



California State Board of Pharmacy

1625 N. Market Blvd, N219, Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
SB 1441 UNIFORM STANDARDS IMPLEMENTATION COMMITTEE
MINUTES**

DATE: June 19, 2015

LOCATION: University of Southern California – Orange County Center
2300 Michelson Drive
Irvine, CA 92612

COMMITTEE MEMBERS

PRESENT: Stanley C. Weisser, Committee Chair
Victor Law, RPh
Amy Gutierrez, PharmD. President

COMMITTEE MEMBERS

NOT PRESENT: Ricardo Sanchez, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne, Sodergren, Assistant Executive Officer
Desiree Kellogg, Deputy Attorney General
Laura Hendricks, Staff Analyst

Call to Order

Chairperson Weisser called the meeting to order at 10:00 a.m.

Chairperson Weisser conducted a roll call. Committee members present: Victor Law and Amy Gutierrez. Committee member Ricardo Sanchez was absent.

1. Review of SB 1441 Uniform Standards Relating to Substance Abusing Healing Arts Licensees

Chairperson Weisser provided a brief background on SB 1441. He explained that in early 2011, the board directed staff to restructure and update its Disciplinary Guidelines. Subsequent to this, in April 2011, the uniform standards required in Professions Code section 315 were finalized.

Chairperson Weisser reported that in addition to the standards themselves, the board received opinions on the implementation of the uniform standards from both the Office of the Attorney General and the DCA Legal Office. The opinions provided did not offer consistent guidance and as such the board requested a formal legal opinion from the Office of the Attorney General in January 2013. Chairperson Weisser noted that the board received a response to this request on April 8, 2015.

Chairperson Weisser reported that during the April 2015 Board Meeting, the board briefly discussed the new legal opinion and was advised that the new opinion provides for some discretion by the board. As this is contrary to prior guidance provided, the members were advised that staff and counsel would work on implementation options and discuss the issue during the June Meeting.

Chairperson Weisser stated that during the June Board meeting, this ad hoc committee was established to allow a complete review of the proposed implementation strategy briefly discussed during the board meeting.

Chairperson Weisser noted that this committee meeting would be the first opportunity to discuss in great detail the proposed changes to the Disciplinary Guidelines. He explained that suggested changes include:

1. Consolidation of license types within the guidelines to improve ease of use.
2. Revisions to implementation of/or modifications to conform with the standards
3. Revisions to improve the board's ability to monitor licensees on probation with the board.

Anne Sodergren, assistant executive officer, provided a PowerPoint presentation which outlined the 16 uniform standards required by Business and Professions Code section 315. The presentation also highlighted the specific ways in which the board will formally implement the uniform standards. Ms. Sodergren noted that in general the board has been following the uniform standards for several years. The PowerPoint presentation has been provided following these minutes.

2. Review of Proposed Changes to Title 16 California Code of Regulations Section 1760 Disciplinary Guidelines

Chairperson Weisser explained that the committee would review the disciplinary guidelines section-by-section. The changes to each section would be discussed and the committee would then vote to approve or modify the proposed changes.

Note: The committee discussed the proposed changes in each section of the guidelines as described below. The guidelines with strikeout and underscores to indicate each change can be viewed in Attachment 2 of the meeting materials. Additionally a high-level overview of the reasoning for the

changes being made to the guidelines can be viewed in Attachment 4 of the meeting materials using the following link. http://www.pharmacy.ca.gov/meetings/agendas/2015/15_jun_sb1441_mat.pdf

Title Page, Table of Contents, Introduction, and Mitigating Evidence – Pages 1-5

Proposed changes:

- Update the revision date on the title page from 10/2007 to 6/2015.
- Update the name of the board’s president to Amy Gutierrez.
- Update the Table of Contents to reflect the consolidation of the individual license types
- Update the introduction to allow for easier reading and consistency as well as to update the revision date.
- Change the mitigating evidence section to further define and clarify examples of appropriate evidence a respondent may submit to include personal or professional references that have knowledge of the respondent’s character and rehabilitation, as well as conduct which the respondent is accused and other pertinent facts that would enable the board to decide a case. The proposed change also details the method by which this information must be provided to the board.

Committee Discussion:

Dr. Gutierrez , board president, noted that the committee needs to consider how to incorporate the expanded scope of practice for advanced practice pharmacists and compounding violations into the various categories of discipline. Ms. Sodergren acknowledged that these two areas need to be addressed and agreed to bring language to the next committee meeting.

Ms. Sodergren stated that in Category 1 the term “relatively minor” will be changed to “less serious than Categories 2 through 4.” The committee agreed with this change.

Ms. Herold, executive officer, commented that throughout the document the phrase “dangerous drugs and devices” was used. She asked the committee if they would like to change the phrase to “dangerous drugs and dangerous devices.” The committee decided to make this change throughout the entire document.

Ms. Herold noted that the introduction paragraph on Page 1 of the guidelines would need to be modified because it incorrectly states that interns can take on the responsibility of a pharmacist-in-charge. Staff agreed to make this modification.

Motion: Approve the changes to the Title Page, Table of Contents, Introduction, and Mitigating Evidence (Pages 1-5). Incorporate the changes discussed by the committee.

M/S: Gutierrez/Law

Support: 0

Oppose: 0

Abstain: 0

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

Proposed Changes:

- Change the title of this section of the guidelines to reflect the consolidation of each of the individual license types into one standardized section
- Categories of Violations and Recommended Penalties
 - Facilitate consolidation of the individual license types
 - Better define the grounds for discipline
 - Explain the structure under each category as well as how the board should use the information provided.
- Category 1 - Category 4
 - The majority of the changes reflected in these sub-sections are to remove the titles associated with each section of law.
 - In place of this list of codes, the board is proposing incorporation of summaries of each of the statutes into narrative language that better describes the types of violations that would constitute such discipline.

Committee Discussion:

Dr. Gutierrez noted that the disciplinary guidelines refer to actions that occur in a pharmacy; however, Advanced Practice Pharmacists (APP) do not have to practice in a pharmacy. Ms. Sodergren responded that staff would review the guidelines to address APP's expanded scope of practice.

Ms. Herold commented that in one section of the guidelines it states that the minimum term of probation is three years, however in Category 1 of this section it states the minimum term is one year. The committee agreed that the minimum term of probation should be three years of probation throughout the entire document.

Tony Park, pharmacist and attorney, asked the committee to consider leaving in the one-year term of probation because often Administrative Law judges do not know that they can choose to assign a probationary term of less than three years.

Desiree Kellogg, Deputy Attorney General, noted that the board always has the authority to deviate from the guidelines if they feel it is appropriate.

Ms. Herold and Ms. Sodergren explained that a one-year term of probation does not provide the board with enough time to monitor the licensee to ensure that they are safe to return to unsupervised practice.

The committee elected to change the minimum discipline in Category 1 to two years of probation.

Motion: Approve the proposed changes to the “Terms of Probation – Individual Licensees” section as provided in the meeting materials (Pages 6-21). Change Category 1 to state that the minimum term of probation is two years.

M/S: Law/Gutierrez

Support: 3 Oppose: 0 Abstain: 0

Model Disciplinary Language – Individual Licensees (Pharmacist, Advanced Practice Pharmacist, Intern Pharmacist, Pharmacy Technician, Designated Representative, Designated Representative-3PL) [Pages 22-27](#)

Proposed Changes:

- Change the title of this section of the guidelines to reflect the consolidation of each of the individual license types into one standardized section as well as add in two additional license types (Advanced Practice Pharmacist and Designated Representative-3PL).
- Revocation: This section is being changed to facilitate consolidation of the individual license types and to clarify that the respondent must relinquish any indicia of licensure. The board is replacing “his or her” with [his/her] to allow for the decision to reflect the gender of the respondent. Further, the board is making the current proposed option of a payment plan the standard language. The current payment in full within 15 days requirement is being changed to optional language. This change is necessary to more accurately reflect the common practice of the board to provide more flexibility and options when requiring cost recovery from a respondent whose license has been revoked.
- Suspension: This section is being changed to facilitate consolidation of the individual license types as well as to clarify what actions are prohibited during a period of any suspension.
- Issuance of Probationary License: The changes in this section are to facilitate consolidation of the individual license types. Further a new option is being proposed that would provide model language for the issuance of a pharmacist intern license. This model language is necessary to ensure the respondent is advised of the effect of potential discipline of the intern pharmacist license on any subsequent application for licensure as a pharmacist and ensure the board has the ability to carry over the discipline imposed on the intern pharmacist license to the pharmacist license should one be issued during the period of probation.

- Surrender: This section is being changed to facilitate consolidation of the individual license types and to clarify that the respondent must relinquish any indicia of licensure. The board is replacing “his or her” with [his/her] to allow for the decision to reflect the gender of the respondent. Further this section is being modified to clarify that any licensing exams and education or experience requirements necessary to fulfill the requirements for a license must be satisfied upon reapplication.
- License Reinstatement Order with Conditions Prior to Issuing License: This language is new and is necessary to provide model language as guidance to those individuals (board members and administrative law judges) responsible for crafting reinstatement orders. The language proposed is consistent with current practice and provides specificity to the requirements for reinstatement of a license, including conditions precedent for passage of an exam as specified as well as appropriate fees. Further, optional language is provided to specify cost recovery owed to the board.
- License Reinstatement: This language is new and is necessary to provide model language as guidance to those individuals (board members and administrative law judges) responsible for crafting reinstatement orders. The language proposed is consistent with current practice.
- Adoption of Stipulation: The board is proposing removal of this language as it is in conflict with the standard language used by the Office of the Attorney General who is responsible for drafting stipulated settlements for the board.
- Standard Conditions Listing: The board is proposing changes to titles and or the renumbering of terms to reflect changes and consolidation of terms as well as to reflect new terms that will be incorporated.
- Optional Conditions Listing: The board is proposing changes to titles and or the renumbering of terms to reflect changes and consolidation of terms as well as to reflect new terms that will be incorporated.

Committee Discussion:

Dr. Gutierrez noted that if the board revokes an APP license, they may want to require them to do more to get their APP license back than a “regular pharmacist.” The committee agreed.

Dr. Gutierrez asked if when the board revokes an APP license, the pharmacist license is automatically revoked as well. Ms. Herold responded that this would not happen automatically, it would be up to the board to revoke *both* licenses. Ms. Sodergren added that staff would review this section and draft language specific to APP licensure.

Motion: Approve the proposed changes to the “Model Disciplinary Language – Individual Licensees” section as provided in the meeting materials (pages 22-27).

M/S: Law/Gutierrez

Support: 3 Oppose: 0 Abstain: 0

Standard Conditions – Pages 28-35

Proposed Changes:

- Cooperate with board Staff: Proposed changes are to clarify what activities are encompassed within the term as well as specify that such cooperation must occur timely.
- Continuing Education: Specifies that this term applies to pharmacist respondents only.
- Reporting of Employment and Notice to Employers: The proposed change in the title is more reflective of the provisions contained within the term. The proposed changes will require the respondent to notify the board in writing of employment information as well as changes in such employment and specifies how such reporting must be made to the board. This change is necessary to provide the board with readily available information on employment to allow for comprehensive probation monitoring, including at a respondent's worksite. Further, the proposed changes clarify who the respondent must notify of the terms and conditions of probation imposed as well as the responsibility of the probationer to ensure that appropriate documentation is submitted to the board confirming compliance with this requirement. This term is also being changed to allow for the consolidation of each of the individual license types.
- Notification of Change(s) in Employment, Name, Address(es) or Phone Number(s): This term is being renamed to better reflect the requirements of the term. Also, this term is being renumbered to ensure better overall flow of the guidelines.
- Restrictions on Supervision and Oversight of Licensed Facilities: This term is being renamed to better reflect the requirements of the term and to specify that it is appropriate only for pharmacist and designated representative licensees. Further this term provides for the consolidation of other existing terms - - No Supervision of Ancillary Personnel and Consultant for Owner or Pharmacist-in-Charge. In the new format, these proposed changes to the term provide optional language that existed in these other terms of probation. This term is also being changed to facilitate consolidation of the probationary terms for all of the individual license types. This term also sets forth various optional terms that will allow limited conditions under which there may be exceptions to this prohibition.
- Reimbursement of Board Costs: This term is being renumbered. Also, a new option is being created that will allow a respondent to submit payments to the board pursuant to an approved plan, and would specify that payment in full must be completed at least one year prior to the end of probation. This option allows the board greater flexibility to address a respondent's financial concerns that may arise. Further, the proposed change

removes the language stating that the filing of bankruptcy does not relieve the respondent of the requirement to pay the board. This change is necessary to recognize that the board cannot determine what debt is released during the filing of bankruptcy.

- Probation Monitoring Costs: This term is being renumbered.
- Status of License: This term is being renumbered and modified to facilitate consolidation of the probationary terms for all of the individual license types.
- License Surrender While of Probation: This term is being renumbered and modified to facilitate consolidation of the probationary terms for all of the individual license types.
- Certification Prior to Resuming Work: For purposes of consolidation, this term is being moved. Further, the term now reflects that it is appropriate only for pharmacy technician licensees.
- Notification of Departure: For purposes of consolidation, this term is being moved. Further, this requirement will now apply to all individual licensees, not just pharmacy technicians and designated representatives. This term is necessary to apply to all individual licensees to ensure the board remains apprised of a respondent's location and availability for probation monitoring purposes.
- License Practice Requirement – Tolling: This term is being renumbered and renamed to better reflect the provisions contained therein. Proposed changes are necessary to facilitate consolidation of the individual license types and well as provide more clarity on what information the board requires to confirm compliance with this provision. Additionally, the optional language is being changed to allow the board greater flexibility in meeting the employment needs of a respondent while balancing the board's probation monitoring needs to ensure that necessary rehabilitation occurs. A new option is also created specific for intern pharmacists to reflect the experiential requirements of pharmacy education.
- Violation of Probation: This term is being renumbered and the provision allowing for automatic revocation is being removed.
- Completion of Probation: This term is being renumbered.

Committee Discussion:

Ms. Sodergren noted that Option 2a, Option 2b, and Option 2c are very lengthy and need to be streamlined. The committee agreed and directed staff to work with the Attorney General's office to modify this section.

Dr. Gutierrez asked if probationers had to notify the board if they are leaving the probationary geographic area both verbally and in writing. Ms. Sodergren confirmed that the notification can occur verbally, but must also be provided in writing.

Motion: Approve the proposed changes to the “Standard Terms” section as provided in the meeting materials (pages 22-27). Direct staff to work with the Attorney General’s Office to streamline Option 2a, Option 2b and Option 2c.

M/S: Gutierrez/Law

Support: 3 Oppose: 0 Abstain: 0

Optional Conditions of Probation – Pages 35-59

Proposed Changes:

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

is being updated to clarify the conditions when inclusion of this term is appropriate. This term also makes conforming changes to the language of the term and is being modified to allow for consolidation of the probationary terms for all of the individual license types. The board is specifying that upon receipt or recommendation by the evaluator, additional restrictions or conditions on respondent's practice may be imposed.

- Option 1 is being added to include that the respondent is suspended from practice until specified conditions are met including:
 - Completion of the evaluation,
 - Submission of the evaluator's report, demonstrating that the respondent is safe to return to practice,
 - The board has determined that respondent is safe to return to practice and under what conditions.
 - Respondent received written notice that practice may resume.

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

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

- Psychotherapy: This term is being renumbered and the guidance provided to the guideline users is being updated to clarify the conditions when inclusion of this term is appropriate. The suspension language is being modified to clarify those activities that are prohibited during any such suspension.

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

- Pharmacists Recovery Program (PRP): The guidance provided to the users of these guidelines is being updated to clarify the conditions when inclusion of this term is appropriate. This term is also being modified to clarify what actions a respondent must take to comply with the term as well as the timeline for completion. (Currently the board has received complaints that this term lacks specificity and has caused confusion for licensees on the board's expectations for compliance.) The term is also clarifying that the respondent must comply with the treatment contracts established

by the PRP and that failure to comply will result in the automatic suspension of practice by the respondent. The suspension language is being modified to clarify those activities that are prohibited during any such suspension. The option language is being modified to clarify the intent of the option, which is to allow the PRP the ability to monitor a respondent under specified conditions prior to the respondent successfully completing the PRP.

- Drug and Alcohol Testing: This term is being renumbered and renamed to better reflect the scope of the term and the guidance provided to the users of these guidelines is being updated to clarify the conditions when inclusion of this term is appropriate.
- Drugs and Abstain from Drugs and Alcohol: This term is being renumbered and portions rewritten to clarify exceptions to the prohibition.
- Prescription Coordination and Monitoring of Prescription Use: The guidance provided to the users of these guidelines is being updated to clarify the conditions when inclusion of this term is appropriate. This term is also being modified to allow for consolidation of the probationary terms for each of the individual license types and to clarify that the board may identify a designee to perform board functions. The suspension language has been changed to clarify those activities that are prohibited during any such suspension.
- Community Service. This term is being renumbered and modified to facilitate consolidation of the probationary terms for each of the individual license types. In addition, the term specifies that proof of completion must be provided and clarifies that the board may allow a designee to perform board functions.
- Restitution: This term is being renumbered.
- Remedial Education: This term is being renumbered and to clarify that approval of the coursework is required. The phrase “his or her” is being replaced with [his/her] to allow the decision to reflect the gender of the respondent.
- Pharmacy Self-Assessment Mechanism: This term is being removed as it is no longer provided by the National Association of Boards of Pharmacy.
- Intern Pharmacist Experience: This term is being renumbered and a notation is being added to indicate that the term is only appropriate for intern pharmacists. In addition, the timeframe to complete the requirement has been extended to allow respondent sufficient time to submit proof to the board.
- Supervised Practice: This term is being renumbered and a notation is being added to indicate this term only applies to pharmacists, pharmacist interns and designated

representatives. This term is being recast to better describe the requirements of the term and to provide better guidance to the respondent on the board's expectations. This term defines what constitutes a violation of probation and the suspension language has been changed to clarify those activities that are prohibited during any such suspension.

- No Supervision of Ancillary Personnel: This term is being consolidated into another term, "Restrictions on Supervision and Oversight of Licensed Facilities" and is therefore no longer needed.
- No Ownership or Management of Licensed Premises: The name of this term is being modified to better reflect the context of the restriction. One grammatical change is being made as well.
- Separate File of Controlled Substances: The name of this term is being modified to better reflect the content of the requirement and a conforming change is being made to ensure consistency of the layout of the document.
- Report of Controlled Substances: A conforming change is being made to ensure the consistency of the document. In addition this term is being modified to allow the board greater flexibility in determining the frequency of reports that must be submitted. This term is also clarifying that the board allows the use of a designee to complete functions on its behalf.
- No Access to Controlled Substances: This section is being changed to incorporate all scheduled drugs.
- Criminal Probation/Parole Reports: This term is being modified to replace the phrase "his or her" with [his/her] to allow for the respondent's gender to be accurately reflected in the decision.
- Consultant for Owner or Pharmacist-in-Charge: This term is being consolidated into another term, "Restrictions on Supervision and Oversight of Licensed Facilities" and is therefore no longer required.
- Tolling of Suspension: This term is being removed as its provisions will be contained in term 15.
- Surrender of DEA Permit: This term is being renumbered and a notation is being added to clarify that this term should only be used for pharmacists, advanced practice pharmacists and pharmacist interns. This term is being modified to replace the phrase "his or her" with [his/her] to allow for the respondent's gender to be accurately reflected in the decision. In addition, this term clarifies what acts are prohibited under this term and the two optional terms are being numbered.

- **Ethics Course:** This term is being renumbered and a notation is being made to clarify that this term should only be used for pharmacists, advanced practice pharmacists and pharmacist interns. In addition, this term is being modified to accurately reflect the course requirements as detailed in Title 16, California Code of Regulations Section 1773.5 and specifies that proof of enrollment and completion must be provided to the board. The term also specifies that failure to provide such proof will be considered a violation of probation.
- **Facilitated Group/Recovery and/or Support Meetings:** The Board proposes the addition of this additional probation condition in consideration of the SACC's uniform standards. Within thirty (30) days from the effective date of the decision, a licensee would be required to submit to the Board or its designee for prior approval the name of one or more meeting facilitators. The licensee would be required to submit verified documentation of attendance with each quarterly report. The licensee would be required to continue attendance in such a group for the duration of probation unless notified by the Board that attendance is no longer required.
- **Attend Substance Abuse Recovery Relapse Prevention and Support Groups.** This term is not new, but is being moved from a previous section of the guidelines and could now apply to any individual license.
- **Work Site Monitor:** This term is not new, but is being moved from a previous section of the guidelines and could now apply to any individual license. In addition guidance is being provided to users of the guidelines for when inclusion of this term is appropriate.

Committee Discussion:

Ms. Sodergren highlighted that the phrase "substance use" is used in most of the terms. Only when a term is specific to SB 1441 is the phrase "substance abuse" used. The committee agreed that this was the correct wording.

Mr. Park asked why probationers are not allowed to leave California for more than 10 days. Ms. Kellogg responded that requiring the probationer to stay in the state allows the board to adequately monitor the probationer (i.e. drug testing, meeting with board staff, completing continuing education). Ms. Herold added that the probationer can still choose to leave California; their probation would just be tolled during the time they are out of the state. Dr. Gutierrez asked Ms. Kellogg to review the legality of this term and report back to the committee.

Motion: Approve the "Optional Conditions of Probation" (pages 35-59) as provided in the meeting materials.

M/S: Law/Gutierrez

Support: 3

Oppose: 0

Abstain: 0

Terms of Probation – Premises (Pages 84-88)

Proposed Changes:

- Many of the changes are proposed to provide clarification and allow for easier reading and consistency.
- Category 1-Category 4
 - The majority of the changes reflected are to remove the titles associated with each section of law. In place of this list of codes, the board is proposing incorporation of summaries of each of the statutes into narrative language that better describes the nature of violations that would constitute such discipline. These changes are necessary to provide for a more useful application. The board notes that the current list of statutes provided is difficult for someone to use that is not familiar with Pharmacy Law and is provided in an overwhelming fashion that defeats the purpose of providing the users with a convenient way of determining the board's recommended penalties. The proposed changes will more easily aid the user in the use of the Disciplinary Guidelines.

Committee Discussion:

Chairperson Weisser noted that the minimum term of probation would need to be changed to two years.

Dr. Gutierrez asked if illicit drugs (marijuana, methamphetamine, etc.) would be considered a controlled substance (see first paragraph on page 84). Ms. Sodergren responded that staff would review this paragraph to ensure that illicit drugs are included.

Dr. Gutierrez commented that there should be more serious consequences when the diversion could lead to a potential infection control risk. Ms. Sodergren responded that at the next meeting staff would provide language for the committee to consider.

Motion: Approve the "Terms of Probation" (pages 84-98) as provided in the meeting materials.

M/S: Gutierrez/Law

Support: 3

Oppose: 0

Abstain: 0

Model Disciplinary Language: Premises – Pages 99-102

Proposed Changes:

- Revocation: This section is being modified to remove the word "owner." A definition of respondent is being added in a separate section to specify the intended licensee. As

such this word would no longer be needed. Further the term is being rewritten to clarify that the premises is responsible for arranging the destruction, transfer, sale or storage of all dangerous drugs or devices.

- Suspension: This section is being modified to allow for the selection of the appropriate license type.
- Issuance of Probationary License: This term is being modified to allow for the selection of the appropriate license type.
- Surrender: This section is being modified to remove the word “owner. In addition the phrase “he or she” is being replaced to allow for an accurate reflection of the gender of the owner in the decision. Option 1 is being added for pharmacy respondents to ensure the continuity of patient care.
- Adoption of Stipulation: The board is proposing removal of this language as it is in conflict the standard language used by the Office of the Attorney General who is responsible for drafting stipulated settlements for the board.

Committee Discussion:

The committee discussed the need to create more aggressive consequences for pharmacists who do not provide patient consultations. Ms. Sodergren asked if the committee wanted to discipline both the pharmacist and the pharmacy. The committee confirmed that the owner of the pharmacy should also be held accountable for lack of consultation.

Mr. Park agreed that more aggressive consequences would encourage patient consultation. However, he warned that it may drive business away from physical pharmacies to mail-order pharmacies. The committee agreed and asked staff to agendize review of mail-order consultation requirements for a future Public Education committee meetings.

A pharmacist from Walgreens reported that Walgreens now requires documentation that the pharmacist provided consultation on *all* new prescriptions.

Motion: Approve the “Model Disciplinary Language” (Pages 99-102) as provided in the meeting materials.

M/S: Gutierrez/Law

Support: 3 Oppose: 0 Abstain: 0

Standard Conditions – Pages 103-107

Proposed Changes:

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

Further a provision that previously specified that the board would retain jurisdiction is being removed as it is no longer needed. Elements of that provision are incorporated elsewhere in these guidelines.

- License Surrender While on Probation: This term is being renumbered and is being modified to remove the word “owner” as a definition of respondent is being added in a separate term. In addition, additions will provide guidance to the user of these guidelines on when inclusion of the option provided is appropriate and a timeframe for compliance with the option is also established.
- Sale or Discontinuance of Business: This is a new term that specifies that the board, in its sole discretion, will determine if it retains jurisdiction over a licensed location that has either changed location or ownership (full or partial) irrespective if a new license number is issued. If the board makes such a determination, the jurisdiction shall be carried over to the new location or license number and the terms and conditions of probation will carry over for the remainder of the probation period. This proposed change was previously contained in a different term (License Surrender While on Probation). This provision allows the board to accommodate a change in ownership or location, etc., without incurring additional costs.

Committee Discussion:

Ms. Sodergren asked the committee to consider requiring pre-approval of the location receiving the drugs and patient records when a pharmacy discontinues business. Ms. Herold noted that staff suspects that some entities are storing patient records in unlicensed locations, which is a violation of pharmacy law.

Ms. Kellogg stated that she would recommend that these provisions be included in the disciplinary guidelines, specifically they should be included in item 10 of this section. The committee agreed with the recommendation.

Ms. Sodergren concluded that since the committee agreed with the recommendation she would work with Ms. Kellogg to finalize the language and bring it to the next committee meeting.

Motion: Approve the “Standard Conditions” (Pages 103-107) as provided in the meeting materials. Direct staff to finalize the language for the transfer of drugs and patient records when a pharmacy discontinues business.

M/S: Law/Gutierrez

Support: 3 Oppose: 0 Abstain: 0

Optional Conditions – Pages 107-108

Proposed Changes:

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

Committee Discussion:

There were no comments from the committee or from the public.

Motion: Approve the “Standard Conditions” (pages 107-108) as provided in the meeting materials.

M/S: Gutierrez/Law

Support: 3 Oppose: 0 Abstain: 0

General Policy Discussion

Ms. Sodergren explained that board staff often encounters pharmacies that surrender their licenses, make slight changes to their ownership structures and then reapply for licensure. This is all done in an attempt to avoid disciplinary action by the board. Ms. Sodergren stated that staff is working with the Attorney General's Office to draft language to prevent this from occurring. The committee asked Ms. Sodergren and Ms. Kellogg to bring the proposed language to the next meeting.

Ms. Kellogg reported that in cases where adulterated or misbranded drugs are suspected, staff is very concerned that these drugs potentially could be transferred to another location and enter into the supply chain. She explained that staff is recommending the addition of a provision to the disciplinary guidelines that would prevent the drugs from being transferred and would require the drugs be properly disposed of. The committee asked Ms. Kellogg and Ms. Sodergren to bring the proposed language to the next meeting.

Motion: Direct staff to prepare language to address the two items discussed above and bring it to the next committee meeting to discuss.

M/S: Law/Gutierrez

Support: 3 Oppose: 0 Abstain: 0

3. Public Comment for Items Not on the Agenda, Matters for Future Meetings

The committee scheduled the next SB 1441 Uniform Standards Implementation Committee meeting for July 27, 2015.

Chairperson Weisser adjourned the meeting at 11:54 a.m.