) submitted to the Office of Administrative Law (OAL) this proposed regulatory action to amend its "Manual of Disciplinary Guidelines and Model Disciplinary Orders" (Disciplinary Guidelines), which is incorporated by reference in section 1760, Title 16, of the California Code of Regulations. The amendments re-organize the Disciplinary Guidelines, incorporate changes that have occurred in pharmacy law, and establish new terms and conditions of probation.

On January 13, 2017, OAL notified the Board that OAL disapproved the proposed regulations indicating that the regulations failed to comply with the consistency, clarity, and necessity standards of Government Code section 11349.1 and the Board failed to follow procedural requirements of the California Administrative Procedure Act (APA). This Decision of Disapproval of Regulatory Action explains the reasons for OAL's action.

DECISION

Although the January 13, 2017, Notice of Disapproval included consistency, this Disapproval Decision is amended to delete "consistency" as it is no longer an issue. OAL disapproved the above-referenced regulatory action for the following reasons:

1. The proposed regulations failed to comply with the clarity standard of Government Code section 11349.1, subdivision (a)(3);
2. The proposed regulations failed to comply with the necessity standard of Government Code section 11349.1, subdivision (a)(1), and Title 1 of the California Code of Regulations (CCR), section 10, subdivision (b); and

3. The Board failed to follow the required procedures of the APA by omitting to:
   a. summarize and respond to all of the public comments made regarding the proposed action pursuant to Government Code section 11346.9, subdivision (a)(3);
   b. make a document relied upon available for at least 15 days for public comment as required by Government Code section 11347.1; and
   c. properly display text, pursuant to Government Code section 11346.2, subdivision (a)(3) and Title 1 of the CCR, sections 8 and 44.

DISCUSSION

The adoption, amendment, or repeal of regulations by the Board must satisfy requirements established by the part of the APA that governs rulemaking by a state agency. Any regulation adopted, amended, or repealed by a state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure, is subject to the APA unless a statute expressly exempts the regulation from APA coverage. (Gov. Code, sec. 11346.)

Before any regulation subject to the APA may become effective, the regulation is reviewed by OAL for compliance with the procedural requirements of the APA and for compliance with the standards for administrative regulations in Government Code section 11349.1. Generally, to satisfy the standards a regulation must be legally valid, supported by an adequate record, and easy to understand. In this review OAL is limited to the rulemaking record and may not substitute its judgment for that of the rulemaking agency with regard to the substantive content of the regulation. This review is an independent check on the exercise of rulemaking powers by executive branch agencies intended to improve the quality of regulations that implement, interpret, and make specific statutory law, and to ensure that the public is provided with a meaningful opportunity to comment on regulations before they become effective.

Senate Bill 1441 (Stats. 2008, ch. 548) established the Substance Abuse Coordination Committee (Committee) within the Department of Consumer Affairs. Business and Professions Code section 315 required the Committee to "formulate uniform and specific standards...that ***each healing arts board shall use*** in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program...." (Emphasis added.) The Committee completed this task in April of 2011. This rulemaking action proposes to implement the Uniform Standards Regarding Substance-Abusing Healing Arts Licensees, April 2011 (Uniform Standards) prepared by the Committee, in accordance with Business and Professions Code section 315.

1. CLARITY STANDARD

In adopting the APA, the Legislature found that the language of many regulations was unclear and confusing to persons who must comply with the regulations. (Gov. Code, sec. 11340, subd. (b).) Government Code section 11349.1, subdivision (a)(3), requires that OAL review all regulations for compliance with the clarity standard. Government Code section 11349,

subdivision (c), defines "clarity" to mean "written or displayed so that the meaning of the regulations will be easily understood by those persons directly affected by them."

The "clarity" standard is further defined in section 16, Title 1, of the CCR, OAL's regulation on "clarity," which provides:

> In examining a regulation for compliance with the "clarity" requirement of Government Code section 11349.1, OAL shall apply the following standards and presumptions:
> (a) A regulation shall be presumed not to comply with the "clarity" standard if any of the following conditions exists:
> (1) the regulation can, on its face, be reasonably and logically interpreted to have more than one meaning....

In this regulatory action, the Board failed to comply with the clarity standard of the APA. In addition to being unclear, some provisions of the proposed Disciplinary Guidelines can be reasonably and logically interpreted to have more than one meaning.

1.1. Form and Format

The Board proposes to amend item 2 of the Standard Conditions in the Disciplinary Guidelines to require the respondent to "report to the board quarterly, on a schedule and in a form or format, as directed by the board or its designee." The Board proposes to add the phrase "and in a form or format" but it does not specify what form or format the respondent is now required to use. Those directly affected would not know which form to use or where to find it. They would not know whether the format they are using will cause them to be in violation of the requirement. Thus, this provision is unclear.

1.2. Geographical Area and Necessary Information and Documentation

In the renumbered item 24 of the Standard Conditions, the Board proposes to add in the Disciplinary Guidelines language which states:

> Prior to any vacation or other period of absence from the ***geographic area*** of the approved testing vendor, respondent shall seek and[1] receive approval from the board or its designee of an alternate testing vendor 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 that alternate vendor with any ***necessary information and documentation***, including any necessary payment by respondent. [Bold and italics added.]

[1] The original Decision of Disapproval erroneously stated "to" instead of "and," affecting the meaning of the paragraph.

This proposed language contains two clarity issues. First, the term "geographic area" can be reasonably and logically interpreted to have more than one meaning. It can mean a distance of one mile from the approved testing vendor or within the county that the approved testing vendor is located or any number of reasonable interpretations. Those directly affected would not know when they are required to seek approval from the board. Therefore, this term is unclear.

Second, it is unclear what information and documentation is considered necessary. Those directly affected by the regulation would not know what information or documentation they are required to provide to the alternate vendor. Thus, this provision does not meet the clarity standard of the APA.

The Board must make proposed modifications available to the public for comment for at least 15 days pursuant to Government Code section 11346.8, subdivision (c), and section 44 of Title 1 of the California Code of Regulations before resubmitting this regulatory action to OAL for review.

1.3. Required Consent Forms and Agreements

In its Disciplinary Guidelines, the Board proposes to add the following language under the Standard Conditions of probation related to work site monitors (renumbered item #30):

> Respondent ***shall complete any required consent forms and sign any 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. [Bold and italics added.]

Uniform Standard #7 specifically addresses worksite monitoring requirements and standards. It imposes the following requirement on work site monitors:

> The licensee ***shall complete the required consent forms and sign an agreement*** with the worksite monitor and the board to allow the board to communicate with the worksite monitor. [Emphasis added.]

The Uniform Standards require the licensee to complete consent forms and to sign an agreement with the worksite monitor and the board. However, the proposed language in the Disciplinary Guidelines suggests that there may or may not be consent forms or an agreement and the respondent only needs to comply with the requirement if there are such forms and agreement. Thus, the Disciplinary Guidelines may not be easily understood by the regulated public and may be inconsistent with the Uniform Standards.

Also, the Uniform Standards ***permit all*** communication between the board and the worksite monitor. However, the proposed language in the Disciplinary Guidelines appears to ***restrict*** the communication to the subjects of work performance and sobriety, which unless clarified, may cause inconsistency in application of the Uniform Standards.

OAL reserves the right to review for "consistency" standard once the clarity issues are resolved.

2. NECESSITY STANDARD

Government Code section 11349.1, subdivision (a)(1), requires OAL to review all regulations for compliance with the necessity standard. Government Code section 11349, subdivision (a), defines "necessity" to mean:

> (a) ...the record of the rulemaking proceeding demonstrates by substantial evidence the need for a regulation to effectuate the purpose of the statute, court decision, or other provision of law that the regulation implements, interprets, or makes specific, taking into account the totality of the record. For purposes of this standard, evidence includes, but is not limited to, facts, studies, and expert opinion.

To further explain the meaning of substantial evidence in the context of the necessity standard, Title 1 of the California Code of Regulations, section 10, subdivision (b) provides:

> (b) In order to meet the "necessity" standard of Government Code section 11349.1, the record of the rulemaking proceeding shall include:
>
> (1) A statement of the specific purpose of ***each*** adoption, amendment, or repeal; and
>
> (2) information explaining why ***each provision*** of the adopted regulations is required to carry out the described purpose of the provision. Such information shall include, but is not limited to, facts, studies, or expert opinion. When the explanation is based upon policies, conclusions, speculation, or conjecture, the rulemaking record must include, in addition, supporting facts, studies, expert opinion, or other information. An "expert" within the meaning of this section is a person who possesses special skill or knowledge by reason of study or experience which is relevant to the regulation in question. [Emphasis added.]

In order to provide the public with an opportunity to review and comment upon an agency's perceived need for a regulation, the APA requires that the agency describe the need for the regulation in the initial statement of reasons (ISOR). (Gov. Code, sec. 11346.2, subd. (b).) The ISOR must include a statement of the specific purpose for each adoption, amendment, or repeal, and the rationale for the determination by the agency that each regulation is reasonably necessary to carry out the purpose for which it is proposed or, simply restated, "why" a regulation is needed and "how" this regulation fills that need. (Gov. Code, sec. 11346.2, subd. (b)(1).) The ISOR must be submitted to OAL with the initial notice of the proposed action and made available to the public during the public comment period, along with all the information upon which the proposal is based. (Gov. Code, sec. 11346.2, subd. (b) and sec. 11346.5, subds. (a)(16)

and (b).) In this way the public is informed of the basis of the regulatory action and may comment knowledgeably.

It is important to note that material proposed to be incorporated by reference shall be reviewed in accordance with the same procedures and standards for a regulation published in the California Code of Regulations. (1 Cal. Code Regs., sec. 20, subd. (b).) Therefore, the ISOR must provide necessity for the content of the Disciplinary Guidelines being incorporated by reference. However, the ISOR submitted with this regulatory action does not meet the necessity standard of Government Code section 11349.1 and section 10 of Title 1 of the California Code of Regulations.

2.1. Describing the Necessity for the Regulation

For some proposed language, the ISOR merely describes the new or revised provisions in the Disciplinary Guidelines rather than explain the reasons for the various standards.

An example can be found in the Disciplinary Guidelines, under the newly proposed item 10 of the section entitled "Standard Conditions: To Be Included In All Probations," which states:

> During the period of probation, should respondent sell, trade, or transfer all or part of the ownership of the licensed entity...the board or its designee shall have the sole discretion to determine whether to exercise continuing jurisdiction over the licensed location, under the current or new premises license number, and/or carry the remaining period of probation forward to be applicable to the current or new premises license number of the new owner.

The ISOR provides the following statement to support the necessity for the proposed added language:

> Sale or Discontinuance of Business: This is a new term that specifies that the board, in its sole discretion, will determine if it retains jurisdiction over a licensed location that has either changed location or ownership (full or partial) irrespective if a new license number is issued. If the board makes such a determination, the jurisdiction shall be carried over to the new location or license number and the terms and conditions of probation will carry over for the remainder of the probation period. This proposed change was previously contained in a different term (License Surrender While on Probation). This provision allows the board to accommodate a change in ownership or location, etc., without incurring additional costs.

In this instance, the ISOR merely paraphrases the proposed language. It does not explain the problem that prompted the need for this language, the purpose, and the rationale for adding it. A more complete ISOR would explain why the Board chose to continue to exercise jurisdiction with the new owner. The rulemaking also does not provide the criteria that the Board would use

to continue jurisdiction and the circumstances under which the Board would exercise this discretion.

Further, it is important to note that although the ISOR states that the above proposed language was previously contained under the "License Surrender While on Probation" term, the language does not currently appear under that term.

2.2. Absent or Inadequate Necessity Statements

In other cases, necessity is missing or is inadequate. The ISOR either omits to address a proposed provision or only addresses the necessity for a portion of the proposed provision. For example, throughout the Disciplinary Guidelines, the Board proposes to remove the following provision:

> 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. [Strikeouts omitted.]

The ISOR, however, is missing an explanation demonstrating why the above language is being repealed from the Disciplinary Guidelines. The APA requires such an explanation.

Another example demonstrates that the ISOR contains inadequate necessity. Throughout the Disciplinary Guidelines, the Board proposes various time frames to meet different requirements. However, the ISOR does not explain the rationale for the time frame selected. To illustrate, the Disciplinary Guidelines require that "[w]ithin thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a group recovery and/or support meeting...." The ISOR generally states that the "Board proposes amendments in consideration of the [Committee]'s uniform standards" but it does not explain why the Board only gives thirty (30) days to meet the requirement. Uniform Standard #5 governs all aspects of group meeting attendance requirements, but it does not have a thirty (30) day time frame to comply with the requirements. Because the Board exercised its discretion to impose this time frame requirement, the ISOR must explain the problem, purpose, and rationale for choosing a time frame of 30 days.

The ISOR must include an explanation of the need and the rationale for each proposed new provision or change to the existing regulatory language and such explanation must be made available to the public. Any supplement to the initial statement of reasons that provides the missing necessity must be made available to the public for comment for at least 15 days prior to adoption of the regulations by the Board pursuant to Government Code section 11347.1.

3. FAILURE TO FOLLOW REQUIRED APA PROCEDURES

The APA requires agencies to follow specific procedures. In this rulemaking action, the Board failed to follow the required procedures by omitting to: (1) summarize and respond to all of the

public comments, (2) make available for a 15-day comment period a document that the agency relied on in amending the proposed regulation, and (3) properly display text.

3.1. Summary and Response to Public Comments

Government Code section 11346.9, subdivision (a), provides that an agency proposing regulations shall prepare and submit to OAL a final statement of reasons. One of the requirements of the final statement of reasons is a summary and response to public comments. Specifically, Government Code section 11346.9, subdivision (a)(3), requires that the final statement of reasons include:

> (a)(3) A summary of ***each*** objection or recommendation made regarding the specific adoption, amendment, or repeal proposed, together with an explanation of how the proposed action has been changed to accommodate ***each*** objection or recommendation, or the reasons for making no change. This requirement applies only to objections or recommendations specifically directed at the agency's proposed action or to the procedures followed by the agency in proposing or adopting the action.... [Emphasis added.]

During the 45-day comment period of this rulemaking action, 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?

This comment was not summarized nor responded to in the final statement of reasons. The Board must summarize and respond to all comments that were not summarized and responded to before resubmitting the rulemaking action to OAL for review.

3.2. Document Relied Upon

Government Code section 11347.1, subdivision (b), requires that the rulemaking file include:

> 11347.1.... (b) At least 15 calendar days before the proposed action is adopted by the agency, the agency shall mail to all of the following persons a notice identifying the added document and stating the place and business hours that the document is available for public inspection:
> (1) Persons who testified at the public hearing.
> (2) Persons who submitted written comments at the public hearing.
> (3) Persons whose comments were received by the agency during the public comment period.
> (4) Persons who requested notification from the agency of the availability of changes to the text of the proposed regulation.

> (c) The document shall be available for public inspection at the location described in the notice for at least 15 calendar days before the proposed action is adopted by the agency....

The Table of Contents in this rulemaking record identified a document entitled "Board of Pharmacy Licensing Statistics Fiscal Year 2014/15" as material relied upon. The document is included in the file; however, it was not made available for public comments and it was not listed in any of the notices to the public. If the Board relied on this document to amend the Disciplinary Guidelines, the document must be noticed to the public for comment pursuant to Government Code section 11347.1 before it can be added to the rulemaking file.

3.3. Improperly Displaying Text

Prior to noticing any modified text to the public for comments, the Board must ensure that the underlying text of the Disciplinary Guidelines is properly displayed. (Gov. Code, sec. 11346.2, subd. (a)(3); 1 Cal. Code Regs., secs. 8 and 44.) The Disciplinary Guidelines were noticed to the public with improperly displayed text. For example, under the newly renumbered item 23 of the Standard Conditions, the Disciplinary Guidelines state:

> 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.

This language was added during the 45-day comment period without any underlines. It remained in the text without any underlines during the first and second 15-day notices. And it remained in the final text of the regulation submitted to OAL without any underlines. The Board must properly display text during its noticed comment periods prior to resubmitting the rulemaking to OAL for review.

CONCLUSION

For these reasons, OAL disapproved the above-referenced rulemaking action. Pursuant to Government Code section 11349.4(a), the Commission may resubmit this rulemaking action within 120 days of its receipt of this Decision of Disapproval.

Any changes made to the regulation text to address the issues discussed above must be made available for at least 15 days for public comment pursuant to Government Code section 11346.8 and section 44 of title 1 of the CCR prior to adoption. Additionally, any document relied upon and any supplement to the ISR or other document the Board may create or otherwise propose to add to the record in order to address the necessity issue discussed above must be made available for at least 15 days for public comment pursuant to Government Code section 11347.1 prior to adoption. The Board must document in the rulemaking file its approval of the final text after consideration of all public comments and relevant information, as well as resolve all other issues raised in this Decision of Disapproval, before resubmitting to OAL.

If you have any questions, please do not hesitate to contact me at (916) 323-6824.

Date: January 23, 2017

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