TITLE 16. BOARD OF PHARMACY

DEPARTMENT OF CONSUMER AFFAIRS

INITIAL STATEMENT OF REASONS

Hearing Date: No hearing scheduled unless requested,

Subject Matter of Proposed Regulation: Disciplinary Guidelines

Section Affected: California Code of Regulations (CCR), Title 16, Division 17, Article 8, Amend Section 1760

Background and Statement of the Problem:

The California State Board of Pharmacy (Board) is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, pharmacists, pharmacy interns, and pharmacy technicians. The Board's mandate and mission are to protect the public (Business and Professions Code (BPC) section 4001.1). The Board regulates the practice of pharmacy and the movement of prescription drugs and devices from the time the drugs and devices leave the manufacturing site to the time a drug or device is dispensed to the patient. The Disciplinary Guidelines are necessary to assist the Board, deputy attorney generals, and administrative law judges in identifying and imposing appropriate disciplinary action against a licensee or applicant who violates the laws governing the practice of pharmacy.

Existing law authorizes the Board (in conjunction with other healing arts boards, as part of a Substance Abuse Coordination Committee) to develop specific standards in dealing with substance-abusing licensees (BPC section 315). Existing law also 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 (BPC section 315.2), if the licensee commits major violations (BPC section 315.4), or when the Board orders a licensee to undergo a clinical diagnostic evaluation (*id*.).

Additionally, existing law authorizes the Board to amend rules and regulations pertaining to the practice of pharmacy (BPC section 4005), and to discipline a licensee (BPC section 4300), refuse to issue a license to an applicant (*id*.), and take action against a licensee "who is guilty of unprofessional conduct" (as defined in BPC section 4301).

The Board proposes amending section 1760 of Division 17 of Title 16 of the CCR. CCR section 1760 incorporates by reference the Disciplinary Guidelines developed by the Board. Board staff, Deputy Attorneys General (DAGs), Administrative Law Judges (ALJs), licensees, and attorneys use these guidelines to assist in determining penalties in disciplinary cases against Board licensees. The Board proposes updating the "Disciplinary Guidelines" to include disclosure of respondent's email address, use gender inclusive language, and use updated terms for consistency throughout the document (including Pharmacy Law Language). Clarification of relevant terms, changes

to categories of violations, additional optional terms, language regarding reinstatement of a license, and timeframes for when specific actions must be taken are also proposed. In addition, the proposed update addresses probation, for new licenses issued, under specified conditions. The current document incorporated by reference was previously amended in February of 2017, and the revised version is dated January 2022.

The amendments proposed are necessary to ensure Disciplinary Guidelines are up to date, relevant, consistent, and meaningful for use by Board staff, DAGs, ALJs, licensees, and attorneys in order 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.

Anticipated Benefits of this Regulatory Action:

The Board's mission is to "protect[] and promote[] the health and safety of Californians by pursuing the highest quality of pharmacist's care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation, and enforcement." (California State Board of Pharmacy, Homepage <https://www.pharmacy.ca.gov> [as of November 22, 2023]) This proposal would ensure that the disciplinary guidelines reflect changes in current law, use gender inclusive language, provide clarification of relevant terminology, and are updated so that terms are consist throughout the document. This proposal addresses changes to categories of violations, additional optional terms, language on reinstatement of a license, timeframes for when specific action must be taken, and probation, for new licenses issued, under specified conditions. Updating and clarifying the disciplinary guidelines (Rev. 1/2022) strengthens the Board's ability to monitor licensees on probation, improves the disciplinary guidelines, and benefits the health, safety, and welfare of California residents. By updating and clarifying the disciplinary guidelines, the Board will be better equipped and possess the tools to ensure licensees—whose licenses are restricted pursuant to administrative action—complete appropriate rehabilitation and prevent further harm to the public.

Specific purpose of, and rationale for, each adoption, amendment, or repeal:

The purpose of amending the regulation is to update the Disciplinary Guidelines that are incorporated by reference in CCR section 1760. The Board uses disciplinary guidelines when suspending or revoking a license or placing a license on probation. This proposal would update the existing disciplinary guidelines following Pharmacy law changes in order to keep the guidelines consistent with the requirements of Government Code section 11425.50(e), which prohibits a penalty from being based upon a guideline unless the guideline has been adopted as a regulation. Additionally, the proposed changes would implement gender inclusive language, clarify terminology, and update terms for consistency throughout the document. This proposal addresses changes to categories of violations, additional optional terms, language on reinstatement of a license, timeframes for when specific action must be taken, and probation, for new licenses issued, under specified conditions.

A summary of the proposed changes follows.

Amend 16 CCR § 1760

The Disciplinary Guidelines Revision date is amended from 2/2017 to 1/2022. The purpose is to change the date in the existing regulation text to match the revision date on the updated disciplinary guidelines. This is necessary to implement the new disciplinary guidelines.

Additionally, the Board proposes capitalizing "Board" throughout the section. This change is non-substantive because it is a grammatical change as part of an effort to "[revise] structure, syntax, cross-reference, grammar, or punctuation" within the meaning of Title 1, CCR section 100(a)(4). This is necessary for consistency throughout the regulations. Inconsistent capitalization may result in misinterpretation and confusion.

The Board also proposes adding commas throughout the section. This change is nonsubstantive because it is part of an effort to "revis[e] structure, syntax, cross-reference, grammar, or punctuation" within the meaning of Title 1, CCR section 100(a)(4). This is necessary for clarity and grammatical correctness.

The Board proposes adding an "s" to the end of the word "section" in the first sentence of the regulation text. This change is nonsubstantive because it is part of an effort to "revis[e] structure, syntax, cross-reference, grammar, or punctuation" within the meaning of Title 1, CCR section 100(a)(4). This is necessary for clarity and grammatical correctness.

Disciplinary Guidelines

Throughout the Disciplinary Guidelines, the Board proposes changing gendered language to gender-inclusive language by changing "he/she" to "they" and "his/her" to "their". This change is necessary to implement the use of inclusive language in the guidelines. Additionally, as of result of the language change, additional grammar edits are necessary for grammatical correctness by making terms singular following the gender-inclusive term change. For example, "he or she fails" was changed to "they fail" or "he or she works" was changed to "they work".

Throughout the guidelines, the Board replaced healthcare titles such as "psychologist" and psychotherapist" with the term "mental health practitioner" and "physician" with the term "health care practitioner" or "practitioner". (Additionally, where appropriate, titles (such as "psychologist") were removed to allow respondents to provide the board with evidence from other healthcare or mental health practitioners.) The purpose of this change is to ensure consistency throughout the document and Pharmacy Law. This change is necessary to provide inclusivity when referring to healthcare practitioners. "Health care practitioner" or "practitioner" are both used for physician and mean the same thing.

Throughout the guidelines, the Board capitalized “Board”. This change is non-substantive because it is a grammatical change as part of an effort to “[revise] structure, syntax, cross-reference, grammar, or punctuation” within the meaning of Title 1, CCR section 100(a)(4). This is necessary for consistency with the regulations, as well as within the document itself. Inconsistent capitalization may result in misinterpretation and confusion.

Throughout the guidelines the Board has stricken the phrase “or its designee”, as the term “Board” is defined in the introduction to mean the Board and/or its designees, so repeating the phrase throughout the document was determined to be repetitive and not necessary. Additionally, the Board added (forms of) the phrases “to the Board”, “by the Board”, and “for consideration by the Board” throughout the guidelines. The purpose of this change is to define who information is to be provided to and that the Board will be using the information provided. This is necessary for clarity, to ensure the Board receives all the information needed to make disciplinary determinations.

Throughout the guidelines the Board replaced the term “mental illness” with the term “mental health issue”. The purpose of this change is to use a term that is more appropriate to describe issues with mental health. This change is necessary to avoid using stigmatizing language when referring to issues with mental health.

Throughout the guidelines, grammatical edits were made to add, move, or remove commas, periods, parentheses, semi-colons, apostrophes, spaces, prepositions, and conjunctions to join phrases. Additionally, spelling errors were corrected/unintentionally included letters were removed. These changes are non-substantive because they are grammatical and syntactical changes, respectively, made as part of an effort to “[revise] structure, syntax, cross-reference, grammar, or punctuation” within the meaning of Title 1, CCR section 100(a)(4). This is necessary for avoiding misinterpretation and confusion.

Throughout the guidelines, the Board lowercased the “s” in “section”. This change is non-substantive because it is a grammatical change as part of an effort to “[revise] structure, syntax, cross-reference, grammar, or punctuation” within the meaning of Title 1, CCR section 100(a)(4). This is necessary for consistency with the regulations, as well as within the document itself. Inconsistent lowercasing/capitalization may result in misinterpretation and confusion.

Throughout the guidelines, the Board changed “practice as a [insert license type” to “practice as a(n) [insert license type]”. This change is non-substantive because it is a grammatical change as part of an effort to “[revise] structure, syntax, cross-reference, grammar, or punctuation” within the meaning of Title 1, CCR section 100(a)(4). This is necessary for grammatical correctness, as the name of some license types begin with the letter “a”, such as “Advanced Practice Pharmacist”.

The Board also changed “Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances” to (forms of)

“Respondent shall not direct or control any aspect of any authorized functions performed within Board-licensed premises”, “Respondent shall not direct or control any aspect of any Board-licensed premises”, or “Respondent shall not exercise any of the privileges conveyed by the Board”. The purpose of these changes is to establish that respondents are not to engage in any aspect of any authorized functions performed within, or direct or control any aspects of, Board-licensed premises (not just the activities previously listed), and that they are not to engage in Board-conveyed privileges while on probation. This is necessary so respondents understand that they cannot engage in or control any of these functions while on probation.

Finally, throughout the guidelines, “of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the Board, or any manufacturer, or any area” is stricken as the Board does not want to limit access of a respondent during suspension to just those licensed premises delineated but rather include any Board licensed premise. The Board determined that listing the all-premises licenses within the guidelines was not necessary as the Board broadly regulates two types of licensees: premises and individuals. Additionally, the phrase “practice pharmacy” was removed and replaced with “exercise any of the privilege conveyed by the Board” to clarify that none of the privileges of a pharmacy license should be conducted while on suspension.

Cover Page
The Disciplinary Guidelines Revision date is amended from 2/2017 to 1/2022 to match the revision date on the updated disciplinary guidelines.

Title Page
This section updated the Board president, executive officer, and address to reflect the most current information.

Table of Contents
The table of contents is updated to appropriately identify the page numbers for the sections, which have changed as a result of added language and edits to formatting.

Introduction (Page 1)
The Disciplinary Guidelines Revision date is amended from 2/2017 to 1/2022 to match the revision date on the updated disciplinary guidelines.

Factors to be Considered in Determining Penalties (Page 3)
From factor 14., the Board deleted “or, if the respondent is being held to account for conduct committed by another, the respondent had knowledge of or knowingly participated in such conduct” and moved the language to be its own separate factor 18., to read “If the respondent is being held accountable for conduct committed by another, whether the respondent had knowledge of or knowingly participated in such conduct.” The purpose of this change was to make this item a separate factor for consideration. It is necessary to move the item for clarity in order to allow this factor to be evaluated individually under 18. and not be analyzed, combined, or confused with the language in factor 14., which speaks to intention, neglect, and incompetence.

The last word on page three is changed from “one” to “penalty”. The purpose of this change is for clarity. This change was necessary to clarify what “one” means.

Terms of Probation – Individual Licensees (Page 6)

The section after the title that reads “(Pharmacist, Advanced Practice Pharmacist, Intern Pharmacist, Pharmacy Technician, Designated Representative and Designated Representative-3PL)” is stricken. The purpose of this change is to provide clarity regarding to whom the section applies. The Board determined that listing the individual license types within the guidelines was not necessary, as the Board broadly regulates two types of licensees: premises and individuals.

In the first (summary) paragraph, the first two sentences were stricken. The purpose of this change is to remove the minimum probation terms because every case has its own set of facts and its own circumstances. This is necessary because the length of the probation would be determined by the “Category” of the offense, and the offenses are identified on pages seven through ten.

Categories of Violations and Recommended Penalties (Page 6)

In paragraph two of this section, the individual license names, “(pharmacists, intern pharmacists, pharmacy technicians, and designated representatives, designated representatives-3PL, and advanced practice pharmacists)”, were removed as they were deemed unnecessary because, as identified above, the Board broadly regulates two types of licensees: premises and individuals.

In paragraph three, “offense” was stricken, as the term reduces clarity of the descriptions provided and is unnecessary.

Categories of Violations and Recommended Penalties (Page 7)

In paragraph one, “assume” was changed “presume”. The purpose of this change is to provide clarity. This change is necessary, as the definition of presume is better suited in the context of a single violation.

Category I (Page 7)

The numbers “2” and “4” were changed to roman numerals “II” and “IV” to correctly identify the numerical categories utilized within the guidelines. Additionally, “Scope of practice requirements” was stricken from category I. The Board determined a licensee performing services outside the scope of the practice could result in potentially more serious harm to a patient and, as such, a violation should result in a high level of discipline. Additionally, the Board determined that “scope of practice” is already listed in category II.

Category II (Page 8)

Drug “products” was changed to drug “preparations”. The purpose of this change is to utilize different terminology. This is necessary, as that terminology is more appropriate and relevant to describe medication that is compounded.

A bullet point was added that reads “repeated violation(s) involving the improper sterile compounding of drug preparations; and”. The purpose of this change is to clarify that repeated violations of improper *sterile* compounding are also included in this particular category. Improper sterile compounding has serious potential for patient harm, as such, it is necessary to include this as a category II violation.

Model Disciplinary Language (Page 11)

The section after the title that reads “(Pharmacist, Intern Pharmacist, Pharmacy Technician, Designated Representative, Designated Representative – 3PL, Advanced Practice Pharmacist)” was stricken, as it was unnecessary. The purpose of this change is to provide clarity regarding to whom the section applies. As identified above, the Board determined that listing the individual license types within the guidelines was not necessary as the Board broadly regulates two types of licensees: premises and individuals.

Revocation, stayed, Probation Order (Page 12)

“It is further ordered that any new license(s) issued while Respondent remains on probation shall also be placed on probation subject to the same terms and conditions applicable to Respondent’s licenses.” was added. The purpose of this addition is to help the Board track and monitor any new license the respondent is issued while still on probation. This is necessary to ensure the new licensee also obeys all laws while the respondent is still serving their original probation term.

Surrender (Page 12/13)

Within the second paragraph, “Respondent understands and agrees that for purposes of Business and Professions Code section 4307, this surrender shall be construed the same as revocation.” was added. The purpose of this inclusion is to inform respondents that surrender and revocation are deemed the same in this context. Adding this clarification sentence is necessary to ensures that the licensee is aware that surrendering their license is considered revocation, as the licensee failed to complete the terms and conditions of probation, and completion of the terms and conditions of probation is required as a result of the original stayed revocation.

Within the third paragraph, “New application for licensure” was replaced with “reinstatement”. “New application for licensure shall not be eligible to” was also stricken from this section, and “petition for reinstatement of licensure” was changed to “petition for reinstatement of a revoked license”. The purpose of these changes is to introduce the requirement that surrendered licenses go through petition for reinstatement of a

license versus submitting a new application for licensure. This change is necessary because the reinstatement process, as identified in BPC section 4309, allows for additional review of rehabilitation after the revocation of the license.

Within the fourth paragraph, the term “apply” was changed to “petition” and “application” to “petition”. The purpose of this change is to reflect that the respondent is petitioning for reinstatement versus applying for licensure. These changes are necessary to mirror the terminology within BPC section 4309.

The sentence “Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the Board, including, but not limited to, taking and passing licensing examination(s) as well as fulfilling any education or experience requirements prior to the issuance of a new license.” was stricken. The purpose of this change is to reflect that respondent is required to apply for reinstatement and not apply for licensure. This change is necessary because this sentence is now contradictory to the reinstatement process.

Option (Page 13)

“Apply” was stricken and replaced with “petition”, “any license” was replaced with “reinstatement of licensure”, and “issuance of new license” was replaced with “reinstatement”. The purpose of these changes is to establish the requirement that the respondent will now apply for reinstatement and not apply for licensure. These changes are necessary to correct the language that is contradictory to the reinstatement process.

Public Reproval (Page 13)

“It is hereby order that a public reproval be issued against license, _____.” was stricken and replaced with “It is hereby ordered that license number _____issued to respondent shall be publicly reproved by the Board of Pharmacy, under Business and Professions Code section 495, in resolution to Accusation No. _____, attached as Exhibit A.” The purpose of this change is to provide clarity. This change is necessary to inform on the authority under which public reproval is allowed and to add the actual accusation number of respondent’s case under exhibit A for further documentation and clarity.

License Reinstatement with Conditions Precedent (Pharmacists and Pharmacy Technicians Only) OPTION (Pharmacists Only) (Page 13)

Section (a) was amended to reflect that the petitioner must satisfy licensure requirements as defined by Business and Professional Code section 4200(a). NAPLEX and CPJE exam language was stricken. The purpose of this change is to add in licensure requirements and proof of qualifications. This change is necessary to inform respondents they might have to meet multiple requirements for reinstatement rather than just the NAPLEX and CPJE exam requirement.

Option (Technicians Only) (Page 14)

Section (a) was amended to reflect that the petitioner must become certified as defined by Business and Professions Code section 4202, subdivision (a)(4). PTCB and passing the exam language were stricken. The purpose of this modification is to reflect the statutory requirements for certification by a certifying organization offering a technician certification program, versus just the PTCB exam. This is necessary to introduce the requirements that must be met.

Optional Conditions (Page 15)

Language in Term 41 stating "Tolling of Suspension" was stricken and replaced with a new optional term for an individual license that includes a requirement to complete the Board's one-day training program on prescription drug abuse prevention and pharmacy law. The Board's training program was added as an optional term, the purpose of which is to provide licenses with a beneficial educational tool that could be utilized during probation. Tolling of Suspension was removed, as the term language was stricken during the 2017 revision; however, the condition was not removed from the list of terms. Optional term 43 was added for Individual Licenses to allow for an administrative fine. This term was added to provide the Board with an optional term that may serve as a deterrent and provides for meaningful and consequential discipline for respondent. These changes are necessary to have the list fully reflect which conditions can be utilized in the disciplinary process.

Standard Conditions: To Be Included in All Probations

1. Obey all Laws (Page 16)

"[P]rovision of the Pharmacy Law . . . food and drug . . ., or state and federal controlled substances laws" was stricken and replaced with "information or indictment" (which are federal filings). The purpose of this change is to add in that respondents are to report any issuance of information or indictment, not just arrest or issuance of criminal complaints. This is necessary so that the Board is fully informed when making disciplinary determinations.

"[W]hich involves respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance." was also stricken. The purpose of this change is to require reporting of any arrest, issuance of a criminal complaint, information, or indictment. This is necessary so that the Board is fully informed when making disciplinary determinations, as the Board has more information on the respondent's activities while on probation with the Board. BPC section 4301 allows the Board to take action against a license for violation of a law beyond pharmacy law, so requiring disclosure of non-pharmacy related violations is appropriate.

3. Interview with the Board (Page 16)

The requirement for “in person” interviews with respondent was stricken to allow for remote interviews. Given the current conditions with COVID, the Board believes in person interviews are not always appropriate or deemed necessary, given the video conferencing technology available.

5. Continuing Education (Pharmacists Only) (Page 17)

This section was amended to reflect that the pharmacists shall provide evidence that their continuing education complies with Title 16 California Code of Regulations section 1732.3. The purpose of this change is to clarify that the CE a pharmacist provides to the Board must comply with the regulation that delineates the requirements for CE courses. This is necessary to ensure compliance with the CE requirements, and assist pharmacists in knowing the requirements.

6. Reporting of Employment and Notice to Employers (Page 17)

This section was modified to include that the respondent shall report email addresses of their supervisor, pharmacist in charge, and/or designated representative. Current reporting requires physical and mailing addresses as well as phone numbers. The purpose of this change is to require respondents to report this information. This change is necessary as email has become a common and more readily accessible form of communication. Currently the respondent is required to provide the reason for leaving prior employment. The “last day worked” was added to this section as well. The purpose of this change is to provide the Board with clear timelines of when and where a respondent was employed. This is necessary to ensure the Board is fully informed when making disciplinary determinations and can contact the respondent.

7. Notification of Change(s) in Name, Address(es), or Phone Number(s) (Page 18)

The Board replaced “in writing” with “as directed”. The purpose of this change is for the Board to obtain changes via email or other methods. This section added in the notification requirement for a change in “email address” and added that failure to notify the Board of any change of employer, name, address, email address, or phone number shall be a violation of probation if not done within 10 days, as stated in the first paragraph. Email is a common form of communication and was thus added into the change notification requirements. The timeframe of 10 days was added to clarify that if the notification is not done within that timeframe, it shall be considered a violation of probation. These changes are necessary to ensure the Board is fully informed when making disciplinary determinations and can contact the respondent.

8. Restrictions on Supervision and Oversight of Licensed Facilities (Not appropriate for Pharmacy Technicians) (Page 18)

This section added that the respondent shall not supervise a “supervising pharmacist” or “quality individual” to ensure inclusivity and clarify that the respondent should not

supervise any managers, supervisors, or quality individuals while on probation. Additionally, “designated individual (as defined in the United States Pharmacopeia (USP), including as an individual responsible and accountable for the performance and operations of the facility and personnel in the preparation of compounded sterile products)” is added, as a respondent should not oversee sterile compounding. The term “compliance” was removed before the word “supervisor”, as respondent should not supervise any supervisor, not just a compliance supervisor. The words “nor serve as a consultant” were rearranged in the sentence to clarify that the respondent should not be a consultant of any entity licensed by the Board. The purpose of these changes is to inform respondents that they cannot engage in these supervisory activities. This change is necessary to implement the requirement and ensure respondents do not engage in these supervisory activities while on probation.

Option 1 (To be included along with standard language when appropriate): (Page 18)

This section was amended to mirror the “designated individuals” language added above and add “production operators”. The purpose of this change is to add to the list of ancillary personnel that shall not be supervised by respondents. Production operators typically work in outsourcing facilities. Outsourcing facilities are a newer license type for the Board since that last draft of this document, and thus a production operator was added to the list, and this change is necessary.

Option 2 (To be used in place of standard language when appropriate): (Page 19)

This section was amended to mirror the “designated individual” language added above. The purpose of this change is to provide consistency. This section also added language regarding the education, training, and professional experience necessary to serve as a consultant, and that the consultant shall not be on probation themselves. These changes are necessary because a respondent cannot provide guidance to other respondents, as they have shown a lack of compliance with (pharmacy) law. Additionally, if a respondent retains an independent consultant, the individual must have the expertise to guide the respondent in order to be helpful to the licensee on probation.

9. Reimbursement of Board Costs (Page 19)

The word “Option” was added to the section that provides for a payment plan. The purpose of this change is to clarify a Board-approved payment plan is an optional method for the respondent to pay costs. This change is necessary to inform respondents of this optional payment method.

13. Certification Prior to Resuming Work (Pharmacy Technicians Only) (Page 19)

The third paragraph is amended to remove “Do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer” and add “exercise any of the privileges conveyed by the Board”. The purpose of these changes is to clarify the restriction that respondent shall not

engage in any technician privileges conveyed by the Board for which a pharmacy technician license is required. This is necessary to inform respondents what activities they cannot engage in while on probation.

OPTIONAL CONDITIONS OF PROBATION

18. Restricted Practice (Page 23)

This section is modified for the purpose of clarifying that the respondent shall not be involved in [sterile] compounding and the changes are necessary to update the language to reflect relevant terms of the practice. “Prepare compounds” was changed to “[sterile] compound” and “preparations” was changed to the more relevant term “product” in this instance. The term [sterile] is in brackets and would be added based on the underlying causes of discipline and whether all compounding is restricted or just sterile compounding.

19. Pharmacist Examination (Pharmacists Only) (Page 23/24)

The first paragraph is amended to reflect that respondent must pass the examinations required for licensure, as defined by Business and Professional Code section 4200(a). NAPLEX and CPJE exam language was stricken. The purpose of these changes is to add in licensure requirements and proof of qualifications. This change is necessary to inform respondents they might have to meet multiple requirements for reinstatement rather than just the NAPLEX and CPJE exam requirement.

The last paragraph is amended to reflect that if respondent fails to comply with licensure requirements, as defined by Business and Professional Code section 4200(a), after four attempts, respondent must take an additional 16 semester units of pharmacy education. NAPLEX and CPJE exam language was also stricken. The purpose of these changes is to add in licensure requirements and proof of qualifications. This change is necessary to inform respondents they might have to meet multiple requirements for reinstatement rather than just the NAPLEX and CPJE exam requirement.

20. Clinical Diagnostic Evaluation (Page 24-26)

The second paragraph is amended to add “or email”. The purpose of this change is to allow for the mental health practitioner to email the Board if the practitioner determines that the respondent is unable to practice safely. This change is necessary to ensure practitioners are able to communicate with the Board, as it allows for an alternate means of communication.

The title and **Option 1** are amended to change “abuse” to “use”. The purpose of this change is to reflect that the use of alcohol or drugs could be a contributing cause of violations. This is necessary because the use may not be considered “abuse” of the substance.

21. Psychotherapy (Page 27/28)

The title information is amended to change the term “abuse” to “use”. The purpose of this change is to reflect that the use of alcohol or drugs could be a contributing cause of violations. This is necessary because the use may not be considered “abuse” of the substance.

This section is amended to require a release authorizing a mental health practitioner to furnish the Board with a current diagnosis and report. The purpose of this inclusion is to ensure the Board is fully informed about the respondent’s ability to function independently in their licensed capacity with no harm to the public. This section’s addition is necessary for public protection to ensure respondents are safe to participate in the activities conveyed upon by their respective license designation.

The fourth paragraph is amended to add the option of email notification. The purpose of this change is to allow for the treating therapist to email the Board if the therapist determines the respondent is unable to practice safely. This change is necessary to ensure therapists are able to communicate with the Board, as it allows for an alternate means of communication.

23. Pharmacists Recovery Program (PRP) (Page 30/31)

“Substance abuse or misuse” was added to the first section of PRP The purpose of this change is to establish that this condition can apply to those with substance use or abuse issues. This change is necessary, as many individuals who would benefit from participation in the program have substance use or abuse issues.

25. Notification of Departure (Page 33)

This section added that within three business days prior to leaving the probationary geographic area designated by the Board for a period of greater than 24 hours, respondent shall notify the Board verbally and in writing. The purpose of this inclusion is to provide clarification to respondent on the timeframe within which they must inform the Board if leaving the probationary geographic area. The Board selected three business days to ensure Board staff are aware of the departure before the respondent leaves the area. Providing this time frame is necessary, for example, in the event that the probationer must complete drug and alcohol testing so that the probationer is able to ensure a testing facility is available, should the respondent be selected to test during that timeframe.

26. Abstain from Drugs and Alcohol (Page 34)

This section was amended to add the respondent shall sign an acknowledgement confirming receipt of a list of examples of prohibited substances. The purpose of this addition is to provide clarification to the respondent on the actual types of prohibited substances. This is necessary to avoid miscommunication and confusion, and to provide

the Board with documented proof that the list of examples was provided to the respondent.

27. Prescription Coordination and Monitoring of Prescription Use (Page 34)

The second paragraph is amended to add “or email”. The purpose of this addition is to allow for the mental health practitioner to email the Board if the practitioner determines the respondent is unable to practice safely. This change is necessary to ensure practitioners are able to communicate with the Board, as it allows for an alternate means of communication.

30. Work Site Monitor (Appropriate for those cases where the evidence demonstrates substance use) (Page 37)

“[R]espondent must identify an acceptable replacement work site monitor" was added. The purpose of this addition is to ensure that a replacement work site monitor is identified should the existing work site monitor no longer be able to monitor the respondent at the work site. This addition is necessary because, as a condition of probation and enrollment in the Pharmacists Recovery Program (PRP), the respondent must have a work site monitor approved by PRP, who is responsible for supervising the respondent during working hours.

33. Remedial Education (Page 38)

In this section, after the completion of each course, the respondent must achieve a passing score on any approved examination, if one exists for said course, and provides a definition for what constitutes “successfully completed”. This section is amended to add that the passing score is determined by the provider. The purpose of this addition is to provide clarification to the respondent that the CE shall not count towards satisfaction of this term if the score is not passing, as determined by the provider. As the provider of the CE controls the course, the provider determines what is considered passing. This addition is necessary so that respondents know what they must do to successfully complete the required CE.

34. Ethics Course (Pharmacists, Advanced Practice Pharmacists and Pharmacist Intern Only) (Page 38/39)

This section was amended to add a requirement that the respondent shall notify the Board within five days of enrollment in the ethics course, including proof of such enrollment. The purpose of this addition is to provide clarification to the respondent about the timeliness of when they should inform the Board that they are enrolled in the ethics course. This change is necessary to alert the Board that the respondent is moving forward with their requirements of probation. The Board selected 5 days to mirror the timeframe for completion, which is also 5 days.

41. Board's One-Day Training Program (This term is added - Page 41)

Term 41 was skipped in the prior disciplinary guidelines by mistake. New term 41 is added, stating "Within the first year of probation, respondent shall enroll in the Board's one-day, six (6) hour training program, *'Preventing Prescription Drug Abuse and Drug Diversion.'* Respondent shall provide proof of enrollment within five (5) days of enrollment. Within five (5) days of completion of this training program, respondent shall submit a copy of the certificate of completion to the Board. Failure to enroll in and successfully complete the training program before the end of the second year of probation, or to timely submit proof of completion to the Board as required by this section, shall be considered a violation of probation."

The purpose of this addition is to establish this as an optional term and establish the requirement that the respondent provide proof of enrollment within five (5) days of enrollment. This new optional term for an individual license includes a requirement to complete the Board's one-day training program on prescription drug abuse prevention and pharmacy law. The inclusion of the Board's training program is necessary to add as an optional term to provide licensees with a beneficial educational tool that could be utilized during probation. The program is frequently provided by the Board and is free to Board licensees.

43. Administrative Fine (This term is added - Page 42)

This language was added "Respondent shall pay an administrative fine to the Board in the amount of _____. Respondent shall have [insert timeframe] from the effective date of this Decision and Order to pay the administrative fine. Failure to pay the administrative fine as ordered shall be considered a violation of probation."

The purpose of the addition of optional term 43 for individual licenses is to allow for an administrative fine. This term's addition is necessary to provide the Board with an optional term that may be a deterrent and provides for meaningful and consequential discipline for the respondent should an administrative fine be ordered and not paid.

TERMS OF PROBATION – PREMISES (Page 43)

The first two sentences under the section title were stricken. The purpose of this change is to remove the minimum probation terms because every case has its own set of facts and its own circumstances. This is necessary because the length of the probation would be determined by the "Category" of the offense, and the categories are identified on pages 44 through 47.

CATEGORIES OF VIOLATIONS AND RECOMMENDED PENALTIES (Page 43)

"Assume" was changed to "presume". The purpose of this change is to provide clarity. This change is necessary, as the definition of presume is better suited in this context. The text now reads "These categories presume a single violation."

Category I (Page 45)

"Scope of practice requirements" was stricken. The Board determined a licensee performing services outside the scope of the practice could result in potentially more serious harm to a patient and, as such, a violation should result in a high level of discipline. Additionally, the Board determined that "scope of practice" is already listed in category II.

"Institution or use of policies and procedures that are in violation of laws or regulations governing pharmacy" was added. The purpose of this addition is to clarify that policies and procedures that violate pharmacy law will be addressed and the Board can bring action against a chain pharmacy under recently enacted BPC section 4317.5(b) for violations that are demonstrated to be a result of a written policy. This addition is necessary to ensure that licensees are aware of possible disciplinary outcomes should the licensee establish or use policies and procedures that violate pharmacy law.

Category II (Pages 45/46)

"[F]ailure(s) to ensure properly trained staff and conduct practice safely" was made its own violation in this category. The purpose of this change is to make this item a separate violation for consideration. It is necessary to move this to be a separate violation so that each entry can be considered and weighed independently.

"[R]epeat failure(s) to provide patient consultation" was added to this section. The purpose of the addition of repeat failure to provide patient consultation is to stress the importance of this activity for patient safety. It is necessary to include this because if patient consultation is not provided to a patient who is being dispensed a drug for the first time, or if there is a change in dosage, strength, or directions, there is serious potential for medication errors and patient harm.

Surrender (Page 49)

Within the second paragraph, "Respondent understands and agrees that for purposes of Business and Professions Code section 4307, this surrender shall be construed the same as revocation." was added. The purpose of this addition is to make respondents aware that surrender and revocation are deemed the same in this context. Adding this clarification sentence is necessary to ensure that the licensee is informed that surrendering the license is considered revocation, as the licensee failed to complete the terms and conditions of probation, which are required as a result of the original stayed revocation.

Optional Conditions (Page 51)

Optional condition "26. Administrative Fine" was added. The purpose of this addition is to clarify that an administrative fine may be assessed on the respondent. This term was necessary to add to provide the Board with an optional term that may be a deterrent and provides for meaningful and consequential discipline for respondent.

Optional condition “27. Consultant Review of Facility Operations” was added to terms of probation for premises. The purpose of adding this section is to establish that a consultant review of facility operations may be required. This is necessary to include because consultant review provides the Board with another tool to assist with oversight of the licensed premise and will aide in meaningful Education and feedback to the respondent.

2. Obey All Laws (Page 52)

“[P]rovision of the Pharmacy Law . . . food and drug . . ., or state and federal controlled substances laws” was stricken and replaced with “information, or indictment” (which are federal filings). The purpose of this change is to add in that respondents are to report any issuance of information or indictment, not just arrest or issuance of criminal complaints. This is necessary so that the Board is fully informed when making disciplinary determinations. “[W]hich involves respondent’s_____ license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.” was also stricken. The purpose of this change is to require reporting of any arrest, issuance of a criminal complaint, information, or indictment. This is necessary so that the Board is fully informed when making disciplinary determinations, as the Board has more information on the respondent’s activities while on probation with the Board. BPC section 4301 allows the Board to take action against a license for violation of a law beyond pharmacy law, so requiring disclosure of non-pharmacy related violations is appropriate.

4. Interview with the Board (Page 52)

The requirement for “in person” interviews with respondent was stricken, given the current conditions with COVID. The Board believes in person interviews are not always appropriate or deemed necessary, given the video conferencing technology available.

6. Reimbursement of Board Costs (Page 53)

The word “Option” was added to the section that provides for a payment plan. The purpose of this change is to clarify a Board-approved payment plan is an optional method for the respondent to pay costs. This change is necessary to inform respondents of this optional payment method.

7. Probation Monitoring Costs (Page 46)

The following language was added to this section “Option (additional language to be used for out of state premises): Probation monitoring costs include travel expenses for an inspector to inspect the premises on a scheduled as determined by the Board.” Probation monitoring is not a revenue source for the Board; however, all costs for monitoring compliance with probation are paid by the probationer. The purpose of this section is to provide clarity to the regulated public. This is necessary to inform the

regulated public that probation monitoring costs for the travel of inspectors to inspect out of state premises is part of the overall probation monitoring costs.

9. License Surrender While on Probation/Suspension (Page 54)

"(5)" was added to the sentence "Within five days of its provision to the pharmacy's ongoing patients . . .". This addition is non-substantive and is made for consistency within the disciplinary guidelines, as all other number references have the number spelled out and the numerical value in parentheses.

13. Premise Open for Business (Page 55)

"[Insert number]" was added in two sections of this term. The purpose of this inclusion is to provide clarification that when drafting terms for a premises, the actual number of hours should be documented. This section requires that if the respondent is not open and engaged in its ordinary business as a [insert number] for a minimum number of hours, respondent shall notify the Board in writing within ten (10) days of the conclusion of that calendar month. In addition, respondent shall further notify the Board in writing with ten (10) days following the next calendar month during which respondent is open and engaged in its ordinary business in California for a minimum of "[insert number]" hours. These additions are necessary to require that when the terms are drafted, the actual number of hours are documented within the terms and conditions of probation for clarity to all parties.

14. Posted Notice of Probation (Page 56)

The sentence **"**In addition, respondent shall prominently post a probation notice, similar to that provided by the Board, on respondent's website in a place that is likely to be frequented by California consumers and health care providers." Was added to this section. The purpose of this amendment is to clarify and specify how a probation notice shall be provided by those types of premises respondents. While premises are currently required to post a notice of probation within their facility, the Board determined that it is necessary that the notice also be posted to the respondent's website, as it is increasingly common for patients to use websites to order prescription refills for shipping rather than getting them in person at a store, so they may not see the notice posted in the store.

In addition, the following language was added to this section "**Option** (include additional language for mail order pharmacies): Respondent shall also provide a copy of the notice of probation in all shipments to and within California." The purpose of this amendment is to address mail order pharmacy respondents and how a probation notice shall be provided by those types of premise respondents. As stated above, the Board determined that this amendment is necessary because patients are now ordering and receiving medication by means other than in person within the premises, and, as it is important for patients to know that the premises is on probation, disclosing this information within shipments is appropriate and necessary to ensure patients are informed.

15. Violation of Probation (Page 56)

This section added "The Board shall post a notice" of the extended probation period on its website. The purpose of this amendment is to specify that if the probation is automatically extended, the Board is required to post a notice of the extended period of probation on its website. The Board determined that this change is necessary because the public has the right to know if a premises is on probation and, as such, posting the extension of probation is necessary to ensure that the information on the Board's website is current.

If a petition to revoke probation or an accusation is filed against respondent during probation, the Board shall have continued jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided. The purpose of this section being amended is to reflect that if the preparation or an accusation or petition to revoke is requested from the Office of the Attorney General, the Board will also have continued jurisdiction in this situation and the period of probation shall be automatically extended until the petition or accusation is heard and decided upon. This addition is necessary to clarify that if the petition or accusation is requested by the Office of the Attorney General, continuing jurisdiction applies in this situation as well and it doesn't just apply to the filing during probation.

24. Destruction of Dangerous Drugs and/or Dangerous Devices [To be used when the violations include misbranded or adulterated drugs.]

"(5)" was added to the sentence "Respondent shall provide written proof of such destruction within five days of disposition". This addition is non-substantive and is made for consistency within the disciplinary guidelines as all other number references have the number spelled out and the numerical value in parentheses.

26. Administrative Fine (This term is added - Page 59)

Term 26 was added to read: "Respondent shall pay an administrative fine to the Board in the amount of _____. Respondent shall have [insert timeframe] from the effective date of this Decision and Order to pay the administrative fine. Failure to pay the administrative fine as ordered shall be considered a violation of probation."

The purpose of this addition is to allow for an administrative fine. This term's addition is necessary to provide the Board with an optional term that may be a deterrent and provides for meaningful and consequential discipline for the respondent.

27. Consultant Review of Facility Operations (This term is added – Page 59)

Consultant Review of Facility Operations was added to terms of probation for premises. Term 27. was added to read: "Respondent shall retain, at its own expense, an independent consultant who shall review the operations of the facility, during the period of probation, on a [monthly/quarterly] basis for compliance of the facility with state and

federal laws and regulations governing the practice of pharmacy, and compliance by respondent. The consultant shall provide the Board with an inspection agenda for approval prior to conducting the inspection. Any inspection conducted without prior approval of the inspection agenda shall not be accepted. The consultant shall also provide the Board with reports documenting the inspection. The reports shall be provided directly to the Board, and the consultant shall receive confirmation of receipt from the Board, prior to the consultant providing a copy of the report to the respondent. Should the Board determine that the consultant is not appropriately assessing the operations of respondent, or providing the appropriate written reports, the Board shall require respondent to obtain a different consultant through the same process outlined above, by submitting a new name of an expert within sixty (60) days of respondent being notified of the need for a new consultant. During the period of probation, the Board shall retain discretion to reduce the frequency of the consultant's review.

Respondent shall submit the name of the proposed consultant for approval within thirty (30) days of the effective date of this decision. The consultant shall be a pharmacist licensed by and not on probation with the Board or other professional as appropriate and not on probation with the Board, who has been approved by the Board to serve in this position. The consultant shall have education, training, and professional experience to be able to provide guidance to respondent related to the causes for discipline in Case No. _____. Assumption of any unauthorized supervision responsibilities shall be considered a violation of probation.

Failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall be considered a violation of probation."

The purpose of this section is to establish that a consultant review of facility operations may be required. This is necessary to include because consultant review provides the Board with another tool to assist with oversight of the licensed premises and will aide in meaningful education and feedback to the respondent to ensure the premises is operating in compliance with pharmacy law.

The date on the last page of the document was changed from 2/2017 to 1/2022 to reflect the update date.

Underlying Data

1. Relevant Public Meeting Materials and Minutes from the Board Meeting held January 27-28, 2022
2. Relevant Public Meeting Materials and Minutes from Enforcement Committee Meeting held January 18, 2022
3. Relevant Public Meeting Materials and Minutes from the Board Meeting held July 28-29, 2021
4. Relevant Public Meeting Materials and Minutes from Enforcement Committee Meeting held July 15, 2021
5. Uniform Standards Regarding Substance Abusing Healing Arts Licensees

Business Impact

The Board has made the initial determination that the proposed regulations will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other States. This initial determination is based on the fact that the proposed regulation does not impose new requirements on licensees, as it only affects individuals and those businesses that are disciplined for serious violations of pharmacy law. Additionally, licensees on probation must already adhere to the Board's disciplinary guidelines. This proposal is updating the guidelines to include disclosure of the respondent's email, gender inclusive language, and updating terms for consistency throughout the document.

Economic Impact Assessment:

The Board has determined that this proposal will not:
(1) create jobs within California;
(2) eliminate jobs within California;
(3) create new businesses within California;
(4) eliminate existing businesses within California;
(5) expand businesses currently doing business in the State of California.

This proposal will not create, expand, or eliminate jobs or businesses within the State of California because the proposed regulation updates an existing regulation and only affects those licensees being disciplined by the Board for violating pharmacy law.

This regulatory proposal does affect the health and welfare of California residents because the proposed regulation updates, clarifies and improves the disciplinary guidelines affecting those licensees who violate pharmacy law. By updating 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.

Additionally, the Board determined that this regulatory proposal will not impact worker safety, or the state's environment as these changes do not involve worker safety or the environment.

Specific Technologies or Equipment

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

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or as effective or less burdensome to affected private persons and equally effective in achieving the purposes

of the regulation in a manner that ensures full compliance with the law being implemented or made specific.

The Board considered not updating the disciplinary guidelines; however, the Board determined that was not acceptable given the requirements of the uniform and specific standards and the knowledge that not updating and clarifying the regulations would be contrary to the Board's public protection mandate, as the proposed changes assist the Board in better monitoring licensees on probation.