

## **Board of Pharmacy**

### **Initial Statement of Reasons**

Subject Matter of Proposed Regulation: Disciplinary Guidelines

Sections Affected: Amend § 1760 of Article 8 of Division 17 of Title 16 Cal. Code Reg.

#### Specific Purpose of the Proposed Changes:

The Board of Pharmacy proposes to amend Section 1760 of Division 17 of Title 16 of the California Code of Regulations. The purpose for amending the regulation is to update the Disciplinary Guidelines that are incorporated by reference in section 1760.

The board uses disciplinary guidelines when taking action to suspend, revoke or place a license on probation. The proposal would replace the existing disciplinary guidelines with guidelines that are consistent with the requirements of Government Code section 11425.50(e).

The proposed changes to the Disciplinary Guidelines are necessary to incorporate changes that have occurred in pharmacy law since the last revision, 10/2007, to ensure the consistent use of titles and terms between the Disciplinary Guidelines and the Pharmacy Law Book, to remove outdated and unnecessary terms and conditions of probation, and to incorporate changes made to facilitate implementation of SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) to ensure rehabilitation of the licensees on probation and the board's ability to meet its consumer protection mandate.

A summary of the proposed changes is below.

#### Amend 16 CCR §1760

Existing regulations at 16 CCR §1760 specify requirements related reaching a decision on a disciplinary action.

The purpose of the board's proposal makes the following changes:

- The "Disciplinary Guidelines" revision date has been changed from 10/2007 to 7/2015.
- Business and Professions Code section 315, 315.2, and 315.4 are added to the Authority Cited and References cited to ensure compliance with the Administrative Procedures Act.

The board also proposes the following changes to the “Disciplinary Guidelines” document:

### **Title Page**

The board proposes to update the revision date on the title page from 10/2007 to 7/2015. The board proposes to update the name of the board’s president to Amy Gutierrez.

### **Table of Contents**

The board proposes to update the Table of Contents to reflect the consolidation of the individual license types (pharmacist/intern pharmacist, advanced practice pharmacist, pharmacy technician, designated representative and designated representative-3PL) into one section, “Individual Licenses”. This change is reflected by showing the elimination of the pharmacy technician and designated representative specific portions as well as replacing reference to “Pharmacist/Intern Pharmacist” with “Individual Licensees.”

These changes are necessary to reflect the consolidation of the individual license types to standardize the language as well as provide the terms and conditions of probation that can be used for individuals whose license is being disciplined by the board. This consolidation will streamline the guidelines and make them easier to use by its intended users: board members, the board’s executive officer, licensees, deputy attorneys general, attorneys and administrative law judges.

### **Introduction (Page 1)**

Changes are proposed to allow for easier reading and consistency as well as to update the revision date. Changes would include: changing the words relating to the exercise of clinical judgment: “for the citizens of California” to “for their patients” as well as providing more description on the vital roles and responsibilities board licensees have. Also the board proposes to add “Category IV” violations to its current requirement for memos transmitted to the board advocating a stipulation.

### **Factors to be Considered in Determining Penalties (Page 3)**

Changes are proposed to direct the users of the guidelines to consider the license history of other licenses held by the respondent as well as the Uniform Standards Regarding Substance-Abusing Healing Arts Licensees.

### **Mitigating Evidence (Pages 4-5)**

Changes are proposed to this section to further define and clarify examples of appropriate evidence a respondent may submit to include personal or professional references that have knowledge of the respondent’s character and rehabilitation, as well as conduct which the respondent is accused and other pertinent facts that would enable the board to

decide a case. The proposed change also details the method by which this information must be provided to the board.

**Terms of Probation – Individual Licensees [Pharmacist, Advanced Practice Pharmacist, Pharmacist Intern, Pharmacy Technician, Designated Representative, Designated Representative-3PL] (Page 6-21)**

The board is proposing to change the title of this section of the guidelines to reflect the consolidation of each of the individual license types into one standardized section as well as to reference the Uniform Standards Regarding Substance-Abusing Licensees. (Page 6)

**Categories of Violations and Recommended Penalties**

The proposed changes are necessary to facilitate consolidation of the individual license types as well as to better define the grounds for discipline as well as to explain the structure under each category as well as how the board should use the information provided. This will assist users in following the format of the Disciplinary Guidelines and serve as a tool to assist in setting the penalties imposed as part of a disciplinary action. Category I (Page 7)

The majority of the changes reflected in this section are to remove the titles associated with each section of law. (These titles were designed to allow the reader brief insight into the requirements detailed in the specific sections, however the titles have no force of law.). In place of this list of codes, the board is proposing incorporation of summaries of each of the statutes into narrative language that better describes the types of violations that would constitute such Discipline and includes violations for improper compounding of drug products as well as violations resulting from the misuse of education. These changes are necessary to provide for a more useful application. The board notes that the current list of statutes provided is difficult for someone to use that is not familiar with Pharmacy Law and is provided in an overwhelming fashion that defeats the purpose of providing users with a convenient way to determining the board's recommended penalties. The proposed changes will more easily aid the user in the use of the Disciplinary Guidelines.

The minimum penalty for this category of violation is changing to two years' probation. The minimum penalty was increased from one year to two years because one year of probation monitoring is not sufficient to properly demonstrate that complete rehabilitation has occurred. (Page 7)

The description for category one reflects that such violations are less serious than Categories II-IV violations. (Page 7)

**Category II (Page 13-14)**

The majority of the changes reflected in this section are to remove the titles associated with each section of law. (These titles were designed to allow the reader brief insight into

the requirements detailed in the specific sections, however the titles have no force of law.). In place of this list of codes, the board is proposing incorporation of summaries of each of the statutes into narrative language that better describes the nature of violations that would constitute such discipline and includes violations for improper compounding of drug products as well as violations resulting from the misuse of education. (Page14)

These changes are necessary to provide for a more useful application. The board notes that the current list of statutes provided is difficult for someone to use that is not familiar with Pharmacy Law and is provided in an overwhelming fashion defeats the intended purpose, which is to provide users with a convenient way of determining the board's recommended penalties. The proposed changes will more easily aid the user in the use of the Disciplinary Guidelines.

#### Category III (Pages 17 – 18)

The majority of the changes reflected in this section are to remove the titles associated with each section of law. (These titles were designed to allow the reader brief insight into the requirements detailed in the specific sections, however the titles have no force of law.). In place of this list of codes, the board is proposing incorporation of summaries of each of the statutes into narrative language that better describes the nature of violations that would constitute such discipline including self-administration of controlled substances that could lead to a potential infection control risk (Page 18). These changes are necessary to provide for a more useful application. The board notes that the current list of statutes provided is difficult for someone to use that is not familiar with Pharmacy Law and is provided in an overwhelming fashion that defeats the intended purpose, which is to provide users with a convenient way of determining the board's recommended penalties. The proposed changes will more easily aid the user in the use of the Disciplinary Guidelines.

#### Category IV (Page 21)

The majority of the changes reflected in this section are to remove the titles associated with each section of law. (These titles were designed to allow the reader brief insight into the requirements detailed in the specific sections, however the titles have no force of law.). In place of this list of codes, the board is proposing incorporation of summaries of each of the statutes into narrative language that better describes the nature of violations that would constitute such discipline including self-administration of controlled substances that could lead to a potential infection control risk (Page 21). These changes are necessary to provide for a more useful application. The board notes that the current list of statutes provided is difficult for someone to use that is not familiar with pharmacy law and is provided in an overwhelming fashion that defeats the intended purposes, which is to provide users with a convenient way of determining the board's recommended penalties. The proposed changes will more easily aid the user in the use of the Disciplinary Guidelines.

## **Model Disciplinary Language – Individual Licensees [Pharmacist, Advanced Practice Pharmacist, Intern Pharmacist, Pharmacy Technician, Designated Representative, Designated Representative-3PL] (Pages 22 - 25)**

The board is proposing to change the title of this section of the guidelines to reflect the consolidation of each of the individual license types into one standardized section as well as add in two additional license types (Advanced Practice Pharmacist and Designated Representative-3PL).

### **Revocation**

This section is being changed to facilitate consolidation of the individual license types and to clarify that the respondent must relinquish any indicia of licensure. The board is replacing “his or her” with [his/her] to allow for the decision to reflect the gender of the respondent. Further, the board is making the current proposed option of a payment plan the standard language. The current payment in full within 15 days requirement is being changed to optional language. This change is necessary to more accurately reflect the common practice of the board to provide more flexibility and options when requiring cost recovery from a respondent whose license has been revoked.

### **Suspension**

This section is being changed to facilitate consolidation of the individual license types as well as to clarify what actions are prohibited during a period of any suspension.

### **Issuance of Probationary License**

The changes in this section are to facilitate consolidation of the individual license types. Further a new option is being proposed that would provide model language for the issuance of a pharmacist intern license. This model language is necessary to ensure the respondent is advised of the effect of potential discipline of the intern pharmacist license on any subsequent application for licensure as a pharmacist and ensure the board has the ability to carry over the discipline imposed on the intern pharmacist license to the pharmacist license should one be issued during the period of probation. (Pharmacy law recognizes the necessity of an intern license for purposes of gaining the experience necessary to become a pharmacist. In practice, pharmacist intern licenses are non-renewable licenses to reflect the progress an person must make from an intern to a licensed pharmacist. As such a provision is necessary to allow for this progression when appropriate.)

### **Surrender**

This section is being changed to facilitate consolidation of the individual license types and to clarify that the respondent must relinquish any indicia of licensure. The board is replacing “his or her” with [his/her] to allow for the decision to reflect the gender of the respondent. Further this section is being modified to clarify that any licensing exams and education or experience requirements necessary to fulfill the requirements for a license must be satisfied upon reapplication.

#### License Reinstatement Order with Conditions Prior to Issuing License

This language is new and is necessary to provide model language as guidance to those individuals (board members and administrative law judges) responsible for crafting reinstatement orders. The language proposed is consistent with current practice and provides specificity to the requirements for reinstatement of a license, including conditions precedent for passage of an exam as specified as well as appropriate fees. Further, optional language is provided to specify cost recovery owed to the board. This term is appropriate for inclusion if the respondent is a pharmacist or pharmacy technician. (Page 24)

#### License Reinstatement

This language is new and is necessary to provide model language as guidance to those individuals (board members and administrative law judges) responsible for crafting reinstatement orders. The language proposed is consistent with current practice and includes

#### Adoption of Stipulation

The board is proposing removal of this language as it is in conflict with the standard language used by the Office of the Attorney General who is responsible for drafting stipulated settlements for the board.

#### **Standard Conditions Listing (Page 26)**

The board is proposing changes to titles and or the renumbering of terms to reflect changes and consolidation of terms as well as to reflect new terms that will be incorporated.

#### **Optional Conditions Listing (Page 26)**

The board is proposing changes to titles and or the renumbering of terms to reflect changes and consolidation of terms as well as to reflect new terms that will be incorporated.

#### **Standard Conditions: To Be Included in All Probations (Page 28 – 34)**

The board is proposed the following changes:

- Cooperate with board Staff: Proposed changes are to clarify what activities are encompassed within the term as well as specify that such cooperation must occur timely.
- Continuing Education: Specifies that this term applies to pharmacist respondents only.
- Reporting of Employment and Notice to Employers: The proposed change in the title is more reflective of the provisions contained within the term. The proposed changes will require the respondent to notify the board in writing of employment information as well as changes in such employment and specifies how such reporting must be made to the board. This change is necessary to provide the board with readily available information on employment to allow for comprehensive probation monitoring, including at a respondent's worksite. Further, the proposed



changes clarify who the respondent must notify of the terms and conditions of probation imposed as well as the responsibility of the probationer to ensure that appropriate documentation is submitted to the board confirming compliance with this requirement. This term is also being changed to allow for the consolidation of each of the individual license types.

- Notification of Change(s) in Employment, Name, Address(es) or Phone Number(s): This term is being renamed to better reflect the requirements of the term. Also, this term is being renumbered to ensure better overall flow of the guidelines.
- Restrictions on Supervision and Oversight of Licensed Facilities: This term is being renamed to better reflect the requirements of the term and to specify that it is appropriate only for pharmacist and designated representative licensees. Further this term provides for the consolidation of other existing terms - - No Supervision of Ancillary Personnel and Consultant for Owner or Pharmacist-in-Charge. In the new format, these proposed changes to the term provide optional language that existed in these other terms of probation. This term is also being changed to facilitate consolidation of the probationary terms for all of the individual license types. This term also sets forth the requirement that approval to work as a pharmacist-in-charge, designated representative-in-charge, responsible manager or other compliance supervisor can only be done upon approval by the board and that such approval is site specific. (Page 31)
- Reimbursement of Board Costs: This term is being renumbered. Also, a new option is being created that will allow a respondent to submit payments to the board pursuant to an approved plan, and would specify that payment in full must be completed at least one year prior to the end of probation. This option allows the board greater flexibility to address a respondent's financial concerns that may arise. Further, the proposed change removes the language stating that the filing of bankruptcy does not relieve the respondent of the requirement to pay the board. This change is necessary to recognize that the board cannot determine what debt is released during the filing of bankruptcy.
- Probation Monitoring Costs: This term is being renumbered.
- Status of License: This term is being renumbered and modified to facilitate consolidation of the probationary terms for all of the individual license types.
- License Surrender While of Probation: This term is being renumbered and modified to facilitate consolidation of the probationary terms for all of the individual license types.
- Certification Prior to Resuming Work: For purposes of consolidation, this term is being moved. Further, the term now reflects that it is appropriate only for pharmacy technician licensees.
- Notification of Departure: For purposes of consolidation, this term is being moved. Further, this requirement will now apply to all individual licensees, not just pharmacy technicians and designated representatives. This term is necessary to apply to all individual licensees to ensure the board remains apprised of a respondent's location and availability for probation monitoring purposes.
- License Practice Requirement – Tolling: This term is being renumbered and renamed to better reflect the provisions contained therein. Proposed changes are necessary to facilitate consolidation of the individual license types and well as

provide more clarity on what information the board requires to confirm compliance with this provision. Additionally, the optional language is being changed to allow the board greater flexibility in meeting the employment needs of a respondent while balancing the board's probation monitoring needs to ensure that necessary rehabilitation occurs. A new option is also created specific for intern pharmacists to reflect the experiential requirements of pharmacy education.

- Violation of Probation: This term is being renumbered and the provision allowing for automatic revocation is being removed.
- Completion of Probation: This term is being renumbered.

### **Optional Conditions of Probation (Page 34 – 58)**

The board is proposed the following changes:

- Suspension: Although the board routinely includes suspension as part of the discipline imposed, it does not have a separate optional term of probation. This proposed change will incorporate the board's current practice of suspending a respondent as part of the penalty imposed. The language provided is similar to suspension language used to define the term and specify the activities that respondent is prohibited from performing during the period of suspension. This term provides clarity to the respondent and a better definition and guidance on how to comply with the term. Further, this term provides optional language that is designed to provide the board with greater flexibility when determining the appropriate penalty. This optional term would prohibit a respondent from leaving California for any period greater than 10 days and sets forth the reporting requirements for compliance with this term. The ten day travel requirement is required as a probationer cannot be monitored for compliance if they are outside of California. Ten days is also used throughout the disciplinary guidelines as a standard reporting requirement.
- Restricted Practice: This term is being renumbered for purposes of consolidation and language would be added to authorize a designee to perform board functions. In addition, this term would be revised to include a requirement for submission of written proof of compliance. It would also add an option to include requirements for "satisfactory proof" of compliance to the Board that may include written acknowledgment of compliance with the restriction on practice from a licensee's direct supervisor, pharmacist in charge, and owner or owner representative.
- Pharmacist Exam: This term is being renumbered and a notation that this term shall be used only for pharmacists is being provided. The phrase "he or she" is being replaced with [he/she] to allow the decision to select the gender of the respondent. The suspension language contained within this term is also being modified to clarify the prohibited functions during any such suspension. Further, if the respondent is required to complete 16 semester units of remedial education, the board is clarifying that proof of completion of such coursework must be provided.
- Clinical Diagnostic evaluation: This term is being renumbered and renamed from the current term "Mental Health Examination." In addition guidance provided to the users is being updated to clarify the conditions when inclusion of this term is appropriate. This term also makes conforming changes to the language of the term



and is being modified to allow for consolidation of the probationary terms for all of the individual license types. The board is specifying that upon receipt or recommendation by the evaluator, additional restrictions or conditions on respondent's practice may be imposed.

Further, in consideration of the Substance Abuse Coordination Committee's (SACC) uniform standards, option 1 is being added to include that the respondent is suspended from practice until specified conditions are met including:

- Completion of the evaluation,
- Submission of the evaluator's report, demonstrating that the respondent is safe to return to practice,
- The board has determined that respondent is safe to return to practice and under what conditions.
- Respondent received written notice that practice may resume.

This optional term also sets forth the that the licensee would be required to cause the evaluator to submit to the Board a written clinical diagnostic evaluation report within 10 days from the date the evaluation was completed, unless an extension, not to exceed 30 days, is granted to the evaluator by the Board. Suspension language is also being provided to advise the respondent of the activity that is prohibited during any such suspension. The timelines required within this section are a requirement of SACC uniform standards, option 1.

Option 2 is being renumbered and recast to facilitate consolidation of the probationary terms for each of the individual license types. Further, the suspension language is being modified to clarify those activities that are prohibited during any such suspension.

Option 3 is being renumbered and recast to facilitate consolidation of the probationary terms for each of the individual license types. The optional term is to be rewritten to better define each of the criteria that must be satisfied prior to a respondent being allowed to return to work. The suspension language is being modified to clarify those activities that are prohibited during any such suspension.

- Psychotherapy: This term is being renumbered and the guidance provided to the guideline users is being updated to clarify the conditions when inclusion of this term is appropriate. The suspension language is being modified to clarify those activities that are prohibited during any such suspension.
- Medical Evaluation: This term is being renumbered and modified to facilitate consolidation of the probationary terms for each of the individual license types. The suspension language is being modified to clarify those activities that are prohibited during any such suspension. The same types of changes are being made to the two options provided in this term.

- **Pharmacists Recovery Program (PRP):** The guidance provided to the users of these guidelines is being updated to clarify the conditions when inclusion of this term is appropriate. This term is also being modified to clarify what actions a respondent must take to comply with the term as well as the timeline for completion. (Currently the board has received complaints that this term lacks specificity and has caused confusion for licensees on the board's expectations for compliance.) The term is also clarifying that the respondent must comply with the treatment contracts established by the PRP and that failure to comply will result in the automatic suspension of practice by the respondent. The suspension language is being modified to clarify those activities that are prohibited during any such suspension. The option language is being modified to clarify the intent of the option, which is to allow the PRP the ability to monitor a respondent under specified conditions prior to the respondent successfully completing the PRP.
- **Drug and Alcohol Testing:** This term is being renumbered and renamed to better reflect the scope of the term and the guidance provided to the users of these guidelines is being updated to clarify the conditions when inclusion of this term is appropriate.

The Board proposes amendments in consideration of the SACC's uniform standards. The proposed amendments specify that the licensee is required to submit to and pay for any random and directed biological fluid or hair sample, breath alcohol or any other mode of testing required by the Board. Respondent is required to make daily contact as directed by the Board to determine if he or she must submit to drug testing. The licensee would be required to have the biological test performed on the same day that he or she is notified that a test is required. If a licensee tests positive for a banned substance, the licensee would be required to be suspended from practice, and may not practice unless and until notified by the Board. The proposed amendments specify that all alternative drug testing sites due to vacation or travel outside of California must be approved by the Board prior to the vacation or travel. The suspension language has also been changed to clarify those activities that are prohibited during any such suspension.

- **Abstain from Drugs and Alcohol:** This term is being renumbered and portions rewritten to clarify exceptions to the prohibition. This term also explicitly states that the respondent must also abstain from use of illicit drugs. (Page 47)
- **Prescription Coordination and Monitoring of Prescription Use:** The guidance provided to the users of these guidelines is being updated to clarify the conditions when inclusion of this term is appropriate. This term is also being modified to allow for consolidation of the probationary terms for each of the individual license types and to clarify that the board may identify a designee to perform board functions. The suspension language has been changed to clarify those activities that are prohibited during any such suspension.
- **Community Service.** This term is being renumbered and modified to facilitate consolidation of the probationary terms for each of the individual license types. In addition, the term specifies that proof of completion must be provided and clarifies that the board may allow a designee to perform board functions.
- **Restitution:** This term is being renumbered.

- Remedial Education: This term is being renumbered and to clarify that approval of the coursework is required. The phrase “his or her” is being replaced with [his/her] to allow the decision to reflect the gender of the respondent.
- Pharmacy Self-Assessment Mechanism: This term is being removed as it is no longer provided by the National Association of Boards of Pharmacy.
- Intern Pharmacist Experience: This term is being renumbered and a notation is being added to indicate that the term is only appropriate for intern pharmacists. In addition, the timeframe to complete the requirement has been extended to allow respondent sufficient time to submit proof to the board.
- Supervised Practice: This term is being renumbered and a notation is being added to indicate this term only applies to pharmacists, pharmacist interns and designated representatives. This term is being recast to better describe the requirements of the term and to provide better guidance to the respondent on the board’s expectations. This term defines what constitutes a violation of probation and the suspension language has been changed to clarify those activities that are prohibited during any such suspension.
- No Supervision of Ancillary Personnel: This term is being consolidated into another term, “Restrictions on Supervision and Oversight of Licensed Facilities” and is therefore no longer needed.
- No Ownership or Management of Licensed Premises: The name of this term is being modified to better reflect the context of the restriction. One grammatical change is being made as well.
- Separate File of Controlled Substances: The name of this term is being modified to better reflect the content of the requirement and a conforming change is being made to ensure consistency of the layout of the document.
- Report of Controlled Substances: A conforming change is being made to ensure the consistency of the document. In addition this term is being modified to allow the board greater flexibility in determining the frequency of reports that must be submitted. This term is also clarifying that the board allows the use of a designee to complete functions on its behalf.
- No Access to Controlled Substances: This section is being changed to incorporate all scheduled drugs.
- Criminal Probation/Parole Reports: This term is being modified to replace the phrase “his or her” with [his/her] to allow for the respondent’s gender to be accurately reflected in the decision.
- Consultant for Owner or Pharmacist-in-Charge: This term is being consolidated into another term, “Restrictions on Supervision and Oversight of Licensed Facilities” and is therefore no longer required.
- Tolling of Suspension: This term is being removed as its provisions will be contained in term 15.
- Surrender of DEA Permit: This term is being renumbered and a notation is being added to clarify that this term should only be used for pharmacists, advanced practice pharmacists and pharmacist interns. This term is being modified to replace the phrase “his or her” with [his/her] to allow for the respondent’s gender to be accurately reflected in the decision. In addition, this term clarifies what acts are prohibited under this term and the two optional terms are being numbered.

- **Ethics Course:** This term is being renumbered and a notation is being made to clarify that this term should only be used for pharmacists, advanced practice pharmacists and pharmacist interns. In addition, this term is being modified to accurately reflect the course requirements as detailed in Title 16, California Code of Regulations Section 1773.5 and specifies that proof of enrollment and completion must be provided to the board. The term also specifies that failure to provide such proof will be considered a violation of probation.
- **Facilitated Group/Recovery and/or Support Meetings:**

The Board proposes the addition of this additional probation condition in consideration of the SACC's uniform standards.

Within thirty (30) days from the effective date of the decision, a licensee would be required to submit to the Board or its designee for prior approval the name of one or more meeting facilitators. The term advises the respondent of the determining factors the board will be considering when determining the frequency of the meetings. When determining the type and frequency of required facilitated group support meeting attendance, the Board would be required to give consideration to: (1) the licensee's history, (2) the documented length of sobriety/time that has elapsed since substance abuse, (3) the recommendation of the clinical evaluator, (4) the scope and pattern of use, (5) the licensee's treatment history, and (5) the nature, duration, and severity of substance abuse. The licensee would be required to submit verified documentation of attendance with each quarterly report. The licensee would be required to continue attendance in such a group for the duration of probation unless notified by the Board that attendance is no longer required. The thirty day requirement is used to maintain consistency within the guidelines.

- **Attend Substance Abuse Recovery Relapse Prevention and Support Groups.** This term is not new, but is being moved from a previous section of the guidelines and could now apply to any individual license.
- **Work Site Monitor:** This term is not new, but is being moved from a previous section of the guidelines and could now apply to any individual license. In addition guidance is being provided to users of the guidelines for when inclusion of this term is appropriate.

In addition, this term is being modified in consideration of the SACC's uniform standards. This term requires a licensee to complete required consent forms and sign an agreement with the worksite monitor and the Board regarding the licensee's and the monitor's requirements and reporting responsibilities. Additionally, the proposed amendments require the monitor to sign an affirmation that he or she has reviewed the terms and conditions of the licensee's probationary order and agrees to monitor the licensee as set forth by the Board. The proposed amendments specify that the monitor is required to have face-to-face contact with the licensee in the work environment on a frequent basis as determined by the Board, but at least once per week. The monitor is required to interview other staff in the office regarding the licensee's behavior, if applicable. The monitor is required to review the licensee's work attendance and

behavior. The monitor would be required to orally report any suspected substance abuse to the Board and the licensee's employer within one (1) business day of occurrence. The monitor would be required to submit a written report to the Board within two business days of occurrence. The monitor would be required to complete and submit a written report monthly or as directed by the board. The report would be required to include: the licensee's name; license number; monitor's name and signature; monitor's license number; worksite location(s); dates licensee had face-to-face contact with monitor; worksite staff interviewed, if applicable; attendance report; any change in behavior and/or personal habits; any indicators that can lead to suspected substance abuse. This condition would allow the Board to monitor the competency of Respondent by use of a fellow practitioner. It should be used in those cases involving substance abuse. The required level of monitoring needs to be clearly defined relative to the necessity for the presence of the monitor. Conforming changes are also being made to the optional language for respondents enrolled or required to enroll in the PRP. The face-to-face contact and reporting requirements are set in consideration of SACC's uniform standards, option 7.

**Proposed Changes to the Terms of Probation for Premises Licensees (Pharmacy, Wholesaler, Sterile Compounding Pharmacy, Third-Party Logistics Provider, Veterinary Food-Animal Drug Retailer, Hypodermic Needle and Syringe and Clinic) (Page 83)**

Many of the changes proposed are to provide clarification and allow for easier reading and consistency.

The introductory paragraph was reworded to clarify that a minimum three years' probation period is appropriate in most cases. (Page 83)

**Categories of Violations and Recommended Penalties (Page 83-84)**

The proposed changes would better define the grounds for discipline as well as types of licensees that may be subject to discipline. In addition proposed changes are incorporated to explain the structure under each category as well as how the board should use the information provided. This will assist users in following the format of the Disciplinary Guidelines and serve as a tool to assist in the penalties imposed as part of a disciplinary action.

**Category I (Page 84)**

The majority of the changes reflected in this section are to remove the titles associated with each section of law. (These titles were designed to allow the reader brief insight into the requirements detailed in the specific sections, however the titles have no force of law.). In place of this list of codes, the board is proposing incorporation of summaries of each of the statutes into narrative language that better describes the nature of violations that would constitute such discipline and includes violations for improper compounding of

drug products. (Page 84) These changes are necessary to provide for a more useful application. The board notes that the current list of statutes provided is difficult for someone to use that is not familiar with Pharmacy Law and is provided in an overwhelming fashion that defeats the purpose of providing the users with a convenient way of determining the board's recommended penalties. The proposed changes will more easily aid the user in the use of the Disciplinary Guidelines.

The minimum penalty for this category of violation is changing to two years' probation. The minimum penalty was increased from one year to two years because one year of probation monitoring is not sufficient to properly demonstrate that complete rehabilitation has occurred.

The description for category one reflects that such violations are less serious than Categories II-IV violations.

#### Category II (Page 89-90)

The majority of the changes reflected in this section are to remove the titles associated with each section of law. (These titles were designed to allow the reader brief insight into the requirements detailed in the specific sections, however the titles have no force of law.). In place of this list of codes, the board is proposing incorporation of summaries of each of the statutes into narrative language that better describes the nature of violations that would constitute such discipline and includes violations for improper compounding of drug products. (Page 90) These changes are necessary to provide for a more useful application. The board notes that the current list of statutes provided is difficult for someone to use that is not familiar with Pharmacy Law and is provided in an overwhelming fashion that defeats the purpose of providing the users with a convenient way of determining the board's recommended penalties. The proposed changes will more easily aid the user in the use of the Disciplinary Guidelines.

#### Category III (Page 94-95)

The majority of the changes reflected in this section are to remove the titles associated with each section of law. (These titles were designed to allow the reader brief insight into the requirements detailed in the specific sections, however the titles have no force of law.). In place of this list of codes, the board is proposing incorporation of summaries of each of the statutes into narrative language that better describes the nature of violations that would constitute such discipline and includes violations for improper compounding of drug products. (Page 95) These changes are necessary to provide for a more useful application. The board notes that the current list of statutes provided is difficult for someone to use that is not familiar with Pharmacy Law and is provided in an overwhelming fashion that defeats the purpose of providing the users with a convenient way of determining the board's recommended penalties. The proposed changes will more easily aid the user in the use of the Disciplinary Guidelines.



## Category IV (Page 97)

The majority of the changes reflected in this section are to remove the titles associated with each section of law. (These titles were designed to allow the reader brief insight into the requirements detailed in the specific sections, however the titles have no force of law.). In place of this list of codes, the board is proposing incorporation of summaries of each of the statutes into narrative language that better describes the nature of violations that would constitute such discipline. These changes are necessary to provide for a more useful application. The board notes that the current list of statutes provided is difficult for someone to use that is not familiar with Pharmacy Law and is provided in an overwhelming fashion that defeats the purpose of providing users with a convenient way of determining the board's recommended penalties. The proposed changes will more easily aid the user in the use of the Disciplinary Guidelines.

### **Model Disciplinary Language – Premises Licensees (Pages 98-100)**

The board is proposed the following changes:

#### Revocation

This section is being modified to remove the word “owner.” A definition of respondent is being added in a separate section to specify the intended licensee. As such this word would no longer be needed. Further the term is being rewritten to clarify that the premises is responsible for arranging the destruction, transfer, sale or storage of all dangerous drugs or devices. In addition, this term specifies that any transfer of records shall be to a premises licensed and approved by the board. (Page 98)

#### Suspension

This section is being modified to allow for the selection of the appropriate license type.

#### Issuance of Probationary License

This term is being modified to allow for the selection of the appropriate license type.

#### Surrender

This section is being modified to remove the word “owner. In addition the phrase “he or she” is being replaced to allow for an accurate reflection of the gender of the owner in the decision. In addition, this term specifies that any transfer of records shall be to a premises licensed and approved by the board (Page 99).

Option 1 is being added for pharmacy respondents to ensure the continuity of patient care.

#### Adoption of Stipulation

The board is proposing removal of this language as it is in conflict the standard language used by the Office of the Attorney General who is responsible for drafting stipulated settlements for the board.

### **Standard Conditions Listing (Page 101)**

The board is proposing to change titles or numbering to reflect changes and consolidation of terms as well as to reflect new terms that will be incorporated.

### **Optional Conditions Listing (Page 101)**

The board is proposing changes to titles or numbering to reflect changes and consolidation of terms as well as to reflect new terms that will be incorporated. New terms include a requirement to destroy dangerous drugs and/or dangerous devices as well as to establish an ownership prohibition. (Page 101)

### **Standard Conditions: To Be Included in All Probations (Pages 101-105)**

The board is proposed the following changes:

- **Definition: Respondent:** This is a new term being incorporated to provide a definition of a respondent as it relates to a business license. This term will provide clarity to users of the guidelines and takes into consideration the various types of business ownerships structures that are authorized to seek and obtain licensure from the board.
- **Obey All Laws:** This term is being renumbered and is being modified to remove the word “owner” as a definition of respondent is being added in a separate term to specify the intended licensee. As such this word would not be needed. In addition the word “dangerous” is being added to clarify the reference to the term drug consistent with Business and Professions Code section 4022.
- **Report to the Board:** This term is being renumbered and is being modified to remove the word “owner” as a definition of respondent is being added in a separate term.
- **Interview with the Board:** This term is being renumbered and is being modified to remove the word “owner” as a definition of respondent is being added in a separate term.
- **Cooperate with Board Staff:** This term is being renumbered and modified to clarify what activities are required in cooperation with the board to ensure the respondent has a clear understanding of the board’s expectations with respect to this term.
- **Reimbursement of Board Costs:** This term is being renumbered and is being modified to remove the word “owner” as a definition of respondent is being added in a separate term. Also, a new option is being created that will allow a respondent to submit payments to the board pursuant to an approved plan, and would specified that payment in full must be completed at least one year prior to the end of probation. This option allows the board greater flexibility to addressing a respondent’s financial concerns that may arise.
- **Probation Monitoring Costs:** This term is being renumbered and is being modified to remove the word “owner” as a definition of respondent is being added in a separate term.
- **Status of License:** This term is being renumbered and is being modified to remove the word “owner” as a definition of respondent is being added in a separate term. Further a provision that previously specified that the board would retain jurisdiction

is being removed as it is no longer needed. Elements of that provision are incorporated elsewhere in these guidelines.

- License Surrender While on Probation: This term is being renumbered and is being modified to remove the word “owner” as a definition of respondent is being added in a separate term.

This term will specify that respondent cannot apply for a new license for a period of three years from the effective date of the surrender as well as establish a requirement that any costs owed will be reimbursed prior to acceptance of the surrender. (Page 103)

In addition, additions will provide guidance to the user of these guidelines on when inclusion of the option provided is appropriate and a timeframe for compliance with the option is also established. This option will also specify that the transfer of records must be to a premises licensed and approved by the board. (Page 103)

- 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.
- Notice to Employees: This term is being renumbered and is being modified to remove the word “owner” as a definition of respondent is being added in a separate term to provide clarity as such this word is not needed.
- Owners and Officers: Knowledge of the Law: This term is being renumbered.
- Premises Open For Business: This is a new term that requires a business to remain open for a specified period of time. The language allows flexibility to the board in determining the minimum number of hours per calendar month the business must be open and sets forth the reporting requirements for this term. This term is necessary to ensure the board has sufficient opportunity to perform its monitoring functions consistent with the board’s consumer protection mandate.
- Posted Notice of Probation: This term is being renumbered and is being modified to remove the word “owner” as a definition of respondent is being added in a separate definitional term. In addition, this term now provides for the timeframe for compliance with the posting requirements. Inclusion of this information provides the respondent with notice of the board’s expectation of compliance with this term.
- Violation of Probation: This term is being renumbered and is being modified to remove the word “owner” as a definition of respondent is being added in a separate definitional term. In addition the provision allowing for the automatic revocation of a license for violations of probation is being removed as it is no longer relevant since automatic termination provisions are no longer used in the guidelines.
- Completion of Probation: This term is being renumbered.

## **Optional Conditions of Probation (Pages 106-107)**

The board is proposed the following changes:

- **Suspension:** Although the board routinely includes suspension as part of the discipline imposed, it currently does not have a separate optional term of probation. This proposed change will incorporate the board's current practice of suspending a respondent as part of the penalty imposed.
- **Community Service:** This term is being renumbered and is being modified to remove the word "owner" as a definition of respondent is being added in a separate term.
- **Restitution:** This term is being renumbered and is being modified to remove the word "owner" as a definition of respondent is being added in a separate term.
- **Separate File of Records:** The name of this term is being modified to better reflect the content of the requirement and a conforming change is being made to ensure consistency of the layout of the document. This term is being renumbered and is being modified to remove the word "owner" as a definition of respondent is being added in a separate term.
- **Report of Controlled Substances:** This term is being modified to allow the board greater flexibility in determining the frequency of reports that are required to be submitted. This term is also clarifying that the board allows the use of a designee to complete functions on its behalf. In addition, this term is being renumbered and is being modified to remove the word "owner" as a definition of respondent is being added in a separate term.
- **Surrender of DEA Permit:** This term is being renumbered and the word "pharmacy" is being removed as an inclusive definition of respondent is being added in a separate term.
- **Posted Notice of Suspension:** This term is being renumbered and the word "owner" is being removed. An inclusive definition of respondent is being added in a separate term, so the word is no longer needed. In addition, the board specifies the timeframe for posting the notice to provide the respondent with clear direction on the board's expectation for compliance with this term. This term would also specify that failure to comply with this requirement will be considered a violation of probation.
- **Destruction of Dangerous Drugs and/or Dangerous Devices:** This is a new term to be used with the violations included misbranded or adulterated drugs. This term establishes a requirement for the respondent to arrange for the destruction of such drugs and/or devices as specified and requires the respondent to provide written proof of the destruction. (Page 107)

In addition, this term establishes an option for the destruction of drugs also when the integrity, quality and strength of a compounded drug is at issue. (Page 107)

- **No Additional Ownership or Management of Licensed Premises:** This is a new term to prohibit the respondent for acquiring additional ownership, legal or beneficial interest in another licensed premises as specified. (Page 107)

## Conforming Changes

To ensure consistent use of the phrase “dangerous drugs and/or dangerous devices” is incorporated throughout the document where appropriate.

## Factual Basis/Rationale

Business and Professions Code section 315 generally authorizes the board to develop specific standard in dealing with substance-abusing licensee.

Business and Professions Code section 315.2 generally authorizes the board to suspend a licensee on probation from the practice of pharmacy if the licensee tests positive for any substance that is prohibited under the terms of the licensee’s probation or diversion program.

Business and Professions Code section 315.4 generally authorizes the board to suspend a licensee on probation from the practice of pharmacy for major violations or when the board orders a licensee to undergo a clinical diagnostic evaluation.

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations pertaining to the practice of pharmacy and the administration of Chapter 9, Division 2.

Business and Professions Code section 4300 authorizes the board to discipline a licensee as well as refuse to issue a license to an applicant.

Business and Professions Code section 4301 authorizes the board to take action against a licensee for unprofessional conduct as defined.

Government Code section 114200.20 authorizes the board to adopt regulations to govern an adjudicative proceeding.

Government Code section 11425.50(e) prohibits a penalty from being based upon a guideline unless the guideline has been adopted as a regulation.

California Code of Regulations section 1760 incorporates by reference the Disciplinary Guidelines.

The Board regulates the practice of pharmacy and the movement of prescription-required drugs and devices from the time the drugs leave the manufacturing site to the time a drug or device is dispensed to the patient. To achieve this mission, the Board has 20 major licensing classifications with separate requirements that must be satisfied prior to the issuance of a license, as well as an impressive enforcement unit. The Board conducts its own inspections and investigations of licensees and applicants.

The Board currently has over 138,000 licensees and received almost 19,000 applications in FY 2014/15. The Board initiated 2,650 complaint investigations and completed 2,511 investigations in FY 2014/2015. As a result of these investigations, 325 cases were referred to the Office of the Attorney General (AG). In addition to AG referrals, the Board issued 1,176 citations and fines.

The Disciplinary Guidelines are necessary to assist the board, deputy attorney generals and administrative law judges to identify and impose appropriate disciplinary action against a licensee or applicant who violates the laws governing the practice of pharmacy. Additionally, uniform and specific standards are required by SB-1441 (Ridley-Thomas, Chapter 548, Statutes of 2008).

The board has held a series of information hearings on the proposed changes and has either considered and or incorporated changes based on the testimony provided as part of these informational hearings.

#### Underlying Data

1. SB-1441 (Ridley-Thomas, Chapter 548, Statutes of 2008)
2. Uniform Standards Regarding Substance-Abusing Healing Arts Licensees
3. Enforcement and licensing statistics.

#### Business Impact

The board does not believe that this regulation will have a significant adverse economic impact on businesses as it only affects individuals and those businesses that are disciplined for serious violations of pharmacy law.

#### Economic Impact Assessment

This regulatory proposal will have the following effects:

- It will not create or eliminate jobs within the State of California because the proposed regulation updates an existing regulation and only affects those licensees being disciplined by the Board of Pharmacy for violating pharmacy law.
- It will not create new business or eliminate businesses within the State of California because the proposed regulation updates an existing regulation and only affects those licensees being disciplined by the Board of Pharmacy for violating pharmacy law.
- It will not affect the expansion of businesses currently doing business within the State of California because the proposed regulation updates an existing regulation and only affects those licensees being disciplined by the Board of Pharmacy for violating pharmacy law.



- This regulatory proposal does affect the health and welfare of California residents because the proposed regulation improves and standardizes the disciplinary guidelines affecting those licensees who violate pharmacy law. By standardizing the disciplinary guidelines, the Board will be better equipped to ensure licensees whose licenses are restricted pursuant to administrative action complete appropriate rehabilitation and prevent further harm to the public consistent with the Board's consumer protection mandate.
- This regulatory proposal does affect worker safety because the proposed regulation improves and standardizes the disciplinary guidelines affecting those licensees who violate pharmacy law. By standardizing the disciplinary guidelines, the Board will be better equipped to ensure licensees whose licenses are restricted pursuant to administrative action complete appropriate rehabilitation and prevent further harm to the public consistent with the Board's consumer protection mandate.
- The regulatory proposal does affect the state's environment because the proposed regulation improves and standardizes the disciplinary guidelines affecting those licensees who violate pharmacy law. By standardizing the disciplinary guidelines, the Board will be better equipped to ensure licensees whose licenses are restricted pursuant to administrative action complete appropriate rehabilitation and prevent further harm to the public consistent with the Board's consumer protection mandate.

### Specific Technologies or Equipment

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

### Consideration of Alternatives

The only alternative to this proposal is to continue to use the existing Disciplinary Guidelines. This alternative is not reasonable given the changes that have occurred in pharmacy law over the past eight years and the requirements of uniform and specific standards. In addition, it would be contrary to the board's public protection mandate to not include proposed changes designed to allow the board better monitoring of licensees on probation with the board.

No reasonable alternative to amending 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 affected private persons than the repeal of the regulation.