MEDICAL BOARD OF BOARD

INITIAL STATEMENT OF REASONS

Hearing Date: October 30, 2015

Subject Matter of Proposed Regulations: Manual of Model Disciplinary Orders and Disciplinary Guidelines (Disciplinary Guidelines)

Section(s) Affected: California Code of Regulations, Title 16, Division 13, Chapter 2, Article 4, Section 1361 (section 1361)

Specific Purpose of Each Adoption, Amendment, or Repeal:

1. Problem being addressed:

   The current Disciplinary Guidelines (11th Edition/2011), incorporated by reference in section 1361, must be amended to be made consistent with current law. Additionally, the Disciplinary Guidelines must be amended to reflect changes that have occurred in the educational and probationary environments since the last update to clarify some conditions of probation, and to strengthen consumer protection. Accordingly, section 1361 must be amended to incorporate by reference the 12th Edition of the Disciplinary Guidelines as amended in 2015.

   The Disciplinary Guidelines must be incorporated by reference because of the length of the document.

2. Anticipated benefits from this regulatory action:

   This regulatory action will amend section 1361 to incorporate by reference the 12th Edition of the Disciplinary Guidelines. This 12th Edition makes the Disciplinary Guidelines consistent with current law, updates and clarifies the terms and conditions of probation for physicians and surgeons (physicians) subject to discipline, and strengthens consumer protection.

3. Specific Purpose of Each Amendment:

   The purpose of this regulatory amendment is to incorporate by reference the 12th Edition of the Disciplinary Guidelines as amended in 2015. This 12th Edition makes the Disciplinary Guidelines consistent with current law, updates and clarifies the terms and conditions of probation for physicians subject to discipline, and strengthens consumer protection.

Factual Basis/Rationale

Currently, section 1316 incorporates by reference the 11th Edition of the Disciplinary Guidelines, as amended in 2011. In the last four years since the last amendment, there have been statutory changes that must be reflected in the Disciplinary Guidelines. Additionally, the Board has identified areas in need of technical changes to improve clarity in the conditions of probation, and to reflect the changing probationary environment. The Board has also identified changes necessary to improve consumer protection. Finally, the Board is proposing some additional non-substantive changes to the Disciplinary Guidelines.

The summary of changes to the Disciplinary Guidelines and the reasons therefore are as follows:

The Board seeks to amend the Disciplinary Guidelines to reflect the new agency name of "Business, Consumer Services, and Housing Agency," and to identify the Disciplinary Guidelines as the 12th Edition, amended in 2015.

> These amendments are necessary to reflect the current agency name, which has changed from "State and Consumer Services Agency," to "Business, Consumer Services, and Housing Agency," and to identify the new edition of the Disciplinary Guidelines being incorporated by reference in section 1361.

The Board seeks to add a statement advising interested parties that the Disciplinary Guidelines are available on the Board's website, and to strike the section advising interested parties to write or call the Board for additional copies of the document.

> This amendment is necessary to reflect the more efficient practice of obtaining Board documents online. This facilitates access to public documents, and improves efficiency for staff.

The Board seeks to strike the summary of changes that appears at the beginning of the Disciplinary Guidelines.

> The rulemaking file is the official record for the justification and summary of all changes. There does not need to be a summary of changes included in the Disciplinary Guidelines.

The Board seeks to amend the Table of Contents as follows: Condition 18 will be amended to read "Clinical Competence Assessment Program;" Condition 19 will be amended to read "Written Examination;" and Condition 28 will be amended to read "Supervision of Physician Assistants and Advanced Practice Nurses." Additionally, the page numbers in the Table of Contents will be changed, if necessary.

> These changes to the Table of Contents are necessary because of the proposed amendments to the titles to Conditions 18, 19, and 28.

Further, it is likely that the page numbers of the conditions may change due to proposed additions and deletions to the Disciplinary Guidelines. If so, the Table of Contents will need to be amended for correctness.

Condition 9. Controlled Substances - Abstain from Use

The Board seeks to amend Condition 9 to make it consistent with a change in Government Code (GC) section 11529, effective January 1, 2014, which extended the timeframe for filing an accusation following the issuance of a suspension order from 15 days to 30 days. The proposed amendments to this condition will also clarify that the Administrative Law Judge (ALJ) and the Board each have 15 days to issue a decision, and will define good cause for the Board's delay in issuing such decision. The Board is proposing additional minor changes to add "the" and "is effective" to the following sentence: "The respondent shall not resume the practice of medicine until the final decision on an accusation and/or a petition to revoke probation is effective."

The amendments are necessary to make Condition 9 consistent with the changes in GC section 11529, and to clarify that the ALJ and Board each have a separate 15 days to issue a decision before a cease practice order dissolves. The Board's deadline may be extended for good cause, and the amendments are necessary to define good cause. Minor changes are also proposed for clarity and ease of reading.

Condition 10. Alcohol - Abstain from Use

The Board seeks to amend Condition 10 to make it consistent with a change in GC section 11529, effective January 1, 2014, which extended the timeframe for filing an accusation following the issuance of a suspension order from 15 days to 30 days. The proposed amendments to this condition will also clarify that the ALJ and the Board would each have 15 days to issue a decision, and will define good cause for the Board's delay in issuing such decision. The Board is proposing additional minor changes to add "the" and "is effective" to the following sentence: "The respondent shall not resume the practice of medicine until the final decision on an accusation and/or a petition to revoke probation is effective."

The amendments are necessary to make Condition 10 consistent with the changes in GC section 11529, and to clarify that the ALJ and Board each have a separate 15 days to issue a decision before a cease practice order dissolves. The Board's deadline may be extended for good cause, and the amendments are necessary to define good cause. Minor changes are also proposed for clarity and ease of reading.

Condition 11. Biological Fluid Testing

The Board seeks to amend Condition 11 to make it consistent with a change in GC section 11529, effective January 1, 2014, which extended the timeframe for

filing an accusation following the issuance of a suspension order from 15 days to 30 days. The proposed amendments to this condition will also clarify that the ALJ and the Board would each have 15 days to issue a decision, and will define good cause for the Board's delay in issuing such decision. The Board is proposing additional minor changes to add "the" and "is effective" to the following sentence: "The respondent shall not resume the practice of medicine until <u>the</u> final decision on an accusation and/or a petition to revoke probation <u>is effective</u>."

The amendments are necessary to make Condition 11 consistent with the changes in GC section 11529, and to clarify that the ALJ and Board each have a separate 15 days to issue a decision before a cease practice order dissolves. The Board's deadline may be extended for good cause, and the amendments are necessary to define good cause. Minor changes are also proposed for clarity and ease of reading.

<u>Condition 14. Prescribing Practice Course</u>

The Board seeks to amend Condition 14 to remove the reference to the Physician Assessment and Clinical Education Program (PACE) at the University of California, San Diego School of Medicine.

The amendments are necessary to eliminate the appearance of endorsing one program's courses over others. The amendments will clarify that the respondent shall enroll in a prescribing practices course approved in advance by the Board or its designee.

<u>Condition 15. Medical Record Keeping Course</u>

The Board seeks to amend Condition 15 to remove the reference to PACE at the University of California, San Diego School of Medicine.

The amendments are necessary to eliminate the appearance of endorsing one program's courses over others. The amendments will clarify that the respondent shall enroll in a medical record keeping course approved in advance by the Board or its designee.

<u>Condition 17. Professional Boundaries Program</u>

The Board seeks to amend Condition 17 to remove the reference to PACE at the University of California, San Diego School of Medicine.

The amendments are necessary to eliminate the appearance of endorsing one program's courses over others. The amendments will clarify that the respondent shall enroll in a professional boundaries program approved in advance by the Board or its designee.

<u>Condition 18. Clinical Training Program</u>

The Board seeks to amend Condition 18 to remove the reference to PACE at the University of California, San Diego School of Medicine, and to modify the components of an approved clinical training program. It further proposes non-substantive, grammatical changes.

The amendment to remove reference to PACE is necessary to eliminate the appearance of endorsing one entity's clinical competence assessment program over others. This amendment will clarify that the respondent shall enroll in an assessment program approved in advance by the Board or its designee.

The current Disciplinary Guidelines describe the clinical training program as a comprehensive assessment program comprised of a two-day assessment of respondent's physical and mental health; basic clinical and communication skills common to all clinicians; and medical knowledge, skill and judgment pertaining to respondent's area of practice in which respondent was alleged to be deficient, and at minimum, a 40-hour program of clinical education in the area of practice in which respondent was alleged to be deficient.

Amendments are needed to this condition to reflect changes to the educational and probationary environments. Under the proposed amendments, Condition 18 will be renamed "Clinical Competence Assessment Program." Moreover, the specific time-frame requirements of a two-day assessment and a 40-hour program will be deleted. The proposed amendments will require a comprehensive assessment of respondent's physical and mental health; and the six general domains of clinical competence as defined by the Accreditation Council on Graduate Medical Education and the American Board of Medical Specialties pertaining to the respondent's current or intended area of practice. The proposed amendments identify what the program shall consider during its assessment of the respondent, and specifies that the program shall require the respondent's on-site participation for a minimum of three to five days as determined by the program. These changes are necessary to better permit the program to design an assessment program particular to each respondent's circumstance to improve consumer protection and rehabilitation of the respondent.

The proposed amendments require the program to submit a comprehensive assessment to the Board that unequivocally states whether the respondent has demonstrated the ability to practice safely and independently, and provide its recommendations for any further education, clinical training, or evaluation or treatment for any medical or psychological condition, or anything else affecting respondent's practice of medicine. These changes are necessary to clarify expectations of the Board for approved clinical competence assessment programs.

The proposed amendments will eliminate the requirement that the respondent pass an examination at the completion of additional education or clinical training. The current language has been interpreted to require an exit examination. This language does not accurately reflect the process, and needs to be corrected.

Testing is done throughout the clinical competence assessment program at various steps in order for the program to draw its conclusions and to make recommendations for further evaluations and training.
Under Option #1: Condition Precedent of Condition 18, the proposed amendment eliminates the exception allowing respondent to practice medicine in a clinical training program. This change is necessary, because this language was deemed superfluous and confusing.

Condition 19. Oral and/or Written Examination

The Board seeks to amend Condition 19 to remove the oral examination as an evaluation tool that could be ordered. It also seeks to strike the language indicating that the respondent shall be allowed to take a second exam if he or she fails the first one.

Condition 19 provides an alternative method of evaluating a physician's medical knowledge when a clinical training program is not considered to be an appropriate condition to order for physicians charged with gross negligence or repeated negligent acts. This condition requires that an oral clinical examination be administered pursuant to the requirements outlined in Business and Professions Code section 2293. This evaluation component requires the Board to convene a panel of 3 experts to develop and administer an oral examination to the respondent. This evaluation tool has been the subject of frequent legal challenges and has been considered a less objective method of determining clinical competency.

In addition, the Board utilized the medical consultants located in each district office to facilitate and coordinate the administration of the oral clinical examination, if ordered. On July 1, 2014, pursuant to Senate Bill 304, the Board's sworn staff and their support staff, including the district medical consultants, were transferred to the Department of Consumer Affairs. The district medical consultants are no longer available to the Board's Probation Unit to provide the coordination of the oral clinical examination should it be ordered as a condition of probation.

As this evaluation tool has been considered a less objective method to test a physician's clinical competence and the Board no longer has the necessary resources to develop and administer the oral clinical examination, an amendment to this condition is required to eliminate the oral clinical examination as a condition that could be ordered.

The proposed amendment will also strike the language indicating that the respondent shall be allowed to take a second exam if he or she fails the first one. This deletion is necessary because it results in an inconsistency with subsequent language in the regulation that indicates that the failure to pass the examination within 180 calendar days after the effective date of the Decision is a probation violation. Accordingly, this change will not limit the number of times that the

respondent can take the written exam, but it will maintain the time limitation for completing this condition of probation.

Condition 23. Monitoring – Practice/Billing

The Board seeks to amend Condition 23 to remove the reference to PACE at the University of California, San Diego School of Medicine.

The amendments are necessary to eliminate the appearance of endorsing one program's courses over others. The amendments will clarify that, in lieu of a monitor, the respondent may participate in a professional enhancement program approved in advance by the Board or its designee.

Condition 25. Third Party Chaperone

The Board seeks to amend Condition 25 to reduce the time allowed to replace a chaperone from 60 days to 30 days.

Condition 25 is ordered in cases where a physician's conduct with a patient has been found to be inappropriate. In order to ensure adequate patient protection measures are in place, a third-party chaperone must be present when patients are being examined. Routinely, the third-party chaperone function is performed by one of the physician's employees such as a medical assistant or another health care professional. The proposed amendment requires the replacement of a chaperone within 30 days. Amending the language in this condition to require that the physician replace the third-party chaperone within 30 days, rather than within 60 days, is appropriate in order to provide increased patient protection from a licensee already disciplined for inappropriate conduct with a patient.

Condition 28. Supervision of Physician Assistants

The Board seeks to amend the title and the terms of this condition to prohibit the supervision of advanced practice nurses in addition to physician assistants.

It has been a well-established requirement that physicians on probation are prohibited from supervising physician assistants. Similar to physician assistants, advanced practice nurses work under the general supervision of a physician, pursuant to established standardized procedures. An amendment to this condition is necessary to add the prohibition to supervise advanced practice nurses.

Condition 31. General Probation Requirements

The Board seeks to amend the language that requires the respondent to comply with all terms and conditions of probation.

This amendment is necessary because Condition 31, which outlines general probation requirements, was found to contain confusing language when read

together with Condition 33, Non-Practice While on Probation. Condition 33 states, in part, that periods of non-practice will relieve the respondent of the responsibility to comply with some of their probationary terms. However, Condition 31 states, in part, that "the respondent shall comply with the Board's Probation Unit and all terms and conditions of this Decision." An amendment is required to eliminate the phrase "and all terms and conditions of this Decision."

Condition 33, as described below, will address the difference between respondents residing in California, who must comply with all terms and conditions of probation, even during periods of non-practice, and respondents residing in another state, who are relieved of the responsibility of complying with certain probationary terms during periods of non-practice.

Condition 33. Non-practice While on Probation

The Board seeks to amend the language to clarify that physicians residing in California are required to comply with all terms and conditions of probation, even during periods of non-practice. Physicians residing outside of California are relieved of complying with the terms and conditions of probation except for this condition (Condition 33), and the following terms and conditions: Obey All Laws; General Probation Requirements; Quarterly Declarations; Abstain from the Use of Alcohol and/or Controlled Substances; and Biological Fluid Testing. Additionally, the Board seeks to amend the requirement that physicians complete a clinical training program if their period of non-practice exceeds 18 months, and instead requires the respondent to successfully complete the Federation of State Medical Board's (FSMB) Special Purpose Examination (SPEX).

When the Disciplinary Guidelines were revised in 2011, two conditions that described what was expected from a physician who was not practicing medicine during probation, either in California or out-of-state, were consolidated into one condition, Non-practice While on Probation. The new language stated that periods of non-practice relieved the respondent of the responsibility to comply with the terms of probation except for this condition (Condition 33), and the conditions entitled "Obey All Laws" and "General Probation Requirements." After implementation, it was discovered that the new language inadvertently conflicted with the existing policy on what was required of non-practicing physicians residing in California. The 10th Edition of the Disciplinary Guidelines (Condition 34) stated that physicians residing in California but not practicing were expected to comply with all terms and condition of probation. Under these same guidelines, physicians residing out of state were only expected to comply with general conditions such as "obey all laws" and "probation unit compliance." An amendment to the language is required to address this inconsistency and clarify the requirements for compliance with terms and conditions of probation during periods of non-practice for respondents residing in California and those residing in other states.

The Board is also proposing that, in lieu of requiring the respondent to enroll in a comprehensive assessment program after 18 months of non-practice, the

respondent be allowed to complete the SPEX, instead. When the Disciplinary Guidelines were revised in 2011, the Board added the requirement that if the period of non-practice exceeded 18 months, an assessment and clinical training program must be completed before the physician could resume practice. This requirement was added to address the Board's concern that a lengthy absence from the practice of medicine could impact the physician's clinical knowledge and skill set. Any disciplinary action taken against a physician for concerns about the quality of care provided, however, will have already included the requirement that the physician complete the clinical assessment program, where appropriate. Condition 33, however, applies to all cases, whether a quality of care concern was involved or not in the underlying discipline. The Board has concluded that any concerns about the physician's current clinical knowledge or skills can be addressed by requiring the physician to successfully complete the SPEX. This test is developed and administered through the FSMB and is used as a component in the testing performed by all approved clinical training programs currently accepted by the Board. This change will provide for consumer protection, and rehabilitation of the physician.

Changes to the Titles of Probation Conditions in the Section on Recommended Range of Penalties for Violations

The Board seeks to change the titles for probation conditions in the section on Recommended Range of Penalties for Violations to correspond with the proposed title changes to these conditions for consistency. The Board is seeking to change "Clinical Training Program" to Clinical Competence Assessment Program," for each reference to Condition 18, and "Oral or Written Examination" to "Written Examination" for the reference to Condition 19.

These amendments are necessary for the document's internal consistency with condition titles in the body, as well as in the Table of Contents.

Technical, Theoretical, and/or Emprical Study Reports, or Documents

- Senate Bill 304, which made statutory changes to GC section 11529.
- Staff report for the July 24-25, 2014 Board Meeting (agenda item 18).
- The relevant section of the approved minutes of the July 24-25, 2014 Board Meeting.
- Staff report for the July 30-31, 2015 Board Meeting (agenda item 16).
- The relevant section of the draft minutes of the July 31, 2015 Board Meeting is included in this rulemaking file, and will be replaced with the approved minutes following Board approval.

- Proposed changes to Condition 18 are based, in part, upon the recommendations of representatives from PACE, including William Norcross, M.D., Peter Boal, and Kate Seippel, M.P.H. These recommendations were presented at the October 23, 2014 Enforcement Committee Meeting. A copy of the presentation is included in this rulemaking file.

- The relevant section of the approved minutes of the October 23, 2014 Enforcement Committee Meeting.

Business Impact

The Board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the fact that these proposed amendments to the Disciplinary Guidelines will simply make this document consistent with current law, amend the document to reflect the changes that have occurred in the educational and probationary environment since the last update, clarify terms and conditions of probation, and improve consumer protection.

Economic Impact Assessment

The Board has made the initial determination that this regulatory proposal will have the following impact:

- It is not likely to create or eliminate jobs within the State of California. This initial determination is based on the fact that these proposed amendments to the Disciplinary Guidelines will simply make this document consistent with current law, amend the document to reflect the changes that have occurred in the educational and probationary environment since the last update, clarify terms and conditions of probation, and improve consumer protection.

- It is not likely to create new businesses or eliminate existing businesses within the State of California. This initial determination is based on the fact that these proposed amendments to the Disciplinary Guidelines will simply make this document consistent with current law, amend the document to reflect the changes that have occurred in the educational and probationary environment since the last update, clarify terms and conditions of probation, and improve consumer protection.

- It will not likely affect the expansion of businesses currently doing business within the State of California. This initial determination is based on the fact that these proposed amendments to the Disciplinary Guidelines will simply make this document consistent with current law, amend the document to reflect the changes that have occurred in the educational and probationary environment since the last update, clarify terms and conditions of probation, and improve

consumer protection.

- It will benefit the health and welfare of California residents because it updates and clarifies the terms and conditions of probation for physicians subject to discipline, makes the Disciplinary Guidelines consistent with current law, and strengthens consumer protection.

- It will not have a significant impact on worker safety because these proposed amendments to the Disciplinary Guidelines will simply make this document consistent with current law, amend the document to reflect the changes that have occurred in the educational and probationary environment since the last update, clarify terms and conditions of probation, and improve consumer protection.

- It will not have an impact on the state's environment because these proposed amendments to the Disciplinary Guidelines will simply make this document consistent with current law, amend the document to reflect the changes that have occurred in the educational and probationary environment since the last update, clarify terms and conditions of probation, and improve consumer protection.

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 would be 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 public is invited to submit such alternatives during the public comment period.

Set forth below are the alternatives which were considered and the reasons each alternative was rejected:

1. Do not seek a change. This alternative was rejected because it would result in the Disciplinary Guidelines being inconsistent with current law, outdated, and containing language that has been deemed confusing and inconsistent with public protection.

2. Adopt the proposed regulatory amendments. This alternative was determined to be the most appropriate because it provides the public with Disciplinary Guidelines which reflect recent changes in law, changes in educational and probationary environments, and which is amended for clarity and consistency, and improvement in public protection.