

**Board of Pharmacy**  
**Initial Statement of Reasons**

Subject Matter of Proposed Regulation: Disciplinary Guidelines

Sections Affected: Amend 1760

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, 1/2001, 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ensure the consistent use of titles and terms between the Disciplinary Guidelines and the Pharmacy Law Book, to remove outdated and unnecessary terms and conditions of probation and to incorporate new changes necessary to ensure rehabilitation of the licensees on probation to ensure the board's ability to meet its consumer protection mandate.

A summary of the proposed changes is below.

**Title Page**

Update the contact information for the board.

**Table of Contents**

Replace the term "exemptee" with designated representative. In 2004, Senate Bill 1307 (Chapter 857, statutes of 2004) replaced the term "exemptee" with "designated representative" in pharmacy law, effective January 1, 2006. In addition the page numbers to be updated to reflect the new location of items.

**Introduction**

Changes are proposed to provide clarification and allow for easier reading and consistency.

## **Factors to be Considered in Determining Penalties**

Changes are proposed to incorporate the various levels of previous action the board may have taken against a licensee and now will require the board to also consider aggravating evidence, as well as compliance with parole or probation, when determining whether the minimum, maximum or an intermediate penalty should be imposed.

## **Mitigating Evidence**

Changes are proposed to this section to further define and clarify examples of appropriate evidence a respondent may submit to demonstrate rehabilitative efforts and competency.

## **Terms of Probation – Pharmacist/Intern Pharmacist**

### Categories of Violations and Recommended Penalties

The proposed changes 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 the penalties imposed as part of a disciplinary action.

### Category 1

The majority of the changes reflected in this section are to titles associated with each section of law. These titles are designed to allow the reader brief insight into the requirements detailed in the specific sections. These titles have no force of law. However, at least one published version of the pharmacy law book, as well as the compilation of pharmacy laws provided on the board's Web site, contains brief titles to assist users. These changes are necessary to aid the user in the use of the Disciplinary Guidelines.

B&PC 4052.1, 4052.5 and 4052.7 are added to category 1 violations as a result of recodification of section 4052 included in Assembly Bill 2408 (Chapter 777, Statutes of 2006).

B&PC 4055 was not included in the previous revision of the Disciplinary Guidelines, rev. 1/2001.

B&P 4068 was added to statute in Section Bill 1913 (Chapter 695, Statutes of 2004) and is now being included.

B&PC 4102 was repealed in Assembly Bill 586 (Chapter 501, Statutes of 2001) and therefore is being removed.

B&PC 4146 was repealed in Senate Bill 1159 (Chapter 608, Statutes of 2004) and therefore is being removed.

CCR 1712 was added to regulation effective 10/2005 and is being added.

CCR 1727 was repealed effective 10/2005 and therefore is being removed.

CCR 1746 was added to regulation effective 12/2004 and is being added.

CCR 1751 – 1751.12 was added to regulation effective 10/2004 and is being added.

H&SC 11124 was repealed in Senate Bill 2026 (Chapter 1013, Statutes of 2002) and is being removed.

H&SC 111225 – 111655 are being moved from the “Miscellaneous – Health and Safety Code, Title 22” to be consolidated with all other Health and Safety Code references.

CFR 1304.11 was inadvertently not included in previous versions of the Disciplinary Guidelines

CFR 1304.18 was renumbered to CFR 1304.21.

CFR 1305.03 – 1305.16 are changing as a result of renumbering that occurred in 2005 to include allowing electronic orders on controlled substances. Changes to relevant sections of the CFR are necessary to reflect the renumbering that occurred as part of this process.

16 CFR 1700.1 to 1707.15 is being moved from “Miscellaneous – Federal Regulations” to be consolidated with all other Code of Federal Regulations references.

## Category II

The majority of the changes reflected in this section are to titles associated with each section of law. These titles are designed to allow the reader brief insight into the requirements detailed in the specific sections. These titles have no force of law. However, at least one the published version of the pharmacy law book, as well as the compilation of pharmacy laws provided on the board’s Web site, contains brief titles to assist users. These changes are necessary to aid the user of the Disciplinary Guidelines.

B&PC 650, 650.1 and 651 were not included in the previous version of the

"Disciplinary Guidelines rev 1/2001."

Section 4125 was added to statute in Senate Bill 1399 (Chapter 677, Statutes of 2000) and is now being included.

B&PC 4169(a)(1) was amended in Senate Bill 1476 (Chapter 658, Statutes of 2006). This reference was not included in the previous version of the "Disciplinary Guidelines rev 1/2001."

CCR 1717.2 was repealed effective March 2007.

CCR 1793.1 – 1793.7 are now being listed as individual references.

CCR 1793.8 allows for a specially trained pharmacy technician to check the work of another technician in the acute care pharmacy setting and was added to regulation effective January 2007.

H&SC 11123, 11124, 11125, 11128, 11129, 11130 & 11131 were repealed in Senate Bill 2026 (Chapter 1013, Statutes of 2002) and are being removed.

H&SC 150205 was added to statute in SB 798 (Chapter 444, Statutes of 2005) to authorize a county to establish, by local ordinance, a repository and distribution program for purposes of distributing surplus unused medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies.

### Category III

The majority of the changes reflected in this section are to titles associated with each section of law. These titles are designed to allow the reader brief insight into the requirements detailed in the specific sections. These titles have no force of law. However, at least one published version of the pharmacy law book, as well as the compilation of pharmacy laws provided on the board's Web site, contains brief titles to assist users. These changes are necessary to aid the user of the Disciplinary Guidelines.

B&PC 4034 establishes the pedigree requirement and was added into statute in Senate Bill 1307 (Chapter 857, Statutes of 2004).

B&PC 4085 makes it unlawful to remove, sell, or dispose of embargoed drugs and was added into statute in Senate Bill 1307 (Chapter 857, Statutes of 2004).

B&PC 4059.5 establishes requirements for the acquisition and disposition of dangerous drugs and was added into statute in Senate Bill 1307 (Chapter 857, Statutes of 2004).

B&PC 4169(a)(2) to 4169(a)(5) defines prohibited acts and was amended in Senate Bill 1476 (Chapter 658, Statutes of 2006). This reference was not included in the previous version of the "Disciplinary Guidelines rev 1/2001."

B&PC 4380 prohibits the resale of preferentially priced drugs and provides some exceptions. This reference was not included in the previous version of the "Disciplinary Guidelines rev 1/2001."

CCR 1707 establishes the waiver requirements to allow for off-site storage of records and became effective in October 2000.

CCR 1771 – 1774 are now being listed as individual references.

H&SC 11122 was repealed in Senate Bill 2026 (Chapter 1013, Statutes of 2002) and is being removed.

H&SC 11167.5 allows for an oral or electronic prescription for Schedule II controlled substances for specified patients and was not included in the previous version of the "Disciplinary Guidelines, rev. 1/2001."

H&SC 111295 was inadvertently not included in the previous version of the Disciplinary Guidelines.

H&SC 111300 was inadvertently not included in the previous version of the Disciplinary Guidelines.

H&SC 111305 was inadvertently not included in the previous version of the Disciplinary Guidelines.

H&SC 111440 was inadvertently not included in the previous version of the Disciplinary Guidelines.

H&SC 111445 was inadvertently not included in the previous version of the Disciplinary Guidelines.

H&SC 111450 was inadvertently not included in the previous version of the Disciplinary Guidelines.

#### Category IV

The majority of the changes reflected in this section are to titles associated with each section of law. These titles are designed to allow the reader brief insight into the requirements detailed in the specific sections. These titles have no force of law. However, at least one published version of the pharmacy law book, as well as

the compilation of pharmacy laws provided on the board's Web site, contains brief titles to assist users. These changes are necessary to aid the user of the Disciplinary Guidelines.

### **Model Disciplinary Language – Pharmacist/Intern Pharmacist**

**Revocation:** This section is being consolidated to include revocations for single and multiple causes under a single term, as the penalty is the same.

**Suspension:** This section is being expanded to better define the parameters of the suspension and specifies that failure to comply with the suspension will be considered a violation of probation.

**Standard Stay/Probation Order:** This section is clarifying that a license is revoked, but the revocation stayed.

**Issuance of Probationary License:** The changes in this section are for clarification only and do not establish new requirements.

**Surrender:** The changes specify that surrender of the license constitutes the imposition of discipline and specifies general criteria for reinstatement and makes other clarifying changes.

**Public Reprimand:** The proposed language now specifies that the respondent is required to report the reprimand as a disciplinary action.

**Adoption of Stipulation:** Change is to correct the reference to the Office of the Attorney General.

**Standard Conditions Listing:** Changes to titles to ensure consistency and clarification.

**Optional Conditions Listing:** Changes to titles to ensure consistency and clarification and include new terms that will be incorporated.

### **Standard Conditions: To Be Included in All Probations**

1. **Obey all Laws:** Specifies that failure to comply with the suspension will be considered a violation of probation.
2. **Reporting to the Board:** Clarifies the reporting requirement.
3. **Interview with the Board:** Clarifies the language and specifies that failure to appear at two or more scheduled interviews will be considered a violation of probation.
4. **Cooperate with board Staff:** Grammatical changes only.
5. **Continuing Education:** Specifies that the respondent must provide proof to the board or now its designee.

6. Notice to Employers: Clarifies 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 requirement. In addition, changes specify that failure to comply will be considered a violation of probation.
7. No Supervision of Interns, Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge or Serving as a Consultant: The proposed changes will now also prohibit a respondent from serving as a designated representative-in-charge or a consultant. In addition, changes specify that failure to comply will be considered a violation of probation.
8. Reimbursement of Board Costs: Clarifies that costs must be paid prior to successful completion of probation and prior board approval must be obtained to deviate from the cost recovery payment schedule established. In addition, changes specify that failure to comply will be considered a violation of probation. An optional component to allow for the automatic revocation of the license of an individual who fails to comply with any directed payment will also be included for board consideration when imposing terms and conditions.
9. Probation Monitoring Costs: Clarifies the requirements and changes it from an annual basis to a schedule as directed by the board. In addition, changes specify that failure to comply will be considered a violation of probation.
10. Status of License: Specifies that failure to comply will be considered a violation of probation and clarifies the intent of the term of probation.
11. License Surrender While of Probation: Specifies that surrender under this term would constitute a record of discipline and will become a part of the respondent's license history with the board. In addition, it clarifies general requirements of surrender and reapplication.
12. Notification of a Change in Name, Residence Address, Mailing Address or Employment Changes: Changes the title of the term, clarifies the requirement and specify that failure to comply will be considered a violation of probation.
13. Tolling of Probation: The changes proposed are designed to clarify the intent of this term. Specifically, a key component during a probationary term is monitoring of the respondent to ensure that necessary changes in his or her practice are occurring to eliminate subsequent violations. This monitoring can only occur if the board has the ability to monitor the respondent while working in pharmacy. The revised term strikes a balance between the needs of the respondent to meet individual employment needs, e.g. part-time work, while allowing the board sufficient opportunity to monitor the respondent at the worksite. An additional option is suggested to allow further flexibility with this term. In addition, changes specify that failure to comply will be considered a violation of probation.
14. Violation of Probation: Clarifies that a notice and opportunity to be heard are not required for those provisions that may lead to automatic termination of the stay. In addition the term is reformatted.
15. Completion of Probation: Clarifies that written notice by the board or its designee is required to fully restore a license upon successful completion.

## Optional Conditions of Probation

All of the Optional Conditions are renumbered.

16. **Restricted Practice:** Provides an option to prohibit the preparation of sterile injectable products during a specified period of probation and states that failure to comply will be considered a violation of probation. This option is necessary for violations that are specific to the preparation of sterile injectable products, especially when the violations are competency based. These products pose an additional, considerable risk to consumers.
17. **Pharmacist Examination:** In 2004, the board changed the licensing examination for pharmacist. These changes were added into statute in Senate Bill 361 (Chapter 539, Statutes of 2003). This term requires updating to reflect the changes in these requirements and clarify the timeframes to comply with the requirement. For licensing purposes, these exams are used by the board to assess the minimum competence of an applicant prior to issuance of a license. Pharmacy law requires that an applicant who fails to pass the examinations as specified is required to complete 16 units of remedial pharmacy education prior to being requalified for the exam. This term now places a similar requirement on certain respondents and specifies that a failure to take and pass the exam within four attempts will require the respondent to complete additional pharmacy education. In addition, changes specify that failure to comply will be considered a violation of probation.
18. **Mental Health Examination:** Replaces “psychiatrist or psychotherapist” with “licensed mental health practitioner.” Clarifies the intent of the term, which is to require a mental health examination by a licensed mental health practitioner and require compliance with any recommendations for treatment made by the mental health practitioner. The term now specifies the timeframes for compliance as well as the frequency of treatment but allows the board’s designee flexibility to modify the frequency as necessary. In addition, the respondent will now be required to provide a copy of the accusation or petition to revoke probation and the decision to the licensed mental health practitioner in advance of an examination, as well as prior to beginning or resuming therapy with a practitioner. The term also clarifies that a respondent will be automatically suspended from practice if the mental health practitioner deems the respondent unable to practice safely as a pharmacist or intern pharmacist. In addition, changes specify that failure to comply will be considered a violation of probation.
19. **Psychotherapy:** Clarifies the process to comply with this term as well as the documentation required to confirm compliance. The term also clarifies that a respondent will be automatically suspended from practice if the mental health practitioner deems the respondent unable to practice safely as a pharmacist or intern pharmacist and defines the parameters of the suspension. In addition, changes specify that failure to comply will be considered a violation of probation.
20. **Medical Evaluation:** Requires the respondent to provide a copy of the accusation or petition to revoke probation and the decision to the approved physician and details the process to comply with this term. The term also

- clarifies that a respondent will be automatically suspended from practice if the physician deems the respondent is unable to practice safely as a pharmacist or intern pharmacist and defines the parameters of the suspension. In addition, changes specify that failure to comply will be considered a violation of probation.
21. Pharmacists Recovery Program (PRP): The title is changed to reflect the name of the rehabilitation program required and established in pharmacy law. In addition, the term now specifies that failure to comply will be considered a violation of probation and states that any confirmed positive test for alcohol or drugs will result in the automatic suspension of practice. This change is necessary to provide the board with the ability to immediately remove a respondent from practice and is essential for consumer protection. The term specifies the parameters for suspension and requires that a respondent pay administrative fees as invoiced by the PRP and that failure to do so will be considered a violation of probation.
  22. Random Drug Screening: Clarifies the intent of the requirement, which is to require the respondent to submit to random drug screenings, a tool used to confirm an individual's sobriety. In addition, the term now specifies that the respondent will need to submit timely documentation of prescription drugs that are legitimately prescribed as part of treatment and that failure to provide such documentation will be considered a violation of probation. The term currently allows for the automatic suspension for a positive drug screen. The proposed language clarifies the conditions under which a suspension would occur and now specifies the parameters for suspension.
  23. Abstain from Drugs and Alcohol Use: Clarifies that a board designee may request documentation of medical treatment on behalf of the board and also states that failure to provide such documentation as requested will be considered a violation of probation. Additionally, the term specifies that a respondent shall not be in the same physical location as individuals who are using illicit substances and that any physical proximity to persons using illicit substances will also be considered a violation of probation.
  24. Prescription Coordination and Monitoring of Prescription Use: This is a new term that should be considered for inclusion in a probationary order when the violations indicate chemical dependency or psychiatric disorders may be a cause for the discipline. This term requires that the respondent provide the board with the name of a single practitioner, as defined, who will be familiar with the respondent's history and will coordinate and monitor any prescriptions for the respondent. The term establishes a reporting requirement and details the procedures for compliance with this section. In addition, should the practitioner at any time determine that the respondent is unable to practice safely or independently; the respondent will be automatically suspended. The parameters for the suspension are also set forth and failure to comply with the suspension will be considered a violation of probation.
  25. Community Service: Clarifies the process by which this term is implemented and specifies that failure to comply will be considered a violation of probation.
  26. Restitution: Specifies that failure to comply will be considered a violation of

probation.

27. Remedial Education: Specifies that a respondent may be required to take an approved examination at the direction of the board or its designee and clarifies that if the respondent does not achieve a passing score, it will be considered a violation of probation. In addition, the term now requires that any failed examination will result in the respondent taking another course approved by the board in the same subject area.
28. Pharmacy Self-Assessment Mechanism: Creates an optional term that requires the respondent to complete the Pharmacist Self-Assessment Mechanism (PSAM) and to submit a record of the completion. Specifies that failure to complete the PSAM and submit documentation will be considered a violation of probation. In addition, two options are also provided; one to allow the board or its designee access to the examination results, and the second to require the respondent to provide the examination results and to allow the board to determine appropriate courses in remedial education to address areas of competency deficiency.
29. Intern Pharmacist Experience: Changes the title to conform to pharmacy law. In addition, nonsubstantive changes are made to define the process and now specifies that failure to comply with be considered a violation of probation.
30. Supervised Practice: Clarifying changes are made to better define the implementation and process used to carry out this term and to specify that a respondent's license will be automatically suspended until the board or its designee approves a supervisor. The term now specifies that it is the respondent's responsibility to ensure that employer(s), pharmacist(s)-in-charge and/or supervisor(s) provide necessary acknowledgements to the board and specifies that failure to comply with the terms shall be considered a violation of probation. The term specifies the parameters for suspension.
31. No Supervision of Ancillary Personnel: Rewords term to ensure consistent use of terms between pharmacy law and the guidelines as well as specifies that failure to comply will be considered a violation of probation.
32. No Ownership of Licensed Premises: Adds trustee to the list of prohibited roles the respondent make assume while on probation. In addition, specifies that failure to comply will be considered a violation of probation.
33. Separate File of Records: Clarifies that the optional term is only appropriate for pharmacist owners and pharmacists in charge. Specifies that the records must be made available for inspection and that failure to comply will be considered a violation of probation.
34. Report of Controlled Substances: Clarifies that the optional term is only appropriate for pharmacist owners and pharmacists in charge. Specifies that the records must be made available for inspection and that failure to comply will be considered a violation of probation.
35. No Access to Controlled Substances: Clarifies that the optional term applies during the period of probation as directed by the board or its designee, replaces the term "triplicate" with "security" in conformance with changes in pharmacy law, and specifies that failure to comply will be considered a violation of probation.

36. Criminal Probation/Parole Reports: Specifies that failure to comply will be considered a violation of probation.
37. Consultant for Owner or Pharmacist-in-Charge: Clarifies when option 1 and option 2 apply and specifies that the term applies during the period of probation, includes the use of a board designee and specifies that failure to comply will be considered a violation of probation.
38. Tolling of Suspension: Rewords the term to better define the provision and the parameters used to implement.
39. Surrender of DEA Permit: Creates a term that requires the respondent to surrender his or her federal DEA permit for cancellation and requires that the respondent provide documentation substantiating the surrender. It further prohibits the respondent from seeking a DEA registration number without prior consent of the board or its designee. In addition two options are created. The first allows for a respondent to obtain a DEA permit that is restricted to specified schedule(s) of controlled substances. The second option prohibits the respondent from ordering, receiving or retailing any federal order forms for controlled substances.
40. Ethics Course: Creates a new term that requires the respondent to enroll in a course of ethics that is approved by the board or its designee. In addition the term specifies that failure to initiate the course during the first year or probation and complete it within the second year is considered a violation of probation.

### **Model Disciplinary Language Pharmacy Technician**

**Revocation:** This section is being consolidated to include revocations for single and multiple causes under a single term, as the penalty is the same. In addition, the Option language is being clarified and the certification requirement is now referencing the appropriate Business and Professions Code section.

**Suspension:** This section is being expanded to better define the parameters of the suspension and specifies that failure to comply with the suspension will be considered a violation of probation. In addition it consolidates language from the previous version's "Optional Conditions of Probation."

**Standard Stay/Probation Order:** This section is clarifying that a license is revoked, but the revocation stayed.

**Issuance of Probationary License:** This term is being added to the Model Disciplinary Language for Pharmacy Technicians and mirrors the language for a similar term used for pharmacist and intern pharmacist.

**Surrender:** The changes specify that surrender of the license constitutes the imposition of discipline and specifies general criteria for reinstatement and makes other clarifying changes.

Public Reprimand: The proposed language now specifies that the respondent is required to report the reprimand as a disciplinary action.

Adoption of Stipulation: Change is to correct the reference to the Office of the Attorney General.

Standard Conditions: To Be Included in All Probations

1. Certification Prior to Resuming Work: This existing term requires the respondent to be certified as specified prior to resuming work as a pharmacy technician. The changes not reference the legal citation, which specify the certification requirements. Additionally, the term now specifies that failure to comply with the term is considered a violation of probation.
2. Obey All Laws: Specifies the reporting timeframes and process for complying with this term and states that failure to comply will be considered a violation of probation.
3. Report to the Board: Specifies that the reports to the board are to be submitted based on a schedule directed by the board or its designee and states that failure to submit reports as directed will be considered a violation of probation. The term also states that any period of delinquency in submitting the reports may be added to the total period of probation.
4. Interview with the Board: Clarifies the language and specifies that failure to appear at two or more scheduled interviews will be considered a violation of probation.
5. Cooperate with Board Staff: Cooperate with board Staff: Grammatical changes only.
6. Notice to Employers: Clarifies who the respondent must notify of the terms and conditions of probation imposed as well as the responsibility of the respondent to ensure that appropriate documentation is submitted to the board confirming compliance with requirement. In addition, changes specify that failure to comply will be considered a violation of probation.
7. Reimbursement of Board Costs: Clarifies that costs must be paid prior to successful completion of probation and prior board approval must be obtained to deviate from the cost recovery payment schedule established. In addition, changes specify that failure to comply will be considered a violation of probation. An optional component to allow for the automatic revocation of the license of an individual who fails to comply with any directed payment will also be included for board consideration when imposing terms and conditions.
8. Probation Monitoring Costs: Clarifies the requirements and changes it from an annual basis to a schedule as directed by the board. In addition, changes specify that failure to comply will be considered a violation of probation.
9. Status of License: Specifies that failure to comply will be considered a violation of probation and clarifies the intent of the term of probation.
10. License Surrender While on Probation/Suspension: Specifies that surrender under this term would constitute a record of discipline and will become a part of

the respondent's license history with the board. In addition, it clarifies general requirements of surrender and reapplication.

11. Notification of a Change in Name, Residence Address, Mailing Address or Employment: Changes the title of the term, clarifies the requirement and specify that failure to comply will be considered a violation of probation.
12. Tolling of Probation: The changes proposed are designed to clarify the intent of this term. Specifically, a key component during a probationary term is monitoring of the respondent to ensure that necessary changes in his or her practice are occurring to eliminate subsequent violations. This monitoring can only occur if the board has the ability to monitor the respondent while working in pharmacy. The revised term strikes a balance between the needs of the respondent to meet individual employment needs, e.g. part-time work, while allowing the board sufficient opportunity to monitor the respondent at the worksite. An additional option is suggested to allow further flexibility with this term. In addition, changes specify that failure to comply will be considered a violation of probation.
13. Violation of Probation: Clarifies that a notice and opportunity to be heard are not required for those provisions that may lead to automatic termination of the stay. In addition the term is reformatted.
14. Completion of Probation: Clarifies that written notice by the board or its designee is required to fully restore a license upon successful completion.

#### Option Conditions of Probation

All of the Optional Conditions are renumbered.

Actual Suspension: This term was consolidated under the Model Disciplinary Language – Pharmacy Technician

15. No Ownership of Licensed Premises: Adds trustee to the list of prohibited roles the respondent make assume while on probation. In addition, specifies that failure to comply will be considered a violation of probation.
16. Attend Substance Abuse Recovery Relapse Prevention and Support Groups: Offers a monitoring and recovery model for technicians when the case involves chemical dependency (alcohol, drugs) and clarifies that failure to attend or submit documentation of compliance with this term will be considered a violation of probation. This requirement is necessary as pharmacy technicians do not qualify for participation in the Pharmacist Recovery Program.
17. Random Drug Screening: Clarifies the intent of the requirement, which is to require the respondent to submit to random drug screenings, a tool used to confirm an individual's sobriety. In addition, the term now specifies that the respondent will need to submit timely documentation of prescription drugs that are legitimately prescribed as part of treatment and that failure to provide such documentation will be considered a violation of probation. The term currently allows for the automatic suspension for a positive drug screen. The proposed language clarifies the conditions under which a suspension would

- occur and now specifies the parameters for suspension.
18. Work Site Monitor: Clarifies that the respondent is responsible to ensure that required reports are submitted and specifies that failure to identify an acceptable initial or replacement worksite monitor, or to ensure that quarterly reports are submitted will be considered a violation of probation.
  19. Notification of Departure: Clarifies that such notification must occur prior to leaving a geographic area as defined by the board or its designee and states that failure to comply with the provision will be considered a violation of probation.
  20. Abstain from Drugs and Alcohol: Clarifies that a board designee may request documentation of medical treatment on behalf of the board and also states that failure to provide such documentation as requested will be considered a violation of probation. Additionally, the term specifies that a respondent shall not be in the same physical location as individuals who are using illicit substances and that any physical proximity to persons using illicit substances will also be considered a violation of probation.
  21. Tolling of Suspension: Rewords the term to better define the provision and the parameters used to implement.
  22. Restitution: Creates a term that requires the respondent to pay restitution within a specified time frame for a specified amount and states that failure to comply will be considered a violation of probation.

### **Model Disciplinary Language Designated Representative**

Throughout this section the term "exemptee" is replaced with the term "designated representative." In 2004 Senate Bill 1307 (Chapter 857, statutes of 2004) replaced the term "exemptee" with "designated representative" in pharmacy law, effective January 1, 2006. This section requires an amendment to ensure consistency with the Business and Professions Code.

Revocation: This section is being consolidated to include revocations for single and multiple causes under a single term, as the penalty is the same. In addition, the Option language is being clarified and the certification requirement is now referencing the appropriate Business and Professions Code section.

Suspension: This section is being expanded to better define the parameters of the suspension and specifies that failure to comply with the suspension will be considered a violation of probation. In addition it consolidates language from the previous version's "Optional Conditions of Probation."

Standard Stay/Probation Order: This section is clarifying that a license is revoked, but the revocation stayed.

Issuance of Probationary License: This term is being added to the Model Disciplinary Language for Pharmacy Technicians and mirrors the language for a similar term used for pharmacist and intern pharmacist.

Surrender: The changes specify that surrender of the license constitutes the imposition of discipline and specifies general criteria for reinstatement and makes other clarifying changes.

Public Reprimand: The proposed language now specifies that the respondent is required to report the reprimand as a disciplinary action.

Adoption of Stipulation: Change is to correct the reference to the Office of the Attorney General.

Standard Conditions: To Be Included in All Probations  
Because of the deletion and creation of new terms, standard conditions are being renumbered.

Certification Prior to Resuming Work: This term is being deleted

1. Obey All Laws: Specifies the reporting requirements, timeframes and process for complying with this term and states that failure to comply will be considered a violation of probation.
2. Report to the Board: Specifies that the reports to the board are to be submitted based on a schedule directed by the board or its designee and states that failure to submit reports as directed will be considered a violation of probation. The term also states that any period of delinquency in submitting the reports may be added to the total period of probation.
3. Interview with the Board: Clarifies the language and specifies that failure to appear at two or more scheduled interviews will be considered a violation of probation.
4. Cooperate with Board Staff: Grammatical changes only.
5. Notice to Employers: Clarifies who the respondent must notify of the terms and conditions of probation imposed as well as the responsibility of the respondent to ensure that appropriate documentation is submitted to the board confirming compliance with requirement. In addition, changes specify that failure to comply will be considered a violation of probation.
6. No Being Designated Representative-in-Charge: Creates a term that prohibits the respondent from serving as the designated representative-in-charge unless otherwise specified in the order and that failure to comply will be considered a violation of probation.
7. Reimbursement of Board Costs: Clarifies that costs must be paid prior to successful completion of probation and prior board approval must be obtained to deviate from the cost recovery payment schedule established. In addition, changes specify that failure to comply will be considered a violation of probation. An optional component to allow for the automatic revocation of the license of an individual who fails to comply with any directed payment will also be included for board consideration when imposing terms and conditions.
8. Probation Monitoring Costs: Clarifies the requirements and changes it from an

- annual basis to a schedule as directed by the board. In addition, changes specify that failure to comply will be considered a violation of probation.
9. Status of License: Specifies that failure to comply will be considered a violation of probation and clarifies the intent of the term of probation.
  10. License Surrender While on Probation/Suspension: Moves this term and rewords to specify that surrender of the respondent's license under this term would constitute a record of discipline and will become a part of the respondent's license history with the board. In addition, it clarifies general requirements of surrender and reapplication.
  11. Notification of a Change in Name, Residence Address, Mailing Address or Employment: Changes the title of the term, clarifies the requirement and specify that failure to comply will be considered a violation of probation.
  12. Tolling of Probation: The changes proposed are designed to clarify the intent of this term. Specifically, a key component during a probationary term is monitoring of the respondent to ensure that necessary changes in his or her practice are occurring to eliminate subsequent violations. This monitoring can only occur if the board has the ability to monitor the respondent while working in pharmacy. The revised term strikes a balance between the needs of the respondent to meet individual employment needs, e.g. part-time work, while allowing the board sufficient opportunity to monitor the respondent at the worksite. An additional option is suggested to allow further flexibility with this term. In addition, changes specify that failure to comply will be considered a violation of probation.
  13. Violation of Probation: Clarifies that a notice and opportunity to be heard are not required for those provisions that may lead to automatic termination of the stay. In addition the term is reformatted.
  14. Completion of Probation: Clarifies that written notice by the board or its designee is required to fully restore a license upon successful completion.

#### Option Conditions of Probation

All of the Optional Conditions are renumbered.

Actual Suspension: This term was consolidated under the Model Disciplinary Language – Pharmacy Technician

15. No Ownership of Licensed Premises: Adds trustee to the list of prohibited roles the respondent make assume while on probation. In addition, specifies that failure to comply will be considered a violation of probation.
16. Attend Substance Abuse Recovery Relapse Prevention and Support Groups: Offers a monitoring and recovery model for technicians when the case involves chemical dependency (alcohol, drugs) and clarifies that failure to attend or submit documentation of compliance with this term will be considered a violation of probation. This requirement is necessary as pharmacy technicians do not qualify for participation in the Pharmacist Recovery Program.
17. Random Drug Screening: Clarifies the intent of the requirement, which is to require the respondent to submit to random drug screenings, a tool used to

confirm an individual's sobriety. In addition, the term now specifies that the respondent will need to submit timely documentation of prescription drugs that are legitimately prescribed as part of treatment and that failure to provide such documentation will be considered a violation of probation. The term currently allows for the automatic suspension for a positive drug screen. The proposed language clarifies the conditions under which a suspension would occur and now specifies the parameters for suspension.

18. Work Site Monitor: Clarifies that the respondent is responsible to ensure that required reports are submitted and specifies that failure to identify an acceptable initial or replacement worksite monitor, or to ensure that quarterly reports are submitted will be considered a violation of probation.
19. Notification of Departure: Clarifies that such notification must occur prior to leaving a geographic area as defined by the board or its designee and states that failure to comply with the provision will be considered a violation of probation.
20. Abstain from Drugs and Alcohol: Clarifies that a board designee may request documentation of medical treatment on behalf of the board and also states that failure to provide such documentation as requested will be considered a violation of probation. Additionally, the term specifies that a respondent shall not be in the same physical location as individuals who are using illicit substances and that any physical proximity to persons using illicit substances will also be considered a violation of probation.
21. Tolling of Suspension: Rewords the term to better define the provision and the parameters used to implement.
22. Restitution: Creates a term that requires the respondent to pay restitution within a specified time frame for a specified amount and states that failure to comply will be considered a violation of probation.

## **Terms of Probation for Premises**

Changes are proposed to provide clarification and allow for easier reading and consistency.

### Categories of Violations and Recommended Penalties

The proposed changes 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 the penalties imposed as part of a disciplinary action.

#### Category 1

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

the requirements detailed in the specific sections. These titles have no force of law. However, at least one published version of the pharmacy law book, as well as the compilation of pharmacy laws provided on the board's Web site, contains brief titles to assist users. These changes are necessary to aid the user in the use of the Disciplinary Guidelines. Changes in the titles only are not listed below.

B&PC 4102 was repealed in Assembly Bill 586 (Chapter 501, Statutes of 2001) and therefore is being removed.

B&PC 4120 was incorrectly referenced in the previous version of the document and the correct reference was inadvertently not included.

B&PC 4146 was repealed in Senate Bill 1159 (Chapter 608, Statutes of 2004) and therefore is being removed.

B&PC 4180 - This section currently makes reference to B&PC 4182. This reference is incorrect and needs to be changed to the appropriate reference, B&PC 4180.

B&PC 4181 - This section currently makes reference to B&PC 4183. This reference is incorrect and needs to be changed to the appropriate reference, B&PC 4180.

B&PC 4231 - This section currently makes reference to B&PC 4233. This reference is incorrect and needs to be changed to the appropriate reference, B&PC 4231.

B&PC 4232 - This section currently makes reference to B&PC 4234. This reference is incorrect and needs to be changed to the appropriate reference, B&PC 4232.

CCR 1727 was repealed in October 2005.

CCR 1751 – 1751.12 was added to regulation effective 10/2004 and is being included into this version of the document.

H&SC 11124 was repealed in Senate Bill 2026 (Chapter 1013, Statutes of 2002) and is being removed.

H&SC 111225 – 111655 are being moved from the "Miscellaneous – Health and Safety Code, Title 22" to be consolidated with all other Health and Safety Code references.

CFR 1301.78 was repealed and therefore is no longer required.

CFR 1304.11 was inadvertently not included in previous versions of the Disciplinary Guidelines

CFR 1304.18 was renumbered to CFR 1304.21.

CFR 1305.03 – 1305.16 are changing as a result of renumbering that occurred in 2005 to include allowing electronic orders on controlled substances. Changes to relevant sections of the CFR are necessary to reflect the renumbering that occurred as part of this process.

CFR 1306.25 This section currently makes reference to Section 1306.26 of the Code of Federal Regulations. This reference is incorrect and needs to be changed to the appropriate CFR section, 1306.25.

16 CFR 1700.1 to 1707.15 is being moved from “Miscellaneous – Federal Regulations” to be consolidated with all other Code of Federal Regulations references.

## Category II

The majority of the changes reflected in this section are to titles associated with each section of law. These titles are designed to allow the reader brief insight into the requirements detailed in the specific sections. These titles have no force of law. However, at least one published version of the pharmacy law book, as well as the compilation of pharmacy laws provided on the board's Web site, contains brief titles to assist users. These changes are necessary to aid the user of the Disciplinary Guidelines. Changes in the titles only are not listed below.

B&PC 650, 650.1 and 651 were not included in the previous version of the “Disciplinary Guidelines rev 1/2001.”

B&PC 4104 - This section currently makes reference to B&PC 4106. This reference is incorrect and needs to be changed to the appropriate B&PC section, 4104.

B&PC 4105 - This section currently makes reference to B&PC 4107. This reference is incorrect and needs to be changed to the appropriate B&PC section, 4105.

B&PC 4112 - This section currently makes reference to B&PC 4113. This reference is incorrect and needs to be changed to the appropriate B&PC section, 4113.

B&PC 4115 - This section currently makes reference to B&PC 4116. This reference is incorrect and needs to be changed to the appropriate B&PC section,

4115.

B&PC 4125 was added to statute in Senate Bill 1399 (Chapter 677, Statutes of 2000) and is now being included.

B&PC 4169 was amended in Senate Bill 1476 (Chapter 658, Statutes of 2006). This reference was not included in the previous version of the "Disciplinary Guidelines rev 1/2001."

B&PC 4305 - This section currently makes reference to B&PC 307 This reference is incorrect and needs to be changed to the appropriate B&PC section, 4305.

B&PC 4306 This section currently makes reference to B&PC 4308. This reference is incorrect and needs to be changed to the appropriate B&PC section, 4306.

B&PC 4381 is being removed as a violation of this section is not grounds for discipline.

16 CCR 1715 corrects an incorrect reference to made to 16CCR 1716 in the previous version of the disciplinary guidelines

16 CCR 1775.3 corrects an incorrect reference to made to 16CCR 1775.4 in the previous version of the disciplinary guidelines

16 CCR 1782 corrects an incorrect reference to made to 16CCR 1784 in the previous version of the disciplinary guidelines

16 CCR 1783 corrects an incorrect reference to made to 16CCR 1785 in the previous version of the disciplinary guidelines

CCR 1793.1 – 1793.7 are now being listed as individual references.

CCR 1793.8 allows for a specially trained pharmacy technician to check the work of another technician in the acute care pharmacy setting and was added to regulation effective January 2007.

H&SC 11123, 11124, 11125, 11128, 11129, 11130 & 11131 were repealed in Senate Bill 2026 (Chapter 1013, Statutes of 2002) and are being removed.

H&SC 11123, 11124, 11125, 11128, 11129, 11130 & 11131 were repealed in Senate Bill 2026 (Chapter 1013, Statutes of 2002) and are being removed.

21 CFR 1306.08 was repealed.

### Category III

The majority of the changes reflected in this section are to titles associated with each section of law. These titles are designed to allow the reader brief insight into the requirements detailed in the specific sections. These titles have no force of law. However, at least one published version of the pharmacy law book, as well as the compilation of pharmacy laws provided on the board's Web site, contains brief titles to assist users. These changes are necessary to aid the user of the Disciplinary Guidelines. Changes in the titles only are not listed below.

B&PC 4059 - This section currently makes reference to B&PC 4060. This reference is incorrect and needs to be changed to the appropriate B&PC section, 4113.

B&PC 4085 makes it unlawful to remove, sell, or dispose of embargoed drugs and was added into statute in Senate Bill 1307 (Chapter 857, Statutes of 2004).

B&PC 4169 was amended in Senate Bill 1476 (Chapter 658, Statutes of 2006). This reference was not included in the previous version of the "Disciplinary Guidelines rev 1/2001."

B&PC 4335 was inadvertently not included in the previous version of the disciplinary guidelines

B&PC 4336 was inadvertently not included in the previous version of the disciplinary guidelines.

B&PC 4380 was inadvertently not included in the previous version of the disciplinary guidelines.

CCR 1771 – 1774 are now being listed as individual references.

H&SC 11122 was repealed in Senate Bill 2026 (Chapter 1013, Statutes of 2002) and is being removed.

H&SC 11167.5 allows for an oral or electronic prescription for Schedule II controlled substances for specified patients and was not included in the previous version of the "Disciplinary Guidelines, rev. 1/2001."

H&SC 111295 was inadvertently not included in the previous version of the Disciplinary Guidelines.

H&SC 111300 was inadvertently not included in the previous version of the

Disciplinary Guidelines.

H&SC 111305 was inadvertently not included in the previous version of the Disciplinary Guidelines.

H&SC 111440 was inadvertently not included in the previous version of the Disciplinary Guidelines.

H&SC 111445 was inadvertently not included in the previous version of the Disciplinary Guidelines.

H&SC 111450 was inadvertently not included in the previous version of the Disciplinary Guidelines.

#### Category IV

The majority of the changes reflected in this section are to titles associated with each section of law. These titles are designed to allow the reader brief insight into the requirements detailed in the specific sections. These titles have no force of law. However, at least one published version of the pharmacy law book, as well as the compilation of pharmacy laws provided on the board's Web site, contains brief titles to assist users. These changes are necessary to aid the user of the Disciplinary Guidelines.

#### Model Disciplinary Language – Premises

**Revocation:** This section is being consolidated to include revocations for single and multiple causes under a single term, as the penalty is the same. In addition, the Option language is being clarified and the certification requirement is now referencing the appropriate Business and Professions Code section.

**Suspension:** This section is being expanded to better define the parameters of the suspension and specifies that failure to comply with the suspension will be considered a violation of probation. In addition it consolidates language from the previous version's "Optional Conditions of Probation."

**Standard Stay/Probation Order:** This section is clarifying that a license is revoked, but the revocation stayed.

**Issuance of Probationary License:** This term is being added to the Model Disciplinary Language for Pharmacy Technicians and mirrors the language for a similar term used for pharmacist and intern pharmacist.

**Surrender:** The changes specify that surrender of the license constitutes the imposition of discipline and specifies general criteria for reinstatement and makes other clarifying

changes.

Public Reprimand: The proposed language now specifies that the respondent is required to report the reprimand as a disciplinary action.

Adoption of Stipulation: Change is to specify that the respondent owner understands the provisions of adoption of a stipulation

Standard Conditions: To Be Included in All Probations

Because of the deletion and creation of new terms, standard conditions are being renumbered.

1. Obey All Laws: Specifies the reporting requirements, timeframes and process for complying with this term and states that failure on the part of the owner to comply will be considered a violation of probation.
2. Report to the Board: Specifies that the owner must report to the board are to be submitted based on a scheduled directed by the board or its designee and states that failure to submit reports as directed will be considered a violation of probation. The term also states that any period of delinquency in submitting the reports may be added to the total period of probation.
3. Interview with the Board: Clarifies the language and specifies that failure of the owner to appear at two or more scheduled interviews will be considered a violation of probation.
4. Cooperate with Board Staff: Clarifies that the owner is responsible to comply with this requirement and makes grammatical changes.
5. Reimbursement of Board Costs: Clarifies that the owner must pay costs prior to successful completion of probation and prior board approval must be obtained to deviate from the cost recovery payment schedule established. In addition, changes specify that failure to comply will be considered a violation of probation. An optional component to allow for the automatic revocation of the license of an individual who fails to comply with any directed payment will also be included for board consideration when imposing terms and conditions.
6. Probation Monitoring Costs: Clarifies that the owner is responsible for costs and clarifies the requirements and changes it from an annual basis to a schedule as directed by the board. In addition, changes specify that failure to comply will be considered a violation of probation.
7. Status of License: Specifies that failure on the part of the owner to comply will be considered a violation of probation and clarifies the intent of the term of probation.
8. License Surrender While of Probation: Specifies that surrender of the license by the owner under this term would constitute a record of discipline and will become a part of the respondent's license history with the board. In addition, it clarifies general requirements of surrender and reapplication
9. Notice to Employees: Clarifies that the owner is responsible for compliance with

- this term and clarifies the reporting requirement. In addition it specifies that failure to comply will be considered a violation of probation.
10. Owners and Officers: Knowledge of the Law: Specifies that failure to comply will be considered a violation of probation.
  11. Posted Notice of Probation: A new term that requires the owner to post notice of probation, in a place readable to the public, during the entire period of probation. In addition, the term prohibits the owner from engaging in any conduct which is intended to mislead a patient, customer or member of the public and specifies that failure to post the notice will be considered a violation of probation.
  12. Violation of Probation: Clarifies that a notice and opportunity to be heard are not required for those provisions that may lead to automatic termination of the stay. In addition the term is reformatted.
  13. Completion of Probation: Clarifies that written notice by the board or its designee is required to fully restore a license upon successful completion.

Actual Suspension: This term was consolidated under the Model Disciplinary Language – Pharmacy Technician

14. Community Service: Clarifies the process by which this term is implemented and specifies that failure to comply will be considered a violation of probation.
15. Restitution: Specifies that failure to comply will be considered a violation of probation.
16. Separate File of Records: Clarifies that the optional term is only appropriate for pharmacist owners and pharmacists in charge. Specifies that the records must be made available for inspection and that failure to comply will be considered a violation of probation.
17. Report of Controlled Substances: Clarifies that the optional term is only appropriate for pharmacist owners and pharmacists in charge. Specifies that the records must be made available for inspection and that failure to comply will be considered a violation of probation.
18. Surrender of DEA Permit: Creates a term that requires the respondent to surrender his or her federal DEA permit for cancellation and requires that the respondent provide documentation substantiating the surrender. It further prohibits the respondent from seeking a DEA registration number without prior consent of the board or its designee. In addition two options are created. The first allows for a respondent to obtain a DEA permit that is restricted to specified schedule(s) of controlled substances. The second option prohibits the respondent from ordering, receiving or retailing any federal order forms for controlled substances.
19. Posted Notice of Suspension: Clarifies that the owner is responsible for compliance with this term.

Factual Basis/Rationale

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 12 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 99,000 licensees and received almost 12,000 applications in FY 2004/05. The Board initiated 1,480 complaint investigations and completed 1,985 investigations in FY 2004/2005. As a result of these investigations, 113 cases were referred to the Office of the Attorney General (AG). In addition to AG referrals, the Board issued 754 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.

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

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.

#### 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 passed six years. 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.