



Legislation and Regulation Committee

Shirley Wheat, Chair, Public Member
Ramón Castellblanch, Public Member
Deborah Veale, RPh
Tappan Zee, Public Member

LEGISLATION AND REGULATION COMMITTEE

The Legislation and Regulation Committee has not met in the last quarter due to travel restrictions on state agencies.

PART I: REGULATION REPORT

a. Approved by the Office of Administrative Law

1. Amend Title 16 Sections 1715, 1784, 1735.2 and 1751 – Update of Self-Assessment Forms for Pharmacies, Sterile Injectable Compounding Pharmacies, Hospitals and Wholesalers.

ATTACHMENT 1

This regulation was approved by the Office of Administrative Law on September 19, 2011, and it will be operative/effective on October 19, 2011.

The board initiated a rulemaking to update four regulatory sections, and four of its self-assessment forms at its February 2011 Board Meeting. The proposed regulation was noticed for a 45-day public comment period in March 2011, and in May 2011 the board directed staff to complete the rulemaking process, to include adoption of the proposed language and the four (4) self-assessment forms incorporated by reference. Staff compiled the rulemaking file and submitted it to the Department of Consumer Affairs for administrative review in June 2011. Following departmental and Agency approval, the rulemaking was filed with the Office of Administrative Law in August 2011, and OAL approved the regulation and self-assessment forms incorporated by reference on September 19, 2011.

A copy of the Adopted Text is provided in Attachment 1. The self-assessment forms incorporated by reference (and as approved by OAL) are available on the board's Web site.

- 17M-13 – Community Pharmacy Self-Assessment; Hospital Outpatient Pharmacy Self-Assessment
- 17M-14 – Hospital Pharmacy Self-Assessment
- 17M-26 – Wholesaler Dangerous Drug & Dangerous Devices Self-Assessment
- 17M-39 – Compounding Self-Assessment

2. Title 16 Section 1793.5 – Pharmacy Technician Application, Requirement for Applicants to Submit a Self-Query from the National Practitioner DataBank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB).

ATTACHMENT 2

The Office of Administrative Law approved the board's regulation on September 1, 2011, and the regulation became effective on October 1st. This regulation updated the Pharmacy Technician Application (Form 17A-5, Rev. 10/10), which is incorporated by reference; and also requires a Pharmacy Technician applicant to submit to the board with his or her application a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB).

The revised Pharmacy Technician Application is now available on the board's Web site. The board utilized its Subscriber Alert to notify subscribers of the regulation's approval. In the first week of October 2011, the board received its first Self-Query Response in a sealed envelope with a Pharmacy Technician Application, as specified in the regulation.

A copy of the Adopted Text, the new Pharmacy Technician Application (Form 17A-5, Rev. 10/10), and a [redacted] copy of a Self-Query Response is provided in **Attachment 2**.

b. Board Approved – Rulemaking File Being Prepared

1. Add Title 16 Section 1727.2 – Requirements for Pharmacist Interns – To Require Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB)
2. Amend Title 16 Section 1728 – Requirements for Pharmacist Examination – Amend to Require Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB)

ATTACHMENT 3

On May 6, 2011, the board initiated a rulemaking to add Title 16 CCR § 1727.2 and to amend Title 16 CCR § 1728. The proposal would require a Pharmacist Intern applicant to submit with his or her application a Self-Query Report from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB). This proposal would also require an applicant seeking board authority to take the pharmacist licensure examination to submit with his or her application a Self-Query Report from the NPDB-HIPDB. The board determined that the requirement(s) to submit a Self-Query Report, as specified in the proposal, is necessary and pertinent to the board's investigation of an applicant and will allow the board to determine if an applicant has been the subject of discipline in another state prior to making a decision on an application. This is the same type of Self-Query Report that was recently approved for Pharmacy Technician applicants.

The 45-day public comment period concluded in June 2011, and the board did not receive any comments to the proposed amendments. In July 2011, the board directed staff to take all steps necessary to complete the rulemaking process and authorized the Executive Officer to adopt the text as noticed for the 45-day public comment period. Staff is compiling the final rulemaking file,

and expects to submit it to the Department of Consumer Affairs for administrative review by the end of October.

A copy of the Adopted Text for 16 CCR § 1727.2 and § 1728 is provided in Attachment. 3.

c. Board Approved – Undergoing Review by the Administration

1. Amend Title 16 CCR Section 1732.2 – Board Accredited Continuing Education

ATTACHMENT 4

The final rulemaking file is currently being reviewed by the Department. As authorized by Section 313.1 of the Business and Professions Code, the DCA on October 5, 2011, extended the one-year notice period for this rulemaking. Following departmental and agency approval, the file will then be submitted to the Office of Administrative Law pursuant to the Administrative Procedure Act.

At the February 2010 Board Meeting, the board voted to initiate the rulemaking process to amend 16 CCR § 1732.2 related to board-accredited continuing education. Following the 45-day public comment period, and at its meeting held February 2011, the board modified the proposed text to strike reference to the Pharmacist Self-Assessment Mechanism (PSAM), because that exam was no longer being administered by the National Association of Boards of Pharmacy. Absent negative comments, the board directed that the rulemaking be completed, to include adoption of the modified text and filing of the final rulemaking file. The modified text was made available for a 15-day public comment period from February 4-21, 2011; the board did not receive any comments to the modified text.

A copy of the Adopted Text is provided in Attachment 4.

2. Proposal to Amend 16 CCR Section 1707.2 and to Add 16 CCR Section 1707.6 Regarding Duty to Consult and Notice to Consumers

ATTACHMENT 5

This completed rulemaking file is currently undergoing administrative review with the Department of Consumer Affairs.

The board initiated its rulemaking to amend 16 CCR § 1707.2 and to add 16 CCR § 1707.6 on May 27, 2011. A Regulation Hearing was conducted on July 27, 2011 in conjunction with a regularly scheduled board meeting. Following the Regulation Hearing, the board discussed the rulemaking and considered comments received during the 45-day public comment period and at the Regulation Hearing. In response, the board modified the text of § 1707.6 (a) related to the requirements to display the Notice to Consumers in a video format, to specify that the pharmacy may seek approval of another format or display methodology from the board, and that the board may delegate authority to a committee or to the Executive Officer to give the approval. In addition, the board modified the text of § 1707.6 (b) to include as the first statement in the Notice to Consumers, “California law requires a pharmacist to speak with you every time you get a new prescription.” The board issued a Notice and made the modified text available for a 15-day public comment period from July 28 – August 12, 2011. The board received two comments during the 15-day comment period; however, the comments were not responsive to the modified text.

Absent adverse comments to the modified text, and as specified in the board's motion, the Executive Officer adopted the text of Sections 1707.2 and 1707.6, as described in the modified text notice, and staff compiled the rulemaking file. The completed rulemaking file was submitted to the Department of Consumer Affairs on September 27.

A copy of the Adopted Text, and the two written comments received during the 15-day comment period are provided in Attachment 5.

d. Board Approved– Undergoing Initial 45-Day Public Comment Period (*Update Only*)

ATTACHMENT 6

The board has noticed for a 45-day public comment period, proposed amendments to 16 CCR § 1760, and to the Disciplinary Guidelines that are incorporated by reference. The 45-day public comment period began on October 14, and will conclude on November 28, 2011. A Regulation Hearing has been scheduled for January 31, 2012 at 1:30 p.m. at the Embassy Suites San Francisco Airport-Waterfront hotel in Burlingame.

A copy of the proposed text to amend 16 CCR § 1760 and the proposed amendments to the Disciplinary Guidelines are provided in Attachment 6.

Background

In July 2011 the board considered the restructure and updating of its Disciplinary Guidelines, to also incorporate recommendations of the Department of Consumer Affairs' Substance Abuse Coordination Committee (Created by Senate Bill 1441).

The Substance Abuse Coordination Committee (SACC) was charged with formulating uniform and specific standards in specified areas that each healing arts board must use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program. To facilitate implementation of these standards, the DCA created a workgroup in 2009 consisting of staff from each of the healing arts board to draft recommended standards for SACC consideration during public meetings. Sixteen (16) standards were developed.

The most recent version of the SACC Uniform Standards was approved in April 2011. In March 2011, a board subcommittee of Stan Weisser and Tappan Zee met in a first step toward incorporating these standards into the Board's Disciplinary Guidelines. At the May and July 2011 Board Meetings, the board discussed the standards and on September 7, 2011, directed staff to initiate the rulemaking.

e. Board Approved Regulations – Under Development

1. Proposed Amendments to § 1746 – Emergency Contraception Protocol (Update Only)

ATTACHMENT 7

At this Board Meeting, the Communication and Public Education Committee Staff will discuss a proposed rulemaking to update the board's Emergency Contraception protocol (16 CCR § 1746), to reflect the language/protocol approved by the Medical Board of California at its July 2011 board meeting. The draft text that will be considered is provided in Attachment 7.

Background

Business and Professions Code Section 4052.3 authorizes a pharmacist to initiate emergency contraception therapy in accordance with either (1) standardized procedures or protocols developed by the pharmacist and an authorized prescriber, as specified; and (2) standardized procedures or protocols developed and approved by both the Medical Board of California and the Board of Pharmacy, as specified. The standardized protocol developed and approved by the Medical Board of California and the Board of Pharmacy is specified at 16 CCR § 1746.

The current state protocol was developed by the Medical Board in 2004; the board adopted the protocol as a regulation later that year. Title 16 CCR § 1746 became operative on December 2, 2004. Since that time, there have been changes in the availability of emergency contraception medicine, the manufacturers who produce the medication, and there is a typographical error in the board's regulation that requires correction (mcg instead of mg).

Following the May 2011 Board Meeting, and working with CPhA's representative (a women's health specialist pharmacist) and two representatives of the American College of Obstetricians and Gynecologists, the Executive Officer finalized a revised draft protocol which was considered and approved by the Medical Board of California. The Executive Officer provided an update to the Communication and Public Education Committee on September 26, 2011, and the committee recommended that the board initiate a rulemaking to repeal and to amend 16 CCR Section 1746 to be consistent with the proposed update of the Emergency Contraception Protocol that was approved by the Medical Board in July 2011.

Following the adoption of a new emergency contraception protocol, the board will then need to update its patient information fact sheet. This fact sheet is required by Section 4052.3(e) of the Business and Professions Code and is provided to the patient by the pharmacist using the protocol to dispense emergency contraception. The update of a fact sheet would be vetted through the board's Communication and Public Education Committee.

2. Proposed Amendments to § 1751.9. – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products (Update Only)

Business and Professions Code section 4127.1 requires a separate license to compound sterile injectable drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. The proposed regulation would specify the criteria the board will utilize to consider approval of

accreditation agency requests. Staff is continuing to work with counsel to develop language for consideration at a future meeting.

3. Proposed Amendments to § 1780 – Update the USP Standards Reference Manual (Minimum Standards for Drug Wholesalers) (Update Only)

Section 1780 of the California Code of Regulations sets minimum standards for drug wholesalers. This regulation currently references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. USP Standards are updated and published annually. Section 1780(b) requires amendment to reflect the 2005 version of the USP Standards and to hold wholesalers accountable to the latest standards, if determined appropriate.

Because of stated concerns about whether referencing the 2005 USP Standards would be an unreasonable burden on wholesalers, at the October 2008 Board Meeting, the board voted to address the issue of updating the USP Standards reference materials within this section.

The board established a subcommittee for this purpose but, as a result of board vacancies, the subcommittee has not held any meetings and no action has been taken with respect to this regulation change.

4. Proposed Amendments to § 1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer (Update Only)

The requirements of § 1785 establish a self-assessment form for veterinary food-animal drug retailers and requires a designated representative-in-charge to complete this form to ensure compliance with pharmacy law. Self-assessment forms also aid licensees in complying with legal requirements of their operations and, therefore, increase public safety as a result of this compliance.

In 2007 the Enforcement Committee and the Board approved draft amendments to the regulation and related self-assessment form; subsequently, the licensing committee was advised of potential problems with the licensing requirements for designated representatives working at these facilities.

The Licensing Committee has not yet initiated a program review of the Veterinary Food-Animal Drug Retailer program. Staff does not anticipate proceeding with this regulation until such time that the Licensing Committee completes its review.

Attachment 1

Order of Adoption
Board of Pharmacy
California Code of Regulations

Amend Section 1715 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.

(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new pharmacy permit has been issued, or

(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.

(3) There is a change in the licensed location of a pharmacy to a new address.

(c) The components of this assessment shall be on Form 17M-13 (Rev. ~~10/08~~ 01/11) entitled "Community Pharmacy Self-Assessment & Hospital Outpatient Pharmacy Self-Assessment" ~~or and on~~ Form 17M-14 (Rev. ~~10/08~~ 01/11) entitled "Hospital Pharmacy Self-Assessment" which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4021, 4022, 4029, 4030, 4037, 4038, 4040, 4050, 4052, 4070, 4081, 4101, 4105, 4113, 4115, 4119, 4127, 4305, 4330, 4332 and 4333, Business and Professions Code, and Sections 1735.2 and 1751. of Title 16 of the California Code of Regulations.

Amend Section 1784 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1784. Self-Assessment of a Wholesaler by the Designated Representative-In-Charge.

(a) The designated representative-in-charge of each wholesaler as defined under section 4160 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new wholesaler permit is issued, or

(2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a wholesaler is responsible for compliance with this subdivision.

(3) There is a change in the licensed location of a wholesaler to a new address.

(c) The components of this assessment shall be on Form 17M-26 (~~rev. 10/08~~ Rev. 01/11) entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment" which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the licensed wholesale premises for three years after it is completed.

(e) The wholesaler is jointly responsible with the designated representative-in-charge for compliance with this section.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4043, 4053, 4059, 4120, 4160, 4161, 4201, 4301 and 4305.5, Business and Professions Code.

Amend Section 1735.2 of Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1735.2. Compounding Limitations and Requirements; Self-Assessment

(a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) A "reasonable quantity" as used in Business and Professions Code section 4052(a)(1) means that amount of compounded drug product that:

- (1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and
- (2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and
- (3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.

(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

- (1) Active ingredients to be used.
- (2) Inactive ingredients to be used.
- (3) Process and/or procedure used to prepare the drug.
- (4) Quality reviews required at each step in preparation of the drug.
- (5) Post-compounding process or procedures required, if any.
- (6) Expiration dating requirements.

- (e) Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.
- (f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.
- (g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.
- (h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.
- (i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.
- (j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the board. (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. ~~01/10~~ 01/11.) That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code, Sections 1735, 1735.1.-1735.8., 1751., and 1751.1.-1715.8 of Title 16 of the California Code of Regulations.

Amend Section 1751. of Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1751. Sterile Injectable Compounding; Compounding Area; Self-Assessment

(a) Any pharmacy engaged in compounding sterile injectable drug products shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile injectable compounding.

(b) Any pharmacy ~~compounding~~ doing sterile injectable compounding drug products shall have a designated area for the preparation of sterile injectable products which shall meet the following standards:

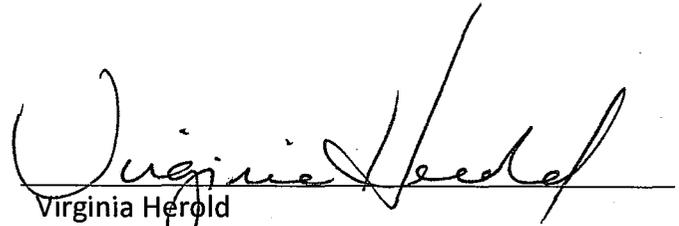
- (1) Clean Room and Work Station Requirements, shall be in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.
- (2) Walls, ceilings and floors shall be constructed in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.
- (3) Be ventilated in a manner in accordance with Section 505.12 of Title 24, Chapter 5 of the California Code of Regulations.
- (4) Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years.
- (5) The pharmacy shall be arranged in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.

(6) A sink shall be included in accordance with Section 1250 of Title 24, Part 2, of the California Code of Regulations.

(7) There shall be a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.

(c) Any pharmacy compounding a sterile injectable product from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4127 and 4127.7, Business and Professions Code; Sections 1735, 1735.1.-1735.8., 1751., and 1751.1.-1715.8 of Title 16 of the California Code of Regulations; and Section 18944, Health and Safety Code.

A handwritten signature in black ink, appearing to read "Virginia Herold", written over a horizontal line.

Virginia Herold

Executive Officer

Board of Pharmacy

Attachment 2

Order of Adoption
Board of Pharmacy
California Code of Regulations

Amend 1793.5. in Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.5. Pharmacy Technician Application.

The "Pharmacy Technician Application" ~~application for a pharmacy technician license~~ (Form 17A-5 (Rev. 9/94 01/11)) required by this section is available from the Board of Pharmacy upon request.

(a) Each application for ~~registration as a pharmacy technician license~~ shall include:

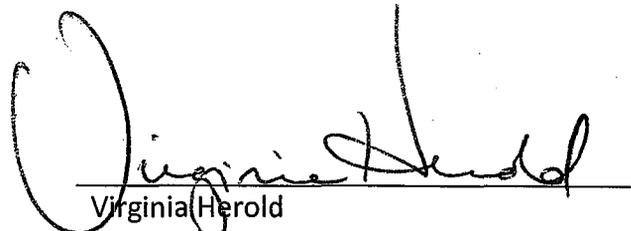
- (1) Information sufficient to identify the applicant.
- (2) A description of the applicant's qualifications and supporting documentation for those qualifications.
- (3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e). ~~In addition, a signed statement whether the applicant has ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States, any state, or local ordinance.~~
- (4) A sealed, original Self-Query from the National Practitioner Data Bank - Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) dated no earlier than 60 days of the date an application is submitted to the board.

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within 30 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete, and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code, the board will notify the applicant within 60 days of a license decision.

(d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in Section 1749, subdivision (c) subdivision (r) of section 4400 of the Business and Professions Code.

Note: Authority cited: Sections 163.5, 4005, 4007, 4038, 4115, ~~and~~ 4202, 4207, and 4400 Business and Professions Code. Reference: Sections 163.5, 4005, 4007, 4038, 4115, ~~and~~ 4202, 4207, 4402, and 4400 Business and Professions Code, Section 11105 of the Penal Code, and sections 1706.2. and 1793.6. of Title 16 of the California Code of Regulations.


Virginia Herold
Executive Officer
Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

*Adopt***PHARMACY TECHNICIAN APPLICATION**

All items of information requested in this application are mandatory. Failure to provide any of the requested information will result in an incomplete application and a deficiency letter being mailed to you. Please read all the instructions prior to completing this application. **Page 1, 2, and 3 of the application must be completed and signed by the applicant.** All questions on this application must be answered. If not applicable indicate N/A. Attach additional sheets on paper if necessary.

Applicant Information – Please Type or Print

Full Legal Name-Last Name		First Name	Middle Name
Previous Names (AKA, Maiden Name, Alias, etc)			
*Official Mailing/Public Address of Record (Street Address, PO Box #, etc)			
City	State		Zip Code
Residence Address (if different from above)			
City	State		Zip Code
Home#	Cell #	Work#	Email Address
Date of Birth (Month/Day/Year)	**Social Security No	Driver's License #	State

Mandatory Education (check one box)

Please indicate how you satisfy the mandatory education requirement in Business and Professions Code Section 4202(a).

High school graduate or foreign equivalent.

Attach a certified copy of your high school transcript, or certificate of proficiency, or foreign secondary school diploma along with a certified translation of the diploma.

Completed a General Education Development (GED)

Attach an official transcript or your GED test results.

TAPE A COLOR PASSPORT STYLE PHOTOGRAPH (2"X2") TAKEN WITHIN 60 DAYS OF THE FILING OF THIS APPLICATION
NO POLAROID
OR
SCANNED IMAGES
PHOTO MUST BE ON PHOTO QUALITY PAPER

Pharmacy Technician Qualifying Method (check one box)

Please check one of the boxes below indicating how you qualify in order to apply for a pharmacy technician license pursuant to Section 4202(a)(1), (2), (3) or (4) of the Business and Professions Code or Title 16 California Code of Regulations Section 1793.6(a), (b) or (c).

Attached Affidavit of Completed Coursework or Graduation for: Associate degree in Pharmacy Technology, Training Course, or Graduate of a school of pharmacy

Attached is a certified copy of PTCB certificate – Date certified: _____

Attached is a copy of your military training DD214.

Self-Query Report by the National Practitioner Data Bank Healthcare Integrity and Protection Data Bank (NPDB-HIPDB)

Attached is the sealed envelope containing my Self-Query Report from the NPDB-HIPDB. (This must be submitted with your application.)

FOR BOARD USE ONLY

Photo <input type="checkbox"/>	FP Cards/Live Scan <input type="checkbox"/>	License no. _____	App fee no. _____
Enf 1 st Check <input type="checkbox"/>	FP Cards Sent _____	Date issued _____	Amount _____
Enf 2 nd Check <input type="checkbox"/>	FP Fees <input type="checkbox"/>	Date expires _____	Date cashiered _____
Qualify Code _____	DOJ Clear Date: _____		
HIPDB <input type="checkbox"/>	FBI Clear Date: _____		

You must provide a written explanation for all affirmative answers indicated below. Failure to do so may result in this application being deemed incomplete and being withdrawn.

<p>1. Do you have a medical condition which in any way impairs or limits your ability to practice your profession with reasonable skill and safety without exposing others to significant health or safety risks? If "yes," attach a statement of explanation. If "no," proceed to #2. Are the limitations caused by your medical condition reduced or improved because you receive ongoing treatment or participate in a monitoring program? If "yes," attach a statement of explanation.</p> <p>If you do receive ongoing treatment or participate in a monitoring program, the board will make an individualized assessment of the nature, the severity and the duration of the risks associated with an ongoing medical condition to determine whether an unrestricted license should be issued, whether conditions should be imposed, or whether you are not eligible for license.</p>	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>																																
<p>2. Do you currently engage, or have you been engaged in the past two years, in the illegal use of controlled substances?</p> <p>If "yes," are you currently participating in a supervised rehabilitation program or professional assistance program which monitors you in order to assure that you are not engaging in the illegal use of controlled dangerous substances? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Attach a statement of explanation.</p>	Yes <input type="checkbox"/> No <input type="checkbox"/>																																
<p>3. Has disciplinary action ever been taken against your pharmacist license, intern permit or technician license in this state or any other state? If "yes," attach a statement of explanation to include circumstances, type of action, date of action and type of license, registration or permit involved.</p>	Yes <input type="checkbox"/> No <input type="checkbox"/>																																
<p>4. Have you ever had an application for a pharmacist license, intern permit or technician license denied in this state or any other state? If "yes," attach a statement of explanation to include circumstances, type of action, date of action and type of license, registration or permit involved.</p>	Yes <input type="checkbox"/> No <input type="checkbox"/>																																
<p>5. Have you ever had a pharmacy permit, or any professional or vocational license or registration, denied or disciplined by a government authority in this state or any other state? If "yes," provide the name of company, type of permit, type of action, year of action and state.</p>	Yes <input type="checkbox"/> No <input type="checkbox"/>																																
<p>6. Are you currently or have you previously been listed as a corporate officer, partner, owner, manager, member, administrator or medical director on a permit to conduct a pharmacy, wholesaler, medical device retailer or any other entity licensed in this state or any other state? If yes, provide company name, type of permit, permit number and state where licensed.</p>	Yes <input type="checkbox"/> No <input type="checkbox"/>																																
<p>7. Have you ever been convicted of any crime in any state, the USA and its territories, military court or foreign country?</p> <p>Check the box next to "Yes" if you have ever been convicted or plead guilty to any crime. "Conviction" includes a plea of no contest and any conviction that has been set aside or deferred pursuant to Sections 1000 or 1203.4 of the Penal Code, including infractions, misdemeanor, and felonies. You do not need to report a conviction for an infraction with a fine of less than \$300 unless the infraction involved alcohol or controlled substances. You must, however, disclose any convictions in which you entered a plea on no contest and any convictions that were subsequently set aside pursuant or deferred pursuant to sections 1000 or 1203.4 of the Penal Code.</p> <p>Check the box next to "NO" if you have not been convicted of a crime.</p> <p>You may wish to provide the following information in order to assist in the processing of your application: descriptive explanation of the circumstances surrounding the conviction (i.e. dates and location of incident and all circumstances surrounding the incident.) If documents were purged by the arresting agency and/or court, a letter of explanation from these agencies is required.</p> <p>Failure to disclose a disciplinary action or conviction may result in the license being denied or revoked for falsifying the application. Attach additional sheets if necessary.</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr style="background-color: #cccccc;"> <th style="width: 15%;">Arrest Date</th> <th style="width: 15%;">Conviction Date</th> <th style="width: 35%;">Violation(s)</th> <th style="width: 35%;">Court of Jurisdiction (Full Name and Address)</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table>	Arrest Date	Conviction Date	Violation(s)	Court of Jurisdiction (Full Name and Address)																													Yes <input type="checkbox"/> No <input type="checkbox"/>
Arrest Date	Conviction Date	Violation(s)	Court of Jurisdiction (Full Name and Address)																														

APPLICANT AFFIDAVIT

You must provide a written explanation for all affirmative answers. Failure to do so will result in this application being deemed incomplete. Falsification of the information on this application may constitute ground for denial or revocation of the license.

All items of information requested in this application are mandatory. Failure to provide any of the requested information may result in the application being rejected as incomplete.

Collection and Use of Personal Information. The California State Board of Pharmacy of the Department of Consumer Affairs collects the personal information requested on this form as authorized by Business and Professions Code Sections 4200 and 4202 and Title 16 California Code of Regulations Section 1793.5 and 1793.6. The California State Board of Pharmacy uses this information principally to identify and evaluate applicants for licensure, issue and renew licenses, and enforce licensing standards set by law and regulation.

Mandatory Submission. Submission of the requested information is mandatory. The California State Board of Pharmacy cannot consider your application for licensure or renewal unless you provide all of the requested information.

Access to Personal Information. You may review the records maintained by the California State Board of Pharmacy that contain your personal information, as permitted by the Information Practices Act. The official responsible for maintaining records is the Executive Officer at the board's address listed on the application. Each individual has the right to review the files or records maintained by the board, unless confidential and exempt by Civil Code Section 1798.40.

Possible Disclosure of Personal Information. We make every effort to protect the personal information you provide us. The information you provide, however, may be disclosed in the following circumstances:

- In response to a Public Act request (Government Code Section 6250 and following), as allowed by the Information Practices Act (Civil Code Section 1798 and following);
- To another government agency as required by state or federal law; or
- In response to a court or administrative order, a subpoena, or a search warrant.

*Once you are licensed with the board, the address of record you enter on this application is considered public information pursuant to the Information Practices Act (Civil Code section 1798 et seq.) and the Public Records Act (Government Code Section 6250 et seq.) and will be placed on the Internet. This is where the board will mail all correspondence. If you do not wish your residence address to be available to the public, you may provide a post office box number or a personal mail box (PMB). However, if your address of record is not your residence address, you must also provide your residence address to the board, in which case your residence will not be available to the public.

**Disclosure of your U.S. social security account number is mandatory. Section 30 of the Business and Professions Code, Section 17520 of the Family Code, and Public Law 94-455 (42 USC § 405(c)(2)(C)) authorize collection of your social security account number. Your social security account number will be used exclusively for tax enforcement purposes, for purposes of compliance with any judgment or order for child or family support in accordance with section 17520 of the Family Law Code, or for verification of license or examination status by a licensing or examination entity which utilizes a national examination and where licensure is reciprocal with the requesting state. If you fail to disclose your social security account number, your application will not be processed and you may be reported to the Franchise Tax Board, which may assess a \$100 penalty against you.

MANDATORY REPORTER

Under California law, each person licensed by the Board of Pharmacy is a "mandated reporter" for both child and elder abuse or neglect purposes.

California Penal Code Section 11166 and Welfare and Institutions Code Section 15630 require that all mandated reporters make a report to an agency specified in Penal Code Section 11165.9 and Welfare and Institutions Code Section 15630(b)(1) [generally law enforcement, state and/or county adult protective services agencies, etc.] whenever the mandated reporter, in his or her professional capacity or within the scope of his or her employment, has knowledge of or observes a child, elder and/or dependent adult whom the mandated reporter knows or reasonably suspects has been the victim of child abuse or elder abuse or neglect. The mandated reporter must contact by telephone immediately or as soon as possible, to make a report to the appropriate agency(ies) or as soon as practicably possible. The mandated reporter must prepare and send a written report thereof within two working days or 36 hours of receiving the information concerning the incident.

Failure to comply with the requirements of Section 11166 and Section 15630 is a misdemeanor, punishable by up to six months in a county jail, by a fine of one thousand dollars (\$1,000), or by both that imprisonment and fine. For further details about these requirements, consult Penal Code Section 11164 and Welfare and Institutions Code Section 15630, and subsequent sections.

APPLICANT AFFIDAVIT

(must be signed and dated by the applicant)

I, _____, hereby attest to the fact that I am the applicant whose signature appears
(Print full Legal Name)

below. I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of all statements, answers and representations made in this application, including all supplementary statements. I also certify that I have read the instructions attached to this application.

Signature of Applicant

Date



**AFFIDAVIT OF COMPLETED COURSEWORK OR GRADUATION
 FOR PHARMACY TECHNICIAN**

Instructions: This form must be completed by the university, college, school, or pharmacist (The person who must complete this form will depend on how the applicant is qualifying). All dates must include the month, day, and year in order for the form to be accepted.

This is to certify that _____ has
Print Name of Applicant

- Completed a pharmacy technician training program accredited by the American Society of Health-System Pharmacists as specified in Title 16 California Code of Regulations Section 1793.6(a) on _____/_____/_____
(completion date must be included)
- Completed 240 hours of instruction as specified in Title 16 California Code of Regulations Section 1793.6(c) on _____/_____/_____
(completion date must be included)
- Completed an Associate Degree in Pharmacy Technology and was conferred on her/him on _____/_____/_____
(graduation date must be included)
- Graduated from a school of pharmacy accredited by the American Council on Pharmaceutical Education (ACPE). The degree of Bachelor of Science in Pharmacy or the degree of PharmD was conferred on her/him on _____/_____/_____
(graduation date must be included)

I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of the above:

Signed: _____ Title: _____ Date: ____/____/____

<p align="center">Affix school seal here.</p> <p align="center" style="margin-top: 100px;">OR</p> <p align="center">Attach a business card of the pharmacist who provided the training pursuant to Section 1793.6(c) of the California Code of Regulation here.</p>	<p>University, College, or School of Pharmacy Name: _____</p> <p>Address: _____</p> <p>_____</p> <p>Print Name of Director, Registrar, or Pharmacist: _____</p> <p>Phone Number: _____</p> <p>Email: _____</p>
--	--

SELF-QUERY RESPONSE

This self-query was processed under the provisions of:

Title IV (NPDB)

Section 1921 (NPDB)

Section 1128E (HIPDB)

A. SEARCH RESULT (Based on the subject identification information provided, the reports found are listed below)

Medical Malpractice Payment Report(s):	No Reports	Health Plan Action(s):	No Reports
State Licensure Action(s):	No Reports	Professional Society Action(s):	No Reports
Exclusion or Debarment Action(s):	No Reports	DEA/Federal Licensure Action(s):	No Reports
Government Administrative Action(s):	No Reports	Judgment or Conviction Report(s):	No Reports
Clinical Privileges Action(s):	No Reports	Peer Review Organization Action(s):	No Reports

B. SUBJECT IDENTIFICATION INFORMATION

Subject Name: [REDACTED]
 Gender: MALE
 Date of Birth: [REDACTED]
 Other Name(s) Used: [REDACTED]
 Organization Name: [REDACTED]
 Organization Type: [REDACTED]
 Home or Work Address: [REDACTED]
 City, State, ZIP: [REDACTED]
 Telephone: [REDACTED]
 Social Security Numbers (SSN): [REDACTED]
 Individual Taxpayer Identification Numbers (ITIN): [REDACTED]
 Professional School(s) & Year of Graduation: CARRINGTON CAREER COLLEGE CALIFORNIA [REDACTED]
 Occupation/Field of Licensure (Code): PHARMACY TECHNICIAN (075)
 State License Number, State of Licensure: NO LICENSE
 Drug Enforcement Administration (DEA) Numbers: [REDACTED]
 National Provider Identifiers (NPI): [REDACTED]
 Federal Employer Identification Numbers (FEIN): [REDACTED]
 Unique Physician Identification Numbers (UPIN): [REDACTED]

C. PAYMENT INFORMATION

Credit Card Number: [REDACTED] Expiration Date: [REDACTED]
 Additional Paper Copies Requested: 1
 NPDB Charge: \$16.00* NPDB Bill Reference Number: [REDACTED]
 HIPDB Charge: \$16.00* HIPDB Bill Reference Number: [REDACTED]
 * Each charge will appear separately on your credit card statement. Transaction Date: [REDACTED]

Copies of these reports are enclosed for restricted/limited use as prescribed by Title IV of Public Law 99-660, as amended, and Section 1921 of the Social Security Act, as amended by Section 5(b) of the Medicare and Medicaid Patient and Program Protection Act of 1987, and as amended by the Omnibus Budget Reconciliation Act of 1990 and by Section 1128E of the Social Security Act. Information from the NPDB and HIPDB is confidential and must be used solely for the purpose for which it was disclosed. ANY PERSON WHO VIOLATES THE CONFIDENTIALITY PROVISIONS AS SPECIFIED IN TITLE IV IS SUBJECT TO A CIVIL MONEY PENALTY OF UP TO \$11,000 FOR EACH VIOLATION. Subjects of reports who obtain information about themselves from the NPDB and/or HIPDB are permitted to share that information with anyone they choose.

the DataBank

P.O. Box 10832
Chantilly, VA 20153-0832

<http://www.npdb-hipdb.hrsa.gov>

Process Date: 09/26/2011

Page: 1 of 1

To: [REDACTED]
[REDACTED]
[REDACTED]

From: National Practitioner Data Bank / Healthcare Integrity and Protection Data Bank

Re: Response to Your Self-Query

The enclosed information is released by the National Practitioner Data Bank (NPDB) for restricted use under the provisions of Title IV of Public Law 99-660, the Health Care Quality Improvement Act of 1986, as amended, and Section 1921 of the Social Security Act as well as the Healthcare Integrity and Protection Data Bank (HIPDB) for restricted use under the provisions of Section 1128E of the Social Security Act.

Title IV established the NPDB as an information clearinghouse to collect and release certain information related to malpractice payment history and professional competence or conduct of physicians, dentists, and other licensed health care practitioners. Regulations governing the NPDB are codified at 45 CFR part 60. Responsibility for operating the NPDB resides with the Secretary of the U.S. Department of Health and Human Services (HHS), HRSA, Division of Practitioner Data Banks.

Section 1921 of the Social Security Act, as amended by Section 5(b) of the Medicare and Medicaid Patient and Program Protection Act of 1987, and as amended by the Omnibus Budget Reconciliation Act of 1990, expanded the scope of the NPDB. Section 1921 was enacted to protect program beneficiaries from unfit health care practitioners and health care entities, and to improve the anti-fraud provisions of Federal and State health care programs. This legislation authorizes the NPDB to collect certain adverse State licensure actions, as well as any negative action or finding that a State licensing authority, peer review organization, or private accreditation organization has concluded against a health care practitioner or health care entity. Regulations governing the NPDB are codified at 45 CFR Part 60.

Section 1128E was established by Section 221(a) of Public Law 104-191, the Health Insurance Portability and Accountability Act of 1996, as amended. The statute established the HIPDB to combat fraud and abuse in health insurance and health care delivery and to improve the quality of patient care. The HIPDB serves as a source of final adverse action information on health care practitioners, providers, and suppliers. The HIPDB collects and releases information related to adverse licensure actions; health care-related convictions and judgments; exclusions from Federal and State health care programs; and other adjudicated actions or decisions. Regulations governing the HIPDB are codified at 45 CFR Part 61. Responsibility for operating the HIPDB resides with the Secretary of the U.S. Department of Health and Human Services (HHS), Office of Inspector General, and HRSA, Division of Practitioner Data Banks.

Reports from the NPDB and HIPDB contain limited summary information and should be used in conjunction with information from other sources in granting clinical privileges or making employment affiliation, contracting, or licensure decisions. The NPDB and HIPDB response may contain more than one report on a particular incident, if two or more actions were taken as a result of a single incident (e.g., an adverse licensure action and an exclusion from the Medicare and Medicaid programs). The NPDB and HIPDB is a flagging system and a report may be included for a variety of reasons that do not necessarily reflect adversely on the professional competence or conduct of the subject named in the report.

All information received from the NPDB and HIPDB is considered confidential and must be used solely for the purpose for which it was disclosed. ANY PERSON WHO VIOLATES THE CONFIDENTIALITY PROVISIONS AS SPECIFIED IN TITLE IV OF PUBLIC LAW 99-660, AS AMENDED, IS SUBJECT TO A CIVIL MONEY PENALTY OF UP TO \$11,000 FOR EACH VIOLATION. Subjects of reports who obtain information about themselves from the NPDB and/or HIPDB are permitted to share that information with anyone they choose.

If you require additional assistance, visit the NPDB-HIPDB web site (<http://www.npdb-hipdb.hrsa.gov>) or contact the NPDB-HIPDB Customer Service Center at 1-800-767-6732 (TDD: 1-703-802-9395). Information Specialists are available to speak with you weekdays from 8:30 a.m. to 6:00 p.m. (5:30 p.m. on Fridays) Eastern Time. The NPDB-HIPDB Customer Service Center is closed on all Federal holidays.

Attachment 3

Order of Adoption
Board of Pharmacy
California Code of Regulations

Add Section 1727.2. to Article 3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1727.2. Requirements for Pharmacist Intern.

Every applicant for a pharmacist intern license shall submit as part of the application process, a sealed, original Self Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB), dated no earlier than 60 days before the date an application is submitted to the board.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4207 and 4208, Business and Professions Code.

Amend Section 1728. in Article 3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1728. Requirements for Examination.

(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:

(1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:

- (A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.
- (B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.
- (C) Experience in both community pharmacy and institutional pharmacy practice settings.
- (D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

(2) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.

(3) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code section 144.

(4) A signed copy of the examination security acknowledgment.

(5) A sealed, original Self Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB), dated no earlier than 60 days before the date an application for examination as a pharmacist is submitted to the board.

(b) Applicants who hold or held a pharmacist license in another state shall provide a current license verification from each state in which the applicant holds or held a pharmacist license prior to being authorized by the board to take the examinations.

(c) Applicants who graduated from a foreign school of pharmacy shall provide the board with satisfactory proof of certification by the Foreign Pharmacy Graduate Examination Committee prior to being authorized by the board to take the examinations.

Note: Authority cited: Sections 851 and 4005, Business and Professions Code. Reference: Sections 144, 851 and 4200, Business and Professions Code.

Virginia Herold
Executive Officer
Board of Pharmacy

Attachment 4

Order of Adoption
Board of Pharmacy
California Code of Regulations

Amend Section 1732.2. of Article 4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1732.2. Board Accredited Continuing Education

(a) Individuals may petition the board to allow continuing education ~~credit~~ hours for specific coursework which is not offered by a provider but meets the standards of Section 1732.3.

(b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.

(c) A pharmacist serving on a designated subcommittee of the board for the purpose of developing the California Practice Standards and Jurisprudence Examination for pharmacists pursuant to section 4200.2 of the Business and Professions Code may annually be awarded up to six hours of continuing education hours for conducting a review of exam test questions. A subcommittee member shall not receive continuing education hours pursuant to this subdivision if that subcommittee member requests reimbursement from the board for time spent conducting a review of exam test questions.

(d) A pharmacist or pharmacy technician who attends a full day board meeting may be awarded up to six hours of continuing education on an annual basis. The board shall designate on its public agenda which day shall be eligible for continuing

education credit. A pharmacist or pharmacy technician requesting continuing education hours pursuant to this subdivision must sign in and out on an attendance sheet at the board meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(e) A pharmacist or pharmacy technician who attends a full committee meeting of the board may be awarded up to two hours of continuing education on an annual basis. A maximum of four continuing education hours may be earned each year by attending the full meetings of two different board committees. A pharmacist or pharmacy technician requesting continuing education hours pursuant to this subdivision must sign in and out on an attendance sheet at the committee meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(f) An individual may be awarded three hours of continuing education for successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy.

Note: Authority cited: Section 4005, Business and Professions Code.
Reference: Sections 4200.2, 4202, 4231 and 4232, Business and Professions Code.



Virginia Herold
Executive Officer
Board of Pharmacy

Attachment 5

Order of Adoption
Board of Pharmacy
California Code of Regulations

Amend §1707.2 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.2. ~~Notice to Consumers and~~ Duty to Consult.

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:

(1) upon request; or

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:

(A) whenever the prescription drug has not previously been dispensed to a patient; or

(B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.

(2) When the patient or agent is not present (including but not limited to a prescription drug that was shipped by mail) a pharmacy shall ensure that the patient receives written notice:

(A) of his or her right to request consultation; and

(B) a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

(3) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.

(c) When oral consultation is provided, it shall include at least the following:

- (1) directions for use and storage and the importance of compliance with directions; and
- (2) precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

(d) Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:

- (1) the name and description of the medication;
- (2) the route of administration, dosage form, dosage, and duration of drug therapy;
- (3) any special directions for use and storage;
- (4) precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;
- (5) prescription refill information;
- (6) therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription

medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;

(7) action to be taken in the event of a missed dose.

(e) Notwithstanding the requirements set forth in subsection (a) and (b), a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation.

~~(f) In every pharmacy subject to the provisions of Business and Professions Code Section 4122, there shall be prominently posted in a place conspicuous to and readable by prescription drug consumers the following notice:~~

"NOTICE TO CONSUMERS"

~~At your request, this pharmacy will provide its current retail price of any prescription without obligation. You may request price information in person or by telephone.~~

~~Ask your pharmacist if a lower cost generic drug is available to fill your prescription.~~

~~Prescription prices for the same drug vary from pharmacy to pharmacy. One reason for differences in price is differences in services provided.~~

~~Before taking any prescription medicine, talk to your pharmacist; be sure you know:~~

~~What is the name of the medicine and what does it do?~~

~~How and when do I take it and for how long? What if I miss a dose?~~

~~What are the possible side effects and what should I do if they occur?~~

~~Will the new medicine work safely with other medicines and herbal supplements I am taking?~~

~~What foods, drinks or activities should I avoid while taking this medicine?~~

Ask your pharmacist if you have additional questions.

(g) In addition to the "NOTICE TO CONSUMERS" referred to in subdivision (f), every pharmacy subject to the provisions of Business and Professions Code §4122 shall prominently post in a place conspicuous to and readable by prescription drug consumers the following notice:

Know your rights under California law concerning medicine and devices prescribed to you.

You have the right to receive medicine and devices legally prescribed to you, unless:

1. The medicine or device is not in stock in the pharmacy,
2. The pharmacist, based upon his or her professional judgment determines providing the item:
 - is against the law,
 - could cause harmful drug interaction, or
 - could have a harmful effect on your health

This pharmacist may decline to fill your prescription for ethical, moral or religious reasons, but the pharmacy is required to help you get the prescription filled at this or another nearby pharmacy timely.

The pharmacy may decline to provide the medicine or device if it is not covered by your insurance or if you are unable to pay for the item or any copayment you owe.

If the pharmacy is unable to fill your prescription, you are entitled to have the prescription returned to you or transferred to another nearby pharmacy. Ask about our procedure to help you get an item that we don't have in stock.

Any questions? Ask the pharmacist!

Note: Authority cited: Sections 4005, 4076 and 4122, Business and Professions Code.

Reference: Sections ~~733~~, 4005, 4076 and 4122, Business and Professions Code.

Add § 1707.6. to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.6. Notice to Consumers.

(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by a prescription drug consumer, a notice containing the text in subdivision (b). Each pharmacy shall use the standardized poster-sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval. As an alternative to a printed notice, the pharmacy may also or instead display the notice on a video screen located in a place conspicuous to and readable by prescription drug consumers, so long as: (1) The video screen is at least 24 inches, measured diagonally; (2) The pharmacy utilizes the video image notice provided by the board; (3) The text of the notice remains on the screen for a minimum of 60 seconds; and (4) No more than five minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or only page of that notice re-displays. The pharmacy may seek approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

(b) The notice shall contain the following text:

NOTICE TO CONSUMERS

California law requires a pharmacist to speak with you every time you get a new prescription.

You have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font.

Interpreter services are available to you upon request at no cost.

Before taking your medicine, be sure you know: the name of the medicine and what it does; how and when to take it, for how long, and what to do if you miss a dose; possible side effects and what you should do if they occur; whether the new medicine will work safely with other medicines or supplements; and what foods, drinks, or activities should be avoided while taking the medicine. Ask the pharmacist if you have any questions.

This pharmacy must provide any medicine or device legally prescribed for you, unless: it is not covered by your insurance; you are unable to pay the cost of a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health. If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner.

You may ask this pharmacy for information on drug pricing and use of generic drugs.

(c) Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text:

Point to your language. Interpreter services will be provided to you upon request at no cost.

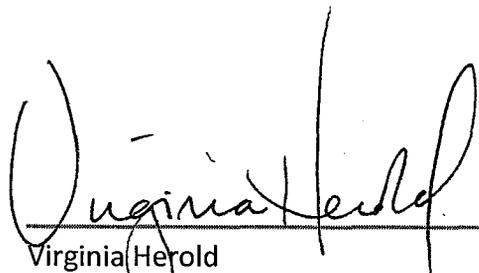
This text shall be repeated in at least the following languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese.

Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches.

Note: Authority cited: Sections 4005 and 4122, Business and Professions Code.

Reference: Sections 733, 4005, 4076.5 and 4122, Business and Professions Code.


Virginia Herold
Executive Officer
Board of Pharmacy

CALIFORNIA COMMISSION ON AGING

ARNOLD SCHWARZENEGGER, Governor

1300 National Drive, Suite 173
Sacramento, CA 95834

Telephone: 916-419-7591
Fax: 916-419-7596
E-Mail: CCoA@ccoac.ca.gov
Web Site: www.CCoA.ca.gov



Executive Director
Sandra Fitzpatrick

August 3, 2011

California Board of Pharmacy
ATTN: Ms. Carolyn Klein
1625 N. Market Blvd., Suite N-219
Sacramento, CA 95834

Via E-Mail to: Carolyn.Klein@dca.ca.gov

Dear Ms. Klein:

The California Commission on Aging requests your consideration of the following concerns regarding the Board of Pharmacy's (CBoP) proposed revised regulatory change for Title 16 Sec. 1707.6.

Posting requirements:

The CCoA has concerns regarding provisions authorizing the posting of consumer notification on video. The 60 second display requirement may be inadequate for an individual with limited reading skills or poor eyesight.

The CCoA would ask the board to require that, even when video notification is available, a printed hard copy must be simultaneously posted in an easily visible and unobstructed location.

Notice to consumers:

The CCoA believes the proposed CBoP notification could be confusing to persons not familiar with font sizes. We would recommend that written notification posted at pharmacies actually be printed in the referenced font sizes for greater clarification, as follows:

"You have the right to ask for and receive from any pharmacy prescription drug labels printed in:

12 point font or 14 point font."

Thank you for your consideration.

A handwritten signature in black ink that reads "H L Staggs".

Havard L. Staggs
Chair

Klein, Carolyn@DCA

From: Peter Scalet [Peter.Scalet@enloe.org]

Sent: Friday, July 29, 2011 6:44 AM

To: Klein, Carolyn@DCA

Subject: Notice to consumers

I am still concerned that my First Amendment rights are no longer part of the Notice to Consumers.

This pharmacy must provide any medicine or device legally prescribed for you, unless: it is not covered by your insurance; you are unable to pay the cost of a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health.

Peter Scalet
Pharmacy Manager
Enloe Medical Center
530-332-7952

This message, including attachments, contains information from Enloe Medical C considered confidential. The information is intended solely for the use of the If you are not an addressee, your disclosure, copying, distribution or use of of this message is prohibited. If this message has been sent to you in error, please notify the sender by return e-mail and then delete this entire message. Thank you.

Attachment 6

Board of Pharmacy
Specific Language to Amend Section 1760

Amend Section 1760 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

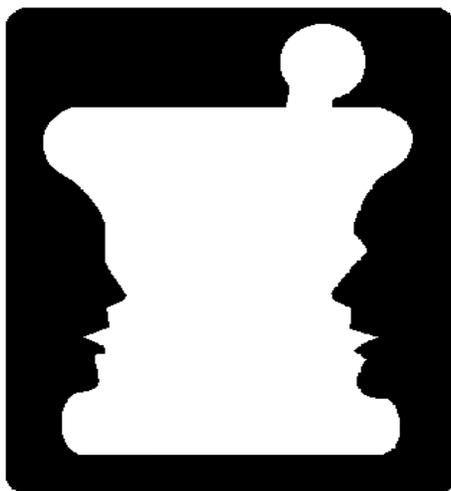
§1760. Disciplinary Guidelines.

In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.) the board shall consider the disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. ~~40/2007~~ 9/2011), which are hereby incorporated by reference. Deviation from these guidelines and orders, including the standard terms of probation, is appropriate where the board, in its sole discretion, determines that the facts of the particular case warrant such a deviation--the presence of mitigating factors; the age of the case; evidentiary problems.

Authority cited: Sections 315, 315.2, 315.4, and 4005, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 315, 315.2, 315.4, 4300 and 4301, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code

DISCIPLINARY GUIDELINES

A Manual of Disciplinary Guidelines
and Model Disciplinary Orders



***BE AWARE & TAKE CARE:
Talk to your pharmacist!***

**California State Board of Pharmacy
Department of Consumer Affairs
(Rev. ~~10/2007~~ 9/2011)**

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS

~~William Powers~~
Stan Weisser
PRESIDENT

Virginia K. Herold
EXECUTIVE OFFICER

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Additional copies of these disciplinary guidelines
may be downloaded from the board's website

BOARD OF PHARMACY
DISCIPLINARY GUIDELINES

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**DEPARTMENT OF CONSUMER AFFAIRS
STATE BOARD OF PHARMACY**

**DISCIPLINARY GUIDELINES
(Rev. ~~10/2007~~ 8/2011)**

INTRODUCTION

The Board of Pharmacy (board) is responsible for the enforcement of statutes and regulations related to the practice of pharmacy (the Pharmacy Law) and to the regulation of controlled substances (the Uniform Controlled Substances Act). The board serves the public by:

- ❑ protecting the health, safety, and welfare of the people of California with integrity and honesty;
- ❑ advocating the highest quality of affordable pharmaceutical care;
- ❑ providing the best available information on pharmaceutical care; and
- ❑ promoting education, wellness and quality of life.

Pharmacists are patient advocates who provide pharmaceutical care and exercise clinical judgment ~~for the citizens of California~~ for their patients, enlightening them about their drug therapy through effective communicating and listening, assessing, collaborating, understanding and intervening. Enforcement officials act quickly, consistently and efficiently in the public's interest to ensure the safe, effective delivery of these services.

The board recognizes the importance of ensuring the safe and effective delivery of dangerous drugs and controlled substances for therapeutic purposes. At the same time, and given the historical and current abuse and diversion of drugs, particularly controlled substances, the board believes there should be no tolerance for licensees who traffic in drugs or who, in the absence of appropriate evidence of rehabilitation, personally abuse drugs or alcohol.

In accordance with Section 1760 of the California Code of Regulations, the board has produced this booklet for those involved in and affected by the disciplinary process: the general public, board licensees, attorneys from the Office of the Attorney General, administrative law judges from the Office of Administrative Hearings, defense attorneys, ~~board licensees~~, the courts, board staff and board members who review and vote on proposed decisions and stipulations.

These guidelines are to be followed in Board of Pharmacy disciplinary actions. Subject to judicial review, the board has the final authority over the disposition of its cases, and, to complete its work, it uses the services of the Office of the Attorney General and the Office of Administrative Hearings. The board recognizes that individual cases may necessitate a departure from these guidelines. In such cases, the mitigating or aggravating circumstances shall be detailed in any proposed decision or any transmittal memorandum accompanying a proposed stipulation, especially where Category III or IV violations are involved.

In general, the position of the board is that revocation should always be an option whenever grounds for discipline are found to exist. Board policy is that revocation is generally an appropriate order where a respondent is in default, such as when he or she fails to file a notice of defense or fails to appear at a disciplinary hearing.

Board policy is that a suspension, where imposed, should be at least 30 days for an individual and at least 14 days for a licensed premises.

The board seeks recovery of all investigative and prosecution costs up to the hearing in all disciplinary cases. This includes all charges of the Office of the Attorney General, including, but not limited to, those for legal services, and includes charges by expert consultants. The board believes that the burden of paying for disciplinary cases should fall on those whose conduct requires investigation and prosecution, not upon the profession as a whole.

The board recognizes there may be situations where an individual licensee deserves a stronger penalty than the pharmacy for which he or she works, but the board also believes in holding a pharmacy owner, manager, and/or pharmacist-in-charge responsible for the acts of pharmacy personnel. Similarly, the board recognizes that in some cases a licensed premises may well be more culpable than any individual licensed by or registered with the board.

For purposes of these guidelines "board" includes the board and/or its designees.

FACTORS TO BE CONSIDERED IN DETERMINING PENALTIES

Section 4300 of the Business and Professions Code provides that the board may discipline the holder of, and suspend or revoke, any certificate, license or permit issued by the board.

In determining whether the minimum, maximum, or an intermediate penalty is to be imposed in a given case, factors such as the following should be considered:

1. actual or potential harm to the public
2. actual or potential harm to any consumer
3. prior disciplinary record, including level of compliance with disciplinary order(s)
4. prior warning(s), including but not limited to citation(s) and fine(s), letter(s) of admonishment, and/or correction notice(s)
5. number and/or variety of current violations
6. nature and severity of the act(s), offense(s) or crime(s) under consideration
7. aggravating evidence
8. mitigating evidence
9. rehabilitation evidence
10. compliance with terms of any criminal sentence, parole, or probation
11. overall criminal record
12. if applicable, evidence of proceedings for case being set aside and dismissed pursuant to Section 1203.4 of the Penal Code
13. time passed since the act(s) or offense(s)
14. whether the conduct was intentional or negligent, demonstrated incompetence, 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
15. financial benefit to the respondent from the misconduct.

No single one or combination of the above factors is required to justify the minimum and/or maximum penalty in a given case, as opposed to an intermediate one.

MITIGATING EVIDENCE

A respondent is permitted to present mitigating circumstances at a hearing or in the settlement process and has the burden of demonstrating any rehabilitative or corrective measures he or she has taken. The board does not intend, by the following references to written statements, letters, and reports, to waive any evidentiary objections to the form or admissibility of such evidence. The respondent must produce admissible evidence in the form required by law in the absence of a stipulation to admissibility by the complainant.

The following are examples of appropriate evidence a respondent may submit to demonstrate his or her rehabilitative efforts and competency:

- a. Recent, dated, written statements and/or performance evaluations from persons in positions of authority who have on-the-job knowledge of the respondent's current competence in the practice of pharmacy including the period of time and capacity in which the person worked with the respondent. Such reports must be signed under penalty of perjury and will be subject to verification by board staff.
- b. Recent, dated, letters from counselors regarding the respondent's participation in a rehabilitation or recovery program, which should include at least a description and requirements of the program, a psychologist's diagnosis of the condition and current state of recovery, and the psychologist's basis for determining rehabilitation. Such letters and reports will be subject to verification by board staff.
- c. Recent, dated, letters describing the respondent's participation in support groups, (e.g., Alcoholics Anonymous, Narcotics Anonymous, professional support groups, etc.). Such letters and reports will be subject to verification by board staff.
- d. Recent, dated, laboratory analyses or drug screen reports, confirming abstention from drugs and alcohol. Such analyses and reports will be subject to verification by board staff.
- e. Recent, dated, physical examination/assessment report(s) by a licensed physician, confirming the absence of any physical impairment that would prohibit the respondent from practicing safely. Such ~~assessments and~~ report(s) will be subject to verification by board staff.
- f. Recent, dated, letters from probation or parole officers regarding the respondent's participation in and/or compliance with terms and conditions of probation or parole, which should include at least a description of the terms and conditions, and the officer's basis for determining compliance. Such letters and reports will be subject to verification by board staff.
- g. Recent, dated, letters from persons familiar with respondent in either a personal or professional capacity regarding their knowledge of: the respondent's character; the respondent's rehabilitation, if any; the conduct of which the respondent is accused; or any other pertinent facts that would enable the board to better decide the case. Such letters must be signed under penalty of perjury and will be subject to verification by board staff.

TERMS OF PROBATION – PHARMACIST/INTERN PHARMACIST INDIVIDUAL LICENSEES (PHARMACIST, INTERN PHARMACIST, PHARMACY TECHNICIAN, DESIGNATED REPRESENTATIVE)

A minimum three-year probation period has been established by the board as appropriate in most cases where probation is imposed. A minimum five-year probation period has been established by the board as appropriate where self-administration or diversion of controlled substances is involved. Terms and conditions are imposed to provide consumer protection and to allow the probationer to demonstrate rehabilitation. A suspension period may also be required as part of the probation order. The board prefers that any stayed order be for revocation rather than for some period of suspension.

Probation conditions are divided into two categories: (1) standard conditions that shall appear in all probation cases, and (2) optional conditions that depend on the nature and circumstances of a particular case. These conditions may vary depending on the nature of the offense(s).

The board may also impose any other condition appropriate to the case where the condition is not contrary to public policy.

CATEGORIES OF VIOLATIONS AND RECOMMENDED PENALTIES

The California Pharmacy Law identifies offenses for which the board may take disciplinary action against the license. Included among grounds for discipline are violations of the Pharmacy Law itself, violations of regulations promulgated by the board, and violations of other state or federal statutes or regulations.

For those licenses issued to individuals (pharmacists, intern pharmacists, pharmacy technicians, and designated representatives), the board has identified four (4) categories of violations and their associated recommended minimum and maximum penalties. These categories of violations are arranged in ascending order from the relatively minor (Category I) to the most serious (Category IV), although any single violation in any category, or any combination of violation(s) in one or more categories, may merit revocation. For pharmacy technicians and designated representatives, the board believes an order of revocation is typically the appropriate penalty when any grounds for discipline are established, and that if revocation is not imposed that a minimum Category III level of discipline should be imposed.

~~The following are categories of possible violations used by the board to determine appropriate disciplinary penalties. These categories represent the judgment of the board as to the perceived seriousness of particular offenses.~~

~~Under each category, the board has grouped statutes and regulations where violations would typically merit the recommended range of minimum to maximum penalties for that category. These lists are representative, and are not intended to be comprehensive or exclusive. For each violation category, the board has given offense descriptions and examples where violations would typically merit the recommended range of minimum to maximum penalties for that category. These descriptions and examples are representative, and are not intended to be comprehensive or exclusive. Where a violation not included in these lists is a basis for disciplinary action, the appropriate penalty for that violation may be best derived by comparison to any analogous violation(s) that are included. Where no such analogous violation is listed, the category descriptions may be consulted.~~

These categories assume a single violation of each listed statute or regulation. For multiple violations, the appropriate penalty shall increase accordingly. Moreover, if an individual has committed violations in more than one category, the minimum and maximum penalties shall be those recommended in the highest category.

The board also has the authority, pursuant to Business and Professions Code section 4301(n), to impose discipline based on disciplinary action taken by another jurisdiction. The discipline imposed by the board will depend on the discipline imposed by the other jurisdiction, the extent of the respondent's compliance with the terms of that discipline, the nature of the conduct for which the discipline was imposed, and other factors set forth in these guidelines.

CATEGORY I

Minimum: Revocation; Revocation stayed; one year probation. All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Category I discipline is recommended for violations which are relatively minor but are potentially harmful. These may include:

- violations which are relatively minor but are potentially harmful of recordkeeping requirements, scope of practice requirements, or inventory control requirements;
- repeated violations of a relatively minor nature: smaller or isolated failure(s) to abide by or enforce prescription or refill requirements, drug-substitution requirements, or labeling requirements;
- violation(s) of obligations to supply or update information to the board, or to other enforcement or regulatory agencies;
- failure(s) to adequately supervise staff or ensure security and sanitation of premises, dangerous drugs, or controlled substances; and
- violation(s) of packaging requirements, security control requirements, or reporting requirements.

CATEGORY II

Minimum: Revocation; Revocation stayed, three years probation (five years probation where self-administration or diversion of controlled substances is involved). All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Category II discipline is recommended for violations with serious potential for harm, as well as for violations involving disregard for public safety or for the laws or regulations pertaining to pharmacy and/or to dispensing or distributing of dangerous drugs or controlled substances, violations that reflect on ethics, competence, or diligence, and criminal convictions not involving alcohol, dangerous drugs, or controlled substances. Violations in this category may include:

- failure(s) to abide by prohibitions on referral rebates or discounts (kickbacks) and/or volume or percentage-based lease agreements;

- violation(s) of advertising or marketing limitations, including use of false or misleading advertising or marketing;
- repeat or serious violation(s) of recordkeeping requirements, scope of practice requirements, or inventory control requirements;
- violation(s) of controlled substance secure prescription requirements, inventory controls, or security requirements;
- failure(s) to meet compliance requirements, including pharmacist-in-charge or designated representative-in-charge designation and duties;
- violation(s) of monitoring and reporting requirements with regard to chemically, mentally, or physically impaired licensees or employees;
- repeat or serious failure(s) to adequately supervise staff or ensure security and sanitation of premises, dangerous drugs, or controlled substances;
- violation(s) of law governing dangerous drugs and controlled substances, including smaller cases of diversion or self-administration;
- unlawful possession(s) of dangerous drugs, controlled substances, hypodermic needles and syringes, or drug paraphernalia;
- smaller scale dispensing or furnishing of dangerous drug(s) or device(s) via the internet without valid prescription(s);
- purchasing, trading, selling, or transferring dangerous drug(s) or device(s) to or from unauthorized person(s);
- failure(s) to make required reports to board or other regulatory agencies, including CURES obligations and reporting to DEA;
- violation(s) of quality assurance and self-assessment obligations, failure(s) to clarify erroneous or uncertain prescription(s);
- gross immorality, incompetence, gross negligence, clearly excessive furnishing of controlled substances, moral turpitude, dishonest, or fraud;
- criminal conviction(s) not involving alcohol, dangerous drugs, or controlled substances;
- violating, or assisting in or abetting violation of, or conspiring to violate the laws and regulation governing pharmacy; and
- subverting or attempting to subvert an investigation conducted by the board.
- ~~violations with a serious potential for harm~~
- ~~violations which involve greater disregard for pharmacy law and public safety~~
- ~~violations which reflect on ethics, care exercised or competence or a criminal conviction not involving dangerous drugs or controlled substances or involving possession or use of dangerous drugs or controlled substances.~~

CATEGORY III

Minimum: Revocation; Revocation stayed, 90 days actual suspension, three to five years probation (five years probation where self-administration or diversion of controlled substances is involved). All standard terms and conditions and optional terms and conditions as appropriate.

Maximum: Revocation

Category III discipline is recommended for violations where potential for harm is greater, more

imminent, or more serious than it is for Category II violations, as well as for violations that involve knowingly or willfully violating laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs or controlled substances, and most criminal convictions involving alcohol, dangerous drugs or controlled substances, and most criminal convictions involving alcohol, dangerous drugs, or controlled substances. Violations in this category may include:

- violation(s) involving creation, manipulation, perpetuation, or disregard of drug shortages;
- failure(s) to deploy or abide by electronic pedigree requirements for dangerous drugs;
- violation(s) of licensee's corresponding responsibility to ensure the proper prescribing and dispensing of controlled substances;
- dispensing or furnishing without valid prescription, dispensing or furnishing to unauthorized person(s);
- violation(s) involving fraudulent acts committed in connection with the licensee's practice;
- repeat or serious violation(s) of controlled substance secure prescription requirements, inventory controls, or security requirements;
- violation(s) of laws governing dangerous drugs and controlled substances, including repeat or serious diversion or self-administration;
- repeat or serious unlawful possession(s) of dangerous drugs, controlled substances, hypodermic needles or syringes, or drug paraphernalia;
- larger scale dispensing or furnishing of dangerous drug(s) or device(s) via the internet, without valid prescription(s);
- purchasing, trading, selling, or transferring adulterated, misbranded, or expired dangerous drug(s) or device(s);
- removal, sale, or disposal of embargoed dangerous drug(s) or device(s);
- failing to maintain record(s) of acquisition and disposition of dangerous drug(s) or device(s);
- resale(s) of preferentially priced drugs, contract bid diversion, or other instances of improper sale(s) or resale(s);
- repeat or serious violation(s) of quality assurance and self-assessment obligations, failure(s) to ensure properly trained staff and conduct practice safely;
- repeat or serious failure(s) to perform drug utilization reviews, monitor patient medication profiles, or promote safety and efficacy of prescribed drugs;
- forgery of prescriptions, passing of forged prescriptions, or other unlawful means of acquiring dangerous drug(s) or controlled substance(s);
- repeat or serious acts violating, assisting in or abetting violation of, or conspiring to violate the laws and regulations governing pharmacy; and
- violation(s) involving providing or offering to provide controlled substance(s) to addict(s).
 - ~~most criminal convictions involving dangerous drugs or controlled substances~~
 - ~~knowing or willfully violating laws or regulations pertaining to dispensing or distributing dangerous drugs or controlled substances~~
 - ~~fraudulent acts committed in connection with the licensee's practice~~
 - ~~drug shortages~~
 - ~~violation of a licensee's corresponding responsibility.~~

CATEGORY IV

Penalty: Revocation

Category IV discipline (Revocation) is recommended for the most serious violations of laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs or controlled substances. Violations in this category may include: the Uniform Controlled Substance Act (Heath and Safety Code 11000 et seq.) involving:

- possession for sale violations involving possession for sale, transportation, importation, and/or use of a minor for unlawful sale of controlled substances;
- transportation criminal convictions involving the above, or repeat convictions involving diversion or abuse of alcohol, dangerous drugs, or controlled substances;
and
- repeated or serious example(s) of conduct described in Category I, Category II, or Category III.
- ~~importation~~
- ~~sale~~
- ~~use of a minor for the unlawful sale of controlled substances~~

Revocation is also recommended when: where a respondent fails to file a notice of defense to an Accusation or to appear at a disciplinary hearing, where a respondent violates the terms and conditions of probation from a previous disciplinary order, or where prior discipline has been imposed on the license.

- ~~a respondent fails to file a notice of defense or to appear at a disciplinary hearing where the board has requested revocation in the accusation~~
- ~~a respondent violates the terms and conditions of probation from a previous disciplinary order~~
- ~~prior discipline has been imposed, as progressive discipline unless the respondent can demonstrate satisfactory evidence of rehabilitation.~~

MODEL DISCIPLINARY LANGUAGE - PHARMACIST/INTERN PHARMACIST INDIVIDUAL LICENSEES (PHARMACIST, INTERN PHARMACIST, PHARMACY TECHNICIAN, DESIGNATED REPRESENTATIVE)

The following standardized language shall be used in every decision where the order or condition is imposed.

Revocation

License number _____, issued to respondent _____, is revoked.

Respondent shall relinquish ~~his or her~~ [his/her] wa license, including any indicia of licensure issued by the board, and pocket renewal license to the board within 10 days of the effective date of this decision. Respondent may not reapply or petition the board for reinstatement of his or her revoked license for three years from the effective date of this decision.

~~Respondent shall pay to the board its costs of investigation and prosecution in the amount of \$_____ within fifteen (15) days of the effective date of this decision.~~

Option: As a condition precedent to reinstatement of his or her revoked license, respondent shall reimburse the board for its costs of investigation and prosecution in the amount of \$_____. Said amount shall be paid in full prior to the reapplication or reinstatement of his or her license unless otherwise ordered by the board.

Option: Respondent shall pay to the board its costs of investigation and prosecution in the amount of \$_____ within fifteen (15) days of the effective date of this decision.

Suspension

As part of probation, respondent is suspended from the practice as a [insert license type] for _____ [day(s)/month(s)/year(s)] of pharmacy for _____ beginning the effective date of this decision.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and devices or controlled substances.

During any such suspension, Respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a pharmacist [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with this any such suspension shall be considered a violation of probation.

Standard Stay/Probation Order

License number _____, issued to respondent is revoked; however, the revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Issuance of Probationary License (In cases where a Statement of Issues has been filed.)

Upon satisfaction of all statutory and regulatory requirements for issuance of a [insert license type] license, a [insert license type] license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Option: (Pharmacist Interns Only)

Should the board subsequently issue a license to practice as a pharmacist during the period of probation, said license shall be immediately revoked. The revocation of such license shall be stayed, and the probation imposed by this decision and order will continue. Respondent shall be subject to the same terms and conditions imposed by this disciplinary order.

Notwithstanding this provision, the Board reserves the right to deny respondent's application for the pharmacist licensure exam. If the board issues a pharmacist license to respondent, the following additional terms and conditions shall be included as part of the disciplinary order:

Surrender

Respondent surrenders license number _____ as of the effective date of this decision. Respondent shall relinquish his or her ~~wa~~ license, including any indicia of licensure issued by the board, and/or pocket renewal license to the board within ten (10) days of the effective date of this decision.

The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board.

Respondent understands and agrees that if ~~he or she~~ [he/she] ever files an application for licensure or a petition for reinstatement in the State of California, the board shall treat it as a new application for licensure.

Respondent may not apply for any license, permit, or registration from the board for three years from the effective date of this decision. Respondent stipulates that should ~~he or she~~ [he/she] apply for any license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct

and admitted by respondent when the board determines whether to grant or deny the application. 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 the California Pharmacist Licensure Examination prior to the issuance of a new license. Respondent is required to report this surrender as disciplinary action.

Respondent further stipulates that ~~he or she~~ [he/she] shall reimburse the board for its costs of investigation and prosecution in the amount of \$ _____ within _____ days of the effective date of this decision.

Option: Respondent stipulates that should ~~he or she~~ [he/she] apply for any license from the board on or after the effective date of this decision the investigation and prosecution costs in the amount of \$ _____ shall be paid to the board prior to issuance of the new license.

Public Reprimand

It is hereby ordered that a public reprimand be issued against licensee, _____. Respondent is required to report this reprimand as a disciplinary action.

License Reinstatement Order with Conditions Prior to Issuing License

It is hereby ordered that the petition for reinstatement filed by _____ is hereby granted and Petitioner's License No. _____ will be reinstated upon the following conditions precedent:

- a. _____ Petitioner shall take and pass the [North American Pharmacist Licensure Examination (NAPLEX) and/or the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)/Pharmacy Technician Certification Board exam] within one (1) year of the effective date of this order.
- b. _____ Petitioner must pay the fee in place at the time for these examinations.
- c. _____ Petitioner must pay a reinstatement fee in the amount of \$ _____.

Option: Petitioner pays the Board's cost recovery or fine amount owed to the Board in the amount of \$ _____.

Upon completion of the conditions precedent above, Petitioner's license shall be REINSTATED. Upon reinstatement, Petitioner's license shall be REVOKED. However, said revocation shall be STAYED, and Petitioner shall be placed on PROBATION for a period of _____ year(s)] under the following terms and conditions:

License Reinstatement

It is hereby ordered that the petition for reinstatement filed by _____ is hereby GRANTED and Petitioner's license shall be REINSTATED. Upon reinstatement, Petitioner's license shall be REVOKED. However, said revocation shall be STAYED, and Petitioner shall be placed on PROBATION for a period of _____ years under the following terms and conditions:

Adoption of Stipulation

It is understood by respondent that, in deciding whether to adopt this stipulation, the board may receive oral and written communication from its staff and the Office of the Attorney General. Communications pursuant to this paragraph shall not disqualify the board or other persons from future participation in this or any other matter affecting respondent. In the event this settlement is not adopted by the board, the stipulation will not become effective and may not be used for any purpose, except this paragraph, which shall remain in effect.

STANDARD CONDITIONS - To be included in all probation decisions/orders.

1. Obey All Laws
2. Report to the Board
3. Interview with the Board
4. Cooperate with Board Staff
5. Continuing Education
6. Reporting of Employment and Notice to Employers
7. Notification of Change(s) in Name, Employment, Address(es), or Phone Number(s)
- ~~7-8.~~ No Supervision of Interns, Serving as Pharmacist In-Charge (PIC), or Serving as a Consultant
- ~~8~~ 9. Reimbursement of Board Costs
- ~~9-10.~~ 10. Probation Monitoring Costs
- ~~10~~ 11. Status of License
- ~~11~~ 12. License Surrender While on Probation/Suspension
- ~~12.~~ 12. Notification of a Change in Name, Residence Address, Mailing Address or Employment
- ~~13.~~ 13. Certification Prior to Resuming Work
- ~~14.~~ 14. Notification of Departure
- ~~13-15.~~ 15. Tolling of Probation License Practice Requirement - Tolling
- ~~14.~~ 16. Violation of Probation
- ~~15.~~ 17. Completion of Probation

OPTIONAL CONDITIONS

- ~~18.~~ 18. Suspension
- ~~16.~~ 19. Restricted Practice
- ~~17.~~ 20. Pharmacist Examination
- ~~18.~~ 21. Mental Health Examination Clinical Diagnostic Evaluation
- ~~19.~~ 22. Psychotherapy
- ~~20.~~ 23. Medical Evaluation
- ~~21.~~ 24. Pharmacists Recovery Program (PRP)
- ~~22.~~ 25. Random Drug Screening Drug and Alcohol Testing
- ~~23.~~ 26. Abstain from Drugs and Alcohol Use
- ~~24.~~ 27. Prescription Coordination and Monitoring of Prescription Use
- ~~28.~~ 28. Facilitated Group Recovery and/or Support Meetings
- ~~29.~~ 29. Attend Substance Abuse Recovery Relapse Prevention and Support Groups
- ~~30.~~ 30. Work Site Monitor
- ~~25.~~ 31. Community Service Program
- ~~26.~~ 32. Restitution
- ~~27.~~ 33. Remedial Education
- ~~28.~~ 34. Pharmacy Self-Assessment Mechanism (PSAM)
- ~~29.~~ 34. Intern Pharmacist Experience
- ~~30.~~ 35. Supervised Practice
- ~~31.~~ 31. No Supervision of Ancillary Personnel
- ~~32.~~ 36. No Ownership or Management of Licensed Premises
- ~~33.~~ 37. Separate File of Controlled Substances Records
- ~~34.~~ 38. Report of Controlled Substances
- ~~35.~~ 39. No Access to Controlled Substances
- ~~36.~~ 40. Criminal Probation/Parole Reports
- ~~37.~~ 37. Consultant for Owner or Pharmacist In-Charge
- ~~41.~~ 41. Tolling of Suspension

~~39.42.~~ Surrender of DEA Permit
~~40.43.~~ Ethics Course

STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which 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.

Failure to timely report such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondent shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of ~~his or her~~ [his/her] probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

5. Continuing Education (Pharmacists Only)

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. Reporting of Employment and Notice to Employers

During the period of probation, respondent shall provide the board with written consent authorizing communication with all employers and shall notify all present and prospective employers of the decision in case number _____ and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of undertaking any new employment, respondent shall report to the board in writing the name, physical address, and mailing address of all of [his/her] employer(s), and the name(s) and telephone number(s) of all of [his/her] direct supervisor(s), as well as any pharmacist(s)-in-charge, designated representative(s)-in-charge, or other compliance supervisor(s). Respondent shall sign and return to the board a written consent authorizing the board or its designee to communicate with all of respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the board or its designee, concerning respondent's work status, performance, and monitoring. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause (a) his or her [his/her] direct supervisor, (b) his or her pharmacist-in-charge, designated representative-in-charge, or other compliance supervisor, (including each new pharmacist-in-charge employed during respondent's tenure of employment) and (c) the owner or owner representative of his or her employer, to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number _____, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be the respondent's responsibility to ensure that these acknowledgement(s) are timely submitted to the board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term of probation, respondent shall cause the person(s) taking over the role(s) to report to the board in writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case number _____, and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If respondent works for or is employed by or through a pharmacy an employment service, respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the board, of the decision in case number _____, and the terms and conditions imposed thereby in advance of respondent commencing work at such licensed entity his or her direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in case number _____ in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy an employment service, respondent shall cause the person(s) described in (a), (b), and (c) above his or her direct supervisor with the pharmacy at the employment service to report to the board in writing

acknowledging that he or she has read the decision in case number _____, and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board ~~his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.~~

Failure to timely notify present or prospective employer(s) or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision ~~shall include~~ any full-time, part-time, temporary, relief, or employment/management service position as a [insert license type], or any position for which a [insert license type] license or pharmacy management service as a pharmacist or any position for which a pharmacist license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. Notification of Change(s) in Employment, Name, Address(es), or Phone Number(s)¹

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule, if known. Respondent shall further notify the board in writing within ten (10) days of any change in name, residence address, mailing address, or phone number.

Failure to timely notify the board of any change in employer, name, address, or phone number shall be considered a violation of probation.

78. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant Restrictions on Supervision and Oversight of Licensed Facilities² (Pharmacists or Designated Representatives only)

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge, ~~or~~ designated representative-in-charge, or other compliance supervisor of any entity licensed by the board, ~~nor~~ serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

Option 1: During the period of probation, respondent shall not supervise any ancillary personnel, including, but not limited to, pharmacy technicians or designated representatives in any entity licensed by the board. Assumption of any such unauthorized ancillary personnel supervision responsibilities shall be considered a violation of probation.

Option 2a: During the period of probation, respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge, designated representative-in-charge, or other compliance supervisor of

¹ This term was renamed and renumbered from previous term 12.

² This term was renamed and consolidated with two additional terms: No Supervision of Ancillary Personnel and Consultant for Owner of Pharmacist-in-Charge.

any single entity licensed by the board, but only if respondent or that entity retains, at his/her/its expense, an independent consultant who shall be responsible for reviewing the operations of the entity on a [monthly/quarterly] basis for compliance by respondent and the entity with state and federal laws and regulations governing the practice of the entity, and compliance by respondent with the obligations of his or her supervisory position. Respondent may serve in such a position at only one entity licensed by the board. The consultant shall be a pharmacist licensed by and not on probation with the board, who has been approved by the board or its designee to serve in this position. Respondent shall submit the name of the proposed consultant to the board or its designee for approval within thirty (30) days of the effective date of the decision. Assumption of any unauthorized supervision responsibilities shall be considered a violation of probation. In addition, failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall be considered a violation of probation.

Option 2b: During the period of probation, respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge, designated representative-in-charge, or other compliance supervisor of any single entity licensed by the board, but only if respondent or that entity retains, at his/her/its expense, an independent consultant who shall be responsible for reviewing the operations of the entity on a [monthly/quarterly] basis for compliance by respondent and the entity with state and federal laws and regulations governing the practice of the entity, and compliance by respondent with the obligations of his or her supervisory position. Respondent may serve in such position at only one entity licensed by the board, and only at an entity of which [he/she] is the sole owner. The consultant shall be a pharmacist licensed by and not on probation with the board, who has been approved by the board or its designee to serve in this position. Respondent shall submit the name of the proposed consultant to the board or its designee for approval within thirty (30) days of the effective date of the decision. Assumption of any unauthorized supervision responsibilities shall be considered a violation of probation. In addition, failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall be considered a violation of probation.

Option 2c: During the period of probation, respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge, designated representative-in-charge, or other compliance supervisor of any single entity licensed by the board, but only if respondent or that entity retains, at his/her/its expense, an independent consultant who shall be responsible for reviewing the operations of the entity on a [monthly/quarterly] basis for compliance by respondent and the entity with state and federal laws and regulations governing the practice of the entity, and compliance by respondent with the obligations of his or her supervisory position. Respondent may serve in such position at only one entity licensed by the board, and only if respondent is already serving in such a position at the time of the effective date of this decision. The consultant shall be a pharmacist licensed by and not on probation with the board, who has been approved by the board or its designee to serve in this position. Respondent shall submit the name of the proposed consultant to the board or its designee for approval within thirty (30) days of the effective date of the decision. Assumption of any unauthorized supervision responsibilities shall be considered a violation of probation. In addition, failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall be considered a violation of probation.

89. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of \$_____. Respondent shall make said payments as follows: _____.

There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

Option: Respondent shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation.

~~The filing of bankruptcy by respondent shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.~~

910. Probation Monitoring Costs

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

4011. Status of License

Respondent shall, at all times while on probation, maintain an active, current [insert license type] license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current [insert license type] license shall be considered a violation of probation.

If respondent's [insert license type] license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's [insert license type] license shall be subject to all terms and conditions of this probation not previously satisfied.

4412. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her [insert license type] license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the [insert license type] license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his or her pocket and/or wall license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

12. ~~Notification of a Change in Name, Residence Address, Mailing Address or Employment~~

~~Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number(s).~~

~~Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.~~

13. Certification Prior to Resuming Work (Pharmacy Technicians Only)³

Respondent shall be suspended, and shall not work as a pharmacy technician, until [he/she] has been certified as defined by Business and Professions Code section 4202, subdivision (a)(4), has submitted proof of certification to the board, and has been notified by the board or its designee that [he/she] may begin work. Failure to achieve certification within six (6) months shall be considered a violation of probation. Respondent shall not resume working as a pharmacy technician until notified by the board.

During any such suspension, respondent shall not enter any pharmacy area or any portion of any other board licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs) which is licensed by the board, or any manufacturer, or any area where dangerous drugs and devices or controlled substances are maintained. Respondent shall do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or assist any licensee of the board. Respondent shall not have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and devices or controlled substances.

During any such suspension, respondent shall not engage in any activity that requires licensure as a pharmacy technician. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs or devices or controlled substances.

Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation.

Option: Respondent shall maintain an active, current certification as defined by Business and Professions Code section 4202, subdivision (a)(4), for the entire period of probation, and shall submit proof of re-certification or renewal of certification to the board within ten (10) days of receipt. Failure to maintain active, current certification or to timely submit proof of same shall be considered a violation of probation.

14. Notification of Departure⁴

³ This probationary term is not new, but is rather being moved from the "Model Disciplinary language - - Pharmacy Technician" Standard Terms and Conditions for purposes of consolidation.

⁴ This probationary term is not new, but is rather being moved from the "Model Disciplinary language - - Pharmacy Technician" for purposes of consolidation.

Prior to leaving the probationary geographic area designated by the board or its designee for a period greater than twenty-four (24) hours, respondent shall notify the board verbally and in writing of the dates of departure and return. Failure to comply with this provision shall be considered a violation of probation.

13.15. Tolling of Probation License Practice Requirement - Tolling

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacist [insert license type] in California for a minimum of _____ hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation, unless the respondent is notified in writing by the board or its designee.

~~Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of _____ hours per calendar month in California, If respondent does not practice as a [insert license type] in California for a minimum of _____ hours in any calendar month, for any reason (including vacation), respondent shall must notify the board in writing within ten (10) days of the cessation of practice, and must further notify the board in writing within ten (10) days of the resumption of practice. conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the interruption or decline in practice; and the anticipated date(s) on which respondent will resume practice at the required level. Respondent shall further notify the board in writing within ten (10) days following the next calendar month during which respondent practices as a [insert license type] in California for a minimum of _____ hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.~~

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

~~"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least _____ hours, as defined by Business and Professions Code section 4000 et seq. "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least _____ hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.~~

Option 1: As a condition precedent to successful completion of probation, during the period of probation respondent shall practice as a [insert license type] in a licensed _____ in California that dispenses dangerous drugs for a minimum of one (1) year. After the first year or probation, the board or its designee may consider a modification of this requirement. Failure to comply with this requirement (or as modified) shall be considered a violation of probation. Respondent is required to practice as a pharmacist in a licensed pharmacy setting that dispenses medication for a minimum of one year prior to the completion of probation. After the first year of probation, the board or its designee may consider a modification of this requirement.

If respondent fails to comply with this requirement or a subsequent modification thereto, such failure shall be considered a violation of probation.

Option 2: (First-year pharmacist interns only) During respondent's first academic year of enrollment in a school or college of pharmacy, no minimum practice hours shall be required. Instead, respondent shall report to the board quarterly in writing, in a format and schedule as directed by the board or its designee, on [his/her] compliance with academic and vocational requirements, and on [his/her] academic progress. This exemption shall apply only once, and only during respondent's first academic year. Respondent must comply with all other terms and conditions of probation, unless notified in writing by the board or its designee.

14.16. Violation of Probation

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. ~~Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license.~~ If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

15.17. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

OPTIONAL CONDITIONS OF PROBATION

18. Suspension

As part of probation, respondent is suspended from practice as a [insert license type] for _____ [day(s)/month(s)/year(s)] beginning the effective date of this decision.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs or devices or controlled substances.

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices or controlled substances.

Failure to comply with any such suspension shall be considered a violation of probation.

Option 1: During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of ten (10) days during the period of suspension shall be considered a violation of probation, and shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation, unless notified in writing by the board or its designee.

Respondent shall notify the board or its designee in writing within ten (10) days of any departure from California, for any period, and shall further notify the board or its designee in writing within ten (10) days of return. Failure to timely provide such notification(s) shall be considered a violation of probation. Upon such departure and return, respondent shall not resume the practice of pharmacy until notified by the board or its designee that the period of suspension has been satisfactorily completed.

16.19. Restricted Practice

Respondent's practice as a [insert license type] of pharmacy shall be restricted to [specify setting or type of practice] for the first _____ year(s) of probation. Respondent shall submit ~~proof satisfactory~~ proof satisfactory to the board or its designee in writing, of compliance with this term of probation.

Option: Respondent shall not prepare, oversee, or participate in the preparation of injectable sterile products during the first _____ year(s) of probation. Upon request, respondent ~~Respondent~~ shall submit to the board or its designee on writing, satisfactory proof ~~satisfactory~~ of compliance with this restriction, including but not limited to a written acknowledgment of this restriction signed by (a) respondent's direct supervisor, (b) the pharmacist-in-charge, and (c) the owner or owner representative of his or her employer, which explains whether the workplace in question compounds drug products and how this restriction will be enforced ~~term of probation~~. Failure to abide by this restriction or to timely submit proof to the board or its designee of ~~compliance therewith~~ shall be considered a violation of probation.

17.20. Pharmacist Examination (Pharmacists Only)

Respondent shall take and pass the [California Pharmacist Jurisprudence Examination (CPJE) and/or the North American Pharmacist Licensure Examination (NAPLEX)] within six (6) months of the effective date of this decision. If respondent fails to take and pass the examination(s) within six (6) months after the effective of this decision, respondent shall be automatically suspended from practice. Respondent shall not resume the practice of pharmacy until ~~he or she~~ he/she takes and passes the [CPJE and/or NAPLEX] and is notified, in writing, that ~~he or she~~ he/she has passed the examination(s) and may resume practice. Respondent shall bear all costs of the examination(s) required by the board.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs or devices and controlled substances. Respondent shall not resume practice until notified by the board.

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices and controlled substances. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with this any such suspension shall be considered a violation of probation.

If respondent fails to take and pass the [CPJE and/or NAPLEX] after four attempts, respondent shall successfully complete, at a minimum, sixteen (16) additional semester units of pharmacy education as approved by the board. The respondent shall submit in writing to the board or its designee satisfactory proof of completion of sixteen (16) additional semester units of pharmacy education. Failure to complete coursework or provide proof of such completion as required shall be considered a violation of probation.

Failure to take and pass the examination(s) within ~~one (1) year~~ six (6) months of the effective date of this decision shall be considered a violation of probation.

18.20. Mental Health Examination Clinical Diagnostic Evaluation (Appropriate for those cases where evidence demonstrates that mental illness psychiatric disorders (mental illness, emotional disturbance, gambling addiction), substance abuse, or disability was a contributing cause of the violation(s).)

Within thirty (30) days of the effective date of this decision, and on a periodic basis thereafter if ~~as may be~~ required by the board or its designee, respondent shall undergo, at ~~his or her~~ [his/her] own expense, psychiatric clinical diagnostic evaluation(s) by a ~~board-appointed or board-approved~~ licensed mental health practitioner selected or approved prior to the evaluation by the board or its designee. The approved evaluator shall be provided with a copy of the board's [accusation, ~~or petition to revoke probation,~~ or other pleading] and decision. Respondent shall sign a release authorizing the evaluator to furnish the board with a current diagnosis and a written report regarding the respondent's judgment and ability to function independently as a pharmacist [insert license type] with safety to the public. ~~Respondent shall comply with all the recommendations of the evaluator if directed by the board or its designee.~~ If the evaluator recommends restrictions or conditions on respondent's practice, including but not limited to, other terms and conditions listed in these guidelines (e.g., required psychotherapy, prescription coordination and monitoring, restricted practice), the board or its designee may by

written notice to respondent adopt these restrictions or conditions as additional probation terms and conditions, violation of which shall be considered a violation of probation.

~~If the evaluator recommends, and the board or its designee directs, respondent shall undergo psychotherapy. Within thirty (30) days of notification by the board that a recommendation for psychotherapy has been accepted, respondent shall submit to the board or its designee, for prior approval, the name and qualification of a licensed mental health practitioner of respondent's choice. Within thirty (30) days of approval thereof by the board, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved licensed mental health practitioner. Should respondent, for any reason, cease treatment with the approved licensed mental health practitioner, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment therewith, submit the name of a replacement licensed mental health practitioner of respondent's choice to the board for its prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved replacement. Failure to comply with any requirement or deadline stated by this paragraph shall be considered a violation of probation.~~

~~Upon approval of the initial or any subsequent licensed mental health practitioner, respondent shall undergo and continue treatment with that therapist, at respondent's own expense, until the therapist recommends in writing to the board, and the board or its designee agrees by way of a written notification to respondent, that no further psychotherapy is necessary. Upon receipt of such recommendation from the treating therapist, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's expense, a mental health evaluation by a separate board-appointed or board-approved evaluator. If the approved evaluator recommends that respondent continue psychotherapy, the board or its designee may require respondent to continue psychotherapy.~~

~~Psychotherapy shall be at least once a week unless otherwise approved by the board. Respondent shall provide the therapist with a copy of the board's [accusation or petition to revoke probation] and decision no later than the first therapy session. Respondent shall take all necessary steps to ensure that the treating therapist submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and other such information as may be required by the board or its designee.~~

~~If at any time the approved evaluator or therapist determines that respondent is unable to practice safely or independently as a pharmacist, the licensed mental health practitioner shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.~~

Option 1: (Appropriate for those cases where evidence demonstrates substance abuse): The evaluation(s) shall be conducted in accordance with acceptable professional standards for alcohol or substance abuse clinical diagnostic evaluations. The written report(s) shall set forth, at least, the opinions of the evaluator as to: whether respondent has an alcohol or substance abuse problem; whether respondent is a threat to him/herself or others; and recommendations for alcohol or substance abuse treatment, practice restrictions, or other steps related to respondent's rehabilitation and safe practice. If the evaluator determines during the evaluation process that respondent is a threat to him/herself or others, the evaluator shall notify the board within twenty-four (24) hours.

Commencing on the effective date of this decision, respondent is suspended from practice and shall not practice as a [insert license type] until:

- Respondent has undergone and completed clinical diagnostic evaluation(s);
- The report(s) of the evaluation(s) has/have been received by the board or its designee;
- One or more report(s) has concluded that respondent is safe to return to practice as a [insert license type];
- Respondent has submitted to observed bodily fluid testing for the presence of alcohol, dangerous drugs, or controlled substances [pursuant to Term and Condition 24] at least twice per week for at least thirty (30) days;
- During the testing period, respondent has not had a confirmed positive test result for alcohol, or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment, for at least thirty (30) days;
- The board or its designee has determined that respondent is safe to return to either full-time or part-time practice as a [insert license type], after considering the evaluation report(s), the results of the fluid testing, and criteria including the license type, respondent's history, respondent's documented period of sobriety or documented time since last use, respondent's scope and pattern of use, respondent's treatment history, respondent's medical history and current medical condition, the nature, duration, and severity of respondent's alcohol or substance abuse, and whether respondent is a threat to him/herself or others; and
- Respondent receives written notice from the board or its designee that practice may resume.

The board or its designee shall select or approve evaluator(s) holding a valid, unrestricted license to practice, with a scope of practice that includes the conduct of clinical diagnostic evaluations and at least three (3) years experience conducting such evaluations of health professionals with alcohol or substance abuse problems. The evaluator(s) shall not have a financial relationship, personal relationship, or business relationship with respondent within the last five (5) years. The evaluator(s) shall provide an objective/ unbiased, and independent evaluation of respondent.

For all such evaluations, a final written report shall be provided to the board no later than ten (10) days from the date the evaluator is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed thirty (30) days. During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs or devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and controlled substances.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs or devices or controlled substances.

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices or controlled substances.

Option 2: Commencing on the effective date of this decision, respondent is suspended from practice and shall not engage in the practice of pharmacy practice as a [insert license type] until notified in writing by the board that respondent has been deemed psychologically fit to practice pharmacy safely, and the board or its designee approves said recommendation the evaluator recommends that respondent return to practice, this recommendation is accepted by the board or its designee, and respondent receives written notice from the board or its designee that practice may resume.

The final written report of the evaluation shall be provided to the board no later than ten (10) days from the date the evaluator is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed thirty (30) days.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs ~~and or~~ devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs or devices and or controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a pharmacist [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with this any such suspension shall be considered a violation of probation.

(Option language to be used in addition to standard language)

Option 3: ~~If recommended by the evaluating licensed mental health practitioner and approved by the board, respondent shall be suspended from practicing pharmacy until respondent's treating therapist recommends, in writing, stating the basis therefor, that respondent can safely practice pharmacy, and the board or its designee approves said recommendation.~~ evaluator, the board or its designee may suspend respondent from practice as a [insert license type] by providing written notice of suspension to the respondent. Upon suspension, respondent shall not resume practice as a [insert license type] until: 1) another evaluation done at respondent's expense by a licensed practitioner selected or approved by the board or its designee; 2) the evaluator recommends that respondent return to practice; 3) the board or its designee accepts

the recommendation; 4) and the board notifies the respondent in writing that practice may resume.

The report(s) from any such additional evaluation(s) shall be provided to the board or its designee in writing by the evaluator no later than ten (10) days from the date the evaluator is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed thirty (30) days.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs ~~and~~ or devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs or devices or ~~and~~ controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a pharmacist [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with this any such suspension shall be considered a violation of probation.

19.21. Psychotherapy (Appropriate for those cases where the evidence demonstrates ~~mental illness~~ psychiatric disorders (mental illness, emotional disturbance, gambling addiction) or alcohol or drug abuse was involved in the violation(s).)

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, the name and qualifications of a licensed mental health practitioner of respondent's choice. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved licensed mental health practitioner. Should respondent, for any reason, cease treatment with the approved licensed mental health practitioner, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment, submit the name of a replacement psychotherapist or licensed mental health practitioner of respondent's choice to the board for its prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved replacement. Failure to comply with any requirement or deadline stated by this paragraph shall be considered a violation of probation.

Upon approval of the initial or any subsequent licensed mental health practitioner, respondent shall undergo and continue treatment with that therapist, at respondent's own expense, until the therapist recommends in writing to the board, and the board or its designee agrees by way of a

written notification to respondent, that no further psychotherapy is necessary. Upon receipt of such recommendation from the treating therapist, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's own expense, a mental health evaluation by a board-appointed or board-approved psychiatrist or psychologist. If the approved evaluator recommends that respondent continue psychotherapy, the board or its designee may require respondent to continue psychotherapy.

Psychotherapy shall be at least once a week unless otherwise approved by the board. Respondent shall provide the therapist with a copy of the board's accusation and decision no later than the first therapy session. Respondent shall take all necessary steps to ensure that the treating therapist submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and such other information as may be required by the board or its designee.

If at any time the treating therapist determines that respondent cannot practice safely or independently, the therapist shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs ~~and~~ or devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs or devices or ~~and~~ controlled substances. Respondent shall not resume practice until notified by the board.

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices or controlled substances

~~During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with any such this suspension shall be considered a violation of probation.

20.22. Medical Evaluation (Appropriate for those cases where the evidence demonstrates that the respondent has had a physical problem/disability which was a contributing cause of the violations and which may affect the respondent's ability to practice.)

Within thirty (30) days of the effective date of this decision, and on a periodic basis thereafter as may be required by the board or its designee, respondent shall undergo a medical evaluation, at respondent's own expense, by a board-appointed or board-approved physician who shall furnish a medical report to the board. The approved physician shall be provided with a copy of the board's [accusation or petition to revoke probation] and decision. A record of this notification must be provided to the board upon request. Respondent shall sign a release authorizing the physician to furnish the board with a current diagnosis and a written report regarding the respondent's ability to function independently as a ~~pharmacist~~ [insert license type] with safety to the public. Respondent shall comply with all the recommendations of the physician if directed by the board or its designee.

If the physician recommends, and the board or its designee directs, that respondent undergo medical treatment, respondent shall, within thirty (30) days of written notice from the board, submit to the board or its designee, for prior approval, the name and qualifications of a licensed physician of respondent's choice. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of treatment with the approved physician. Should respondent, for any reason, cease treatment with the approved physician, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment, submit the name of a replacement physician of respondent's choice to the board or its designee for prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of treatment with the approved replacement. Failure to comply with any deadline stated by this paragraph shall be considered a violation of probation.

Upon approval of the initial or any subsequent physician, respondent shall undergo and continue treatment with that physician, at respondent's own expense, until the treating physician recommends in writing to the board, and the board or its designee agrees by way of a written notification to respondent, that no further treatment is necessary. Upon receipt of such recommendation from the treating physician, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's own expense, a medical evaluation by a separate board-appointed or board-approved physician. If the approved evaluating physician recommends that respondent continue treatment, the board or its designee may require respondent to continue treatment.

Respondent shall take all necessary steps to ensure that any treating physician submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and other such information as may be required by the board or its designee.

If at any time an approved evaluating physician or respondent's approved treating physician determines that respondent is unable to practice safely or independently as a ~~pharmacist~~ [insert license type], the evaluating or treating physician shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or

be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs or devices or ~~and~~ controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a pharmacist [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation.

(Option language to be used in addition to standard language)

Option 1: Commencing on the effective date of this decision, respondent shall not engage in the practice of ~~pharmacy~~ as a [insert license type] until notified in writing by the board that respondent has been deemed medically fit to practice safely and independently, and the board or its designee approves said recommendation.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs ~~and~~ or devices or controlled substances are maintained. Respondent shall not practice ~~pharmacy~~ as a [insert license type] nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs or controlled substances. Respondent shall not resume practice until notified by the board.

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a pharmacist [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation.

(Option language to be used in addition to standard language)

Option 2: If recommended by the evaluating physician and approved by the board, respondent shall be suspended from practicing ~~pharmacy~~ as a [insert license type] until the treating physician recommends, in writing, stating the basis therefor, that respondent can safely and independently resume the practice of a pharmacist, and the board or its designee approves said

recommendation. Respondent shall not resume practice until notified by the board that practice may be resumed.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs ~~and~~ or devices or controlled substances are maintained. Respondent shall not practice ~~pharmacy as a [insert license type]~~ nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs ~~and~~ or devices or controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a pharmacist [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation.

21-23. Pharmacists Recovery Program (PRP) (Appropriate for those cases where evidence demonstrates substance abuse chemical dependency (alcohol, drugs), or psychiatric disorders (mental illness, emotional disturbance, gambling addiction) (Pharmacists and Pharmacist Interns Only)

~~By no later than ten (10) days after~~ Within thirty (30) days of the effective date of this decision, respondent shall have completed all of the following: contacted the Pharmacists Recovery Program (PRP) for evaluation; enrolled in the PRP; completed, signed, and returned the treatment contract plus any addendums required or suggested by the PRP; successfully completed registration for any drug or alcohol testing mandated by the treatment contract and/or by enrollment in the PRP; and begun compliance with the drug or alcohol testing protocol(s). ~~contact the Pharmacists Recovery Program (PRP) for evaluation, and shall immediately thereafter enroll, successfully participate in, and complete the treatment contract and any subsequent addendums as recommended and provided by the PRP and as approved by the board or its designee. Respondent shall successfully participate in the PRP and complete the treatment contract and any addendums required or suggested by the PRP and approved by the board or its designee.~~ The costs for PRP participation shall be borne by the respondent.

If respondent is currently enrolled in the PRP, said participation is now mandatory and as of the effective date of this decision is no longer considered a self-referral under Business and Professions Code section 4362(e) (a)(2). Respondent shall successfully participate in and complete his or her current contract and any subsequent addendums with the PRP.

Failure to timely contact or enroll in the PRP, complete the treatment contract and any addendums, complete testing registration, comply with testing, and/or successfully participate in and complete the treatment contract and/or any addendums, shall result in the automatic suspension of practice by respondent and shall be considered a violation of probation. Respondent shall not resume practice until notified in writing by the board or its designee.

Probation shall be automatically extended until respondent successfully completes the PRP. Any person terminated from the PRP program shall be automatically suspended by the board. Respondent may not resume the practice of pharmacy until notified by the board in writing.

Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall result in the automatic suspension of practice by respondent and shall be considered a violation of probation. Respondent may not resume the practice of pharmacy until notified by the board in writing.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and or devices or controlled substances are maintained. Respondent shall not practice pharmacy as a [insert license type] nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and or devices or controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a pharmacist [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with any such ~~this~~ suspension shall be considered a violation of probation.

Respondent shall pay administrative fees as invoiced by the PRP or its designee. Fees not timely paid to the PRP shall constitute a violation for probation. The board will collect unpaid administrative fees as part of the annual probation monitoring costs if not submitted to the PRP.

(Option language to be used in addition to standard language)

Option: Respondent shall work in a pharmacy setting with access to controlled substances for six (6) consecutive months before successfully completing ~~probation~~ the PRP. If respondent fails to do so, probation shall be automatically extended until this condition has been met. Failure to satisfy this condition within six (6) months beyond the original date of expiration of the term of probation shall be considered a violation of probation.

22. 24. Random Drug Screening Drug and Alcohol Testing (If PRP provision is required, this term is also to be included to allow for continued fluid monitoring by the Board in cases where a respondent successfully completes the PRP before completion of the probation period; terms is also appropriate for those cases where the evidence demonstrates that the respondent may have a problem with chemical dependency (drugs, alcohol) but where the PRP is not required—(Appropriate for those cases where the evidence demonstrates substance abuse.)

Respondent, at his or her [his/her] own expense, shall participate in random testing, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other drug screening program as directed by the board or its designee. Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be determined by the board or its designee. At all times, respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples for the detection of alcohol, narcotics, hypnotics, controlled substances, and dangerous drugs, or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and shall result in the automatic suspension of practice of pharmacy by respondent. Respondent may not resume the practice of pharmacy until notified by the board in writing. Testing protocols may include biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other testing protocols as directed by the board or its designee. All testing must be pursuant to an observed testing protocol, unless respondent is informed otherwise in writing by the board or its designee. Respondent may be required to participate in testing for the entire probation period and frequency of testing will be determined by the board or its designee.

By no later than thirty (30) days after the effective date of this decision, respondent shall have completed all of the following tasks: enrolled and registered with an approved drug and alcohol testing vendor; provided that vendor with any necessary information and documentation, and any information necessary for payment by respondent; commenced testing protocols, including all required contacts with the testing vendor to determine testing date(s); and begun testing. At all times, respondent shall fully cooperate with the testing vendor, and with the board or its designee, with regard to enrollment, registration, and payment for, and compliance with, testing. Any failure to cooperate timely shall be considered a violation of probation.

Respondent may be required to test on any day, including weekends and holidays. Respondent is required to make daily contact with the testing vendor to determine if a test is required, and if a test is required must submit to testing on the same day.

Though the frequency of testing will be determined by the board or its designee, and shall be designed so as to prevent respondent from anticipating testing dates (either randomized testing or unpredictable dates), the frequency of testing shall be at least the following: at least fifty-two (52) test dates during the first year of probation; at least thirty-six (36) test dates during the second, third, fourth, and fifth years of probation; and at least one (1) test per month in each year of probation after the fifth so long as there have been no positive test results during the previous five (5) years. The board or its designee may require less frequent testing if any of the following applies:

- Where respondent has previously participated in a treatment or monitoring program requiring testing, the board or its designee may consider that prior testing record in applying the three-tier testing frequency schedule described above;
- Where the basis for probation or discipline is a single incident or conviction involving alcohol or drugs, or two incidents or convictions involving alcohol or drugs that were at least seven (7) years apart, that did not occur at work or on the way to or from work, the board or its designee may skip the first-year testing frequency requirement(s);
- Where respondent is not employed in any health care field, frequency of testing may be reduced to a minimum of twelve (12) tests per year. If respondent wishes to thereafter return to employment in a health care field, respondent shall be required to test at least once a week for a period of sixty (60) days before commencing such employment, and shall thereafter be required to test at least once a week for a full year, before [he/she] may be reduced to a testing frequency of at least thirty-six (36) tests per year, and so forth;
- Respondent's testing requirement may be suspended during any period of tolling of the period of probation;
- Where respondent has a demonstrated period of sobriety and/or non-use, the board or its designee may reduce the testing frequency to no less than twenty-four (24) tests per year.

Any detection through testing of alcohol, or of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment, may cause the board or its designee to increase the frequency of testing, in addition to any other action including but not limited to further disciplinary action.

Prior to any vacation or other period of absence from the geographic area of the approved testing vendor, respondent shall seek and receive approval from the board or its designee of an alternate testing vendor in the geographic area to be visited or resided in by respondent. Upon approval, respondent shall enroll and register with the approved alternate drug testing vendor, provide that alternate vendor with any necessary information and documentation, including any necessary payment by respondent. During the period of visitation or residence in the alternate geographic area, respondent shall commence testing protocols with the alternate vendor, including required daily contacts with the testing vendor to determine if testing is required, and required testing. Any failure to timely seek or receive approval from the board or its designee, or to timely enroll and register with, timely commence testing protocols with, or timely undergo testing with, the alternate testing vendor, shall be considered a violation of probation.

Upon detection through testing of a controlled substance or dangerous drug, the board or its designee may require respondent to timely provide documentation from a licensed practitioner authorized to prescribe the detected substance demonstrating that the substance was administered or ingested pursuant to a legitimate prescription issued as a necessary part of treatment. All such documentation shall be provided by respondent within ten (10) days of being requested.

Any of the following shall be considered a violation of probation and shall result in respondent being immediately suspended from practice as a [insert license type] until notified by the board in writing that [he/she] may resume practice: failure to timely complete all of the steps required for enrollment/registration with the drug testing vendor, including making arrangements for payment; failure to timely commence drug testing protocols; failure to contact the drug testing vendor as required to determine testing date(s); failure to test as required; failure to timely supply documentation demonstrating that a detected substance was taken pursuant to a

legitimate prescription issued as a necessary part of treatment; and/or detection through testing of alcohol, or of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment. In the event of a suspension ordered after detection through testing of alcohol, or of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment, the board or its designee shall inform respondent of the suspension and inform [him/her] to immediately leave work, and shall notify respondent's employer(s) and work site monitor(s) of the suspension.⁵

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs ~~and~~ or devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a pharmacist [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with this any such suspension shall be considered a violation of probation.

Specimen collectors must either be certified by the Drug and Alcohol Testing Industry Association or have completed the training required to serve as a collector for the U.S. Department of Transportation. Specimen collectors shall adhere to the current U.S. Department of Transportation Specimen Collection Guidelines. Testing locations shall comply with the Urine Specimen Collection Guidelines published by the U.S. Department of Transportation, regardless of the type of test administered. Laboratories shall be certified and accredited by the U.S. Department of Health and Human Services.

A collection site must submit a specimen to the laboratory within one (1) business day of receipt. A chain of custody shall be used on all specimens. The laboratory shall process results and provide legally defensible test results within seven (7) days of receipt of the specimen. The board or its designee will be notified of non-negative test results within one (1) business day and will be notified of negative test results within seven (7) business days.

23-25. Abstain from Drugs and Alcohol Use

Respondent shall completely abstain from the possession or use of alcohol, controlled

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2. The Terms of Probation Designated Representative are now consolidated into "Terms of Probation – Individual Licensees."

substances, dangerous drugs, ~~or~~ and their associated paraphernalia, except when possessed or used pursuant to a legitimate prescription issued as a necessary part of treatment. ~~the drugs are lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon request of the board or its designee, respondent shall provide documentation from the licensed practitioner that the prescription for the drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation.~~ Respondent shall ensure that he or she [he/she] is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Any possession or use of alcohol, dangerous drugs or controlled substances, or their associated paraphernalia not supported by for which a legitimate prescription has been issued as a necessary part of treatment, ~~the documentation timely provided, and/or~~ or any physical proximity to persons using illicit substances, shall be considered a violation of probation.

24.26. Prescription Coordination and Monitoring of Prescription Use (Appropriate for those cases where the evidence demonstrates substance abuse chemical dependency (alcohol, drugs), or psychiatric disorders (mental illness, emotional disturbance, gambling addiction))

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board, for its prior approval, the name and qualifications of a single physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice, who shall be aware of the respondent's history [with the use of alcohol, controlled substances, and/or dangerous drugs, and/or of mental illness, and/or of gambling addiction] and who will coordinate and monitor any prescriptions for respondent for dangerous drugs, controlled substances or mood-altering drugs. The approved practitioner shall be provided with a copy of the board's [accusation or petition to revoke probation] and decision. A record of this notification must be provided to the board upon request. Respondent shall sign a release authorizing the practitioner to communicate with the board or its designee about respondent's treatment(s). The coordinating physician, nurse practitioner, physician assistant, or psychiatrist shall report to the board on a quarterly basis for the duration of probation regarding respondent's compliance with this condition. If any substances considered addictive have been prescribed, the report shall identify a program for the time limited use of any such substances. The board or its designee may require that the single coordinating physician, nurse practitioner, physician assistant or psychiatrist be a specialist in addictive medicine, or consult a specialist in addictive medicine. Should respondent, for any reason, cease supervision by the approved practitioner, respondent shall notify the board or its designee immediately and, within thirty (30) days of ceasing treatment, submit the name of a replacement physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice to the board or its designee for its prior approval. Failure to timely submit the selected practitioner or replacement practitioner to the board or its designee for approval, or to ensure the required reporting thereby on the quarterly reports, shall be considered a violation of probation.

If at any time an approved practitioner determines that respondent is unable to practice safely or independently as a ~~pharmacist~~ [insert license type], the practitioner shall notify the board or its designee immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice as a [insert license type] until notified by the board or its designee that practice may be resumed.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs ~~and~~ or devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs or devices and controlled substances. Respondent shall not resume practice until notified by the board.

During any such suspension, respondent shall not engage in any activity that requires the professional judgment and/or licensure as a [insert license type] ~~of a pharmacist.~~ Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with any such ~~this~~ suspension shall be considered a violation of probation.

25.27. Community Services Program

Within sixty (60) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free [insert type of service e.g., health-care related services] on a regular basis to a community or charitable facility or agency for at least _____ hours per _____ for the first _____ of probation. Within thirty (30) days of board approval thereof, respondent shall submit documentation to the board or its designee demonstrating commencement of the community service program. ~~A record of this notification must be provided to the board upon request.~~ Respondent shall report on progress with the community service program in the quarterly reports and provide satisfactory documentary evidence of such progress to the board or its designee upon request. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

26.28. Restitution (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)

Within _____ days of the effective date of this decision, respondent shall pay restitution to _____ in the amount of \$ _____. Failure to make restitution by this deadline shall be considered a violation of probation.

27.29. Remedial Education

Within [thirty (30), sixty (60), ninety (90)] days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to [the grounds for discipline]. The program of remedial education shall consist of at least _____ hours, which shall be completed within _____ months/year at respondent's own expense. All remedial education shall be in addition to, and shall not be

credited toward, continuing education (CE) courses used for license renewal purposes for pharmacists.

Failure to timely submit for approval or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require the respondent, at ~~his or her~~ [his/her] own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require respondent to take another course approved by the board in the same subject area.

Option: Respondent shall be restricted from the practice of [areas where a serious deficiency has been identified] until the remedial education program has been successfully completed.

~~28.~~ Pharmacy Self-Assessment Mechanism

~~Within the first year of probation, respondent shall complete the Pharmacist Self-Assessment Mechanism (PSAM) examination provided by the National Association of Boards of Pharmacy (NABP). Respondent shall submit a record of completion to the board demonstrating he/she has completed this examination. Respondent shall bear all costs for the examination. Continuing education hours received for this examination shall not be used as part of the required continuing education hours for renewal purposes.~~

~~Failure to timely complete the PSAM or submit documentation thereof shall be considered a violation of probation.~~

~~Option A:~~ ~~Respondent shall waive any rights to confidentiality and provide examination results to the board or its designee.~~

~~Option B:~~ ~~(This term must be accompanied by the "Remedial Education" term. [Include/Modify Remedial Education Term to Conform].) Respondent shall waive any rights to confidentiality and provide examination results to the board or its designee. Based on the results of the examination, the board shall determine which courses are appropriate for remedial education.~~

~~29.~~ 30. Intern Pharmacist Experience (Pharmacist Interns Only)

Within ninety (90) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, a pharmacy intern training program consisting of _____ hours to be served as an intern pharmacist in a community and/or institutional pharmacy as directed. Respondent shall successfully complete the intern hours within the first year of probation and shall, by no later than one (1) year and ten (10) days from the effective date of this decision, submit proof satisfactory to the board of completion of this experience signed under penalty of perjury by both the respondent and supervising pharmacist. Failure to timely complete or document the required intern experience shall be considered a violation of probation.

~~30.~~ 31. Supervised Practice (Pharmacists, Pharmacist Interns and Designated

Representatives Only)

~~During the period of probation, respondent shall practice only under the supervision of a licensed pharmacist not on probation with the board. Upon and after the effective date of this decision, respondent shall not practice pharmacy and his or her license shall be automatically suspended until a supervisor is approved by the board or its designee. The supervision shall be, as required by the board or its designee, either: Within thirty (30) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, the name of a [insert license type] licensed by and not on probation with the board, to serve as respondent's practice supervisor. As part of the documentation submitted, respondent shall cause the proposed practice supervisor to report to the board in writing acknowledging that he or she has read the decision in case number [insert case number], and is familiar with the terms and conditions imposed thereby, including the level of supervision required by the board or its designee. This level will be determined by the board or its designee, will be communicated to the respondent on or before the effective date of this decision and shall be one of the following:~~

Continuous – At least 75% of a work week

Substantial - At least 50% of a work week

Partial - At least 25% of a work week

Daily Review - Supervisor's review of probationer's daily activities within 24 hours

~~Respondent may practice only under the required level of supervision by an approved practice supervisor. If, for any reason, including change of employment, respondent is no longer supervised at the required level by an approved practice supervisor, within ten (10) days of this change in supervision respondent shall submit to the board or its designee, for prior approval, the name of a [insert license type] licensed by and not on probation with the board, to serve as respondent's replacement practice supervisor. As part of the documentation submitted, respondent shall cause the proposed replacement practice supervisor to report to the board in writing acknowledging that he or she has read the decision in case number [insert case number], and is familiar with the terms and conditions imposed thereby, including the level of supervision required.~~

~~Any of the following shall be considered a violation of probation: failure to timely nominate either an initial or a replacement practice supervisor; failure to cause the practice supervisor to timely report to the board in writing acknowledging the decision, terms and conditions, and supervision level; practicing in the absence of an approved practice supervisor after lapse of the nomination period; and/or failure to adhere to the level of supervision required by the board or its designee. If any of these obligations or prohibitions is not met, respondent shall be automatically suspended from practice as a [insert license type] and may not resume such practice until notified by the board or its designee in writing..~~

~~Within thirty (30) days of the effective date of this decision, respondent shall have his or her supervisor submit notification to the board in writing stating that the supervisor has read the decision in case number _____ and is familiar with the required level of supervision as determined by the board or its designee. It shall be the respondent's responsibility to ensure that his or her employer(s), pharmacist in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Failure to cause the direct supervisor and the pharmacist in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.~~

~~If respondent changes employment, it shall be the respondent's responsibility to ensure that his or her employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Respondent shall have his or her new supervisor, within fifteen (15) days after employment commences, submit notification to the board in writing stating the direct supervisor and pharmacist-in-charge have read the decision in case number _____ and is familiar with the level of supervision as determined by the board. Respondent shall not practice pharmacy and his or her license shall be automatically suspended until the board or its designee approves a new supervisor. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.~~

~~Within ten (10) days of leaving employment, respondent shall notify the board in writing.~~

~~During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and or devices or controlled substances. Respondent shall not resume practice until notified by the board.~~

~~During any such suspension, respondent shall not engage in any activity that requires the professional judgment and/or licensure as a [insert license type] of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs or devices or controlled substances. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with this any such suspension shall be considered a violation of probation.~~

31. ~~No Supervision of Ancillary Personnel~~²

~~During the period of probation, respondent shall not supervise any ancillary personnel, including, but not limited to, pharmacy technicians or designated representatives in any entity licensed by the board.~~

~~Failure to comply with this provision shall be considered a violation of probation.~~

32. No Ownership or Management of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, ~~or~~ nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written

proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

Option: Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

33. Separate File of Controlled Substances Records (~~For pharmacist~~ Pharmacist owners and pharmacists-in-charge)

Respondent shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

34. Report of Controlled Substances (~~For pharmacist~~ Pharmacist owners and pharmacists-in-charge)

Respondent shall submit ~~quarterly~~ reports to the board detailing the total acquisition and disposition of such controlled substances as the board or its designee may direct. Respondent shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent shall report on a quarterly basis or as directed by the board or its designee. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period as determined by the board or its designee. Failure to timely prepare or submit such reports shall be considered a violation of probation.

35. No Access to Controlled Substances

During the period of probation and as directed by the board or its designee, respondent shall not order, possess, dispense or otherwise have access to any controlled substance(s) in Schedules I, II, III, IV or V (Health and Safety Code sections ~~11055~~ 11054 -11058 inclusive). Respondent shall not order, receive or retain any security prescription forms. Failure to comply with this restriction shall be considered a violation of probation.

36. Criminal Probation/Parole Reports

Respondent shall provide a copy of the conditions of any criminal probation/parole to the board, in writing, within ten (10) days of the issuance or modification of those conditions. Respondent shall provide the name of ~~his or her~~ [his/her] probation/parole officer to the board, in writing, within ten (10) days after that officer is designated or a replacement for that officer is designated. Respondent shall provide a copy of all criminal probation/parole reports to the board within ten (10) days after respondent receives a copy of such a report. Failure to timely make any of the submissions required hereby shall be considered a violation of probation.

37. ~~Consultant for Owner or Pharmacist-In-Charge⁶~~

~~(Option #1 for pharmacist owners – primarily intended for appropriate cases where the respondent is the sole owner and pharmacist-in-charge of his or her own pharmacy, the standard language should be used in most cases.)~~

~~During the period of probation, respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge. However, if during the period of probation respondent serves as a pharmacist-in-charge, respondent shall retain an independent consultant at his or her own expense who shall be responsible for reviewing pharmacy operations on a [monthly/quarterly] basis for compliance by respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by respondent with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. Respondent shall not be a pharmacist-in-charge at more than one pharmacy or at any pharmacy of which he or she is not the sole owner. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.~~

~~(Option #2 – appropriate for pharmacists who are not pharmacy owners, but who wish, because of their current employment, to remain as the pharmacist-in-charge, and have provided documented mitigating evidence to warrant this option.)~~

~~During the period of probation, respondent shall not supervise any intern pharmacist, or serve as a consultant to any entity licensed by the board. In the event that the respondent is currently the pharmacist-in-charge of a pharmacy, the pharmacy shall retain an independent consultant at its own expense who shall be responsible for reviewing pharmacy operations on a [monthly/quarterly] basis for compliance by respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by respondent with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for prior approval. Within thirty (30) days of the effective date of this decision. Respondent shall not be a pharmacist-in-charge at more than one pharmacy or at any pharmacy of which he or she is not the current PIC. The board may, in case of an employment change by respondent or for other reasons as deemed appropriate by the board or its designee, preclude the respondent from acting as a pharmacist-in-charge. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.~~

38. ~~Tolling of Suspension~~

~~During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of the (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation.~~

⁶ This term was consolidated in new term 8 – Restrictions on Supervision and Oversight of Licensed Facilities.

~~Respondent must notify the board in writing within ten (10) days of departure, and must further notify the board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent shall not resume the practice of pharmacy until notified by the board that the period of suspension has been satisfactorily completed.~~

39 37. Surrender of DEA Permit (Pharmacists and Pharmacist Interns Only)

Within thirty (30) days of the effective date of this decision, respondent shall surrender ~~his or her~~ [his/her] federal Drug Enforcement Administration (DEA) permit to the DEA, for cancellation. Respondent shall provide documentary proof of such cancellation to the board or its designee. Respondent is prohibited from ~~prescribing~~ dispensing, furnishing, or otherwise providing dangerous drugs or devices or controlled substances until the board has received satisfactory proof of cancellation. Thereafter, respondent shall not apply/reapply for a DEA registration number without the prior written consent of the board or its designee.

Option 1: Respondent may obtain a DEA permit restricted to Schedule(s) _____ controlled substance(s).

Option 2: Respondent shall not order, receive, or retain any federal order forms, including DEA form 222 forms, for controlled substances.

40 38. Ethics Course (Pharmacists and Pharmacist Interns Only)

Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the board or its designee that complies with Title 16 California Code of Regulations section 1773.5. Respondent shall provide proof of enrollment upon request. Within five (5) days of completion, respondent shall submit a copy of the certificate of completion to the board or its designee. Failure to timely enroll in an approved ethics course, to initiate the course during the first year of probation, to successfully and complete it before the end of within the second year of probation, or to timely submit proof of completion to the board or its designee, shall be considered is a violation of probation.

~~Respondent shall submit a certificate of completion to the board or its designee within five days after completing the course.~~

39. Facilitated Group Recovery and/or Support Meetings (Appropriate for those cases where the evidence demonstrates substance abuse.)

Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a group recovery and/or support meeting that is run by a trained facilitator approved in advance by the board or its designee. The required frequency of group meeting attendance shall be determined by the board or its designee, after taking into consideration respondent's history, the documented length of the respondent's sobriety or time since last use, any recommendation(s) from any clinical diagnostic evaluation(s), the scope and pattern of respondent's use, respondent's treatment history, and the nature, duration, and severity of respondent's prior or present substance abuse. Respondent shall continue regular attendance as directed at an approved facilitated group meeting until the board or its designee advises the respondent in writing that [he/she] may cease regular attendance.

The facilitator shall, upon request by the board or its designee, provide the board with a dated document signed by the facilitator that includes respondent's name, the group's name, if any, the date and time of its regular meeting(s), respondent's attendance record, and respondent's participation level and progress. Respondent shall provide signed and dated documentation of attendance as required with each quarterly report. Failure to attend as required or to submit documentation of attendance shall be considered a violation of probation.

The approved facilitator shall report any unexcused absence by respondent from a facilitated group meeting to the board within twenty four (24) hours of its occurrence.

The board or its designee shall select or approve facilitators with at least three (3) years of experience in the treatment and rehabilitation of substance abuse, with a license or certificate from the state or other nationally certified organization. The facilitator(s) shall not have had a financial, personal, or business relationship with respondent within the last year.

40. Attend Substance Abuse Recovery Relapse Prevention and Support Groups
(Appropriate for those cases where the evidence demonstrates substance abuse.)

Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a recognized and established substance abuse recovery support group in California (e.g., Alcoholics Anonymous, Narcotics Anonymous, etc.) which has been approved by the board or its designee. Respondent must attend at least one group meeting per week unless otherwise directed by the board or its designee. Respondent shall continue regular attendance and submit signed and dated documentation confirming attendance with each quarterly report for the duration of probation. Failure to attend or submit documentation thereof shall be considered a violation of probation.

41. Work Site Monitor (Appropriate for those cases where the evidence demonstrates substance abuse.)⁷

Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board or its designee, who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the board monthly or on another schedule as directed by the board or its designee. Should the designated work site monitor suspect at any time during the probationary period that respondent has abused alcohol or drugs, he or she shall notify the board immediately.

The initial notification shall be made orally within one (1) business day of the occurrence, and shall be followed by written notification within two (2) business days of the occurrence. If, for any reason, including change of employment, respondent is no longer able to be monitored by the approved work site monitor within ten (10) days respondent shall designate a new work site monitor for approval by the board or its designee. Failure to timely identify an acceptable initial or replacement work site monitor, or to ensure monthly reports are submitted to the board by the monitor, shall be considered a violation of probation.

⁷ This probationary term is not new, but is being moved from the previous section "Pharmacy Technician – Standard Terms and Conditions" for purposes of consolidation. The language of this term is also changing from the previous version.

The work site monitor shall not have a financial, personal, familial or other relationship with the respondent that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the board or its designee. If it is impractical for anyone but respondent's employer to serve as work site monitor, this requirement may be waived by the board or its designee; however, under no circumstances shall respondent's work site monitor be respondent's employee.

The work site monitor shall hold a license with a scope of practice including the scope of practice of the respondent's license, shall be another health care professional if no monitor with like practice is available, or, as approved by the board or its designee, shall be a person in a position of authority who is capable of monitoring respondent while at work.

If the work site monitor is a licensed healthcare professional he or she shall have an active unrestricted license, with no disciplinary action within the last five (5) years.

Within thirty (30) days of being approved by the board or its designee, the work site monitor shall sign an affirmation that he or she has reviewed the terms and conditions of respondent's disciplinary order and agrees to monitor respondent. The work site monitor shall at least:

- 1) Have regular face-to-face contact with respondent in the work environment, at least once per week or with greater frequency if required by the board or its designee;
- 2) Interview other staff in the office regarding respondent's behavior, if applicable; and
- 3) Review respondent's work attendance.

The written reports submitted to the board or its designee by the work site monitor shall include at least the following information: respondent's name and license number; the monitor's name, license number (if applicable) and work site location; the date(s) the monitor had face-to-face contact with respondent; the staff interviewed, if applicable; an attendance report; notes on any changes in respondent's behavior or personal habits; notes on any indicators that may lead to substance abuse; and the work site monitor's signature.

Respondent shall complete any required consent forms and sign any required agreement with the work site monitor and/or the board to allow the board or its designee to communicate freely on the subject of respondent's work performance and sobriety with the work site monitor.

Option for respondents enrolled in PRP or who are given the PRP enrollment term: It is a condition of respondent's enrollment in the Pharmacists Recovery Program (PRP) that [he/she] is required to have a work site monitor approved by the PRP who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the PRP monthly or on another schedule as directed by the PRP. Should the designated work site monitor suspect at any time during the probationary period that respondent has abused alcohol or drugs, he or she shall notify the PRP immediately. The initial notification shall be made orally within one (1) business day of the occurrence, and shall be followed by written notification within two (2) business days of the occurrence. If, for any reason, including change of employment, respondent is not longer able to be monitored by the approved work site monitor, within ten (10) days of commencing new employment for prior approval by the PRP. Failure to identify an acceptable initial or replacement work site monitor, or to ensure monthly reports are submitted to the PRP by the work site monitor, shall be considered a violation of probation.

The work site monitor shall not have a financial, personal, familial or other relationship with the respondent that could reasonably be expected to compromise the ability of the monitor to render

impartial and unbiased reports to the PRP. If it is impractical for anyone but respondent's employer to serve as work site monitor, this requirement may be waived by the PRP; however, under no circumstances shall respondent's work site monitor be respondent's employee.

The work site monitor shall hold a license with a scope of practice including the scope of practice of the respondent's license, shall be another health care professional if no monitor with like practice is available, or, as approved by the PRP, shall be a person in a position of authority who is capable of monitoring respondent while at work.

If the work site monitor is a licensed healthcare professional he or she shall have an active unrestricted license, with no disciplinary action within the last five (5) years.

Within thirty (30) days of being approved by the PRP, the work site monitor shall sign an affirmation that he or she has reviewed the terms and conditions of respondent's disciplinary order and agrees to monitor respondent. The work site monitor shall at least:

- 1) Have regular face-to-face contact with respondent in the work environment, at least once per week or with greater frequency if required by the board or its designee;
- 2) Interview other staff in the office regarding respondent's behavior, if applicable; and
- 3) Review respondent's work attendance.

The written reports submitted to the PRP by the work site monitor shall include at least the following information: respondent's name and license number; the monitor's name, license number (if applicable) and work site location; the date(s) the monitor had face-to-face contact with respondent; the staff interviewed, if applicable; an attendance report; notes on any changes in respondent's behavior or personal habits; notes on any indicators that may lead to substance abuse; and the work site monitor's signature.

Respondent shall complete any required consent forms and sign any required agreement with the work site monitor and/or the PRP to allow the PRP to communicate freely on the subject of respondent's work performance and sobriety with the work site monitor.

-TERMS OF PROBATION – PREMISES

A minimum three-year probation period has been established by the board as appropriate in most cases where probation is imposed. A minimum five-year probation period has been established by the board as appropriate where self-administration or diversion of dangerous drugs or devices or controlled substances has occurred at a licensed premises. Terms and conditions are imposed to provide consumer protection. A suspension period may also be required as part of the probation order. The board prefers that any stayed order be for revocation rather than for some period of suspension.

Probation conditions are divided into two categories: (1) standard conditions that shall appear in all probation cases, and (2) optional conditions that depend on the nature and circumstances of a particular case. These conditions may vary depending on the nature of the offense(s).

The board may also impose any other condition appropriate to the case where the condition is not contrary to public policy.

CATEGORIES OF VIOLATIONS AND RECOMMENDED PENALTIES

The California Pharmacy Law identifies offenses for which the board may take disciplinary action against a license. Included among grounds for discipline are violations of the Pharmacy Law itself, violations of regulations promulgated by the board, and violations of other state or federal statutes or regulations.

~~The following are categories of possible violations used by the board to determine appropriate disciplinary penalties. These categories represent the judgment of the board as to the perceived seriousness of particular offenses.~~

For those licenses issued to premises (pharmacies and wholesalers, resident and nonresident), the board has identified four (4) categories of violations and associated recommended minimum and maximum penalties for each. These categories of violations are arranged in ascending order from the relatively minor (Category I) to the most serious (Category IV), although any violation in any category, or any combination of violation(s) in one or more categories, may merit revocation.

~~Under each category, the board has grouped statutes and regulations where violations would typically merit the recommended range of minimum to maximum penalties for that category. These lists are representative, and are not intended to be comprehensive or exclusive. For each violation category, the board has given offense descriptions and examples where violations would typically merit the recommended range of minimum to maximum penalties for that category. These descriptions and examples are representative, and are not intended to be comprehensive or exclusive.~~ Where a violation not included in these lists is a basis for disciplinary action, the appropriate penalty for that violation may be best derived by comparison to any analogous violation(s) that are included. Where no such analogous violation is listed, the category descriptions may be consulted.

These categories assume a single violation of ~~each listed statute or regulation~~. For multiple violations, the appropriate penalty shall increase accordingly. Moreover, if an individual has committed violations in more than one category, the minimum and maximum penalties shall be those recommended in the highest category.

The board also has the authority, pursuant to Business and Professions Code section 4301(n), to impose discipline based on disciplinary action taken by another jurisdiction. The discipline imposed by the board will depend on the discipline imposed by the other jurisdiction, the extent of the respondent's compliance with the terms of that discipline, the nature of the conduct for which the discipline was imposed, and other factors set forth in these guidelines.

CATEGORY I

Minimum: Revocation; Revocation stayed; one-year probation. All standard terms and conditions shall be included and may include optional terms and conditions, as appropriate.

Maximum: Revocation

Category I discipline is recommended for violations which are relatively minor but are potentially harmful:

- violation(s) of recordkeeping requirements, scope of practice requirements, or inventory control requirements;
- smaller or isolated failure(s) to abide by or enforce prescription or refill requirements, drug-substitution requirements, or labeling requirements;
- violation(s) of obligations to supply or update information to the board, or to other enforcement or regulatory agencies;
- failure(s) to adequately supervise staff to ensure security and sanitation of premises, dangerous drugs or devices or controlled substances;
- violation(s) of packaging requirements, security control requirements, or reporting requirements; and
- failure(s) to display original license(s), or to supply name(s) of owner(s), manager(s), or employee(s).
- ~~violations which are relatively minor but are potentially harmful~~
- ~~repeated violations of a relatively minor nature~~

CATEGORY II

Minimum: Revocation; Revocation stayed, three years probation (five years probation where self-administration or diversion of dangerous drugs or devices or controlled substances occurred at the licensed premises). All standard terms and conditions shall be included and may include optional terms and conditions, as appropriate.

Maximum: Revocation

Category II discipline is recommended for violations with serious potential for harm, as well as for violations involving disregard for public safety or for laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs or devices or controlled substances, violations that reflect on ethics, competency, or diligence, and criminal convictions not involving alcohol, dangerous drugs or devices or controlled substances. Violations in this category may include:

- failure(s) to abide by prohibitions on referral rebates or discounts (kickbacks) and/or volume or percentage-based lease agreements;
- violation(s) of advertising or marketing limitations, including use of false or misleading advertising or marketing;
- repeat or serious violation(s) of recordkeeping requirements, scope of practice requirements, or inventory control requirements;
- violation(s) of controlled substance secure prescription requirements, inventory controls, or security requirements;
- failure(s) to meet compliance requirements, including pharmacist-in-charge or designated representative-in-charge designation and duties;
- violation(s) of monitoring and reporting requirements with regard to chemically, mentally, or physically impaired licensees or employees;
- repeat or serious failure(s) to adequately supervise staff or ensure security and sanitation of premises, dangerous drugs or devices or controlled substances;
- violation(s) of laws governing dangerous drugs or devices and controlled substances, including smaller cases of diversion or self-administration;
- unlawful possession(s) of dangerous drugs or devices, controlled substances, hypodermic needles or syringes, or drug paraphernalia;
- smaller scale dispensing or furnishing of dangerous drugs or devices via the internet, without valid a prescription;
- purchasing, trading, selling, or transferring dangerous drugs or devices to or from unauthorized person(s);
- failure(s) to make required reports to the board or to other regulatory agencies, including CURES obligations and reporting to the DEA;
- violation(s) of quality assurance and self-assessment obligations, failure(s) to ensure properly trained staff and conduct practice safely;
- failure(s) to perform drug utilization reviews, monitor patient medication profiles, or promote safety and efficacy of prescribed drugs or devices or controlled substances;
- repeat or serious deviation(s) from the requirements of prescription(s) or failure(s) to clarify erroneous or uncertain prescription(s);
- gross immorality, incompetence, gross negligence, clearly excessive furnishing of controlled substances, moral turpitude, dishonestly, or fraud;
- criminal conviction(s) not involving alcohol, dangerous drugs or devices or controlled substances;
- violating, assisting in or abetting violation of, or conspiring to violate the laws and regulations governing pharmacy; and
- subverting or attempting to subvert an investigation conducted by the board.
- ~~violations with a serious potential for harm~~
- ~~violations which involve greater disregard for pharmacy law and public safety~~
- ~~violations which reflect on ethics, care exercised or competence or a criminal conviction not involving dangerous drugs or controlled substances or involving possession or use of dangerous drugs or controlled substances.~~

CATEGORY III

Minimum: Revocation; Revocation stayed, 90 days actual suspension, three to five years probation (five years probation where self-administration or diversion of dangerous drugs or devices or controlled substances occurred at the licensed premises). All standard terms and conditions shall be included and may include optional terms and conditions, as appropriate.

Maximum: Revocation

Category III discipline is recommended for violations where potential for harm is greater, more imminent, or more serious than it is for Category II violations, as well as for violations that involve knowingly or willfully violating laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs or devices or controlled substances, and most criminal convictions involving alcohol, dangerous drugs or controlled substances. Violations in this category may include:

- violation(s) involving creation, manipulation, perpetuation, or disregard of drug shortages;
- failure(s) to deploy or abide by electronic pedigree requirements for dangerous drugs;
- violation(s) of licensee's corresponding responsibility to ensure the proper prescribing and dispensing of controlled substances;
- dispensing or furnishing without valid prescription, dispensing or furnishing to unauthorized person(s);
- violation(s) involving fraudulent acts committed in connection with the licensee's practice;
- repeat or serious unlawful possession(s) of dangerous drugs or dangerous devices, controlled substances, hypodermic needles or syringes, or drug paraphernalia;
- larger scale dispensing or furnishing of dangerous drug(s) or device(s) via the internet, without valid prescription(s);
- purchasing, trading, selling, or transferring adulterated, misbranded, or expired dangerous drug(s) or device(s);
- removal, sale, or disposal of embargoed dangerous drug(s) or device(s);
- failing to maintain record(s) of acquisition and disposition of dangerous drug(s) or device(s) or controlled substances
- resale(s) of preferentially priced drugs, contract bid diversion, or other instances of improper sale(s) or resale(s);
- repeat or serious violation(s) of quality assurance and self-assessment obligations, failure(s) to ensure properly trained staff and conduct practice safely;
- repeat or serious failure(s) to perform drug utilization reviews, monitor patient medication profiles, or promote safety and efficacy of prescribed drugs;
- forgery of prescriptions, passing of forged prescriptions, or other unlawful means of acquiring dangerous drug(s) or device(s) or controlled substances(s);
- repeat or serious acts violating, assisting in or abetting violation of, or conspiring to violate the laws and regulations governing pharmacy; and
- violation(s) involving providing or offering to provide controlled substance(s) to addict(s).
- ~~most criminal convictions involving dangerous drugs or controlled substances~~
- ~~knowing or willfully violating laws or regulations pertaining to dispensing or distributing dangerous drugs or controlled substances~~
- ~~fraudulent acts committed in connection with the licensee's practice~~
- ~~drug shortages~~
- ~~violation of a licensee's corresponding responsibility.~~

CATEGORY IV

Penalty: Revocation

Category IV discipline (Revocation revocation) is recommended for the most serious violations of the Uniform Controlled Substance Act (Heath and Safety Code 11000 et seq.) involving laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs or devices or controlled substances. Violations in this category may include:

- violation(s) involving possession for sale, transportation, importation, and/or use of a minor for unlawful acquisition of sale, of controlled substances;
- criminal conviction(s) involving the above, or repeat convictions involving diversion or abuse of alcohol, dangerous drugs or devices, or controlled substances; and
- repeat or serious example(s) of conduct described in Category I, Category II, or Category III.
- ~~possession for sale~~
- ~~transportation~~
- ~~importation~~
- ~~sale~~
- ~~use of a minor for the unlawful sale of controlled substances~~

Revocation is also recommended ~~when~~ where a respondent fails to file a notice of defense to an Accusation or to appear at a disciplinary hearing, where a respondent violates the terms and conditions of probation from a previous disciplinary order, or where prior discipline has been imposed on the license.:

- ~~a respondent fails to file a notice of defense or to appear at a disciplinary hearing where the board has requested revocation in the accusation~~
- ~~a respondent violates the terms and conditions of probation from a previous disciplinary order~~
- ~~prior discipline has been imposed, as progressive discipline unless the respondent can demonstrate satisfactory evidence of rehabilitation.~~

MODEL DISCIPLINARY LANGUAGE - PREMISES

The following standardized language shall be used in every decision where the order or condition is imposed.

Revocation

License number _____, issued to respondent _____, is revoked.

Respondent ~~owner~~ shall, by the effective date of this decision, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed by the board of all dangerous drugs or devices or controlled substances and dangerous drugs and devices. Respondent ~~owner~~ shall provide written proof of such disposition, submit a completed Discontinuance of Business form and return the wall and renewal license to the board within five (5) days of disposition.

Option: Respondent ~~owner~~ shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five (5) days of its provision to the pharmacy's ongoing patients, Respondent ~~owner~~ shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing

patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Suspension

License number _____, issued to respondent _____ is suspended for a period of _____ days beginning the effective of this decision.

Respondent shall cease all ~~pharmacy~~ operations as a [insert license type] during the period of suspension. Failure to comply with this any such suspension shall be considered a violation of probation.

Standard Stay/Probation Order

License number _____, issued to respondent is revoked; however, the revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Issuance of Probationary License (In cases where a Statement of Issues has been filed.)

Upon satisfaction of all statutory and regulatory requirements for issuance of a [insert license type] license, a license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Surrender

Respondent ~~owner~~ surrenders license number _____ as of the effective date of this decision. Respondent ~~owner~~ shall relinquish the premises wall license and renewal license to the board within ten (10) days of the effective date of this decision.

The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board.

Respondent ~~owner~~ shall, within ten (10) days of the effective date, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed by the board of all controlled substances and dangerous drugs and devices. Respondent ~~owner~~ shall further provide written proof of such disposition and submit a completed Discontinuance of Business form according to board guidelines.

Respondent ~~owner~~ shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent ~~owner~~ shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills

outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent ~~owner~~ understands and agrees that if ~~he or she~~ [he/she] ever files an application for a licensed premises or a petition for reinstatement in the State of California, the board shall treat it as a new application for licensure.

Respondent ~~owner~~ may not reapply for any license from the board for three (3) years from the effective date of this decision. Respondent ~~owner~~ stipulates that should ~~he or she~~ [he/she] apply for any license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board. Respondent is required to report this surrender as disciplinary action.

Respondent ~~owner~~ further stipulates that ~~he or she~~ [he/she] shall reimburse the board for its costs of investigation and prosecution in the amount of \$_____ within _____ days of the effective date of this decision.

Option: Respondent ~~owner~~ stipulates that should ~~he or she~~ [he/she] apply for any license from the board on or after the effective date of this decision the investigation and prosecution costs in the amount of \$_____ shall be paid to the board prior to issuance of the new license.

Public Reprimand

It is hereby ordered that a public reprimand be issued against licensee, _____.
Respondent ~~owner~~ is required to report this reprimand as a disciplinary action.

Adoption of Stipulation

~~It is understood by respondent owner that, in deciding whether to adopt this stipulation, the board may receive oral and written communication from its staff and the Attorney General's Office. Communications pursuant to this paragraph shall not disqualify the board or other persons from future participation in this or any other matter affecting respondent. In the event this settlement is not adopted by the board, the stipulation will not become effective and may not be used for any purpose, except this paragraph, which shall remain in effect.~~

STANDARD CONDITIONS - To be included in all probation decisions/orders.

1. Definition: Respondent
- ~~4~~ 2. Obey All laws
- ~~2~~ 3. Report to the Board
- ~~3~~ 4. Interview with the Board
- ~~4~~ 5. Cooperate with Board Staff
- ~~5~~ 6. Reimbursement of Board Costs
- ~~6~~ 7. Probation Monitoring Costs
- ~~7~~ 8. Status of License
- ~~8~~ 9. License Surrender While on Probation/Suspension
10. Sale or Discontinuance of Business
- ~~9~~ 11. Notice to Employees
- ~~10~~ 12. Owners and Officers: Knowledge of the Law
13. Premises Open for Business
- ~~14~~ 14. Posted Notice of Probation
- ~~12~~ 15. Violation of Probation
- ~~13~~ 16. Completion of Probation

OPTIONAL CONDITIONS

17. Suspension
- ~~14~~ 18. Community Services Program
- ~~15~~ 19. Restitution
- ~~16~~ 20. Separate File of Records
- ~~17~~ 21. Report of Controlled Substances
- ~~18~~ 22. Surrender of DEA Permit
- ~~19~~ 23. Posted Notice of Suspension

STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS

1. Definition: Respondent

For the purposes of these terms and conditions, "respondent" shall refer to [insert name] and all terms and conditions stated herein shall bind and be applicable to the licensed premises and to all owners, managers, officers, administrators, members, directors, trustees, associates, or partners thereof. For purposes of compliance with any term or condition, any report, submission, filing, payment, or appearance required to be made by respondent to or before the board or its designee shall be made by an owner or executive officer with authority to act on behalf of and legally bind the licensed entity.

4 2. Obey All Laws

Respondent ~~owner~~ shall obey all state and federal laws and regulations.

Respondent ~~owner~~ shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;
- a plea of guilty or nolo contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment;
- a conviction of any crime; or
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's _____ license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any dangerous drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

2 3. Report to the Board

Respondent ~~owner~~ shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent ~~owner~~ shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3 4. Interview with the Board

Upon receipt of reasonable prior notice, respondent ~~owner~~ shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4 5. Cooperate with Board Staff

Respondent ~~owner~~ shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of ~~his or her~~ the probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

5 6. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent ~~owner~~ shall pay to the board its costs of investigation and prosecution in the amount of \$_____. Respondent ~~owner~~ shall make said payments as follows: _____. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent ~~owner~~ shall not relieve respondent of ~~his or her~~ its responsibility to reimburse the board its costs of investigation and prosecution.

OPTION: Respondent shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation.

6 7. Probation Monitoring Costs

Respondent ~~owner~~ shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

7 8. Status of License

Respondent ~~owner~~ shall, at all times while on probation, maintain current licensure with the board. ~~If respondent owner submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain continuing jurisdiction over the license, and the respondent shall remain on probation as determined by the board.~~ Failure to maintain current licensure shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

8 9. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent ~~owner~~ discontinue business, respondent ~~owner~~ may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other

action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

OPTION (To be included if the respondent is a pharmacy): Upon acceptance of the surrender, respondent ~~owner~~ shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent ~~owner~~ shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer within five (5) days.

Respondent ~~owner~~ shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent ~~owner~~ shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent ~~owner~~ may not apply for any new licensure license from the board for three (3) years from the effective date of the surrender. Respondent ~~owner~~ shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent ~~owner~~ further stipulates that ~~he or she~~ it shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

10. Sale or Discontinuance of Business

During the period of probation, should respondent sell, trade or transfer all or part of the ownership of the licensed entity, discontinue doing business under the license issued to respondent and the assumption of practice at that location by another full or partial owner, person, firm, business, or entity, under the same or a different premises license number, the board or its designee shall have the sole discretion to determine whether to exercise continuing jurisdiction over the licensed location, under the current or new premises license number, and/or carry the remaining period of probation forward to be applicable to the current or new premises license number.

9 11. Notice to Employees

Respondent ~~owner~~ shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent ~~owner~~ shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent ~~owner~~ shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

10 12. Owners and Officers: Knowledge of the Law

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

13. Premises Open for Business

Respondent shall remain open and engaged in its ordinary business as a [insert license type] in California for a minimum of _____ hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation, unless respondent is informed otherwise in writing by the board or its designee. If respondent is not open and engaged in its ordinary business as a [insert license type] for a minimum of _____ hours in any calendar month, for any reason (including vacation), respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at minimum all of the following: the date(s) and hours respondent was open; the reason(s) for the interruption or why business was not conducted; and the anticipated date(s) on which respondent will resume business as required. 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 as a [insert license type] in California for a minimum of _____ hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

14 14. Posted Notice of Probation

Respondent owner shall prominently post a probation notice provided by the board or its designee in a place conspicuous to and readable by the public within two (2) days of receipt thereof from the board or its designee. Failure to timely post such notice, or to maintain the posting during the entire period of probation, shall be considered a violation of probation. The probation notice shall remain posted during the entire period of probation.

Respondent ~~owner~~ shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

~~Failure to post such notice shall be considered a violation of probation.~~

12 15. Violation of Probation

If a respondent ~~owner~~ has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent license, and probation shall be automatically extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent ~~owner~~ violates probation in any respect, the board, after giving respondent ~~owner~~ notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. ~~Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license.~~ If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

~~13~~ 16. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent license will be fully restored.

OPTIONAL CONDITIONS OF PROBATION

14 17. Suspension

As part of probation, respondent's license to operate a [insert license type] is suspended for _____ [day(s)/month(s)/year(s)] beginning the effective date of this decision. Respondent shall cease all operations as a [insert license type] during the period of suspension. Failure to comply with any such suspension shall be considered a violation of probation.

14. 18. Community Services Program

Within sixty (60) days of the effective date of this decision, respondent ~~owner~~ shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free health-care related services to a community or charitable facility or agency for at least _____ hours per _____ for the first _____ of probation.

Within thirty (30) days of board approval thereof, respondent ~~owner~~ shall submit documentation to the board demonstrating commencement of the community service program. Respondent ~~owner~~ shall report on progress with the community service program in the quarterly reports.

Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

15. 19. Restitution (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)

Within _____ days of the effective date of this decision, respondent ~~owner~~ shall pay restitution to _____ in the amount of \$ _____. Failure to make restitution by this deadline shall be considered a violation of probation.

16. 20. Separate File of Controlled Substances Records

Respondent ~~owner~~ shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

17. 21. Report of Controlled Substances

Respondent ~~owner~~ shall submit ~~quarterly~~ reports to the board detailing the total acquisition and disposition of such controlled substances as the board or its designee may direct. Respondent ~~owner~~ shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent ~~owner~~ shall report on a quarterly basis or as directed by the board or its designee. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period as determined by the board or its designee. Failure to timely prepare or submit such reports shall be considered a violation of probation.

18. 22. Surrender of DEA Permit

Within thirty (30) days of the effective date of this decision, respondent ~~pharmacy~~ shall surrender its federal Drug Enforcement Administration (DEA) permit to the DEA, for cancellation. Respondent ~~pharmacy~~ shall provide documentary proof of such cancellation to the board or its designee. Thereafter, respondent ~~pharmacy~~ shall not apply/reapply for a DEA registration number without the prior written consent of the board or its designee.

Option: Respondent ~~pharmacy~~ may obtain a DEA permit restricted to Schedule(s) _____ controlled substance(s).

Option: Respondent ~~pharmacy~~ shall not order, receive, or retain any federal order forms, including DEA Form 222 forms, for controlled substances.

19. 23. Posted Notice of Suspension

Respondent ~~owner~~ shall prominently post a suspension notice provided by the board in a place conspicuous and readable to the public within two (2) days of receipt thereof from the board or its designee. The suspension notice shall remain posted during the entire period of suspension ordered by this decision. Failure to timely post such notice, or to maintain the posting during the entire period of suspension, shall be considered a violation of probation.

Respondent ~~owner~~ shall not, directly or indirectly, engage in any conduct or make any statement, orally, electronically or in writing, which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the closure of the licensed entity.

6/2007 9/2011

Attachment 7

Title 16. Board of Pharmacy Proposed Language

To Amend § 1746 in Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1746. Emergency Contraception

(a) A pharmacist furnishing emergency contraception pursuant to Section ~~4052(a)(8)~~ 4052.3.(a)(2) of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Emergency Contraception (EC).

~~(1) Authority: Section 4052 of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to the protocols specified in Business and Professions Code section 4052.3. Use of the following protocol satisfies that requirement.~~

(1) Authority: Section 4052.3(a)(2) of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol specified in this section satisfies that requirement.

(2) Purpose: To provide timely access to emergency contraceptive medication ~~within required limits~~ and ensure that the patient receives adequate information to successfully complete therapy.

(3) Procedure: When a patient requests emergency contraception, the pharmacist will ask and ~~state~~ communicate the following:

Are you allergic to any medications?

Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) ~~of~~ after unprotected intercourse. ~~EC effectiveness declines gradually over five days and EC use will not interfere with an established pregnancy.~~

EC use will not interfere with an established or implanted pregnancy.

If more than 72 hours have elapsed since unprotected intercourse, the use of ella™ (ulipristal) may be more effective than levonorgestrel. Other options for EC include consultation with your physician regarding insertion of an IUD.

(4) The pharmacist shall provide ~~the~~ a fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medication record required by Section 1707.1 of Title 16 of the California Code of Regulations.

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy as required by Business and Professions Code Section ~~4052(b)(3)~~ 4052.3(e).

(5) Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(6) The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

(7) Advanced provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

(8) EC Product Selection: The pharmacist will provide emergency contraception medication ~~compatible with product information~~ from the list of products specified in this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC containing estrogen. Patients will be provided information concerning dosing and potential adverse effects.

(9) Documentation: Each prescription authorized by a pharmacist will be documented in a patient medication record as required by law.

(10) Training: Prior to furnishing emergency contraception, pharmacists who participate in ~~the~~ this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

~~(11) Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.~~

(11) Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.

Dedicated Emergency Contraception

Brand	Manufacturer	Tablets per Dose	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
One-Dose Regimen				
Plan-B	Women's Capital Corporation	2 tablets	0	1.5
Two-Dose Regimens				
Plan-B	Women's Capital Corporation	1 tablet per dose	0	0.75
Preven	Gynetics	2 tablets per dose	100	0.50
Oral Contraceptive Pills				
Brand	Manufacturer	Tablets per Dose (two doses 12 hours apart*)	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
Levora	Watson	4 white tablets	120	0.60
Ovral	Wyeth	2 white tablets	100	0.50
Ogestrel	Watson	2 white tablets	100	0.50
Nordette	Wyeth	4 light-orange tablets	120	0.60
Tri-Levlen	Berlex	4 yellow tablets	100	0.50
Alesse	Wyeth	5 pink tablets	100	0.50
Aviane	Duramed	5 orange tablets	100	0.50
Triphasil	Wyeth	4 yellow tablets	120	0.50
Levlen	Berlex	4 light-orange tablets	120	0.60
Trivora	Watson	4 pink tablets	120	0.50
Levlite	Berlex	5 pink tablets	100	0.50
Lo/Ovral	Wyeth	4 white tablets	120	0.60
Low-Ogestrel	Watson	4 white tablets	120	0.60
Ovrette	Wyeth	20 yellow tablets	0	0.75

* The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel

(11) Medications Used for Emergency Contraception

<u>Dedicated Approved Products for Emergency Contraception</u>			
<u>Brand</u>	<u>Dose</u>	<u>Ethinyl Estradiol per dose (mcg)</u>	
<u>One Dose Regimen</u>			
<u>Plan B™ One-Step</u>	<u>1 tablet</u>	<u>0</u>	<u>1.5mg levonorgestrel</u>
<u>ella™</u>	<u>1 tablet</u>	<u>0</u>	<u>30mg ulipristal</u>
<u>Two Dose Regimen</u>			
<u>Next Choice™</u>	<u>1 tablet per dose</u>	<u>0</u>	<u>1.5mg levonorgestrel</u>
<u>Oral Contraceptive Pills</u>			
<u>Brand</u>	<u>Tablets per Dose (two doses 12 hours apart*)</u>	<u>Ethinyl Estradiol per dose (mcg)</u>	<u>Levonorgestrel per dose (mg)*</u>
<u>Allesse</u>	<u>5 pink tablets</u>	<u>100</u>	<u>0.50</u>
<u>Aviane</u>	<u>5 orange tablets</u>	<u>100</u>	<u>0.50</u>
<u>Levlen</u>	<u>4 light-orange tablets</u>	<u>120</u>	<u>0.60</u>
<u>Levlite</u>	<u>5 pink tablets</u>	<u>100</u>	<u>0.50</u>
<u>Levora</u>	<u>4 white tablets</u>	<u>120</u>	<u>0.60</u>
<u>Lo/Ovral</u>	<u>4 white tablets</u>	<u>120</u>	<u>0.50</u>
<u>Low-Ogestrel</u>	<u>4 white tablets</u>	<u>120</u>	<u>0.60</u>
<u>Nordette</u>	<u>4 light-orange tablets</u>	<u>120</u>	<u>0.60</u>
<u>Ogestrel</u>	<u>2 white tablets</u>	<u>100</u>	<u>0.50</u>
<u>Ovral</u>	<u>2 white tablets</u>	<u>100</u>	<u>0.50</u>
<u>Tri-Levlen</u>	<u>4 yellow tablets</u>	<u>100</u>	<u>0.50</u>
<u>Triphasil</u>	<u>4 yellow tablets</u>	<u>120</u>	<u>0.50</u>
<u>Trivora</u>	<u>4 pink tablets</u>	<u>120</u>	<u>0.50</u>
<u>Ovrette</u>	<u>20 yellow tablets</u>	<u>0</u>	<u>0.75</u>

*The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.

In addition to the products specified in this paragraph, generic equivalent products may be furnished. Estrogen containing regimens are not preferred and should be used only when the other options are not available.

(12) Anti-nausea Treatment Options for use with Emergency Contraception

<u>Anti-Nausea Treatment Options For Use With Emergency Contraception</u>		
Drug	Dose	Timing of Administration
Non-prescription Drugs		
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25 mg tablets	1 hour before first EC dose; Repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25 mg tablets or capsules.	1 hour before first EC dose; repeat as needed every 4-6 hours
Dimenhydrinate (Dramamine)	One or two 50 mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first ECP <u>EC</u> dose; repeat as needed every 4-6 hours
Cyclizine hydrochloride (Marezine)	One 50 mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.3, Business and Professions Code. Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.3, Business and Professions Code.