

California State Board of Pharmacy 1625 N. Market Blvd, N219, Sacramento, CA 95834 Phone: (916) 574-7900 Fax: (916) 574-8618 www.pharmacy.ca.gov

SB 1441 Uniform Standards Implementation Committee

Stan Weisser, RPh, Chair Ricardo Sanchez, Member Victor Law, RPh, Member

Relevant Sections

California Code of Regulations Section 1760 requires the board to consider disciplinary guidelines when reaching a decision on a disciplinary action.

Business and Professions Code Section 315 established the Substance Abuse Coordination Committee (SACC) within the Department of Consumer Affairs. The committee was charged with formulating uniform and specific standards in several areas for dealing with substanceabusing licensees.

Chapter 9, Division 2, Chapter 19 (Business and Professions Code sections 4300-4315) defines disciplinary proceeding for the board as well as the grounds for taking such discipline.

Background

In early 2011, the board directed staff to restructure and update its Disciplinary Guidelines. Subsequent to this, in April 2011, the uniform standards required in B&PC section 315 were finalized. Over the course of the next year, the board initiated a rulemaking to update the disciplinary guidelines and incorporate the SB 1441 uniform standards as it deemed appropriate considering comments from counsel and staff on how best to proceed.

In addition to the standards themselves, the board also received opinions on what was required to implement the uniform standards. The board was provided a copy of a legal opinion from the Legislative Counsel Bureau, executive summary issued by the Office Of the Attorney General as well as an implementation memo from Doreatha Johnson, Deputy Director of Legal Affairs, DCA. The opinions provided did not provide consistent guidance and as such the board requested a formal legal opinion from the Office of the Attorney General in January 2013. The board received a response to this request on April 8, 2015.

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

More recently, during the June Board meeting, an ad hoc committee was established to allow a complete review of the proposed implementation strategy briefly discussed during the board meeting.

Committee Discussion

The first meeting of this ad hoc committee occurred on June 19, 2015. During this meeting the committee discussed in detail the proposed changes to the Disciplinary Guidelines. The proposed changes included three types of changes:

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

The committee reviewed several areas of the proposed disciplinary guidelines and requested additional changes be drafted for consideration during its next meeting.

July Committee Meeting

The committee will meet again on July 27, 2015 to consider additional changes. The board will be provided an update on the work of the committee and any recommendations it may have.

The following items have been included for board consideration:

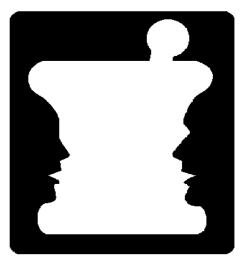
- Attachment 1 includes the revised draft disciplinary guidelines. (Items in red reflect changes resulting from the uniform standards.)
- Attachment 2 includes a brief description of all of the suggested changes. (Items in red reflect changes resulting from the uniform standards.)
- Attachment 3 includes the proposed amendment to California Code of Regulations Section 1760.
- Attachment 4 includes the Uniform Standards Regarding Substance-Abusing Healing Arts Licensees.
- Attachment 5 includes a copy of the minutes from the first committee meeting. Because of the timing minutes will not be available for the July board meeting, however a summary will be provided.

If additional changes are made during the committee meeting, revised materials may be presented during the board meeting.

Attachment 1

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 7/2015)

STATE BOARD OF PHARMACY

DEPARTMENT OF CONSUMER AFFAIRS

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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 <u>7/2015</u>)

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;
- 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 and intern pharmacists are patient advocates and vital members of the clinical care team who provide pharmaceutical care and exercise clinical judgment for the citizens of California for their patients,. They also exercise critical vigilance and control over medication stocks, drug inventories, and quality assurance protocols. Pharmacy technicians provide crucial assistance to pharmacists and intern pharmacists in all of their pharmacy tasks. Pharmacists and intern pharmacists enlighten their patients enlightening them about their drug therapy therapies through effective communicating and listening, assessing, collaborating, understanding and intervening. They also, under appropriate conditions, initiate or terminate drug therapies, compound drug preparations, ensure safety and security of drug stocks, and otherwise contribute to clinical safety and performance. Also, pharmacists and intern pharmacists are always vigilant to ensure that drug therapies are being appropriately and effectively utilized. When a pharmacist takes on the responsibility of a pharmacist-in-charge, the pharmacist also ensure the pharmacy's compliance with state and federal law, quality assurance responsibilities, and inventory controls. Likewise, the premises and other individuals licensed by the board help to ensure the reliability, safety, and security of the dangerous drug and/or dangerous device supply chain, so that patients and prescribers can be confident in the drugs prescribed. 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 <u>and/or dangerous devices</u> 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, <u>board licensees</u>, 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 on 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. Typically, the board also believes in holding a pharmacy owner, manager, and/or pharmacist-in-charge responsible for the acts of pharmacy for the board also believes in holding a pharmacy owner, manager, and/or pharmacist-in-charge responsible for the acts of pharmacy owner, manager, and/or pharmacist-in-charge responsible for the acts of pharmacy owner.

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.
- <u>16. consideration of other licenses held by the respondent and license history of those licenses.</u>
- 17. Uniform Standards Regarding Substance-Abusing Healing Arts Licensees

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 <u>or it</u> 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 relevant to the disciplinary proceeding 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/<u>-or</u> assessment report(<u>s</u>) by a licensed physician, confirming the absence of any physical impairment that would prohibit the respondent from practicing safely. Such assessments and report(<u>s</u>) 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. <u>Recent, dated, letters from persons familiar with respondent in either a personal or</u> 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.
- h. For premises licensees, recent, dated letters from appropriate licensees or representatives of licensees of the board in good standing, or from appropriate consultants and/or experts in the field, written by persons familiar with respondent in either a personal or professional capacity regarding their knowledge of: the character and rehabilitation, if any, of respondent's owner(s), officer(s), or managerial employee(s); the conduct of which the respondent is accused; the details of respondent's operation(s); 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, ADVANCED PRACTICE PHARMACIST, INTERN PHARMACIST, PHARMACY TECHNICIAN, DESIGNATED REPRESENTATIVE AND DESIGNATED REPRESENTATIVE-3PL)

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 in cases involving self-administration or diversion of controlled substances or dangerous drugs and/or dangerous devices, or abusive use of alcohol. 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. The board is also guided by the Uniform Standards Regarding Substance-Abusing Licensees developed by the Substance Abuse Coordinating Committee of the Department of Consumer Affairs (2011). Where appropriate and to the extent practicable, the terms and conditions that are specified below incorporate and/or are impacted by those Uniform Standards.

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 least serious (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 two years probation. All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Category I discipline is recommended for <u>violations which are less serious that Category 2</u> <u>through 4 but are potentially harmful. These may include</u>:

- 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 and/or dangerous devices, or controlled substances; and
- violation(s) of packaging requirements, security control requirements, or reporting requirements.
- violation(s) involving the improper compounding of drug products
- violation(s) resulting from the misuse of education or licensing privileges irrespective of whether it occurs outside of an entity licensed by the board.

Violations of the following codes are representative of this category:

BUSINESS AND PROFESSIONS CODE

Article 3. Scope of Practice and Exemptions

4052.1 Skin Puncture by Pharmacist; Conditions Permitting 4052.5 Pharmacist May Select Different Form of Medication with Same Active Chemical

- Ingredients; Exceptions
- 4052.7 Repackage Previously Dispensed Drugs; Requirements
- 4053 Exemptee Supervisor of Manufacturer, etc.: Requirements
- 4054 Supply by Manufacturer, etc. of Certain Dialysis Drugs and Devices
- 4055 Sale of Devices to Licensed Clinics, etc.
- 4056 Purchase of Drugs at Wholesale Hospital Containing 100 Beds or Less
- 4057 Exceptions to Application of this Chapter
- 4058 Display of Original License
- 4062 Furnishing Dangerous Drugs During Emergency
- 4064 Emergency Refill of Prescription Without Prescription Authorization
- 4065 Injection Card System; Requirements of Administration
- 4066 Furnishing Dangerous Drugs to Master or First Officer of Vessel
- 4068 Dispense Dangerous Drug or Controlled Substance to Emergency Room Patient; Requirements

Article 4. Requirements for Prescription

- 4070 Reduction of Oral or Electronic Prescription to Writing
- 4071 Prescriber May Authorize Agent to Transmit Prescription; Schedule II Excluded
- 4072 Oral or Electronic Transmission of Prescription Health Care Facility
- 4073 Substitution of Generic Drug Requirements and Exceptions
- 4074 Drug Risk: Informing Patient; Providing Consultation for Discharge Medications
- 4076 Prescription Container Requirements for Labeling
- 4077 Dispensing Dangerous Drug in Incorrectly Labeled Container

Article 5. Authority of Inspectors

4082 Names of Owners, Managers and Employees Open for Inspection

Article 6. General Requirements

- 4100 Change of Address or Name Notification to Board
- 4103 Blood Pressure Taking by Pharmacist

Article 7. Pharmacies

- 4114 Intern Pharmacist: Activities Permitted
- 4119 Furnish Prescription Drug to Licensed Health Care Facility Secured
- 4119.1 Pharmacy May Provide Services to Health Facility
- 4119.5 Transfer or Repackaging Dangerous Drugs by Pharmacy
- 4121 Advertisement for Prescription Drug: Requirements; Restrictions
- 4122 Required Notice at Availability of Prescription Price Information, General Product Availability, Pharmacy Services; Providing Drug Price Information; Limitations on Price Information Requests
- 4123 Compounding Drug for Other Pharmacy for Parenteral Therapy; Notice to Board
- 4124 Dispensing Replacement Contact Lenses: Requirements; Patient Warnings;

Registration with Medical Board; Application of Section to Nonresident Pharmacies

Article 9. Hypodermic Needles and Syringes

- 4141 Furnishing Without License
- 4142 Prescription Required
- 4143 Exemption: Sale to Other Entity, Physician, etc.
- 4144 Industrial Use Exception

- 4145 Exception: Furnishing for Administration of Insulin, Adrenaline, or Specified Animal Uses: Conditions
- 4148 Confiscation if Found Outside Licensed Premises
- 4149 Sale by Distributor

Article 10. Pharmacy Corporations

- 4151 Licensure Requirements
- 4152 Corporate Name Requirements
- 4153 Shareholder Income While Disqualified
- 4156 Unprofessional Conduct by Corporation

Article 11. Wholesalers and Manufacturers

- 4161 Nonresident Wholesaler: When License Required; Application
- 4162 Issuance or Renewal of Wholesaler License; Surety Bond
- 4163 Unauthorized Furnishing by Manufacturer or Wholesaler
- 4165 Sale or Transfer of Dangerous Drug or Device Into State: Furnishing Records to Authorized Officer on Demand; Citation for Non-compliance
- 4166 Shipping of Dangerous Drugs or Devices Wholesaler or Distributor
- 4167 Wholesaler: Bar on Obtaining Dangerous Drugs or Devices It Cannot Maintain on Licensed Premises

Article 13. Non-Profit or Free Clinics

- 4180 Purchase of Drugs at Wholesale Only with License: Eligible Clinics
- 4181 License Requirements; Policies and Procedures; Who May Dispense
- 4182 Duties of Professional Director; Consulting Pharmacist Required
- 4183 No Professional Dispensing Fee
- 4184 Dispensing Schedule II Substance Prohibited
- 4186 Automated Drug Delivery Systems

Article 14. Surgical Clinics

- 4190 Purchase of Drugs at Wholesale: Permitted Uses of Drugs; Required Records and Policies; License Required
- 4191 Compliance with Department of Health Services Requirements; Who May Dispense Drugs
- 4192 Duties of Professional Director; Providing Information to Board
- 4193 Clinic Not Eligible for Professional Dispensing Fee; Ban on Offering Drugs for Sale
- 4194 Dispensing of Schedule II Substance by Clinic Prohibited; Physician May Dispense; Administration Authorized in Clinic

Article 15. Veterinary Food-Animal Drug Retailers

- 4196 License Required: Temporary License on Transfer of Ownership; Persons Authorized in Storage Area
- 4197 Minimum Standards: Security; Sanitation; Board Regulations; Waivers
- 4198 Written Policies and Procedures Required: Contents; Training of Personnel; Quality Assurance; Consulting Pharmacist

Article 17. Continuing Education

4231 Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee

4232 Content of Course

Article 18. Poisons

4240 Application of Act

Article 20. Prohibitions and Offenses

- 4341 Advertisement of Prescription Drugs or Devices
- 4343 Buildings: Prohibition Against Use of Certain Signs Unless Licensed Pharmacy Within

CALIFORNIA CODE OF REGULATIONS, TITLE 16

1704	Change of Address
	Discontinuance of Business
1708.4	Pharmacist Handling Radioactive Drugs
	Pharmacy Furnishing Radioactive Drugs
	Names of Owners and Pharmacist in Charge
	Use of Pharmacist Identifiers
1714	Operational Standards and Security
	Reporting Drug Loss
	-Variation From Prescriptions
1717	Pharmaceutical Practice
1717.1	Common Electronic Files
1717.4	Electronic Transmission of Prescriptions
1718.1	Manufacturer's Expiration Date
1726	Supervision of Intern Pharmacists
1728	Requirements for Examination
1732.1	Requirements for Accredited Providers
1732.3	Requirements for Continuing Education Courses
1732.4	Provider Audit Requirements
1732.5	Renewal Requirements for Pharmacist
1744 	- Drug Warnings
1746	Emergency Contraception
1751	Sterile Injectable Compounding Area
1751.01	Facility and Equipment Standards for Sterile Injectable Compounding from Non-
	Sterile Ingredients
1751.02	Policies and Procedures
1751.1	Laminar Flow Biological Safety Cabinet
	Labeling Requirements
1751.3 —	Recordkeeping Requirements
1751.4	
	Training of Staff, Patient, and Caregiver
1751.6	Disposal of Waste Material

- 1751.7 Quality Assurance and Process Evaluation
- 1751.9 Reference Materials
- 1751.11 Furnishing to Home Health Agencies and Licensed Hospices
- 1751.12 Obligations of a Pharmacy Furnishing Portable Containers
- 1771 Posting Notice of Suspension
- 1772 Disciplinary Condition of Suspension
- 1780 Minimum Standards for Wholesalers
- 1780.1 Minimum Standards for Veterinary Food-Animal Drug Retailers
- 1781 Exemption Certificate
- 1786 Exemptions
- 1787 Authorization to Distribute Hemodialysis Drugs and Devices
- 1790 Assembling and Packaging
- 1791 Labeling
- 1792 Receipt for Shipment

HEALTH AND SAFETY CODE

11100 Report of Certain Chemical: Chemicals Included; Exclusions; Penalties 11100.1 Report of Chemicals Received from Outside State; Penalties 11151 Limitation on Filling Prescriptions From Medical Students 11158 Prescription Required for Schedule II, III, IV, or V Controlled Substance; Exception for Limited Dispensing, Administration 11159 Chart Order Exemption for Patient in County or Licensed Hospital; Maintaining **Record for Seven Years** 11159.1 Chart Order Exemption for Clinic Patient; Maintaining Record for Seven Years 11159.2 Exception to Triplicate Prescription Requirement 11167 Emergency Dispensing of Schedule II Substance: Circumstances and Requirements 11167.5 Oral or Electronic Prescriptions for Scheduled II Controlled Substances for Specified Inpatients, Residents, and Home Hospice Patients; Requirements 11171 Prescribing, etc. Controlled Substance Only as Authorized 11172 Antedating or Postdating Prescription Prohibited 11175 Prohibition on Obtaining or Possessing Nonconforming Prescription; Prohibition on Obtaining Controlled Substance by Nonconforming Prescription 11180 Prohibition on Controlled Substance Obtained or Possessed by Nonconforming Prescription 11200 Restrictions on Dispensing or Refilling: Refill of Schedule II Prescription Barred 11201 Emergency Refill of Schedule III, IV, or V Prescription; Circumstances; Requirements 11205 Maintenance and Retention of Records in Separate File 11206 Required information on Prescription 11209 Delivery and Receiving Requirements for Schedule II, III, and IV Substances; Violation 11210 Issuing Prescription: By Whom; For What Purpose; Quantity to Be Prescribed 11250 Authorized Retail Sale by Pharmacists to Physicians, etc.; Required Order Form 11251 Authorized Wholesale Sale by Pharmacists 11252 Preservation of Federally Required Forms 11253 **Duration of Retention** 11255 Actions Constituting Sale 11256 Required Report of Order By or Sale to Out-of-State Wholesaler or Manufacturer 111225 to

CODE OF FEDERAL REGULATIONS, TITLE 21

1301.11	Persons required to register.
	Separate registrations for separate locations.
1301.71	Security requirements generally.
1301.72	Physical security controls for non-practitioners; narcotic treatment programs and
	compounders for narcotic treatment programs; storage areas.
1301.73	Physical security controls for non-practitioners; compounders for narcotic treatment
	programs; manufacturing and compounding areas.
1301.74	Other security controls for non-practitioners; narcotic treatment programs and
	compounders for narcotic treatment programs.
	Physical security controls for practitioners.
1301.76	Other security controls for practitioners.
1301.90	Employee screening procedures.
1301.91	Employee responsibility to report drug diversion.
1301.92	Illicit activities by employees.
1302.03	Symbol required; exceptions.
1302.04	Location and size of symbol on label and labeling.
1302.05	Effective dates of labeling requirements.
1302.06	Sealing of controlled substances.
	Labeling and packaging requirements for imported and exported substances.
1304.11	Inventory requirements.
	Inventories of importers and exporters
1304.31	Reports from manufacturers importing narcotic raw materials.
1304.32	Reports of manufacturers importing coca leaves.
	Reports to ARCOS.
1305.03	Distributions requiring a Form 222 or a digitally signed electronic order.
1305.04	Persons entitled to order Schedule I and II controlled substances.
	Power of attorney.
	Persons entitled to fill orders for Schedule I and II controlled substances.
	Procedure for obtaining DEA Forms 222.
	Procedure for executing DEA Forms 222.
	Procedure for endorsing DEA Forms 222.
	Unaccepted and defective DEA Forms 222.
	Lost and stolen DEA Forms 222.
	Persons entitled to issue prescriptions.
1306.05	Manner of issuance of prescriptions.
	Labeling of substances and filling of prescriptions.
	Labeling of substances and filing of prescriptions.
1306.25	Transfer between pharmacies of prescription information for Schedules III, IV, and V
	controlled substances for refill purposes.
	Dispensing without a prescription.
1307.11	Distribution by dispenser to another practitioner or reverse distributor.
	Distribution to supplier or manufacture.
	Incidental manufacture of controlled substances.
	Procedure for disposing of controlled substances.
1700.1 to	
1707.15	Child-resistant containers.

CATEGORY II

Minimum: Revocation; Revocation stayed, three years probation (five years probation where self-administration or diversion of controlled substances is involved in cases involving self-administration or diversion of controlled substances or dangerous drugs and/or dangerous devices, or abusive use of alcohol). All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Category II discipline is recommended for <u>violations with serious potential for harm, as well as</u> 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 and/or dangerous devices or <u>controlled substances</u>, <u>violations that reflect on ethics</u>, <u>competence</u>, <u>or diligence</u>, <u>and criminal</u> <u>convictions not involving alcohol</u>, dangerous drugs and/or dangerous devices, or <u>controlled</u> 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;
- <u>failure(s) to meet compliance requirements, including pharmacist-in-charge or</u> 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 and/or dangerous devices, or controlled substances;
- violation(s) of law governing controlled substances, dangerous drugs and/or dangerous devices, or alcohol, including smaller cases of diversion or selfadministration or abusive use of a controlled substance, dangerous drug and/or dangerous device, or alcohol;
- unlawful possession(s) of dangerous drugs and/or dangerous devices, controlled substances, hypodermic needles and syringes, or drug paraphernalia;
- <u>smaller scale dispensing or furnishing of dangerous drug(s) and/or dangerous</u> <u>device(s) via the internet without valid prescription(s);</u>
- purchasing, trading, selling, or transferring dangerous drug(s) and/or dangerous device(s) to or from unauthorized percent(a);
 - unauthorized person(s);
- <u>failure(s) to make required reports to the board or other regulatory agencies</u>, 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, dishonesty, or fraud;
- <u>criminal conviction(s) not involving alcohol, dangerous drugs and/or</u> <u>dangerous devices, or controlled substances;</u>
- violating, or 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.
- repeated violation(s) involving the improper compounding of drug products
- violations resulting from the misuse of education or licensing privileges irrespective of whether these violations occur in a entity regulated 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.

Violations of the following codes are representative of this category:

BUSINESS AND PROFESSIONS CODE

- 650 Rebates or Discounts for Referral Prohibited
- 650.1 Lease Prohibition Hospitals or Prescribers
- 651 Professional Advertising Requirements

Article 3. Scope of Practice and Exemptions

- 4051(b) Conduct Authorized by Pharmacist
- 4052 Furnishing to Prescriber; Permissible Procedures by Pharmacist in Health Care Facility or Clinic or for Other Health Care Provider
- 4060 Controlled Substance Prescription Required; Exceptions
- 4061 Distribution of Drug as Sample; Written Request Required
- 4063 Refill of Prescription for Dangerous Drug or Device; Prescriber Authorization
- 4067 Internet; Dispensing Dangerous Drugs or Devices without Prescription
- 4075 Proof of Identity Required Oral or Electronic Prescription
- 4078 False or Misleading Label on Prescription

Article 6. General Requirements

- 4101 Pharmacist in Charge, Exemptee: Termination of Employment; Notification to Board
- 4104 Licensed Employee, Theft or Impairment: Pharmacy Procedures
- 4105 Retaining Records of Dangerous Drugs and Devices on Licensed Premises; Temporary Removal; Waivers; Access to Electronically Maintained Records

Article 7. Pharmacies

- 4112 Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation
- 4113 Pharmacist in Charge: Notification to Board; Responsibilities
- 4115 Pharmacy Technician: Activities Permitted; Required Supervision; Activities Limited to Pharmacist; Registration; Requirements for Registration; Ratios
- 4115.5 Pharmacy Technician Trainee; Placement; Supervisions; Requirements
- 4116 Security of Dangerous Drugs and Devices in Pharmacy: Pharmacist Responsibility for Individuals on Premises; Regulations
- 4117 Admission to Area Where Narcotics are Stored, etc. Who May Enter
- 4120 Nonresident Pharmacy: Registration Required
- 4125 Pharmacy Quality Assurance Program Required; Records Considered Peer Review Documents

Article 9. Hypodermic Needle and Syringes

4140 Unlawful Possession 4147 Disposal of Needle or Syringe

Article 11. Wholesalers and Manufacturers

- 4160 Wholesaler: License Required
- 4163 Unauthorized Furnishing by Manufacturer or Wholesaler
- 4164 Reports Required
- 4169(a)(1) Prohibited Acts

Article 13. Non-Profit of Free Clinics

4185 Inspection Permitted

Article 14. Surgical Clinics

4195 Inspection Permitted

Article 19. Disciplinary Proceedings

- 4301 Unprofessional Conduct subsections (a)-(h), (j), and (l)-(q)
- 4302 Discipline of Corporate Licensee for Conduct of Officer, Director, Shareholder
- 4303 Nonresident Pharmacy: Grounds for Discipline
- 4304 Out-of-state Distributor: Authority to Discipline

4305 Disciplinary Grounds: Failure of Pharmacy, Pharmacist to Notify Board of Termination of Pharmacist in Charge; Continuing to Operate Without Pharmacist

- 4305.5 Disciplinary Grounds: Failure of Other Entity Licensed by Board, of Pharmacist or Exemptee to Notify Board of Termination of Pharmacist in Charge or Exemptee; Continuing to Operate Without Pharmacist or Exemptee
- 4306 Violation of Professional Corporation Act as Unprofessional Conduct
- 4306.5 Misuse of Education, etc. by Pharmacist Outside Course of Practice of Pharmacy as Unprofessional Conduct

Article 20. Prohibitions and Offenses

4326 Misdemeanor: Obtaining Needle or Syringe by Fraud, etc.; Unlawful Use of Needle or Syringe Obtained from Another Misdemeanor: Permitting Compounding, Dispensing, or Furnishing by Non-4328 pharmacist 4330 Misdemeanor: Non-pharmacist Owner Failing to Place Pharmacist in Charge, Dispensing or Compounding Except by Pharmacist. Interfering with Pharmacist in Charge 4331 Misdemeanor: Medical Device Retailer, Wholesaler, Veterinary Food-Animal Drug Retailer Failing to Place Pharmacist or Exemptee in Charge, Permitting Dispensing or Compounding Except by Pharmacist or Exemptee 4333 Maintaining Prescriptions, Other Drug Records on Premises, Open to Inspection; Waiver; Willful Failure to Keep or Permit Inspection of Records of Prescriptions, Other Records as Misdemeanor 4340 Unlawful Advertising by Nonresident Pharmacy Not Registered with Board

Article 22. Unfair Trade Practices

4380Resale of Preferentially Priced Drugs: Prohibition; Exceptions4381Violation of Section 4380 as Unfair Competition; Right of Private Action to Enforce4382Board May Audit Sales to Walk-in Customers

CALIFORNIA CODE OF REGULATIONS, TITLE 16

Duty to Maintain Medication Profiles (Patient Medication Records)
Notice to Consumers and Duty to Consult
Duty to Review Drug Therapy and Patient Medication Record Prior to Delivery
Designation of Pharmacist in Charge
Pharmacy Operations During the Temporary Absence of a Pharmacist
Self-Assessment of a Pharmacy by the Pharmacist-in-Charge
Implementation of Electronic Monitoring of Schedule II Prescriptions
Compounding Unapproved Drugs for Prescriber Office Use
Record Requirements-Compounding for Future Furnishing
Preprinted, Multiple Checkoff Prescription Blanks
Confidentiality of Examination Questions
Partial Filling of Schedule II Prescriptions
Furnishing to Parenteral Patient at Home
Erroneous or Uncertain Prescriptions
Unauthorized Disclosure of Prescriptions
Commissions, Gratuities, and Rebates
False or Misleading Advertising
Compliance with Orders of Abatement
Reporting Sales of Drugs Subject to Abuse
Manufacturer or Wholesaler Furnishing Drugs or Devices
Duties of a Pharmacist
Duties of a Pharmacy Technician

- 1793.3 Other Non-Licensed Pharmacy Personnel
- 1793.7 Requirements for Pharmacies Employing Pharmacy Technicians
- 1793.8 Technicians in Hospitals with Clinical Pharmacy Programs

HEALTH AND SAFETY CODE

- 11103 Report of Theft, Loss, or Shipping Discrepancy
- 11150 Persons Authorized to Write or Issue a Prescription
- 11152 Nonconforming Prescriptions Prohibited
- 11154 Prescription, etc, Must Be for Treatment; Knowing Solicitation of Unlawful Prescription, etc.
- 11156 Prescribing, etc. Controlled Substances to Addict Only as Authorized
- 11164 Prescriptions for Schedule II, III, IV and V Controlled Substances: Form and Content; Record of Practitioner Dispensing Schedule II Controlled Substances
- 11166 Time Limit for Filling Schedule II Prescription; Knowingly Filling Mutilated, Forged, or Altered Prescription Prohibited
- 11170 Prohibition on Prescribing, etc. Controlled Substance for Self
- 11179 Retention of Controlled Substance Prescription

- 11207 Only Pharmacist or Intern Authorized to Fill Prescription
- 11209 Delivery and Receiving Requirements for Schedule II, III, and IV Substances; Violation
- 11350 Possession of Specified Controlled Substance
- 11377 Unlawful Possession of Specified Substance
- 11165(d) CURES Transmission
- 150204 Surplus Medication Collection and Distribution Program

CODE OF FEDERAL REGULATIONS, TITLE 21

- 1304.03 Persons required to keep records and file reports.
- 1304.04 Maintenance of records and inventories.
- 1304.11 Inventory requirements .
- 1304.21 General requirements for continuing records.
- 1304.22 Records for manufacturers.
- 1305.07 Special procedure for filling certain orders.
- 1305.13 Procedure for filling DEA Forms 222.
- 1306.04 Purpose of issue of prescription.
- 1306.06 Persons entitled to fill prescriptions.
- 1306.07 Administering or dispensing of narcotic drugs.
- 1306.11 Requirement of prescription.
- 1306.12 Refilling prescription.
- 1306.13 Partial filling of prescriptions.
- 1306.21 Requirement of prescription.
- 1306.22 Refilling of prescriptions.
- 1306.23 Partial filling of prescriptions.

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 in cases involving self-administration or diversion of controlled substances or dangerous drugs and/or dangerous devices, or abusive use of alcohol). All standard terms and conditions and optional terms and conditions as appropriate.

Maximum: Revocation

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

- violation(s) involving creation, manipulation, perpetuation, or disregard of drug shortages;
- <u>failure(s)</u> to deploy or abide by track and trace, pedigree, transaction history, and other similar requirements for dangerous drugs and/or dangerous devices;
- violation(s) of licensee's corresponding responsibility to ensure the proper prescribing and dispensing of controlled substances;

- <u>dispensing or furnishing without valid prescription</u>, <u>dispensing or furnishing to</u> <u>unauthorized person(s)</u>;
- 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 controlled substances, dangerous drugs and/or dangerous devices, or alcohol, including repeat or serious diversion or self-administration, or abuse;
- violation(s) of law governing self-administration of controlled substances that could lead to a potential infection control risk.
- repeat or serious unlawful possession(s) of dangerous drugs and/or dangerous devices, controlled substances, hypodermic needles or syringes, or drug paraphernalia;
- larger scale dispensing or furnishing of dangerous drug(s) and/or dangerous device(s) via the internet,

without valid prescription(s);

- purchasing, trading, selling, or transferring adulterated, misbranded, or expired dangerous drug(s) and/or dangerous device(s);
- removal, sale, or disposal of embargoed dangerous drug(s) and/or dangerous device(s);
- <u>failing to maintain record(s) of acquisition and disposition of dangerous drug(s)</u> and/or dangerous 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) and/or dangerous device(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.
- repeat or serious violation(s) involving the improper compounding of drug products
- repeat or serious violation(s) resulting from the misuse of education or licensing privileges irrespective of whether is occurs outside of an entity licensed by the board.

Violations of the following codes are representative of this category:

BUSINESS AND PROFESSIONS CODE

Article 3. Scope of Practice and Exemptions

4034 Pedigree

4051(a) Conduct Limited To Pharmacist

4059 Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions 4059.5 Who May Order Dangerous Drugs or Devices: Exceptions

Article 5. Authority of Inspectors

- 4080 Stock of Dangerous Drugs and Devices Kept Open for Inspection
- 4081 Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
- 4085(a) Unlawful to Remove, Sell, Dispose of Embargoed Dangerous Drug or Dangerous Device

Article 6. General Requirements

4105 Retaining Records of Dangerous Drugs and Devices on Licensed Premises; Temporary Removal; Waivers; Access to Electronically Maintained Records

Article 7. Pharmacies

4110 Licensed Required; Temporary Permit Upon Transfer of Ownership 4111 Restrictions on Prescriber Ownership

Article 11. Wholesalers and Manufacturers

4169(a)(2) to 4169(a)(5) Prohibited Acts

Article 15. Veterinary Food-Animal Retailers

4199 Labeling Requirements; Maintaining Prescription Records

Article 19. Disciplinary Proceedings

- 4301 Unprofessional Conduct subsections (i) (k) and (o)
- 4307 Prohibition of Association of Individual with Entity License by Board: Length of Prohibition; Individuals Covered; Imposition of Prohibition Through Administrative Act Proceeding
- 4308 Prohibited Association: Notification of Affected Licensees Known to Board

Article 20. Prohibitions and Offenses

- 4322 Misdemeanor or Infraction: False Representations to Secure License for Self or Others; False Representation of Licensure; Penalties
- 4323 Misdemeanor: False Representation of Self as Physician, Agent of Physician, etc. to Obtain Drug
- 4324 Felony or Misdemeanor: Forgery of Prescription; Possession of Drugs Obtained Through Forged Prescription
- 4325 Misdemeanor: Manufacture, Possession, etc. of False Prescription Blank
- 4327 Misdemeanor: Sale, Dispensing, or Compounding While Under the Influence of Drugs or Alcoholic Beverages
- 4329 Misdemeanor: Non-pharmacist Acting as Manager, Compounding, Dispensing or Furnishing Drugs
- 4332 Misdemeanor: Failure or Refusal to Maintain or Produce Required Drug or Device Records; Willful Production of False Records

 4335 Voided License: Knowing Failure to Arrange for Disposition of Stock as Misdemeanor
 4336 Felony: Knowing or Willful Use of Minor to Violate Specified Sections of Pharmacy Law: Exception for Pharmacist Furnishing Pursuant to a Prescription

Article 22. Unfair Trade Practices

4380 Resale of Preferentially Priced Drugs: Prohibition; Exceptions

CALIFORNIA CODE OF REGULATIONS, TITLE 16

- 1707 Waiver Requirements for Off-Site Storage of Records 1718 Current Inventory Defined
- 1761(b) Erroneous or Uncertain Prescriptions
- 1771 Posting of Notice of Suspension
- 1772 Disciplinary Condition of Suspension
- 1773 Disciplinary Conditions of Probation of Pharmacist
- 1774 Disciplinary Conditions of Probation of Permit

HEALTH AND SAFETY CODE

11104	Providing Chemical for Illicit Manufacturing; Evasion of Reporting Requirements;
	Penalties
11105	False Statement in Report
11150	Persons Authorized to Write or Issue a Prescription
11153	Responsibility for Legitimacy of Prescription; Corresponding Responsibility of
	Pharmacist; Knowing Violation
11153.5	Wholesaler or Manufacturer Furnishing Controlled Substance Other Than for
	Legitimate Medical Purpose; Knowing Violation; Factors in Assessing Legitimacy
11157	No False or Fictitious Prescriptions
11162.5	Counterfeiting or Possession of Counterfeit Triplicate Prescription Blank; Penalty
11173	Fraud, Deceit, Misrepresentation or False Statement; False Representation; False
	Label
11174	Prohibition on Providing False Name or Address in Connection with Prescription,
	etc.
11351	Possession or Purchase for Sale of Specified Controlled Substance
11368	Forged or Altered Prescriptions
11375	Possession for Sale or Selling Specified Substance
11378	Possession for Sale
11550	Using or Being Under Influence of Controlled Substance
11167.5	Pharmacy Generated Prescription for Schedule II Controlled Substances in a Skilled
	Nursing Facility
111295	Manufacturing, Selling, or Offering for Sale an Adulterated Drug or Device
111300	Unlawful to Adulterate a Drug
111305	Unlawful to Receive in Commerce an Adulterated Drug
111440	Unlawful Manufacturer, Selling a Misbranded Drug
111445	Unlawful for a Person to Misbrand
111450	Unlawful to Receive into Commerce a Drug that is Misbranded

CATEGORY IV

Penalty: Revocation

<u>Category IV discipline (Rrevocation)</u> is recommended for <u>the most</u> serious violations <u>of laws or</u> regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs and/or dangerous devices 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 and/or dangerous devices, or controlled substances;
 - and
- repeated or serious example(s) of conduct described in Category I, Category II, or Category III.
- violation(s) of law governing self-administration of controlled substances that could lead to a potential infection control risk.
- importation
- <u>■ sale</u>
- 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 Petition to Revoke Probation 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.

Violations of the following codes are representative of this category:

HEALTH AND SAFETY CODE

- 11352 Importing, Selling, Furnishing Controlled Substance
- 11353 Adult Inducing Minor to Violate Provisions
- 11379 Transporting, Importing, Selling Controlled Substance
- 11380 Adult Using, Soliciting or Intimidating Minor for Violation

MODEL DISCIPLINARY LANGUAGE - PHARMACIST/INTERN PHARMACIST INDIVIDUAL LICENSEES (PHARMACIST, INTERN PHARMACIST, PHARMACY TECHNICIAN, DESIGNATED REPRESENTATIVE, DESIGNATED REPRESENTATIVE – 3PL, ADVANCED PRACTICE PHARMACIST)

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] wall 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

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, <u>third-party logistics provider</u>, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or <u>any area</u> where dangerous drugs and/<u>or dangerous</u> 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, <u>distributing</u>, manufacturing or dispensing of dangerous drugs and/<u>or dangerous</u> devices or controlled substances.

<u>During suspension</u>, Rrespondent shall not engage in any activity that requires the professional judgment of <u>and/or licensure as</u> a pharmacist <u>[insert license type]</u>. Respondent shall not direct or control any aspect of the practice of pharmacy <u>or of the manufacturing, distributing</u>, <u>wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled</u> <u>substances</u>. 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 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 <u>[insert license</u> type] license, a <u>[insert license type]</u> 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: (Intern Pharmacist Only)

Should the board subsequently issue a license to practice as a pharmacist to respondent 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 remain 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 wall license, <u>including any indicia of licensure issued by</u> <u>the board</u>, 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 may only seek a new or reinstated license form the board by way of a new application for licensure. 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 shall not be eligible to petition for reinstatement of 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 <u>he or she [he/she]</u> 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 <u>\$</u>______shall be paid to the board prior to issuance of the new license.

Public Reprimand Reproval

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 with Conditions Precedent (Pharmacists and Pharmacy Technicians Only)

It is hereby ordered that the petition for reinstatement is granted. Upon satisfaction of the following conditions precedent to licensure, Petitioner's License No. ______ will be reinstated:

- 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. Failure to take and pass both examinations within one (1) year of the effective date of this order shall invalidate the order granting the petition for reinstatement, Petitioner shall be deemed to have failed the conditions precedent for re-licensure, and Petitioner's License No. shall remain [revoked or surrendered]."
- 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 foregoing conditions precedent, Petitioner's license shall be reinstated and immediately revoked, with revocation stayed and Petitioner placed on probation for a period of year(s)] on 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. Petitioner's license shall be reinstated and immediately revoked, with revocation stayed and Petitioner placed on probation for a period of year(s)] on 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. <u>Reporting of Employment and Notice to Employers</u>
- 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 Restrictions on Supervision and Oversight of Licensed Facilities
- 8 9. Reimbursement of Board Costs
- 9-10. Probation Monitoring Costs
- 10 11. Status of License
- 11 <u>12</u>.License Surrender While on Probation/Suspension
- 12. Notification of a Change in Name, Residence Address, Mailing Address or Employment
- 13. Certification Prior to Resuming Work
- 14. Notification of Departure
- 13. 15. Tolling of Probation License Practice Requirement Tolling
- 14. 16. Violation of Probation
- 15. <u>17.</u> Completion of Probation

OPTIONAL CONDITIONS

- 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. Facilitated Group Recovery and/or Support Meetings
- 29. Attend Substance Abuse Recovery Relapse Prevention and Support Groups
- 30. Work Site Monitor
- 25. 31. Community Service Program
- 26. 32. Restitution
- 27. 33. Remedial Education
- 28. Pharmacy Self-Assessment Mechanism (PSAM)
- 29. 34. Intern Pharmacist Experience
- 30. 35. Supervised Practice
- 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._ Consultant for Owner or Pharmacist-In-Charge
- 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 seventytwo (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 contendre 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 <u>and in a form or format</u>, 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 <u>timely</u> 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 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. <u>Reporting of Employment and Notice to Employers (Standard 3)</u>

During the period of probation, respondent 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, responsible manager, 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/her] pharmacist-in-charge, designated representative-in-charge, responsible manager, 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 acknowledgment(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 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 <u>failure</u> to cause <u>the identified</u> <u>person(s) with</u> that/those employer(s) to submit timely <u>written</u> acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall-includes 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)-

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 <u>Restrictions on</u> Supervision and Oversight of Licensed Facilities² (Not appropriate for Pharmacy Technicians)

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge, or designated representative-in-charge, responsible manager 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, designated representatives, designated representative-3PL in any entity licensed by the board. Assumption of any such

unauthorized ancillary personnel supervision responsibilities shall be considered a violation of probation.

Option 2: 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 pharmacistin-charge, designated representative-in-charge, responsible manager 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 a position only upon approval by the board or its designee and at only one entity licensed by the board. This approval is site specific. 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.

8<u>9</u>. 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.

1011. Status of License

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

If respondent's <u>[insert license type]</u> 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 <u>[insert license type]</u> license

shall be subject to all terms and conditions of this probation not previously satisfied.

11<u>12</u>. 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 <u>may tender [his/her] [insert license type]</u> license to the board for shall relinquish [his/her] license, including any indicia of licensure issued by 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/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)

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 of the effective date 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, third-party logistics provider, veterinary food-animal drug retailer or any other distributor of drugs) which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not 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/or dangerous 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 and/or dangerous 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 Departure

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 respondent is notified otherwise 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 <u>et seq</u>. "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 and/or dangerous devices 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, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, 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 suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or

any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous 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 dangerous devices or controlled substances.

During this 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 and/or dangerous 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 respondent is notified otherwise 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 practice until notified by the board or its designee that the period of suspension has been satisfactorily completed.

16.19. Restricted Practice

Respondent's practice <u>as a [insert license type]</u> of pharmacy shall be restricted to [specify setting or type of practice] for the first _____year(s)_of probation. Respondent shall submit proof satisfactory to the board <u>or its designee</u> 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. <u>Upon request, respondent</u> Respondent shall submit to the board <u>or its designee on writing, satisfactory</u> proof satisfactory of compliance with this <u>restriction, including but not limited to a written acknowledgment of this</u> 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 <u>question compounds drug products and how this restriction will be enforced term of probation</u>. Failure to abide by this restriction or to timely submit proof to the board <u>or its designee</u> of <u>compliance therewith</u> 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 <u>any such</u> suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, <u>third-party logistics provider</u>, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or <u>any area</u> where dangerous drugs and/<u>or dangerous</u> 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, <u>distributing</u>, manufacturing or dispensing of dangerous drugs <u>and/or</u> <u>dangerous devices</u> and controlled substances. Respondent shall not resume practice until-notified by the board.

During <u>any such</u> suspension, respondent shall not engage in any activity that requires the professional judgment of <u>and/or licensure as</u> a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy <u>or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices and controlled susbtances</u>. 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.

Failure to take <u>and pass</u> the examination(s) within one (1) year <u>six (6) months</u> of the effective date of this decision 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. <u>Respondent shall complete the coursework, and submit proof of completion satisfactory to the board or its designee, within three (3) months of the fourth failure of the examination.</u> Failure to complete coursework <u>or provide proof of such completion</u> as required shall be considered a violation of probation.

18.20. **Mental Health Examination** <u>Clinical Diagnostic Evaluation</u> (Appropriate for those cases where evidence demonstrates that mental illness <u>psychiatric disorders [mental illness,</u> emotional disturbance, gambling addiction), diversion, self-administration, or abuse of alcohol or <u>drugs</u> or disability was a contributing cause of the <u>violation(s)</u>.) (Standard 1 & 6)

Within thirty (30) days of the effective date of this decision, and on a periodic basis <u>thereafter if</u> <u>as may be</u> required by the board or its designee, respondent shall undergo, at <u>his or her</u> [his/her] own expense, <u>psychiatric clinical diagnostic</u> evaluation(s) by a <u>board-appointed or</u> <u>board-approved</u> licensed <u>mental health</u> practitioner <u>selected or approved prior to the evaluation</u> <u>by the board or its designee</u>. The approved evaluator shall be provided with a copy of the board's [accusation, or petition to revoke probation, <u>or other pleading</u>] 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 <u>pharmacist [insert license type]</u> 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, inpatient treatment, 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. Failure to comply with any requirement or deadline stated by this paragraph 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, 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 commencement of 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 shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved. 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 <u>or its designee</u> that practice may be resumed.

Option 1: (Appropriate for those cases where evidence demonstrates abuse of alcohol or drugs. Option language to be used in addition to standard language): (Standards 1, 2 & 6) 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];
- <u>The board or its designee is satisfied that respondent is safe to return to practice as a</u> [insert license type];
- <u>Respondent receives written notice from the board or its designee that practice may</u>
 <u>resume.</u>

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, third-party logistics provider, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous 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 dangerous 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 and/or dangerous devices or controlled substances.

Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

Option 2: Commencing on the effective date of this decision, respondent <u>is suspended from</u> <u>practice and</u> shall not engage in the practice of pharmacy <u>practice as a [insert license type]</u> 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 <u>any such</u> suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, <u>third-party logistics provider</u>, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or <u>any area</u> where dangerous drugs and/<u>or dangerous</u> 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, <u>distributing</u>, manufacturing or dispensing of dangerous drugs <u>and/or</u> <u>dangerous devices</u> and <u>or</u> controlled substances. Respondent shall not resume practice until-notified by the board.

During <u>any such</u> suspension, respondent shall not engage in any activity that requires the professional judgment of <u>and/or licensure as</u> a <u>pharmacist [insert license type]</u>. Respondent shall not direct or control any aspect of the practice of pharmacy, <u>or of the manufacturing</u>, <u>distributing</u>, <u>wholesaling</u>, <u>or retailing of dangerous drugs and/or dangerous devices or</u> <u>controlled substances</u>. 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 <u>any such</u> suspension shall be considered a violation of probation. Failure to comply with any requirement or deadline stated by this term 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 <u>any such</u> suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, <u>third-party logistics provider</u>, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or <u>any area</u> where dangerous drugs and/<u>or dangerous</u> 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, <u>distributing</u>, manufacturing or dispensing of dangerous drugs <u>and/or</u> <u>dangerous devices or</u> and controlled substances. Respondent shall not resume practice until-notified by the board.

During <u>any such</u> suspension, respondent shall not engage in any activity that requires the professional judgment of <u>and/or licensure as</u> a <u>pharmacist [insert license type]</u>. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing,

distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances. 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 <u>any such</u> suspension shall be considered a violation of probation. Failure to comply with any requirement or deadline stated by this term 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 <u>any such</u> suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, <u>third-party logistics provider</u>, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or <u>any area</u> where dangerous drugs and/<u>or dangerous</u> 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, <u>distributing</u>, manufacturing or dispensing of dangerous drugs <u>and/or</u> <u>dangerous devices or</u> 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 and/or dangerous 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 <u>any such</u> this suspension shall be considered a violation of probation. Failure to comply with any requirement or deadline stated by this term 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. or other pleading] 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 <u>a pharmacist [insert license type]</u> 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 <u>any such</u> suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, <u>third-party logistics providers</u>, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or <u>any area</u> where dangerous drugs and/<u>or dangerous</u> 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, <u>distributing</u>, manufacturing or dispensing of dangerous drugs <u>and/or</u> <u>dangerous devices or</u> and controlled substances. Respondent shall not resume practice untilnotified by the board.

During <u>any such</u> suspension, respondent shall not engage in any activity that requires the professional judgment of <u>and/or licensure as</u> a <u>pharmacist [insert license type]</u>. Respondent shall not direct or control any aspect of the practice of pharmacy, <u>or of the manufacturing</u>, <u>distributing</u>, <u>wholesaling</u>, <u>or retailing of dangerous drugs and/or dangerous devices or</u> <u>controlled substances</u>. 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 <u>any such</u> suspension shall be considered a violation of probation. Failure to comply with any requirement or deadline stated by this term 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 <u>any such</u> suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, <u>third-party logistics provider</u>, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or <u>any area</u> where dangerous drugs and/<u>or dangerous</u> 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, <u>distributing</u>, manufacturing or dispensing of dangerous drugs <u>and/or dangerous devices</u> or controlled substances. Respondent shall not resume practice until notified by the board.

During <u>any such</u> suspension, respondent shall not engage in any activity that requires the professional judgment of <u>and/or licensure as</u> a <u>pharmacist [insert license type]</u>. Respondent shall not direct or control any aspect of the practice of pharmacy, <u>or of the manufacturing</u>, <u>distributing</u>, <u>wholesaling</u>, <u>or retailing of dangerous drugs and/or dangerous devices or</u> <u>controlled substances</u>. 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 <u>any such</u> suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, <u>third-party logistics provider</u>, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or <u>any area</u> where dangerous drugs and/<u>or dangerous</u> devices or controlled substances are maintained. Respondent shall not practice pharmacy <u>as a [insert license type]</u> 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, <u>distributing</u>, manufacturing or dispensing of dangerous

drugs and <u>or devices or</u> controlled substances. Respondent shall not resume practice until notified by the board.

During <u>any such</u> suspension, respondent shall not engage in any activity that requires the professional judgment of <u>and/or licensure as</u> a <u>pharmacist [insert license type]</u>. Respondent shall not direct or control any aspect of the practice of pharmacy, <u>or of the manufacturing</u>, <u>distributing</u>, <u>wholesaling</u>, <u>or retailing of dangerous drugs and/or dangerous devices or</u> <u>controlled substances</u>. 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 <u>those cases where</u> <u>evidence demonstrates substance abuse chemical dependency (alcohol, drugs)</u>, or psychiatric disorders (mental illness, emotional disturbance, gambling <u>addiction</u>) (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 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(c) (a)(2). Respondent shall successfully participate in and complete his or her current contract and any subsequent addendums with the PRP.

Respondent shall pay administrative fees as invoiced by the PRP or its designee. Fees not timely paid to the PRP shall constitute a violation of probation. The board will collect unpaid administrative fees as part of the annual probation monitoring costs if not submitted to 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 <u>any such</u> suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, <u>third-party logistics provider</u>, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or <u>any area</u> where dangerous drugs and/<u>or dangerous</u> 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, <u>distributing</u>, manufacturing or dispensing of dangerous drugs and/<u>or dangerous devices or</u> controlled substances. Respondent shall not-resume practice until notified by the board.

During <u>any such</u> suspension, respondent shall not engage in any activity that requires the professional judgment of <u>and/or licensure as</u> a <u>pharmacist [insert license type]</u>. Respondent shall not direct or control any aspect of the practice of pharmacy, <u>or of the manufacturing</u>, <u>distributing</u>, <u>wholesaling</u>, <u>or retailing of dangerous drugs and/or dangerous devices or controlled substances</u>. 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 <u>any such</u> this suspension shall be considered a violation of probation. Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

(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 use.) (Standards 4, 8, 9 & 10)

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 and/or dangerous devices. or other controlled substances as the board or its designee may direct.

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.

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 and/or dangerous device, 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 and/or dangerous device 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 and/or dangerous device 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.³

During <u>any such</u> suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, <u>third-party-logistics provider</u>, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or <u>any area</u> where dangerous drugs and/<u>or dangerous</u> 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, <u>distributing</u>, manufacturing or dispensing of dangerous drugs <u>and/or dangerous devices</u> and controlled substances. Respondent shall not resume-practice until notified by the board.

During <u>any such</u> suspension, respondent shall not engage in any activity that requires the professional judgment of <u>and/or licensure as</u> a <u>pharmacist [insert license type]</u>. Respondent shall not direct or control any aspect of the practice of pharmacy, <u>or of the manufacturing</u>, <u>distributing</u>, <u>wholesaling</u>, <u>or retailing of dangerous drugs and/or dangerous devices</u>. 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 <u>any such</u> suspension shall be considered a violation of probation. Failure to comply with any requirement or deadline stated by this term shall be considered a violation of probation.

23.25. Abstain from Drugs and Alcohol Use

(Appropriate for those cases where the evidence demonstrates substance use.) (Standard 4)

Respondent shall completely abstain from the possession or use of alcohol, controlled substances, <u>illicit drugs</u>, dangerous drugs <u>and/or dangerous devices</u>, or and their associated paraphernalia, except when possessed

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

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 and/or dangerous devices or controlled substances, or their associated paraphernalia not supportedby for which a legitimate prescription has not 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 use 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 dangerous devices, and/or of mental illness, and/or of gambling addiction] and who will coordinate and monitor any prescriptions for respondent for dangerous drugs and/or dangerous devices, 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, or other pleading] 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

to timely submit the selected practitioner or replacement practitioner to the board <u>or its designee</u> 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 <u>any such</u> suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, <u>third-party logistics provider</u>, veterinary food-animal drug

retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or <u>any area</u> where dangerous drugs and/<u>or dangerous</u> 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, <u>distributing</u>, manufacturing or dispensing of dangerous drugs <u>and/or</u> <u>dangerous devices</u> and controlled substances. Respondent shall not resume practice until notified by the board.

During <u>any such</u> suspension, respondent shall not engage in any activity that requires the professional judgment <u>and/or licensure as a [insert license type]</u> of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy <u>or of the manufacturing</u>, <u>distributing</u>, wholesaling, or retailing of dangerous drugs and/or dangerous devices or <u>controlled substances</u>. 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 <u>any such</u> this suspension shall be considered a violation of probation. Failure to comply with any requirement or deadline stated by this term 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 <u>or its designee</u> 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 <u>or its designee</u> 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 <u>for approval</u> 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 (Intern Pharmacist 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 <u>and ten (10) days</u> 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 (This term is not appropriate for Pharmacy Technicians.)

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 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 <u>any such</u> suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, <u>third-party logistics provider</u>, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or <u>any area</u> where dangerous drugs and/<u>or dangerous</u> 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, <u>distributing</u>, manufacturing or dispensing of dangerous drugs and/<u>or</u> <u>dangerous devices or</u> controlled substances. <u>Respondent shall not resume practice until-notified by the board</u>.

During <u>any such</u> suspension, respondent shall not engage in any activity that requires the professional judgment <u>and/or licensure as a [insert license type]</u>of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy <u>or of the manufacture</u>, <u>distribution</u>, wholesaling, or retailing of dangerous drugs and/or dangerous devices or <u>controlled substances</u>. 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 Personnel²

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 <u>nor</u> 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 <u>Controlled Substances</u> Records (For <u>pharmacist</u> <u>Pharmacist</u> 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 <u>Pharmacist</u> 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 <u>or its designee</u> 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 <u>or its designee</u>. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period <u>as determined by the board or its designee</u>. 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 $\frac{11055}{11054}$ -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-Charge

(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.

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, Advanced Practice Pharmacists and Pharmacist Intern 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 and/or dangerous 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 <u>1</u>: Respondent may obtain a DEA permit restricted to Schedule(s) ______controlled substance(s).

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

40 <u>38</u>. Ethics Course (Pharmacists, Advanced Practice Pharmacists and Pharmacist Intern 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.

<u>39. Facilitated Group Recovery and/or Support Meetings</u> (Appropriate for those cases where the evidence demonstrates substance use. Pharmacists and Pharmacist Interns Only) (Standard 5)

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. 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. Respondent shall provide signed and dated documentation of attendance as required with each guarterly report. Failure to attend as required or to submit documentation of attendance shall be considered a violation of probation.

If respondent is required to participate in the PRP, compliance with this term can be demonstrated through that program. Where respondent is enrolled in the PRP, participation as required in a facilitated group meeting approved by the PRP shall be sufficient for satisfaction of this requirement. Any deviation from participation requirements for the PRP-approved group shall be considered a violation of probation.

40. Attend Substance Abuse Recovery Relapse Prevention and Support Groups (Appropriate for those cases where the evidence demonstrates substance use.) (Standard 5)

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 guarterly report for the duration of probation. Failure to attend or submit documentation thereof shall be considered a violation of probation.

If respondent is required to participate in the PRP, compliance with this term can be demonstrated through that program. Where respondent is enrolled in the PRP, participation as required in a recovery group meeting approved by the PRP shall be sufficient for satisfaction of this requirement. Any deviation from participation requirements for the PRP-approved group shall be considered a violation of probation.

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

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:
 Have regular face-to-face contact with respondent in the work environment, at least once

- <u>per week or with greater frequency if required by the board or its designee;</u>
 <u>Interview other staff in the office regarding respondent's behavior, if applicable; and</u>
- 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 obe 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.

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.

PHARMACY TECHNICIAN

The board files cases against pharmacy technicians where the violation(s) involve significant misconduct on the part of the licensee. The board believes that revocation is typically the appropriate penalty when grounds for discipline are found to exist. Grounds for discipline include, but are not limited to the following violation(s) of law(s) involving:

- Possession of dangerous drugs and/or controlled substances
- Use of dangerous drugs and/or controlled substances
- Possession for sale of dangerous drugs and/or controlled substances
- Personal misuse of drugs or alcohol

If revocation is not imposed, the board recommends a minimum Category III level of discipline be imposed on the pharmacy technician. This would include suspension and probation.

In addition, a pharmacy technician would be required to obtain certification as defined by Business and Professions Code section 4202(a)(4) prior to resuming work as a pharmacy technician. The board believes that certification prior to resuming work is always warranted in cases where a pharmacy technician license is disciplined but not revoked.

Pharmacy technicians are issued a license based on minimal education, training requirements or certification. No examination is required for issuance of the registration. Pharmacy technicians are not independent practitioners and must work under the supervision of a pharmacist. To place a pharmacy technician on probation places an additional burden on the pharmacist (who may or may not be on probation) to ensure that the respondent pharmacy technician complies with the terms and conditions of his or her probation.

TERMS OF PROBATION – PHARMACY TECHNICIAN⁴

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.

CATEGORY OF VIOLATIONS AND RECOMMENDED PENALTIES

CATEGORY III - Penalty

 Minimum: Revocation; Revocation stayed, 90 days actual suspension, three years probation. All standard terms and conditions shall be included and optional terms and conditions as appropriate.

- Maximum: Revocation

Applies to all applicable statutes and regulations

MODEL DISCIPLINARY LANGUAGE – PHARMACY TECHNICIAN⁵

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

Revocation

Pharmacy technician license number ______, issued to respondent ______is revoked. Respondent shall relinquish his or her technician license to the board within ten (10) days of the effective date of this decision. Respondent may not reapply or petition the board for reinstatement of his or her revoked technician license for three (3) years from the effective date of this decision.

A condition of reinstatement shall be that the respondent is certified as defined in Business and Professions Code section 4202(a)(4) and provides satisfactory proof of certification to the board.

Respondent shall pay to the board its costs of investigation and prosecution in the amount of <u>within fifteen (15) days of the effective date of this decision.</u>

Option: As a condition precedent to reinstatement of his or her revoked technician 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 revoked technician license, unless otherwise ordered by the board.

Suspension

As part of probation, respondent is suspended from working as a pharmacy technician for ______beginning the effective date of this decision.

During suspension, respondent shall not enter any pharmacy area or any portion of or any other board licensed premises (wholesaler, veterinary food-animal drug retailer or any other distributor of drugs) any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not 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

⁵ All information specific to Pharmacy Technician is being removed and consolidated into Terms of Probation – Individual Licensees.

access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.

Respondent shall not direct, control or perform any aspect of the practice of pharmacy. 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 suspension shall be considered a violation of probation.

Standard Stay/Probation Order

Pharmacy technician license number _____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 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 surrenders pharmacy technician license number _____as of the effective date of this decision. Respondent shall relinquish his or her pharmacy technician 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 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 (3) years from the effective date of this decision. Respondent stipulates that should he or 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 certification by a nationally recognized body 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 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 apply for any license from the board on or after the effective date of this decision, investigation and prosecution costs in the amount of \$_____shall be paid to the board prior to issuance of the license.

Public Reprimand

It is hereby ordered that a public reprimand be issued against pharmacy technician license, _______. Respondent is required to report this reprimand as a disciplinary action.

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. Certification Prior to Resuming Work
- 2. Obey All Laws
- 3. Report to the Board
- 4. Interview with the Board
- 5. Cooperate with Board Staff
- 6. Notice to Employers
- 7. Reimbursement of Board Costs
- 8. Probation Monitoring Costs
- 9. Status of License
- 10. License Surrender While on Probation/Suspension
- 11. Notification of a Change in Name, Residence Address, Mailing Address or Employment
- 12. Tolling of Probation
- 13. Violation of Probation
- 14. Completion of Probation

OPTIONAL CONDITIONS

- 15. No Ownership of Licensed Premises
- 16. Attend Substance Abuse Recovery Relapse Prevention and Support Groups
- 17. Random Drug Screening
- 18. Work Site Monitor
- 19. Notification of Departure
- 20. Abstain from Drugs and Alcohol Use
- 21. Tolling of Suspension
- 22. Restitution

STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS

1. Certification Prior to Resuming Work

Respondent shall be automatically suspended from working as a pharmacy technician until he or she is certified as defined by Business and Professions Code section 4202(a)(4) and provides satisfactory proof of certification to the board. Respondent shall not resume working as a pharmacy technician until notified by the board. Failure to achieve certification within one (1) year shall be considered a violation of probation. Respondent shall not resume working as a pharmacy technician until notified by the board.

During suspension, respondent shall not enter any pharmacy area or any portion of any other board licensed premises (wholesaler, veterinary food-animal drug retailer or any other distributor of drugs) any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not 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, manufacturing or dispensing of dangerous drugs and devices or controlled substances. Respondent shall not resume work until notified by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises by the board 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 suspension shall be considered a violation of probation.

2. 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 seventytwo (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 contendre 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 any such occurrence shall be considered a violation of probation.

3. 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.

4. 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 at two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

5. Cooperate with Board Staff

Respondent shall 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 probation. Failure to cooperate shall be considered a violation of probation.

6. Notice to Employers

During the period of probation, respondent 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 respondent undertaking any new employment, respondent shall cause his or her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have 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 acknowledgement(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify his or her direct supervisor, pharmacist-in-charge and owner at every pharmacy of the terms and conditions of the decision in case number ______ in advance of the respondent commencing work at each pharmacy. 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 employment service, respondent shall cause his or her direct supervisor with the pharmacy 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 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 to cause that/those employer(s) to submit timely acknowledgements 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 or relief service or pharmacy management service as a pharmacy technician or in any position for which a pharmacy technician license is a requirement or criterion for employment, whether the respondent is considered an employee, independent contractor or volunteer.

7. 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.

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.

8. 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.

9. Status of License

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

If respondent's pharmacy technician 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 license shall be subject to all terms and conditions of this probation not previously satisfied.

10. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease work due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her pharmacy technician 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. 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 pharmacy technician 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, permit, or registration 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.

11. 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 and mailing address, or phone number.

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.

12. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacy technician 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.

Should respondent, regardless of residency, for any reason (including vacation) cease working as a pharmacy technician for a minimum of ______hours per calendar month in California, respondent must notify the board in writing within ten (10) days of cessation of work and must further notify the board in writing within ten (10) days of the resumption of the work. Any failure to 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 work" means calendar month during which respondent is not working for at least ______hours as a pharmacy technician, as defined in Business and Professions Code section 4115. "Resumption of work" means any calendar month during which respondent is working as a pharmacy technician for at least ______hours as a pharmacy technician for at least ______hours as a pharmacy technician as defined by Business and Professions Code section 4115.

13. 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.

14. Completion of Probation

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

OPTIONAL CONDITIONS OF PROBATION

15. No Ownership of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, or 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 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 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 of this decision. Violation of this restriction shall be considered a violation of probation.

16. Attend Substance Abuse Recovery Relapse Prevention and Support Groups (Appropriate for those cases with chemical dependency (alcohol, drugs))

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.

17. Random Drug Screening (Appropriate for those cases with chemical dependency (alcohol, drugs))

Respondent, at his or 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, 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 work by respondent. Respondent may not resume work as a pharmacy technician until notified by the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of or any other board licensed premises (wholesaler, veterinary food-animal drug retailer or any other distributor of drugs) any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not 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, manufacturing or dispensing of dangerous drugs and devices or controlled substances. Respondent shall not resume work until notified by the board.

Respondent shall not direct, control or perform any aspect of the practice of pharmacy. 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 suspension shall be considered a violation of probation.

18. Work Site Monitor (Appropriate for those cases with chemical dependency (alcohol, drugs))

Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board, 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 quarterly. Should the designated work site monitor determine at any time during the probationary period that respondent has not maintained sobriety, he or she shall notify the board immediately, either orally or in writing as directed. Should respondent change employment, a new work site monitor must be designated, for prior approval by the board, within ten (10) days of commencing new employment. Failure to identify an acceptable initial or replacement work site monitor, or to ensure quarterly reports are submitted to the board, shall be considered a violation of probation.

19. Notification of Departure (Appropriate for those cases with chemical dependency (alcohol, drugs))

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.

20. Abstain from Drugs and Alcohol Use (Appropriate for those cases with chemical dependency (alcohol, drugs))

Respondent shall completely abstain from the possession or use of alcohol, controlled substances, dangerous drugs and their associated paraphernalia except when 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 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, controlled substances, or their associated paraphernalia not supported by the documentation timely provided, and/or any physical proximity to persons using illicit substances, shall be considered a violation of probation.

21. 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 ten (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.

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 return to work until notified by the board that the period of suspension has been satisfactorily completed.

- **22. 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.

DESIGNATED REPRESENTATIVE

The board files cases against designated representatives where the violation(s) involve significant misconduct on the part of the licensee. The board believes that revocation is typically the appropriate penalty when grounds for discipline are found to exist. Grounds for discipline include, but are not limited to, the following violation(s) of law(s) involving:

- Possession of dangerous drugs and/or controlled substances
- Use of dangerous drugs and/or controlled substances
- Possession for sale of dangerous drugs and/or controlled substances
- Personal misuse of drugs or alcohol

If revocation is not imposed, the board recommends a minimum Category III level of discipline be imposed on the designated representative. This would include suspension and probation.

TERMS OF PROBATION – DESIGNATED REPRESENTATIVE⁶

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.

CATEGORY OF VIOLATIONS AND RECOMMENDED PENALTIES

CATEGORY III - Penalty

 Minimum: Revocation; Revocation stayed, 90 days actual suspension, three years probation. All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Applies to all applicable statutes and regulations

MODEL DISCIPLINARY LANGUAGE – DESIGNATED REPRESENTATIVE

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

Revocation

Designated Representative license number ______, issued to respondent _______ is revoked. Respondent shall relinquish his or her designated representative license to the board within ten (10) days of the effective date of this decision. Respondent may not petition the board for reinstatement of his or her revoked designated representative license for three (3) 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 designated representative 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 reinstatement of his or her revoked designated representative license, unless otherwise ordered by the board.

Suspension

During 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 licensed by the board, or any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not perform any of the duties of a designated representative, nor do any act involving drug selection, selection of stock, manufacturing, dispensing; 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 and devices and controlled substances. Respondent shall not resume work until notified by the board.

Respondent shall not direct, control or perform any aspect involving the distribution of dangerous drugs and devices and controlled substances. Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed entity 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 suspension shall be considered a violation of probation.

Standard Stay/Probation Order

Designated representative license number ______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 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 surrenders designated representative license number _____as of the effective date of this decision. Respondent shall relinquish his or her designated representative 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 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 (3) years from the effective date of this decision. Respondent stipulates that should he or 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 prior to issuance of a new license. Respondent is required to report this surrender as disciplinary action.

Respondent further stipulates that he or 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 apply for any license from the board on or after the effective date of this decision, 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 designated representative license, ______. Respondent is required to report this reprimand as a disciplinary action.

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. Notice to Employers
- 6. No Being Designated Representative-in-Charge
- 7. Reimbursement of Board Costs
- 8. Probation Monitoring Costs
- 9. Status of License
- 10. License Surrender While on Probation/Suspension
- 11. Notification of a Change in Name, Residence Address, Mailing Address or Employment
- 12. Tolling of Probation
- 13. Violation of Probation
- 14. Completion of Probation

OPTIONAL CONDITIONS

- 15. No Ownership of Licensed Premises
- 16. Attend Substance Abuse Recovery Relapse Prevention and Support Groups
- 17. Random Drug Screening
- 18. Work Site Monitor
- 19. Notification of Departure
- 20. Abstain from Drugs and Alcohol Use
- 21. Tolling of Suspension
- 22. Restitution

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 seventytwo (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
- an arrest or issuance of a criminal complaint for violation of any state or federal law
- a plea of guilty or nolo contendre 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 or distribution or billing or charging for of any drug, device or controlled substance.

Failure to timely report any 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, upon request 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 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 probation. Failure to cooperate shall be considered a violation of probation.

5. Notice to Employers

During the period of probation, respondent 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 respondent undertaking any new employment, respondent shall cause his or her direct supervisor, designated representative-in-charge (including each new designated representative-in-charge employed during respondent's tenure of employment) and owner 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. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgement(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify his or her direct supervisor, designated representative-in-charge and owner at each 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 employment service, respondent shall cause his or her direct supervisor with the pharmacy 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 the respondent's responsibility to ensure that 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 to cause that/those employer(s) to submit timely acknowledgements 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 or relief service or pharmacy management service as a designated representative or in any position for which a designated representative license is a requirement or criterion for employment, whether the respondent is considered an employee or independent contractor or volunteer.

6. No Being Designated Representative-in-Charge

During the period of probation, respondent shall not be the designated representative-in-charge of any entity licensed by the board unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

7. 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.

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.

8. 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.

9. Status of License

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

If respondent's designated representative 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 license shall be subject to all terms and conditions of this probation not previously satisfied.

10. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease work due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her designated representative 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. 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 designated representative 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, permit, or registration 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.

11. 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 and the address of the new employer, supervisor and owner and work schedule, if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address and mailing address, or phone number.

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.

12. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a designated representative 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.

Should respondent, regardless of residency, for any reason (including vacation) cease working as a designated representative for a minimum of _____hours in California, respondent must notify the board in writing within ten (10) days of cessation of work and must further notify the board in writing within ten (10) days of the resumption of work. Any failure to 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 work" means any calendar month during which respondent is not working as a designated representative for at least _____hours as a designated representative as defined by Business and Professions Code section 4053. "Resumption of work" means any calendar month during which respondent is working as a designated representative for at least _____hours as a designated representative as defined by Business and Professions Code section 4053.

13. 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.

14. Completion of Probation

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

OPTIONAL CONDITIONS OF PROBATION

15. No Ownership of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, or 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 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 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.

16. Attend Substance Abuse Recovery Relapse Prevention and Support Groups (Appropriate for those cases with chemical dependency (alcohol, drugs))

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.

17. Random Drug Screening (Appropriate for those cases with chemical dependency (alcohol, drugs))

Respondent, at his or 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, 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 work by respondent. Respondent may not resume work as a designated representative until notified by the board in writing.

During 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 licensed by the board, or any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not perform any of the duties of a designated representative, nor do any act involving drug selection, selection of stock, manufacturing, dispensing; 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 and devices and controlled substances. Respondent shall not resume work until notified by the board.

Respondent shall not direct, control or perform any aspect involving the distribution of dangerous drugs and devices and controlled substances. Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed entity 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 suspension shall be considered a violation of probation.

18. Work Site Monitor (Appropriate for those cases with chemical dependency (alcohol, drugs))

Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board, 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 quarterly. Should the designated work site monitor determine at any time during the probationary period that respondent has not maintained sobriety, he or she shall notify the board immediately, either orally or in writing as directed. Should respondent change employment, a new work site monitor must be designated, for prior approval by the board, within ten (10) days of commencing new employment. Failure to identify an acceptable initial or replacement work site monitor, or to ensure quarterly reports are submitted to the board, shall be considered a violation of probation.

19. Notification of Departure (Appropriate for those cases with chemical dependency (alcohol, drugs))

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.

20. Abstain from Drugs and Alcohol Use (Appropriate for those cases with chemical dependency (alcohol, drugs))

Respondent shall completely abstain from the possession or use of alcohol, controlled substances, dangerous drugs and their associated paraphernalia except when 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 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, controlled substances, or their associated paraphernalia not supported by the documentation timely provided, and/or any physical proximity to persons using illicit substances, shall be considered a violation of probation.

21. 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 ten (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.

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 work until notified by the board that the period of suspension has been satisfactorily completed.

22. 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.

TERMS OF PROBATION – PREMISES

A minimum three-year probation period has been established by the board as the minimum appropriate length 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 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 less serious (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; <u>one-two</u> year<u>s</u> probation. All standard terms and conditions shall be included <u>and the disciplinary order may include</u> optional terms and conditions, as appropriate.

Maximum: Revocation

Category I discipline is recommended for <u>violations which are less serious than Categories II</u> through IV but are potentially <u>harmful</u>:

- violation(s) of recordkeeping requirements, scope of practice requirements, or inventory control requirements;
- <u>smaller or isolated failure(s) to abide by or enforce prescription or refill requirements,</u> 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;
- <u>failure(s) to adequately supervise staff to ensure security and sanitation of premises,</u> <u>dangerous drugs and/or dangerous devices or controlled substances;</u>
- 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).
- violation(s) involving the improper compounding of drug products
- violations which are relatively minor but are potentially harmful
- repeated violations of a relatively minor nature

Violations of the following codes are representative of this category:

BUSINESS AND PROFESSIONS CODE

Article 3. Scope of Practice and Exemptions

- 4053 Exemptee Supervisor of Manufacturer, etc.: Requirements
- 4054 Supply by Manufacturer, etc. of Certain Dialysis Drugs and Devices
- 4056 Purchase of Drugs at Wholesale Hospital Containing 100 Beds or Less
- 4057 Exceptions to Application of this Chapter
- 4058 Display of Original License
- 4062 Furnishing Dangerous Drugs During Emergency
- 4064 Emergency Refill of Prescription Without Prescriber Authorization
- 4065 Injection Card System; Requirements for Administration
- 4066 Furnishing Dangerous Drugs to Master or First Officer of Vessel

Article 4. Requirements for Prescription

- 4070 Reduction of Oral or Electronic Prescription to Writing
- 4071 Prescriber May Authorize Agent to Transmit Prescription; Schedule II Excluded
- 4072 Oral or Electronic Transmission of Prescription Health Care Facility
- 4073 Substitution of Generic Drug Requirements and Exceptions
- 4074 Drug Risk: Informing Patient; Providing Consultation for Discharge Medications
- 4076 Prescription Container Requirements for Labeling
- 4077 Dispensing Dangerous Drug in Incorrectly Labeled Container

Article 5. Authority of Inspectors

4082 Names of Owners, Managers and Employees Open for Inspection

Article 6. General Requirements

- 4100 Change of Address or Name Notification to Board
- 4103 Blood Pressure Taking by Pharmacist

Article 7. Pharmacies

4114	Intern Pharmacist: Activities Permitted
4119.5	Transfer or Repackaging Dangerous Drugs by Pharmacy
4120	Nonresident Pharmacy: Registration Required
4121	Advertisement for Prescription Drug: Requirements; Restrictions
4122	Required Notice at Availability of Prescription Price Information, General Product
	Availability, Pharmacy Services; Providing Drug Price Information; Limitations on
	Price Information Requests
4123	Compounding Drug for Other Pharmacy for Parenteral Therapy; Notice to Board
4124	Dispensing Replacement Contact Lenses: Requirements; Patient Warnings;
	Registration with Medical Board; Application of Section to Nonresident Pharmacies

Article 9. Hypodermic Needles and Syringes

- 4141 Furnishing Without License
- 4142 Prescription Required
- 4143 Exemption: Sale to Other Entity, Physician, etc.
- 4144 Industrial Use Exception
- 4145 Exception: Furnishing for Administration of Insulin, Adrenaline, or Specified Animal Uses; Conditions
- 4148 Confiscation if Found Outside Licensed Premises
- 4149 Sale by Distributor

Article 10. Pharmacy Corporations

- 4151 Licensure Requirements
- 4152 Corporate Name Requirements
- 4153 Shareholder Income While Disqualified
- 4156 Unprofessional Conduct by Corporation

Article 11. Wholesalers and Manufacturers

4161 Nonresident Wholesaler: When License Required; Application

- 4162 Issuance or Renewal of Wholesaler License; Surety Bond
- 4164 Reports Required
- 4165 Sale or Transfer of Dangerous Drug or Device Into State: Furnishing Records to Authorized Officer on Demand; Citation for Non-compliance
- 4166 Shipping of Dangerous Drugs or Devices Wholesaler or Distributor
- 4167 Wholesaler: Bar on Obtaining Dangerous Drugs or Devices It Cannot Maintain on Licensed Premises

Article 13. Non-Profit or Free Clinics

- 4180 Purchase of Drugs at Wholesale Only with License: Eligible Clinics
- 4181 License Requirements; Policies and Procedures; Who May Dispense
- 4182 Duties of Professional Director; Consulting Pharmacist Required
- 4183 No Professional Dispensing Fee
- 4184 Dispensing Schedule II Substance Prohibited
- 4186 Automated Drug Delivery Systems

Article 14. Surgical Clinics

- 4190 Purchase of Drugs at Wholesale: Permitted Uses of Drugs; Required Records and Policies; License Required
- 4191 Compliance with Department of Health Services Requirements; Who May Dispense Drugs
- 4192 Duties of Professional Director; Providing Information to Board
- 4193 Clinic Not Eligible for Professional Dispensing Fee; Ban on Offering Drugs for Sale
- 4194 Dispensing of Schedule II Substance by Clinic Prohibited; Physician May Dispense; Administration Authorized in Clinic

Article 15. Veterinary Food-Animal Drug Retailers

- 4196 License Required: Temporary License on Transfer of Ownership; Persons Authorized in Storage Area
- 4197 Minimum Standards: Security; Sanitation; Board Regulations; Waivers
- 4198 Written Policies and Procedures Required: Contents; Training of Personnel; Quality Assurance; Consulting Pharmacist

Article 17. Continuing Education

- 4231 Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee
- 4232 Content of Courses

Article 18. Poisons

4240 Application of Act

Article 20. Prohibitions and Offenses

- 4341 Advertisement of Prescription Drugs or Devices
- 4343 Buildings: Prohibition Against Use of Certain Signs Unless Licensed Pharmacy Within

CALIFORNIA CODE OF REGULATIONS, TITLE 16

1704	Change of Address
1705	Notification of Bankruptcy, Receivership or Liquidation
1708.2	Discontinuance of Business
1708.4	Pharmacist Handling Radioactive Drugs
1708.5	Pharmacy Furnishing Radioactive Drugs
1709	Names of Owners and Pharmacist in Charge
1714	Operational Standards and Security
1715.6	Reporting Drug Loss
1716	Variation from Prescriptions
1717	Pharmaceutical Practice
1717.1	Common Electronic Files
1717.4	Electronic Transmission of Prescriptions
1718.1	Manufacturer's Expiration Date
1726	Supervision of Intern Pharmacists
1728	Requirements for Examination
1732.1	Requirements for Accredited Providers
1732.3	Requirements for Continuing Education Courses
1732.4	Provider Audit Requirements
1732.5	Renewal Requirements for Pharmacist
1744 	- Drug Warnings
1751	Sterile Injectable Compounding Area
1751.01	Facility and Equipment Standards for Sterile Injectable Compounding from Non-
	Sterile Ingredients
1751.02	Policies and Procedures
	 Furnishing to Home Health Agencies and Licensed Hospices
1751.12	Obligations of a Pharmacy Furnishing Portable Containers
1771	Posting of Notice of Suspension
<u>1772</u>	Disciplinary Condition of Suspension
1780	Minimum Standards for Wholesalers
1780.1	Minimum Standards for Veterinary Food-Animal Drug Retailers
1781	Exemption Certificate
1786	- Exemptions
1787 	 Authorization to Distribute Hemodialysis Drugs and Devices
1790	Assembling and Packaging
1791	-Labeling
1792	Receipt for Shipment

HEALTH AND SAFETY CODE

- 11100 Report of Certain Chemical: Chemicals Included; Exclusions; Penalties
- 11100.1 Report of Chemicals Received from Outside State; Penalties
- 11151 Limitation on Filling Prescriptions From Medical Students
- 11158 Prescription Required for Schedule II, III, IV, or V Controlled Substance; Exception for Limited Dispensing, Administration
- 11159 Chart Order Exemption for Patient in County or Licensed Hospital; Maintaining Record for Seven Years

11159.1	Chart Order Exemption for Clinic Patient; Maintaining Record for Seven Years
11159.2	Exception to Triplicate Prescription Requirement
11167	Emergency Dispensing of Schedule II Substance: Circumstances and Requirements
11167.5	Oral or Electronic Prescriptions for Schedule II Controlled Substance for Specified
	Inpatients, Residents, and Home Hospice Patients; Requirements
11171	Prescribing, etc. Controlled Substance Only as Authorized
11172	Antedating or Postdating Prescription Prohibited
11175	Prohibition on Obtaining or Possessing Nonconforming Prescription; Prohibition on
	Obtaining Controlled Substance by Nonconforming Prescription
11180	Prohibition on Controlled Substance Obtained or Possessed by Nonconforming
	Prescription
11200	Restrictions on Dispensing or Refilling; Refill of Schedule II Prescription Barred
11201	Emergency Refill of Schedule III, IV, or V Prescription; Circumstances;
	Requirements
11205	Maintenance and Retention of Records in Separate File
11206	Required Information on Prescription
11209	Delivery and Receiving Requirements for Schedule II, III, and IV Substances;
	Violation
11210	Issuing Prescription: By Whom; For What Purpose; Quantity to Be Prescribed
11250	Authorized Retail Sale by Pharmacists to Physicians, etc.; Required Order Form
11251	Authorized Wholesale Sale by Pharmacists
11252	Preservation of Federally Required Forms
11253	Duration of Retention
11255	Actions Constituting Sale
11256	Required Report of Order By or Sale to Out-of-State Wholesaler or Manufacturer
111225 to	

111655 Adulterated or Misbranded Drugs or Devices

CODE OF FEDERAL REGULATIONS, TITLE 21

1301.13	Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.
1301.14	Filing of application; acceptance for filing; defective applications.
1301.71	-Security requirements generally.
1301.72	Physical security controls for non-practitioners; narcotic treatment programs and
	compounders for narcotic treatment programs; storage areas.
1301.73	Physical security controls for non-practitioners; compounders for narcotic treatment
	programs; manufacturing and compounding areas.
1301.74	Other security controls for non-practitioners; narcotic treatment programs and
	compounders for narcotic treatment programs.
1301.77	Security controls for freight forwarding facilities.
1301.90	Employee screening procedures.
1301.91	Employee responsibility to report drug diversion.
1301.92	Illicit activities by employees.
1302.03	Symbol required; exceptions.
1302.04	Location and size of symbol on label and labeling.
1302.05	Effective dates of labeling requirements.
1302.06	Sealing of controlled substances.
1000 07	

1302.07 Labeling and packaging requirements for imported and exported substances.

- 1304.11 Inventory requirements. 1304.31 Reports from manufacturers importing narcotic raw material.
- 1304.32 Reports of manufacturers importing coca leaves.
- 1304.33 Reports to ARCOS.
- 1305.03 Distributions requiring a Form 222 or a digitally signed electronic order.
- 1305.04 Persons entitled to order Schedule I and II controlled substances.
- 1305.05 Power of attorney.
- 1305.06 Persons entitled to fill orders for Schedule I and II controlled substances.
- 1305.11 Procedure for obtaining DEA Forms 222.
- 1305.12 Procedure for executing DEA Forms 222.
- 1305.14 Procedure for endorsing DEA Forms 222.
- 1305.15 Unaccepted and defective DEA Forms 222.
- 1305.16 Lost and stolen DEA Forms 222.
- 1306.03 Persons entitled to issue prescriptions.
- 1306.05 Manner of issuance of prescriptions.
- 1306.14 Labeling of substances and filling of prescriptions.
- 1306.24 Labeling of substances and filing of prescriptions.
- 1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.
- 1306.26 Dispensing without a prescription.
- 1307.11 Distribution by dispenser to another practitioner or reverse distributor.
- 1307.12 Distribution to supplier or manufacturer.
- 1307.13 Incidental manufacture of controlled substances.
- 1307.21 Procedure for disposing of controlled substances.
- 1700.1 to
- 1707.15 Child-resistant containers.

CATEGORY II

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

Maximum: Revocation

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

- <u>failure(s) to abide by prohibitions on referral rebates or discounts (kickbacks) and/or</u> 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 and/or dangerous devices or controlled substances;
- violation(s) of laws governing dangerous drugs and/or dangerous devices and controlled substances, including smaller cases of diversion or selfadministration;
- unlawful possession(s) of dangerous drugs and/or dangerous devices, controlled substances,
 - hypodermic needles or syringes, or drug paraphernalia;
- <u>smaller scale dispensing or furnishing of dangerous drugs and/or dangerous devices</u> via the internet, without a valid prescription;
- purchasing, trading, selling, or transferring dangerous drugs and/or dangerous 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 and/or dangerous 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.
- repeat or serious violation(s) involving the improper compounding of drug products
- 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.

Violations of the following codes are representative of this category:

BUSINESS AND PROFESSIONS CODE

- 650 Rebates or Discounts for Referral Prohibited
- 650.1 Lease Prohibition Hospitals or Prescribers
- 651 Professional Advertising Requirements

Article 3. Scope of Practice and Exemptions

4051(b) Conduct Authorized by Pharmacist

- 4052 Furnishing to Prescriber; Permissible Procedures by Pharmacist in Health Care Facility or Clinic or for Other Health Care Provider
 4060 Controlled Substance – Prescription Required; Exceptions
 4061 Distribution of Drug as Sample; Written Request Required
 4064 Emergency Refill of Prescription Without Prescriber Authorization
 4067 Internet; Dispensing Dangerous Drugs or Devices without Prescription
 4075 Proof of Identity Required – Oral or Electronic Prescription
- 4078 False or Misleading Label on Prescription

Article 6. General Requirements

4101	Pharmacist in Charge, Exemptee: Termination of Employment; Notification to Board
4104	Licensed Employee, Theft or Impairment: Pharmacy Procedures
4105	Retaining Records of Dangerous Drugs and Devices on Licensed Premises;
	Temporary Removal; Waivers; Access to Electronically Maintained Records

Article 7. Pharmacies

4112	Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining
	Records; Patient Consultation
4113	Pharmacist in Charge: Notification to Board; Responsibilities
4115	Pharmacy Technician: Activities Permitted; Required Supervision; Activities Limited
	to Pharmacist; Registration; Requirements for Registration; Ratios
4115.5	Pharmacy Technician Trainee; Placement; Supervision; Requirements
4116	Security of Dangerous Drugs and Devices in Pharmacy: Pharmacist Responsibility
	for Individuals on Premises; Regulations
4117	Admission to Area Where Narcotics are Stored, etc. – Who May Enter
4120	Nonresident Pharmacy: Registration Required
4125	Pharmacy Quality Assurance Program Required; Records Considered Peer Review
	Documents

Article 9. Hypodermic Needle and Syringes

- 4140 Unlawful Possession
- 4147 Disposal of Needle or Syringe

Article 11. Wholesalers and Manufacturers

- 4161 Nonresident Wholesaler: When License Required; Application
- 4163 Unauthorized Furnishing by Manufacturer or Wholesale
- 4164 Reports Required
- 4169(a)(1) Prohibited Acts

Article 13. Non-Profit of Free Clinics

- 4185 Inspection Permitted
- Article 14. Surgical Clinics
- 4195 Inspection Permitted

Article 19. Disciplinary Proceedings

4301 Unprofessional Conduct - subsections (a)-(h), (j), and (l) - (q)

- 4302 Discipline of Corporate Licensee for Conduct of Officer, Director, Shareholder
- 4303 Nonresident Pharmacy: Grounds for Discipline
- 4304 Out-of-state Distributor: Authority to Discipline
- 4305 Disciplinary Grounds: Failure of Pharmacy, Pharmacist to Notify Board of Termination of Pharmacist in Charge; Continuing to Operate Without Pharmacist
- 4305.5 Disciplinary Grounds: Failure of Other Entity Licensed by Board, of Pharmacist or Exemptee to Notify Board of Termination of Pharmacist in Charge or Exemptee; Continuing to Operate Without Pharmacist or Exemptee
- 4306 Violation of Professional Corporation Act as Unprofessional Conduct
- 4306.5 Misuse of Education, etc. by Pharmacist Outside Course of Practice of Pharmacy as Unprofessional Conduct

Article 20. Prohibitions and Offenses

- 4326 Misdemeanor: Obtaining Needle or Syringe by Fraud, etc.; Unlawful Use of Needle or Syringe Obtained from Another
- 4328 Misdemeanor: Permitting Compounding, Dispensing, or Furnishing by Nonpharmacist
- 4330 Misdemeanor: Non-pharmacist Owner Failing to Place Pharmacist in Charge, Dispensing or Compounding Except by Pharmacist, Interfering with Pharmacist in Charge
- 4331 Misdemeanor: Medical Device Retailer, Wholesaler, Veterinary Food-Animal Drug Retailer Failing to Place Pharmacist or Exemptee in Charge, Permitting Dispensing or Compounding Except by Pharmacist or Exemptee
- 4333 Maintaining Prescriptions, Other Drug Records on Premises, Open to Inspection; Waiver; Willful Failure to Keep or Permit Inspection of Records of Prescriptions, Other Records as Misdemeanor
- 4340 Unlawful Advertising by Nonresident Pharmacy Not Registered with Board

Article 22. Unfair Trade Practices

- 4380 Resale of Preferentially Priced Drugs; Prohibition; Exceptions
- 4382 Board May Audit Sales to Walk-in Customers

CALIFORNIA CODE OF REGULATIONS, TITLE 16

- 1707.1 Duty to Maintain Medication Profiles (Patient Medication Records)
- 1707.2 Notice to Consumers and Duty to Consult
- 1707.3 Duty to Review Drug Therapy and Patient Medication Record Prior to Deliver
- 1709.1 Designation of Pharmacist in Charge
- 1714.1 Pharmacy Operation During Temporary Absence of a Pharmacist
- 1715 Self-Assessment of a Pharmacy by the Pharmacist-in-Charge
- 1715.5 Implementation of Electronic Monitoring of Schedule II Prescriptions
- 1716.1 Compounding Unapproved Drugs for Prescriber Office Use
- 1716.2 Record Requirements-Compounding for Future Furnishing
- 1717.2 Notice of Electronic Prescription Files
- 1717.3 Preprinted, Multiple Checkoff Prescription Blanks
- 1723.1 Confidentiality of Examination Questions
- 1745 Partial Filling of Schedule II Prescriptions
- 1751.10 Furnishing to Parenteral Patient at Home

- 1761(a) Erroneous or Uncertain Prescriptions
- 1764 Unauthorized Disclosure of Prescriptions
- 1765 Commissions, Gratuities, and Rebates
- 1766 False or Misleading Advertising
- 1775.3 Compliance with Orders of Abatement
- 1782 Reporting Sales of Drugs Subject to Abuse
- 1783 Manufacturer or Wholesaler Furnishing Drugs or Devices
- 1793.1 Duties of a Pharmacist
- 1793.2 Duties of a Pharmacy Technician
- 1793.3 Other Non-Licensed Pharmacy Personnel
- 1793.4 Qualifications for Registration as a Pharmacy Technician
- 1793.7 Requirements for Pharmacies Employing Pharmacy Technicians
- 1793.8 Technicians in Hospitals with Clinical Pharmacy Programs

HEALTH AND SAFETY CODE

- 11103 Report of Theft, Loss, or Shipping Discrepancy
- 11150 Persons Authorized to Write or Issue a Prescription
- 11152 Nonconforming Prescriptions Prohibited
- 11154 Prescription, etc. Must Be for Treatment; Knowing Soliciting of Unlawful Prescription, etc.
- 11156 Prescribing, etc. Controlled Substances to Addict Only as Authorized
- 11164 Prescriptions for Schedule II, III, IV and V Controlled Substance: Form and Content; Record of Practitioner Dispensing Schedule II Controlled Substance
- 11165(d) CURES Transmission
- 11166 Time Limit for Filling Schedule II Prescription; Knowingly Filling Mutilated, Forged, or Altered Prescription Prohibited
- 11170 Prohibition on Prescribing, etc. Controlled Substance for Self
- 11179 Retention of Controlled Substance Prescription
- 11207 Only Pharmacist or Intern Authorized to Fill Prescription
- 11209 Delivery and Receiving Requirements for Schedule II, III, and IV Substances; Violation
- 11350 Possession of Specified Controlled Substance
- 11377 Unlawful Possession of Specified Substance

CODE OF FEDERAL REGULATIONS, TITLE 21

- 1304.03 Persons required to keep records and file reports.
- 1304.04 Maintenance of records and inventories.
- 1304.11 Inventory requirements.
- 1304.21 General requirements for continuing records.
- 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers and exporters.
- 1305.07 Special procedures for filling certain orders.
- 1305.13 Procedure for filling DEA Forms 222.
- 1306.04 Purpose of issue of prescription.
- 1306.06 Persons entitled to fill prescriptions.
- 1306.11 Requirement prescription.
- 1306.12 Refilling prescriptions.

1306.13Partial filling of prescriptions.1306.21Requirement of prescription.

1306.22 Refilling of prescriptions.

1306.23 Partial filling of prescriptions.

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 and/or dangerous devices or controlled substances, or abusive use of alcohol, occurred at the licensed premises). All standard terms and conditions shall be included and the disciplinary order 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 and/or dangerous devices or controlled substances, and most criminal convictions involving alcohol, dangerous drugs and/or dangerous devices 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 druas:
- 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 and/or dangerous devices.
- controlled substances, hypodermic needles or syringes, or drug paraphernalia;
- larger scale dispensing or furnishing of dangerous drug(s) and/or dangerous device(s) via the internet, without valid prescription(s);
- purchasing, trading, selling, or transferring adulterated, misbranded, or expired dangerous drug(s) and/or dangerous device(s);
- removal, sale, or disposal of embargoed dangerous drug(s) and/or dangerous device(s):
- failing to maintain record(s) of acquisition and disposition of dangerous drug(s) • and/or dangerous devise(s) or controlled substances
- resale(s) of preferentially prices 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) and/or dangerous 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).
- repeat or serious violation(s) involving the improper compounding of drug products
- 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.

Violations of the following codes are representative of this category:

BUSINESS AND PROFESSIONS CODE

Article 3. Scope of Practice and Exemptions

4051(a) Conduct Limited to Pharmacist

4059 Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions

4059.5 Who May Order Dangerous Drugs or Devices: Exceptions

Article 5. Authority of Inspectors

- 4080 Stock of Dangerous Drugs and Devices Kept Open for Inspection
- 4081 Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
- 4085(a) Unlawful to Remove, Sell, Dispose of Embargoed Dangerous Drug or Dangerous Device

Article 7. Pharmacies

4110 License Required; Temporary Permit Upon Transfer of Ownership 4111 Restrictions on Prescriber Ownership

Article 11. Wholesalers and Manufacturers

4169(a)(2) to 4169(a)(5) Prohibited Acts

Article 15. Veterinary Food-Animal Retailers

4199 Labeling Requirements; Maintaining Prescription Records

Article 19. Disciplinary Proceedings

- 4301 Unprofessional Conduct subsections (i) (k) and (o)
- 4307 Prohibition of Association of Individual with Entity License by Board: Length of Prohibition; Individuals Covered; Imposition of Prohibition Through Administrative Act Proceeding
- 4308 Prohibited Association: Notification of Affected Licensees Known to Board

Article 20. Prohibitions and Offenses

4322	Misdemeanor or Infraction: False Representations to Secure License for Self or
	Others; False Representation of Licensure; Penalties
4323	Misdemeanor: False Representation of Self as Physician, Agent of Physician, etc. to
	Obtain Drug
4324	Felony or Misdemeanor: Forgery of Prescription; Possession of Drugs Obtained
	Through Forged Prescription
4325	Misdemeanor: Manufacture, Possession, etc. of False Prescription Blank
4327	Misdemeanor: Sale, Dispensing, or Compounding While Under the Influence of
	Drugs or Alcoholic Beverages
4329	Misdemeanor: Non-pharmacist Acting as Manager, Compounding, Dispensing or
	Furnishing Drugs
4332	Misdemeanor: Failure or Refusal to Maintain or Produce Required Drug or Device
	Records; Willful Production of False Records
4335	Voided License: Knowing Failure to Arrange for Disposition of Stock as
	Misdemeanor
4336	Felony: Knowing or Willful Use of Minor to Violate Specified Sections of Pharmacy
	Law: Exception for Pharmacist Furnishing Pursuant to a Prescription
Article 22.	Unfair Trade Practices

4380 Resale of Preferentially Priced Drugs: Prohibition; Exceptions

CALIFORNIA CODE OF REGULATIONS, TITLE 16

1718	Current Inventory Defined
1761(b)	Erroneous or Uncertain Prescriptions
1771	Posting of Notice of Suspension
1772	Disciplinary Condition of Suspension
1773	Disciplinary Conditions of Probation of Pharmacist
1774	Disciplinary Conditions of Probation of Permit

HEALTH AND SAFETY CODE

11104	Providing Chemical for Illicit Manufacturing; Evasion of Reporting Requirements;
	Penalties
11105	False Statement in Report
11150	Persons Authorized to Write or Issue a Prescription
11153	Responsibility for Legitimacy of Prescription; Corresponding Responsibility of
	Pharmacist
11153.5	Wholesaler or Manufacturer Furnishing Controlled Substance Other Than for
	Legitimate Medical Purpose; Knowing Violation; Factors in Assessing Legitimacy
11157	No False or Fictitious Prescriptions
11162.5	Counterfeiting or Possession of Counterfeit Triplicate Prescription Blank; Penalty
11167.5	Pharmacy Generated Prescription for Schedule II Controlled Substance in a Skilled
	Nursing Facility
11173	Fraud, Deceit, Misrepresentation or False Statement; False Representation; False

Label

- 11174 Prohibition on Providing False Name or Address in Connection with Prescription, etc.
- 11351 Possession or Purchase for Sale of Specified Controlled Substance
- 11368 Forged or Altered Prescriptions
- 11375 Possession for Sale or Selling Specified Substance
- 11378 Possession for Sale
- 11550 Using or Being Under Influence of Controlled Substance
- 111295 Manufacturing, Selling or Offering for Sale an Adulterated Drug or Device
- 111300 Unlawful to Adulterate a Drug
- 111305 Unlawful to Receive in Commerce an Adulterated Drug
- 111440 Unlawful Manufacturer, selling a misbranded Drug
- 111445 Unlawful for a Person to Misbrand
- 111450 Unlawful to Receive into Commerce a Drug that is Misbranded

CATEGORY IV

Penalty: Revocation

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

- 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 and/or dangerous 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
- -<u>sale</u>
- 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 a pleading requiring a timely notice of defense 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.

Violations of the following codes are representative of this category:

HEALTH AND SAFETY CODE

11352 Importing, Selling, Furnishing Controlled Substance

11353	Adult Inducing Minor to Violate Provisions
11379	Transporting, Importing, Selling Controlled Substance
11380	Adult Using, Soliciting or Intimidating Minor for Violation

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 <u>dangerous drugs and/or</u> <u>dangerous devices or</u> controlled substances and dangerous drugs and/<u>or dangerous</u> devices. <u>Respondent shall further arrange for the transfer of all records of acquisition and disposition</u> <u>of dangerous drugs to premises licensed and approved by the board</u>. 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 (<u>5</u>) 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 <u>as a [insert license type]</u> during the period of suspension. Failure to comply with this 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 on 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 <u>[insert license</u> <u>type]</u> license, a license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for <u>_____years upon on the</u> 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 <u>and approved</u> by the board of all controlled substances and dangerous drugs and/<u>or dangerous</u> devices. <u>Respondent shall</u> <u>further arrange for the transfer of all records of acquisition and disposition of dangerous</u> <u>drugs to premises licensed and approved by the board</u>. 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 <u>[he/she]</u> 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 may only seek a new or reinstated license from the board by way of a new application for licensure. Respondent shall not be eligible to petition for reinstatement of 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 <u>within</u> days of the effective date of this decision.

OPTION 1: (To be included if the respondent is a pharmacy.) 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.

Option 2: Respondent owner stipulates that should <u>he or she [he/she]</u> 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 Reproval

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
- 1 2. Obey All laws
- $2\overline{3}$. Report to the Board
- 3 <u>4</u>. Interview with the Board
- 4 <u>5</u>. Cooperate with Board Staff
- 5 <u>6</u>. Reimbursement of Board Costs
- 6-7. Probation Monitoring Costs
- $7 \overline{8}$. Status of License
- $\frac{1}{9}$. License Surrender While on Probation/Suspension
- 10. Sale or Discontinuance of Business
- 9 <u>11</u>. Notice to Employees
- 10 12. Owners and Officers: Knowledge of the Law
- 13. Premises Open for Business
- 11 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
- 24. Destruction of Dangerous Drugs and/or Dangerous Devices
- 25. No Additional Ownership or Management of Licensed Premises

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.

1 <u>2</u>. 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 contendre 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 <u>dangerous</u> drug, <u>and/or dangerous</u> device or controlled substance.

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

2 <u>3</u>. 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 <u>4</u>. 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 <u>5</u>. 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 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 wish to 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.

Respondent may not apply for any new 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.

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

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 <u>within five (5) days</u>. <u>Respondent shall</u> <u>further arrange for the transfer of all records of acquisition and disposition of dangerous</u> <u>drugs and/or devices to premises licensed and approved by the board</u>.

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 <u>licensure</u> <u>license</u> 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, or should practice at that location be assumed by 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 with 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.

<u>11</u><u>14</u>. Posted Notice of Probation

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

19. 18. 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 <u>within two (2) days of receipt thereof from the board or its designee</u>. The suspension notice shall remain posted during the entire period of suspension ordered by this decision. <u>Failure to timely post such notice</u>, 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.

14. <u>19.</u> Community Services Program

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. 20. 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. 21. 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. 22. 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 <u>or its designee</u> 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 <u>or its designee</u>. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period <u>as determined by the board or its designee</u>. Failure to timely prepare or submit such reports shall be considered a violation of probation.

18. 23. 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 <u>DEA Form</u> 222 forms, for controlled substances.

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

Respondent shall, by the effective date of this decision, arrange for the destruction of all dangerous drugs and/or dangerous devices or controlled substances and dangerous drugs and devices by a waste management company or reverse distributor. All products must be inventoried with an exact count prior to destruction. Respondent shall provide written proof of such destruction within five days of disposition.

Option: [To be used when the integrity, quality and strength of compounded drug products is at issue]

Respondent shall, by the effective date of this decision, arrange for the destruction of all compounded drug products and the components used to compound drug products by a waste management company. Respondent shall provide written proof of such destruction within five days of disposition. The Board or its designee shall have the right to retain a sample(s) of any and all compounded drug products or components used to compound drug products by Respondent.

25. No Additional Ownership or Management of Licensed Premises

Respondent shall not acquire any additional ownership, legal or beneficial interest in, nor serve as a manager, administrator, member, officer, director, associate, partner or any business, firm, partnership, or corporation currently or hereinafter licensed by the board except as approved by the board or its designee. Violations of this restriction shall be considered a violation of probation.

<u>6/2007 7/2015</u>

Attachment 2

Brief Description of All Suggested Changes

Title Page

The board proposes to update the revision date on the title page from 10/2007 to 7/2015. The board proposes to update the name of the board's president to Amy Gutierrez.

Table of Contents

The board proposes to update the Table of Contents to reflect the consolidation of the individual license types (pharmacist/intern pharmacist, advanced practice pharmacist, pharmacy technician, designated representative and designated representative-3PL) into one section, "Individual Licenses". This change is reflected by showing the elimination of the pharmacy technician and designated representative specific portions as well as replacing reference to "Pharmacist/Intern Pharmacist" with "Individual Licenses."

These changes are necessary to reflect the consolidation of the individual license types to standardize the language as well as provide the terms and conditions of probation that can be used for individuals whose license is being disciplined by the board. This consolidation will streamline the guidelines and make them easier to use by its intended users: board members, the board's executive officer, licensees, deputy attorneys general, attorneys and administrative law judges.

Introduction (Page 1)

Changes are proposed to allow for easier reading and consistency as well as to update the revision date. Changes would include: changing the words relating to the exercise of clinical judgment: "for the citizens of California" to "for their patients" as well as providing more description on the vital roles and responsibilities board licensees have. Also the board proposes to add "Category IV" violations to its current requirement for memos transmitted to the board advocating a stipulation.

Factors to be Considered in Determining Penalties (Page 3)

Changes are proposed to direct the users of the guidelines to consider the license history of other licenses held by the respondent as well as the Uniform Standards Regarding Substance-Abusing Healing Arts Licensees.

Mitigating Evidence (Pages 4-5)

Changes are proposed to this section to further define and clarify examples of appropriate evidence a respondent may submit to include personal or professional references that have knowledge of the respondent's character and rehabilitation, as well as conduct which the respondent is accused and other pertinent facts that would enable the board to decide a case. The proposed change also details the method by which this information must be provided to the board.

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

The board is proposing to change the title of this section of the guidelines to reflect the consolidation of each of the individual license types into one standardized section as well as to reference the Uniform Standards Regarding Substance-Abusing Licensees.

Categories of Violations and Recommended Penalties

The proposed changes are necessary to facilitate consolidation of the individual license types as well as to better define the grounds for discipline as well as to explain the structure under each category as well as how the board should use the information provided. This will assist users in following the format of the Disciplinary Guidelines and serve as a tool to assist in setting the penalties imposed as part of a disciplinary action.

Category I

The majority of the changes reflected in this section are to remove the titles associated with each section of law. (These titles were designed to allow the reader brief insight into the requirements detailed in the specific sections, however the titles have no force of law.). In place of this list of codes, the board is proposing incorporation of summaries of each of the statutes into narrative language that better describes the types of violations that would constitute such Discipline and includes violations for improper compounding of drug products as well as violations resulting from the misuse of education. These changes are necessary to provide for a more useful application. The board notes that the current list of statutes provided is difficult for someone to use that is not familiar with Pharmacy Law and is provided in an overwhelming fashion that defeats the purpose of providing users with a convenient way to determining the board's recommended penalties. The proposed changes will more easily aid the user in the use of the Disciplinary Guidelines.

The minimum penalty for this category of violation is changing to two years' probation.

The description for category one reflects that such violations are less serious than Categories II-IV violations.

Category II

The majority of the changes reflected in this section are to remove the titles associated with each section of law. (These titles were designed to allow the reader brief insight into the requirements detailed in the specific sections, however the titles have no force of law.). In place of this list of codes, the board is proposing incorporation of summaries of each of the statutes into narrative language that better describes the nature of violations that would constitute such discipline and includes violations for improper compounding of drug products as well as violations resulting from the misuse of education.

These changes are necessary to provide for a more useful application. The board notes that the current list of statutes provided is difficult for someone to use that is not familiar with Pharmacy Law and is provided in an overwhelming fashion defeats the intended purpose, which is to provide users with a convenient way of determining the board's recommended penalties. The proposed changes will more easily aid the user in the use of the Disciplinary Guidelines.

Category III

The majority of the changes reflected in this section are to remove the titles associated with each section of law. (These titles were designed to allow the reader brief insight into the requirements detailed in the specific sections, however the titles have no force of law.). In place of this list of codes, the board is proposing incorporation of summaries of each of the statutes into narrative language that better describes the nature of violations that would constitute such discipline including self-administration of controlled substances that could lead to a potential infection control risk. These changes are necessary to provide for a more useful application. The board notes that the current list of statutes provided is difficult for someone to use that is not familiar with Pharmacy Law and is provided in an overwhelming fashion that defeats the intended purpose, which is to provide users with a convenient way of determining the board's recommended penalties. The proposed changes will more easily aid the user in the use of the Disciplinary Guidelines.

Category IV

The majority of the changes reflected in this section are to remove the titles associated with each section of law. (These titles were designed to allow the reader brief insight into the requirements detailed in the specific sections, however the titles have no force of law.). In place of this list of codes, the board is proposing incorporation of summaries of each of the statutes into narrative language that better describes the nature of violations that would constitute such discipline including self-administration of controlled substances that could lead to a potential infection control risk. These changes are necessary to provide for a more useful application. The board notes that the current list of statutes provided is difficult for someone to use that is not familiar with pharmacy law and is provided in an overwhelming fashion that defeats the intended purposes, which is to provide users with a convenient way of determining the board's recommended penalties. The proposed changes will more easily aid the user in the use of the Disciplinary Guidelines.

Model Disciplinary Language – Individual Licensees [Pharmacist, Advanced Practice Pharmacist, Intern Pharmacist, Pharmacy Technician, Designated Representative, Designated Representative-3PL] (Pages 22 -25)

The board is proposing to change the title of this section of the guidelines to reflect the consolidation of each of the individual license types into one standardized section as well as add in two additional license types (Advanced Practice Pharmacist and Designated Representative-3PL).

Revocation

This section is being changed to facilitate consolidation of the individual license types and to clarify that the respondent must relinquish any indicia of licensure. The board is replacing "his or her" with [his/her] to allow for the decision to reflect the gender of the respondent. Further, the board is making the current proposed option of a payment plan the standard language. The current payment in full within 15 days requirement is being changed to optional language. This change is necessary to more accurately reflect the common practice of the board to provide more flexibility and options when requiring cost recovery from a respondent whose license has been revoked.

Suspension

This section is being changed to facilitate consolidation of the individual license types as well as to clarify what actions are prohibited during a period of any suspension.

Issuance of Probationary License

The changes in this section are to facilitate consolidation of the individual license types. Further a new option is being proposed that would provide model language for the issuance of a pharmacist intern license. This model language is necessary to ensure the respondent is advised of the effect of potential discipline of the intern pharmacist license on any subsequent application for licensure as a pharmacist and ensure the board has the ability to carry over the discipline imposed on the intern pharmacist license to the pharmacist license should one be issued during the period of probation. (Pharmacy law recognizes the necessity of an intern license for purposes of gaining the experience necessary to become a pharmacist. In practice, pharmacist intern licenses are non-renewable licenses to reflect the progress an person must make from an intern to a licensed pharmacist. As such a provision is necessary to allow for this progression when appropriate.)

<u>Surrender</u>

This section is being changed to facilitate consolidation of the individual license types and to clarify that the respondent must relinquish any indicia of licensure. The board is replacing "his or her" with [his/her] to allow for the decision to reflect the gender of the respondent. Further this section is being

modified to clarify that any licensing exams and education or experience requirements necessary to fulfill the requirements for a license must be satisfied upon reapplication.

License Reinstatement Order with Conditions Prior to Issuing License This language is new and is necessary to provide model language as guidance to those individuals (board members and administrative law judges) responsible for crafting reinstatement orders. The language proposed is consistent with current practice and provides specificity to the requirements for reinstatement of a license, including conditions precedent for passage of an exam as specified as well as appropriate fees. Further, optional language is provided to specify cost recovery owed to the board. This term is appropriate for inclusion if the respondent is a pharmacist or pharmacy technician.

License Reinstatement

This language is new and is necessary to provide model language as guidance to those individuals (board members and administrative law judges) responsible for crafting reinstatement orders. The language proposed is consistent with current practice and includes

Adoption of Stipulation

The board is proposing removal of this language as it is in conflict with the standard language used by the Office of the Attorney General who is responsible for drafting stipulated settlements for the board.

Standard Conditions Listing (Page 26)

The board is proposing changes to titles and or the renumbering of terms to reflect changes and consolidation of terms as well as to reflect new terms that will be incorporated.

Optional Conditions Listing (Page 26)

The board is proposing changes to titles and or the renumbering of terms to reflect changes and consolidation of terms as well as to reflect new terms that will be incorporated.

Standard Conditions: To Be Included in All Probations (Page 28 – 34)

The board is proposed the following changes:

- Cooperate with board Staff: Proposed changes are to clarify what activities are encompassed within the term as well as specify that such cooperation must occur timely.
- Continuing Education: Specifies that this term applies to pharmacist respondents only.
- Reporting of Employment and Notice to Employers: The proposed change in the title is more reflective of the provisions contained within the term. The proposed changes will require the respondent to notify the board in writing of employment information as well as changes in such employment and specifies how such reporting must be made to the board. This change is necessary to

provide the board with readily available information on employment to allow for comprehensive probation monitoring, including at a respondent's worksite. Further, the proposed changes clarify who the respondent must notify of the terms and conditions of probation imposed as well as the responsibility of the probationer to ensure that appropriate documentation is submitted to the board confirming compliance with this requirement. This term is also being changed to allow for the consolidation of each of the individual license types.

- Notification of Change(s) in Employment, Name, Address(es) or Phone Number(s): This term is being renamed to better reflect the requirements of the term. Also, this term is being renumbered to ensure better overall flow of the guidelines.
- Restrictions on Supervision and Oversight of Licensed Facilities: This term is being renamed to better reflect the requirements of the term and to specify that it is appropriate only for pharmacist and designated representative licensees. Further this term provides for the consolidation of other existing terms - - No Supervision of Ancillary Personnel and Consultant for Owner or Pharmacist-in-Charge. In the new format, these proposed changes to the term provide optional language that existed in these other terms of probation. This term is also being changed to facilitate consolidation of the probationary terms for all of the individual license types. This term also sets forth the requirement that approval to work as a pharmacist-in-charge, designated representative-in-charge, responsible manager or other compliance supervisor can only be done upon approval by the board and that such approval is site specific.
- Reimbursement of Board Costs: This term is being renumbered. Also, a new option is being created that will allow a respondent to submit payments to the board pursuant to an approved plan, and would specify that payment in full must be completed at least one year prior to the end of probation. This option allows the board greater flexibility to address a respondent's financial concerns that may arise. Further, the proposed change removes the language stating that the filing of bankruptcy does not relieve the respondent of the requirement to pay the board. This change is necessary to recognize that the board cannot determine what debt is released during the filing of bankruptcy.
- Probation Monitoring Costs: This term is being renumbered.
- Status of License: This term is being renumbered and modified to facilitate consolidation of the probationary terms for all of the individual license types.
- License Surrender While of Probation: This term is being renumbered and modified to facilitate consolidation of the probationary terms for all of the individual license types.
- Certification Prior to Resuming Work: For purposes of consolidation, this term is being moved. Further, the term now reflects that it is appropriate only for pharmacy technician licensees.
- Notification of Departure: For purposes of consolidation, this term is being moved. Further, this requirement will now apply to all individual licensees, not just pharmacy technicians and designated representatives. This term is necessary to apply to all individual licensees to ensure the board remains apprised of a respondent's location and availability for probation monitoring purposes.

- License Practice Requirement Tolling: This term is being renumbered and renamed to better reflect the provisions contained therein. Proposed changes are necessary to facilitate consolidation of the individual license types and well as provide more clarity on what information the board requires to confirm compliance with this provision. Additionally, the optional language is being changed to allow the board greater flexibility in meeting the employment needs of a respondent while balancing the board's probation monitoring needs to ensure that necessary rehabilitation occurs. A new option is also created specific for intern pharmacists to reflect the experiential requirements of pharmacy education.
- Violation of Probation: This term is being renumbered and the provision allowing for automatic revocation is being removed.
- Completion of Probation: This term is being renumbered.

Optional Conditions of Probation (Page 34 – 58)

The board is proposed the following changes:

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

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

Further, in consideration of the SACC's uniform standards, option 1 is being added to include that the respondent is suspended from practice until specified conditions are met including:

Completion of the evaluation,

Submission of the evaluator's report, demonstrating that the respondent is safe to return to practice,

> The board has determined that respondent is safe to return to practice and under what conditions.

> Respondent received written notice that practice may resume.

This optional term also sets forth the that the licensee would be required to cause the evaluator to submit to the Board a written clinical diagnostic evaluation report within 10 days from the date the evaluation was completed, unless an extension, not to exceed 30 days, is granted to the evaluator by the Board. Suspension language is also being provided to advise the respondent of the activity that is prohibited during any such suspension.

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

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

- Psychotherapy: This term is being renumbered and the guidance provided to the guideline users is being updated to clarify the conditions when inclusion of this term is appropriate. The suspension language is being modified to clarify those activities that are prohibited during any such suspension.
- Medical Evaluation: This term is being renumbered and modified to facilitate consolidation of the probationary terms for each of the individual license types. The suspension language is being modified to clarify those activities that are prohibited during any such suspension. The same types of changes are being made to the two options provided in this term.
- Pharmacists Recovery Program (PRP): The guidance provided to the users of these guidelines is being updated to clarify the conditions when inclusion of this term is appropriate. This term is also being modified to clarify what

actions a respondent must take to comply with the term as well as the timeline for completion. (Currently the board has received complaints that this term lacks specificity and has caused confusion for licensees on the board's expectations for compliance.) The term is also clarifying that the respondent must comply with the treatment contracts established by the PRP and that failure to comply will result in the automatic suspension of practice by the respondent. The suspension language is being modified to clarify those activities that are prohibited during any such suspension. The option language is being modified to clarify the intent of the option, which is to allow the PRP the ability to monitor a respondent under specified conditions prior to the respondent successfully completing the PRP.

• Drug and Alcohol Testing: This term is being renumbered and renamed to better reflect the scope of the term and the guidance provided to the users of these guidelines is being updated to clarify the conditions when inclusion of this term is appropriate.

The Board proposes amendments in consideration of the SACC's uniform standards. The proposed amendments specify that the licensee is required to submit to and pay for any random and directed biological fluid or hair sample, breath alcohol or any other mode of testing required by the Board. Respondent is required to make daily contact as directed by the Board to determine if he or she must submit to drug testing. The licensee would be required to have the biological test performed on the same day that he or she is notified that a test is required. If a licensee tests positive for a banned substance, the licensee would be required to be suspended from practice, and may not practice unless and until notified by the Board. The proposed amendments specify that all alternative drug testing sites due to vacation or travel outside of California must be approved by the Board prior to the vacation or travel. The suspension language has also been changed to clarify those activities that are prohibited during any such suspension.

- Abstain from Drugs and Alcohol: This term is being renumbered and portions rewritten to clarify exceptions to the prohibition. This term also explicitly states that the respondent must also abstain from use of illicit drugs.
- Prescription Coordination and Monitoring of Prescription Use: The guidance provided to the users of these guidelines is being updated to clarify the conditions when inclusion of this term is appropriate. This term is also being modified to allow for consolidation of the probationary terms for each of the individual license types and to clarify that the board may identify a designee to perform board functions. The suspension language has been changed to clarify those activities that are prohibited during any such suspension.
- Community Service. This term is being renumbered and modified to facilitate consolidation of the probationary terms for each of the individual license types. In addition, the term specifies that proof of completion must be provided and clarifies that the board may allow a designee to perform board functions.
- Restitution: This term is being renumbered.
- Remedial Education: This term is being renumbered and to clarify that approval of the coursework is required. The phrase "his or her" is being

replaced with [his/her] to allow the decision to reflect the gender of the respondent.

- Pharmacy Self-Assessment Mechanism: This term is being removed as it is no longer provided by the National Association of Boards of Pharmacy.
- Intern Pharmacist Experience: This term is being renumbered and a notation is being added to indicate that the term is only appropriate for intern pharmacists. In addition, the timeframe to complete the requirement has been extended to allow respondent sufficient time to submit proof to the board.
- Supervised Practice: This term is being renumbered and a notation is being added to indicate this term only applies to pharmacists, pharmacist interns and designated representatives. This term is being recast to better describe the requirements of the term and to provide better guidance to the respondent on the board's expectations. This term defines what constitutes a violation of probation and the suspension language has been changed to clarify those activities that are prohibited during any such suspension.
- No Supervision of Ancillary Personnel: This term is being consolidated into another term, "Restrictions on Supervision and Oversight of Licensed Facilities" and is therefore no longer needed.
- No Ownership or Management of Licensed Premises: The name of this term is being modified to better reflect the context of the restriction. One grammatical change is being made as well.
- Separate File of Controlled Substances: The name of this term is being modified to better reflect the content of the requirement and a conforming change is being made to ensure consistency of the layout of the document.
- Report of Controlled Substances: A conforming change is being made to ensure the consistency of the document. In addition this term is being modified to allow the board greater flexibility in determining the frequency of reports that must be submitted. This term is also clarifying that the board allows the use of a designee to complete functions on its behalf.
- No Access to Controlled Substances: This section is being changed to incorporate all scheduled drugs.
- Criminal Probation/Parole Reports: This term is being modified to replace the phrase "his or her" with [his/her] to allow for the respondent's gender to be accurately reflected in the decision.
- Consultant for Owner or Pharmacist-in-Charge: This term is being consolidated into another term, "Restrictions on Supervision and Oversight of Licensed Facilities" and is therefore no longer required.
- Tolling of Suspension: This term is being removed as its provisions will be contained in term 15.
- Surrender of DEA Permit: This term is being renumbered and a notation is being added to clarify that this term should only be used for pharmacists, advanced practice pharmacists and pharmacist interns. This term is being modified to replace the phrase "his or her" with [his/her] to allow for the respondent's gender to be accurately reflected in the decision. In addition, this term clarifies what acts are prohibited under this term and the two optional terms are being numbered.
- Ethics Course: This term is being renumbered and a notation is being made to clarify that this term should only be used for pharmacists, advanced

practice pharmacists and pharmacist interns. In addition, this term is being modified to accurately reflect the course requirements as detailed in Title 16, California Code of Regulations Section 1773.5 and specifies that proof of enrollment and completion must be provided to the board. The term also specifies that failure to provide such proof will be considered a violation of probation.

• Facilitated Group/Recovery and/or Support Meetings:

The Board proposes the addition of this additional probation condition in consideration of the SACC's uniform standards. Within thirty (30) days from the effective date of the decision, a licensee would be required to submit to the Board or its designee for prior approval the name of one or more meeting facilitators. The licensee would be required to submit verified documentation of attendance with each quarterly report. The licensee would be required to continue attendance in such a group for the duration of probation unless notified by the Board that attendance is no longer required.

- Attend Substance Abuse Recovery Relapse Prevention and Support Groups. This term is not new, but is being moved from a previous section of the guidelines and could now apply to any individual license.
- Work Site Monitor: This term is not new, but is being moved from a previous section of the guidelines and could now apply to any individual license. In addition guidance is being provided to users of the guidelines for when inclusion of this term is appropriate.

In addition, this term is being modified in consideration of the SACC's uniform standards. This term requires a licensee to complete required consent forms and sign an agreement with the worksite monitor and the Board regarding the licensee's and the monitor's requirements and reporting responsibilities. Additionally, the proposed amendments require the monitor to sign an affirmation that he or she has reviewed the terms and conditions of the licensee's probationary order and agrees to monitor the licensee as set forth by the Board. The proposed amendments specify that the monitor is required to have face-to-face contact with the licensee in the work environment on a frequent basis as determined by the Board, but at least once per week. The monitor is required to interview other staff in the office regarding the licensee's behavior, if applicable. The monitor is required to review the licensee's work attendance and behavior. The monitor would be required to orally report any suspected substance abuse to the Board and the licensee's employer within one (1) business day of occurrence. The monitor would be required to submit a written report to the Board within two business days of occurrence. The monitor would be required to complete and submit a written report monthly or as directed by the board. The report would be required to include: the licensee's name; license number; monitor's name and signature; monitor's license number; worksite location(s); dates licensee had face-toface contact with monitor; worksite staff interviewed, if applicable; attendance report; any change in behavior and/or personal habits; any indicators that can lead to suspected substance abuse. This condition would allow the Board to

monitor the competency of Respondent by use of a fellow practitioner. It should be used in those cases involving substance abuse. The required level of monitoring needs to be clearly defined relative to the necessity for the presence of the monitor. Conforming changes are also being made to the optional language for respondents enrolled or required to enroll in the PRP.

Proposed Changes to the Terms of Probation for Premises Licensees (Pharmacy, Wholesaler, Sterile Compounding Pharmacy, Third-Party Logistics Provider, Veterinary Food-Animal Drug Retailer, Hypodermic Needle and Syringe and Clinic) (Page 83)

Many of the changes proposed are to provide clarification and allow for easier reading and consistency.

The introductory paragraph was reworded to clarify that a minimum three years' probation period is appropriate in most cases.

Categories of Violations and Recommended Penalties

The proposed changes would better define the grounds for discipline as well as types of licensees that may be subject to discipline. In addition proposed changes are incorporated to explain the structure under each category as well as how the board should use the information provided. This will assist users in following the format of the Disciplinary Guidelines and serve as a tool to assist in the penalties imposed as part of a disciplinary action.

Category I

The majority of the changes reflected in this section are to remove the titles associated with each section of law. (These titles were designed to allow the reader brief insight into the requirements detailed in the specific sections, however the titles have no force of law.). In place of this list of codes, the board is proposing incorporation of summaries of each of the statutes into narrative language that better describes the nature of violations that would constitute such discipline and includes violations for improper compounding of drug products. These changes are necessary to provide for a more useful application. The board notes that the current list of statutes provided is difficult for someone to use that is not familiar with Pharmacy Law and is provided in an overwhelming fashion that defeats the purpose of providing the users with a convenient way of determining the board's recommended penalties. The proposed changes will more easily aid the user in the use of the Disciplinary Guidelines.

The minimum penalty for this category of violation is changing to two years' probation.

The description for category one reflects that such violations are less serious

than Categories II-IV violations.

Category II (Page 89-90)

The majority of the changes reflected in this section are to remove the titles associated with each section of law. (These titles were designed to allow the reader brief insight into the requirements detailed in the specific sections, however the titles have no force of law.). In place of this list of codes, the board is proposing incorporation of summaries of each of the statutes into narrative language that better describes the nature of violations that would constitute such discipline and includes violations for improper compounding of drug products. These changes are necessary to provide for a more useful application. The board notes that the current list of statutes provided is difficult for someone to use that is not familiar with Pharmacy Law and is provided in an overwhelming fashion that defeats the purpose of providing the users with a convenient way of determining the board's recommended penalties. The proposed changes will more easily aid the user in the use of the Disciplinary Guidelines.

Category III (Page 94-95)

The majority of the changes reflected in this section are to remove the titles associated with each section of law. (These titles were designed to allow the reader brief insight into the requirements detailed in the specific sections, however the titles have no force of law.). In place of this list of codes, the board is proposing incorporation of summaries of each of the statutes into narrative language that better describes the nature of violations that would constitute such discipline and includes violations for improper compounding of drug products. These changes are necessary to provide for a more useful application. The board notes that the current list of statutes provided is difficult for someone to use that is not familiar with Pharmacy Law and is provided in an overwhelming fashion that defeats the purpose of providing the users with a convenient way of determining the board's recommended penalties. The proposed changes will more easily aid the user in the use of the Disciplinary Guidelines.

Category IV (Page 97)

The majority of the changes reflected in this section are to remove the titles associated with each section of law. (These titles were designed to allow the reader brief insight into the requirements detailed in the specific sections, however the titles have no force of law.). In place of this list of codes, the board is proposing incorporation of summaries of each of the statutes into narrative language that better describes the nature of violations that would constitute such discipline. These changes are necessary to provide for a more useful application. The board notes that the current list of statutes provided is difficult for someone to use that is not familiar with Pharmacy Law and is provided in an overwhelming fashion that defeats the purpose of providing users with a convenient way of determining the board's recommended penalties. The proposed changes will more easily aid the user in the use of the Disciplinary Guidelines.

Model Disciplinary Language – Premises Licensees (Pages 98-100)

The board is proposed the following changes:

Revocation

This section is being modified to remove the word "owner." A definition of respondent is being added in a separate section to specify the intended licensee. As such this word would no longer be needed. Further the term is being rewritten to clarify that the premises is responsible for arranging the destruction, transfer, sale or storage of all dangerous drugs or devices. In addition, this term specifies that any transfer of records shall be to a premises licensed and approved by the board.

Suspension

This section is being modified to allow for the selection of the appropriate license type.

Issuance of Probationary License

This term is being modified to allow for the selection of the appropriate license type.

Surrender

This section is being modified to remove the word "owner. In addition the phrase "he or she" is being replaced to allow for an accurate reflection of the gender of the owner in the decision. In addition, this term specifies that any transfer of records shall be to a premises licensed and approved by the board.

Option 1 is being added for pharmacy respondents to ensure the continuity of patient care.

Adoption of Stipulation

The board is proposing removal of this language as it is in conflict the standard language used by the Office of the Attorney General who is responsible for drafting stipulated settlements for the board.

Standard Conditions Listing (Page 101)

The board is proposing to change titles or numbering to reflect changes and consolidation of terms as well as to reflect new terms that will be incorporated.

Optional Conditions Listing (Page 101)

The board is proposing changes to titles or numbering to reflect changes and consolidation of terms as well as to reflect new terms that will be incorporated. New terms include a requirement to destroy dangerous drugs and/or dangerous devices

as well as to establish an ownership prohibition.

Standard Conditions: To Be Included in All Probations (Pages 101-105)

The board is proposed the following changes:

- Definition: Respondent: This is a new term being incorporated to provide a definition of a respondent as it relates to a business license. This term will provide clarity to users of the guidelines and takes into consideration the various types of business ownerships structures that are authorized to seek and obtain licensure from the board.
- Obey All Laws: This term is being renumbered and is being modified to remove the word "owner" as a definition of respondent is being added in a separate term to specify the intended licensee. As such this word would not be needed. In addition the word "dangerous" is being added to clarify the reference to the term drug consistent with Business and Professions Code section 4022.
- Report to the Board: This term is being renumbered and is being modified to remove the word "owner" as a definition of respondent is being added in a separate term.
- Interview with the Board: This term is being renumbered and is being modified to remove the word "owner" as a definition of respondent is being added in a separate term.
- Cooperate with Board Staff: This term is being renumbered and modified to clarify what activities are required in cooperation with the board to ensure the respondent has a clear understanding of the board's expectations with respect to this term.
- Reimbursement of Board Costs: This term is being renumbered and is being modified to remove the word "owner" as a definition of respondent is being added in a separate term. Also, a new option is being created that will allow a respondent to submit payments to the board pursuant to an approved plan, and would specified that payment in full must be completed at least one year prior to the end of probation. This option allows the board greater flexibility to addressing a respondent's financial concerns that may arise.
- Probation Monitoring Costs: This term is being renumbered and is being modified to remove the word "owner" as a definition of respondent is being added in a separate term.
- Status of License: This term is being renumbered and is being modified to remove the word "owner" as a definition of respondent is being added in a separate term. Further a provision that previously specified that the board would retain jurisdiction is being removed as it is no longer needed. Elements of that provision are incorporated elsewhere in these guidelines.
- License Surrender While on Probation: This term is being renumbered and is being modified to remove the word "owner" as a definition of respondent is being added in a separate term.

This term will specify that respondent cannot apply for a new license for a period of three years from the effective date of the surrender as well as establish a requirement that any costs owned will be reimbursed prior to acceptance of the surrender.

In addition, additions will provide guidance to the user of these guidelines on when inclusion of the option provided is appropriate and a timeframe for compliance with the option is also established. This option will also specify that the transfer of records must be to a premises licensed and approved by the board.

- Sale or Discontinuance of Business: This is a new term that specifies that the board, in its sole discretion, will determine if it retains jurisdiction over a licensed location that has either changed location or ownership (full or partial) irrespective if a new license number is issued. If the board makes such a determination, the jurisdiction shall be carried over to the new location or license number and the terms and conditions of probation will carry over for the remainder of the probation period. This proposed change was previously contained in a different term (License Surrender While on Probation). This provision allows the board to accommodate a change in ownership or location, etc., without incurring additional costs.
- Notice to Employees: This term is being renumbered and is being modified to remove the word "owner" as a definition of respondent is being added in a separate term to provide clarity as such this word is not needed.
- Owners and Officers: Knowledge of the Law: This term is being renumbered.
- Premises Open For Business: This is a new term that requires a business to remain open for a specified period of time. The language allows flexibility to the board in determining the minimum number of hours per calendar month the business must be open and sets forth the reporting requirements for this term. This term is necessary to ensure the board has sufficient opportunity to perform its monitoring functions consistent with the board's consumer protection mandate.
- Posted Notice of Probation: This term is being renumbered and is being modified to remove the word "owner" as a definition of respondent is being added in a separate definitional term. In addition, this term now provides for the timeframe for compliance with the posting requirements. Inclusion of this information provides the respondent with notice of the board's expectation of compliance with this term.
- Violation of Probation: This term is being renumbered and is being modified to remove the word "owner" as a definition of respondent is being added in a separate definitional term. In addition the provision allowing for the automatic revocation of a license for violations of probation is being removed as it is no longer relevant since automatic termination provisions are no longer used in the guidelines.
- Completion of Probation: This term is being renumbered.

Optional Conditions of Probation (Pages 106-107)

The board is proposed the following changes:

• Suspension: Although the board routinely includes suspension as part of the discipline imposed, it currently does not have a separate optional term of

probation. This proposed change will incorporate the board's current practice of suspending a respondent as part of the penalty imposed.

- Community Service: This term is being renumbered and is being modified to remove the word "owner" as a definition of respondent is being added in a separate term.
- Restitution: This term is being renumbered and is being modified to remove the word "owner" as a definition of respondent is being added in a separate term.
- Separate File of Records: The name of this term is being modified to better reflect the content of the requirement and a conforming change is being made to ensure consistency of the layout of the document. This term is being renumbered and is being modified to remove the word "owner" as a definition of respondent is being added in a separate term.
- Report of Controlled Substances: This term is being modified to allow the board greater flexibility in determining the frequency of reports that are required to be submitted. This term is also clarifying that the board allows the use of a designee to complete functions on its behalf. In addition, this term is being renumbered and is being modified to remove the word "owner" as a definition of respondent is being added in a separate term.
- Surrender of DEA Permit: This term is being renumbered and the word "pharmacy" is being removed as an inclusive definition of respondent is being added in a separate term.
- Posted Notice of Suspension: This term is being renumbered and the word "owner" is being removed. An inclusive definition of respondent is being added in a separate term, so the word is no longer needed. In addition, the board specifies the timeframe for posting the notice to provide the respondent with clear direction on the board's expectation for compliance with this term. This term would also specify that failure to comply with this requirement will be considered a violation of probation.
- Destruction of Dangerous Drugs and/or Dangerous Devices: This is a new term to be used with the violations included misbranded or adulterated drugs. This term establishes a requirement for the respondent to arrange for the destruction of such drugs and/or devices as specified and requires the respondent to provide written proof of the destruction.

In addition, this term establishes an option for the destruction of drugs also when the integrity, quality and strength of a compounded drug is at issue.

• No Additional Ownership or Management of Licensed Premises: This is a new term to prohibit the respondent for acquiring additional ownership, legal or beneficial interest in another licensed premises as specified.

Conforming Changes

To ensured consistent use of the phrase "dangerous drugs and/or dangerous devices" is incorporated throughout the document where appropriate.

Attachment 3

California State Board of Pharmacy Specific Language to Amend 16 CCR § 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. 10/2007 7/2015), 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.

Note: Authority cited: Sections <u>315</u>, <u>315</u>, <u>315</u>, <u>315</u>, <u>4</u>, <u>4005</u>, Business and Professions Code; and Section <u>11400</u>, Government Code. Reference: Sections <u>315</u>, <u>315</u>, <u>315</u>, <u>315</u>, <u>315</u>, <u>4300</u> and 4301, Business and Professions Code; and Sections <u>11400</u>, 20 and <u>11425</u>, <u>50(e)</u>, Government Code.

Attachment 4

Uniform Standards Regarding Substance-Abusing Healing Arts Licensees

Senate Bill 1441 (Ridley-Thomas)

Implementation by Department of Consumer Affairs, Substance Abuse Coordination Committee



Brian J. Stiger, Director April 2011



Substance Abuse Coordination Committee

Brian Stiger, Chair Director, Department of Consumer Affairs

Elinore F. McCance-Katz, M.D., Ph. D. CA Department of Alcohol & Drug Programs

Janelle Wedge Acupuncture Board

Kim Madsen California Board of Behavioral Sciences

Robert Puleo Board of Chiropractic Examiners

Lori Hubble Dental Hygiene Committee of California

Richard De Cuir Dental Board of California

Linda Whitney Medical Board of California

Heather Martin California Board of Occupational Therapy

Mona Maggio California State Board of Optometry

Teresa Bello-Jones Board of Vocational Nursing and Psychiatric Technicians Donald Krpan, D.O. Osteopathic Medical Board of California

Francine Davies Naturopathic Medicine Committee

Virginia Herold California State Board of Pharmacy

Steve Hartzell Physical Therapy Board of California

Elberta Portman
Physician Assistant Committee

Jim Rathlesberger Board of Podiatric Medicine

Robert Kahane Board of Psychology

Louise Bailey Board of Registered Nursing

Stephanie Nunez Respiratory Care Board of California

Annemarie Del Mugnaio Speech-Language Pathology & Audiology <u>&</u> Hearing Aid Dispenser Board

Susan Geranen Veterinary Medical Board

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#1 SENATE BILL 1441 REQUIREMENT

Specific requirements for a clinical diagnostic evaluation of the licensee, including, but not limited to, required qualifications for the providers evaluating the licensee.

#1 Uniform Standard

If a healing arts board orders a licensee who is either in a diversion program or whose license is on probation due to a substance abuse problem to undergo a clinical diagnosis evaluation, the following applies:

1. The clinical diagnostic evaluation shall be conducted by a licensed practitioner who:

holds a valid, unrestricted license, which includes scope of practice to conduct a clinical diagnostic evaluation;

has three (3) years experience in providing evaluations of health professionals with substance abuse disorders; and,

is approved by the board.

- 2. The clinical diagnostic evaluation shall be conducted in accordance with acceptable professional standards for conducting substance abuse clinical diagnostic evaluations.
- 3. The clinical diagnostic evaluation report shall:

set forth, in the evaluator's opinion, whether the licensee has a substance abuse problem;

set forth, in the evaluator's opinion, whether the licensee is a threat to

himself/herself or others; and,

set forth, in the evaluator's opinion, recommendations for substance abuse treatment, practice restrictions, or other recommendations related to the licensee's rehabilitation and safe practice.

The evaluator shall not have a financial relationship, personal relationship, or business relationship with the licensee within the last five years. The evaluator shall provide an objective, unbiased, and independent evaluation.

If the evaluator determines during the evaluation process that a licensee is a threat to himself/herself or others, the evaluator shall notify the board within 24 hours of such a determination.

For all 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 30 days.

#2 SENATE BILL 1441 REQUIREMENT

Specific requirements for the temporary removal of the licensee from practice, in order to enable the licensee to undergo the clinical diagnostic evaluation described in subdivision (a) and any treatment recommended by the evaluator described in subdivision (a) and approved by the board, and specific criteria that the licensee must meet before being permitted to return to practice on a full-time or part-time basis.

#2 Uniform Standard

The following practice restrictions apply to each licensee who undergoes a clinical diagnostic evaluation:

- 1. The Board shall order the licensee to cease practice during the clinical diagnostic evaluation pending the results of the clinical diagnostic evaluation and review by the diversion program/board staff.
- 2. While awaiting the results of the clinical diagnostic evaluation required in Uniform Standard #1, the licensee shall be randomly drug tested at least two (2) times per week.

After reviewing the results of the clinical diagnostic evaluation, and the criteria below, a diversion or probation manager shall determine, whether or not the licensee is safe to return to either part-time or fulltime practice. However, no licensee shall be returned to practice until he or she has at least 30 days of negative drug tests.

the license type;

the licensee's history;

the documented length of sobriety/time that has elapsed since substance use

the scope and pattern of use;

the treatment history;

the licensee's medical history and current medical condition;

the nature, duration and severity of substance abuse, and

whether the licensee is a threat to himself/herself or the public.

<u>#3 SENATE BILL 1441 REQUIREMENT</u>

Specific requirements that govern the ability of the licensing board to communicate with the licensee's employer about the licensee's status or condition.

#3 Uniform Standard

If the licensee who is either in a board diversion program or whose license is on probation has an employer, the licensee shall provide to the board the names, physical addresses, mailing addresses, and telephone numbers of all employers and supervisors and shall give specific, written consent that the licensee authorizes the board and the employers and supervisors to communicate regarding the licensee's work status, performance, and monitoring.

#4 SENATE BILL 1441 REQUIREMENT

Standards governing all aspects of required testing, including, but not limited to, frequency of testing, randomnicity, method of notice to the licensee, number of hours between the provision of notice and the test, standards for specimen collectors, procedures used by specimen collectors, the permissible locations of testing, whether the collection process must be observed by the collector, backup testing requirements when the licensee is on vacation or otherwise unavailable for local testing, requirements for the laboratory that analyzes the specimens, and the required maximum timeframe from the test to the receipt of the result of the test.

#4 Uniform Standard

The following standards shall govern all aspects of testing required to determine abstention from alcohol and drugs for any person whose license is placed on probation or in a diversion program due to substance use:

TESTING FREQUENCY SCHEDULE

A board may order a licensee to drug test at any time. Additionally, each licensee shall be tested RANDOMLY in accordance with the schedule below:

Level	Segments of Probation/Diversion	Minimum Range of Number of Random Tests
I	Year 1	52-104 per year
*	Year 2+	36-104 per year

*The minimum range of 36-104 tests identified in level II, is for the second year of probation or diversion, and each year thereafter, up to five (5) years. Thereafter, administration of one (1) time per month if there have been no positive drug tests in the previous five (5) consecutive years of probation or diversion.

Nothing precludes a board from increasing the number of random tests for any reason. Any board who finds or has suspicion that a licensee has committed a violation of a board's testing program or who has committed a Major Violation, as identified in Uniform Standard 10, may reestablish the testing cycle by placing that licensee at the beginning of level I, in addition to any other disciplinary action that may be pursued.

EXCEPTIONS TO TESTING FREQUENCY SCHEDULE

I. PREVIOUS TESTING/SOBRIETY

In cases where a board has evidence that a licensee has participated in a treatment or monitoring program requiring random testing, prior to being subject to testing by the board, the board may give consideration to that testing in altering the testing frequency schedule so that it is equivalent to this standard.

II. VIOLATION(S) OUTSIDE OF EMPLOYMENT

An individual whose license is placed on probation for a single conviction or incident or two convictions or incidents, spanning greater than seven years from each other, where those violations did not occur at work or while on the licensee's way to work, where alcohol or drugs were a contributing factor, may bypass level I and participate in level II of the testing frequency schedule.

III. NOT EMPLOYED IN HEALTH CARE FIELD

A board may reduce testing frequency to a minimum of 12 times per year for any person who is not practicing OR working in any health care field. If a reduced testing frequency schedule is established for this reason, and if a licensee wants to return to practice or work in a health care field, the licensee shall notify and secure the approval of the licensee's board. Prior to returning to any health care employment, the licensee shall be subject to level I testing frequency for at least 60 days. At such time the person returns to employment (in a health care field), if the licensee has not previously met the level I frequency standard, the licensee shall be subject to completing a full year at level I of the testing frequency schedule, otherwise level II testing shall be in effect.

IV. TOLLING

A board may postpone all testing for any person whose probation or diversion is placed in a tolling status if the overall length of the probationary or diversion period is also tolled. A licensee shall notify the board upon the licensee's return to California and shall be subject to testing as provided in this standard. If the licensee returns to employment in a health care field, and has not previously met the level I frequency standard, the licensee shall be subject to completing a full year at level I of the testing frequency schedule, otherwise level II testing shall be in effect.

V. SUBSTANCE USE DISORDER NOT DIAGNOSED

In cases where no current substance use disorder diagnosis is made, a lesser period of monitoring and toxicology screening may be adopted by the board, but not to be less than 24 times per year.

OTHER DRUG STANDARDS

Drug testing may be required on any day, including weekends and holidays.

The scheduling of drug tests shall be done on a random basis, preferably by a computer program, so that a licensee can make no reasonable assumption of when he/she will be tested again. Boards should be prepared to report data to support back-to-back testing as well as, numerous different intervals of testing.

Licensees shall be required to make daily contact to determine if drug testing is required.

Licensees shall be drug tested on the date of notification as directed by the board.

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.

Collection of specimens shall be observed.

Prior to vacation or absence, alternative drug testing location(s) must be approved by the board.

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 appropriate board 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.

A board may use other testing methods in place of, or to supplement biological fluid testing, if the alternate testing method is appropriate.

PETITIONS FOR REINSTATEMENT

Nothing herein shall limit a board's authority to reduce or eliminate the standards specified herein pursuant to a petition for reinstatement or reduction of penalty filed pursuant to Government Code section 11522 or statutes applicable to the board that contains different provisions for reinstatement or reduction of penalty.

OUTCOMES AND AMENDMENTS

For purposes of measuring outcomes and effectiveness, each board shall collect and report historical and post implementation data as follows:

Historical Data - Two Years Prior to Implementation of Standard

Each board should collect the following historical data (as available), for a period of two years, prior to implementation of this standard, for each person subject to testing for banned substances, who has 1) tested positive for a banned substance, 2) failed to

appear or call in, for testing on more than three occasions, 3) failed to pay testing costs, or 4) a person who has given a dilute or invalid specimen.

Post Implementation Data- Three Years

Each board should collect the following data annually, for a period of three years, for every probationer and diversion participant subject to testing for banned substances, following the implementation of this standard.

Data Collection

The data to be collected shall be reported to the Department of Consumer Affairs and the Legislature, upon request, and shall include, but may not be limited to:

Probationer/Diversion Participant Unique Identifier License Type Probation/Diversion Effective Date General Range of Testing Frequency by/for Each Probationer/Diversion Participant **Dates Testing Requested Dates Tested** Identify the Entity that Performed Each Test Dates Tested Positive Dates Contractor (if applicable) was informed of Positive Test Dates Board was informed of Positive Test Dates of Questionable Tests (e.g. dilute, high levels) Date Contractor Notified Board of Questionable Test Identify Substances Detected or Questionably Detected Dates Failed to Appear Date Contractor Notified Board of Failed to Appear Dates Failed to Call In for Testing Date Contractor Notified Board of Failed to Call In for Testing Dates Failed to Pay for Testing Date(s) Removed/Suspended from Practice (identify which) Final Outcome and Effective Date (if applicable)

#5 SENATE BILL 1441 REQUIREMENT

Standards governing all aspects of group meeting attendance requirements, including, but not limited to, required qualifications for group meeting facilitators, frequency of required meeting attendance, and methods of documenting and reporting attendance or nonattendance by licensees.

#5 Uniform Standard

If a board requires a licensee to participate in group support meetings, the following shall apply:

When determining the frequency of required group meeting attendance, the board shall give consideration to the following:

the licensee's history;

the documented length of sobriety/time that has elapsed since substance use;

the recommendation of the clinical evaluator;

the scope and pattern of use;

the licensee's treatment history; and,

the nature, duration, and severity of substance abuse.

Group Meeting Facilitator Qualifications and Requirements:

- 1. The meeting facilitator must have a minimum of three (3) years experience in the treatment and rehabilitation of substance abuse, and shall be licensed or certified by the state or other nationally certified organizations.
- 2. The meeting facilitator must not have a financial relationship, personal relationship, or business relationship with the licensee within the last year.
- 3. The group meeting facilitator shall provide to the board a signed document showing the licensee's name, the group name, the date and location of the meeting, the licensee's attendance, and the licensee's level of participation and progress.
- 4. The facilitator shall report any unexcused absence within 24 hours.

<u>#6 SENATE BILL 1441 REQUIREMENT</u>

Standards used in determining whether inpatient, outpatient, or other type of treatment is necessary.

#6 Uniform Standard

In determining whether inpatient, outpatient, or other type of treatment is necessary, the board shall consider the following criteria:

recommendation of the clinical diagnostic evaluation pursuant to Uniform Standard #1;

license type;

licensee's history;

documented length of sobriety/time that has elapsed since substance abuse;

scope and pattern of substance use;

licensee's treatment history;

licensee's medical history and current medical condition;

nature, duration, and severity of substance abuse, and

threat to himself/herself or the public.

#7 SENATE BILL 1441 REQUIREMENT

Worksite monitoring requirements and standards, including, but not limited to, required qualifications of worksite monitors, required methods of monitoring by worksite monitors, and required reporting by worksite monitors.

<u>#7 Uniform Standard</u>

A board may require the use of worksite monitors. If a board determines that a worksite monitor is necessary for a particular licensee, the worksite monitor shall meet the following requirements to be considered for approval by the board.

- The worksite monitor shall not have financial, personal, or familial relationship with the licensee, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the board. If it is impractical for anyone but the licensee's employer to serve as the worksite monitor, this requirement may be waived by the board; however, under no circumstances shall a licensee's worksite monitor be an employee of the licensee.
- 2. The worksite monitor's license scope of practice shall include the scope of practice of the licensee that is being monitored, be another health care professional if no monitor with like practice is available, or, as approved by the board, be a person in a position of authority who is capable of monitoring the licensee at work.
- 3. If the worksite 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.
- 4. The worksite monitor shall sign an affirmation that he or she has reviewed the terms and conditions of the licensee's disciplinary order and/or contract and agrees to monitor the licensee as set forth by the board.
- 5. The worksite monitor must adhere to the following required methods of monitoring the licensee:
 - a) Have face-to-face contact with the licensee in the work environment on a frequent basis as determined by the board, at least once per week.
 - b) Interview other staff in the office regarding the licensee's behavior, if applicable.
 - c) Review the licensee's work attendance.

UNIFORM STANDARDS

Reporting by the worksite monitor to the board shall be as follows:

- Any suspected substance abuse must be verbally reported to the board and the licensee's employer within one (1) business day of occurrence. If occurrence is not during the board's normal business hours the verbal report must be within one (1) hour of the next business day. A written report shall be submitted to the board within 48 hours of occurrence.
- 2. The worksite monitor shall complete and submit a written report monthly or as directed by the board. The report shall include:

the licensee's name;

license number;

worksite monitor's name and signature;

worksite monitor's license number;

worksite location(s);

dates licensee had face-to-face contact with monitor;

staff interviewed, if applicable;

attendance report;

any change in behavior and/or personal habits;

any indicators that can lead to suspected substance abuse.

The licensee shall complete the required consent forms and sign an agreement with the worksite monitor and the board to allow the board to communicate with the worksite monitor.

<u>#8 SENATE BILL 1441 REQUIREMENT</u>

Procedures to be followed when a licensee tests positive for a banned substance.

#8 Uniform Standard

When a licensee tests positive for a banned substance:

- 1. The board shall order the licensee to cease practice;
- 2. The board shall contact the licensee and instruct the licensee to leave work; and
- 3. The board shall notify the licensee's employer, if any, and worksite monitor, if any, that the licensee may not work.

Thereafter, the board should determine whether the positive drug test is in fact evidence of prohibited use. If so, proceed to Standard #9. If not, the board shall immediately lift the cease practice order.

In determining whether the positive test is evidence of prohibited use, the board should, as applicable:

- 1. Consult the specimen collector and the laboratory;
- 2. Communicate with the licensee and/or any physician who is treating the licensee; and
- 3. Communicate with any treatment provider, including group facilitator/s.

#9 SENATE BILL 1441 REQUIREMENT

Procedures to be followed when a licensee is confirmed to have ingested a banned substance.

#9 Uniform Standard

When a board confirms that a positive drug test is evidence of use of a prohibited substance, the licensee has committed a major violation, as defined in Uniform Standard #10 and the board shall impose the consequences set forth in Uniform Standard #10.

#10 SENATE BILL 1441 REQUIREMENT

Specific consequences for major and minor violations. In particular, the committee shall consider the use of a "deferred prosecution" stipulation described in Section 1000 of the Penal Code, in which the licensee admits to self-abuse of drugs or alcohol and surrenders his or her license. That agreement is deferred by the agency until or unless licensee commits a major violation, in which case it is revived and license is surrendered.

<u>#10 Uniform Standard</u>

Major Violations include, but are not limited to:

- 1. Failure to complete a board-ordered program;
- 2. Failure to undergo a required clinical diagnostic evaluation;
- 3. Multiple minor violations;
- 4. Treating patients while under the influence of drugs/alcohol;
- 5. Any drug/alcohol related act which would constitute a violation of the practice act or state/federal laws;
- 6. Failure to obtain biological testing for substance abuse;
- Testing positive and confirmation for substance abuse pursuant to Uniform Standard #9;
- 8. Knowingly using, making, altering or possessing any object or product in such a way as to defraud a drug test designed to detect the presence of alcohol or a controlled substance.

Consequences for a major violation include, but are not limited to:

- 1. Licensee will be ordered to cease practice.
 - a) the licensee must undergo a new clinical diagnostic evaluation, and
 - b) the licensee must test negative for at least a month of continuous drug testing before being allowed to go back to work.
- 2. Termination of a contract/agreement.
- 3. Referral for disciplinary action, such as suspension, revocation, or other action as determined by the board.

Minor Violations include, but are not limited to:

- 1. Untimely receipt of required documentation;
- 2. Unexcused non-attendance at group meetings;
- 3. Failure to contact a monitor when required;
- 4. Any other violations that do not present an immediate threat to the violator or to the public.

Consequences for minor violations include, but are not limited to:

- 1. Removal from practice;
- 2. Practice limitations;
- 3. Required supervision;
- 4. Increased documentation;
- 5. Issuance of citation and fine or a warning notice;
- 6. Required re-evaluation/testing;
- 7. Other action as determined by the board.

#11 SENATE BILL 1441 REQUIREMENT

Criteria that a licensee must meet in order to petition for return to practice on a full time basis.

<u>#11 Uniform Standard</u>

"Petition" as used in this standard is an informal request as opposed to a "Petition for Modification" under the Administrative Procedure Act.

The licensee shall meet the following criteria before submitting a request (petition) to return to full time practice:

- 1. Demonstrated sustained compliance with current recovery program.
- 2. Demonstrated the ability to practice safely as evidenced by current work site reports, evaluations, and any other information relating to the licensee's substance abuse.
- 3. Negative drug screening reports for at least six (6) months, two (2) positive worksite monitor reports, and complete compliance with other terms and conditions of the program.

#12 SENATE BILL 1441 REQUIREMENT

Criteria that a licensee must meet in order to petition for reinstatement of a full and unrestricted license.

#12 Uniform Standard

"Petition for Reinstatement" as used in this standard is an informal request (petition) as opposed to a "Petition for Reinstatement" under the Administrative Procedure Act.

The licensee must meet the following criteria to request (petition) for a full and unrestricted license.

- 1. Demonstrated sustained compliance with the terms of the disciplinary order, if applicable.
- 2. Demonstrated successful completion of recovery program, if required.
- 3. Demonstrated a consistent and sustained participation in activities that promote and support their recovery including, but not limited to, ongoing support meetings, therapy, counseling, relapse prevention plan, and community activities.
- 4. Demonstrated that he or she is able to practice safely.
- 5. Continuous sobriety for three (3) to five (5) years.

#13 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, (1) standards for immediate reporting by the vendor to the board of any and all noncompliance with process for providers or contractors that provide diversion services, including, but not limited to, specimen collectors, group meeting facilitators, and worksite monitors; (3) standards requiring the vendor to disapprove and discontinue the use of providers or contractors that fail to provide effective or timely diversion services; and (4) standards for a licensee's termination from the program and referral to enforcement.

#13 Uniform Standard

- 1. A vendor must report to the board any major violation, as defined in Uniform Standard #10, within one (1) business day. A vendor must report to the board any minor violation, as defined in Uniform Standard #10, within five (5) business days.
- 2. A vendor's approval process for providers or contractors that provide diversion services, including, but not limited to, specimen collectors, group meeting facilitators, and worksite monitors is as follows:
 - (a) Specimen Collectors:
 - (1) The provider or subcontractor shall possess all the materials, equipment, and technical expertise necessary in order to test every licensee for which he or she is responsible on any day of the week.
 - (2) The provider or subcontractor shall be able to scientifically test for urine, blood, and hair specimens for the detection of alcohol, illegal, and controlled substances.
 - (3) The provider or subcontractor must provide collection sites that are located in areas throughout California.
 - (4) The provider or subcontractor must have an automated 24-hour toll-free telephone system and/or a secure on-line computer database that allows the participant to check in daily for drug testing.
 - (5) The provider or subcontractor must have or be subcontracted with operating collection sites that are engaged in the business of collecting urine, blood, and hair follicle specimens for the testing of drugs and alcohol within the State of California.
 - (6) The provider or subcontractor must have a secure, HIPAA compliant, website or computer system to allow staff access to drug test results and compliance reporting information that is available 24 hours a day.

- (7) The provider or subcontractor shall employ or contract with toxicologists that are licensed physicians and have knowledge of substance abuse disorders and the appropriate medical training to interpret and evaluate laboratory drug test results, medical histories, and any other information relevant to biomedical information.
- (8) A toxicology screen will not be considered negative if a positive result is obtained while practicing, even if the practitioner holds a valid prescription for the substance.
- (9) Must undergo training as specified in Uniform Standard #4 (6).

(b) Group Meeting Facilitators:

A group meeting facilitator for any support group meeting:

- (1) must have a minimum of three (3) years experience in the treatment and rehabilitation of substance abuse;
- (2) must be licensed or certified by the state or other nationally certified organization;
- (3) must not have a financial relationship, personal relationship, or business relationship with the licensee within the last year;
- (4) shall report any unexcused absence within 24 hours to the board, and,
- (5) shall provide to the board a signed document showing the licensee's name, the group name, the date and location of the meeting, the licensee's attendance, and the licensee's level of participation and progress.

(c) Work Site Monitors:

The worksite monitor must meet the following qualifications:

- (1) Shall not have financial, personal, or familial relationship with the licensee, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the board. If it is impractical for anyone but the licensee's employer to serve as the worksite monitor, this requirement may be waived by the board; however, under no circumstances shall a licensee's worksite monitor be an employee of the licensee.
- (2) The monitor's licensure scope of practice shall include the scope of practice of the licensee that is being monitored, be another health care professional if no

monitor with like practice is available, or, as approved by the board, be a person in a position of authority who is capable of monitoring the licensee at work.

- (3) Shall have an active unrestricted license, with no disciplinary action within the last five (5) years.
- (4) Shall sign an affirmation that he or she has reviewed the terms and conditions of the licensee's disciplinary order and/or contract and agrees to monitor the licensee as set forth by the board.
- 2. The worksite monitor must adhere to the following required methods of monitoring the licensee:
 - a) Have face-to-face contact with the licensee in the work environment on a frequent basis as determined by the board, at least once per week.
 - b) Interview other staff in the office regarding the licensee's behavior, if applicable.
 - c) Review the licensee's work attendance.
- 3. Any suspected substance abuse must be verbally reported to the contractor, the board, and the licensee's employer within one (1) business day of occurrence. If occurrence is not during the board's normal business hours the verbal report must be within one (1) hour of the next business day. A written report shall be submitted to the board within 48 hours of occurrence.
- 4. The worksite monitor shall complete and submit a written report monthly or as directed by the board. The report shall include:

the licensee's name;

license number;

worksite monitor's name and signature;

worksite monitor's license number;

worksite location(s);

dates licensee had face-to-face contact with monitor;

staff interviewed, if applicable;

attendance report;

any change in behavior and/or personal habits;

• •any indicators that can lead to suspected substance abuse.

(d) Treatment Providers

Treatment facility staff and services must have:

- (1) Licensure and/or accreditation by appropriate regulatory agencies;
- (2) Sufficient resources available to adequately evaluate the physical and mental needs of the client, provide for safe detoxification, and manage any medical emergency;
- (3) Professional staff who are competent and experienced members of the clinical staff;
- (4) Treatment planning involving a multidisciplinary approach and specific aftercare plans;
- (5) Means to provide treatment/progress documentation to the provider.

(e) General Vendor Requirements

The vendor shall disapprove and discontinue the use of providers or contractors that fail to provide effective or timely diversion services as follows:

- (1) The vendor is fully responsible for the acts and omissions of its subcontractors and of persons either directly or indirectly employed by any of them. No subcontract shall relieve the vendor of its responsibilities and obligations. All state policies, guidelines, and requirements apply to all subcontractors.
- (2) If a subcontractor fails to provide effective or timely services as listed above, but not limited to any other subcontracted services, the vendor will terminate services of said contractor within 30 business days of notification of failure to provide adequate services.
- (3) The vendor shall notify the appropriate board within five (5) business days of termination of said subcontractor.

#14 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, the extent to which licensee participation in that program shall be kept confidential from the public.

<u>#14 Uniform Standard</u>

The board shall disclose the following information to the public for licensees who are participating in a board monitoring/diversion program regardless of whether the licensee is a self-referral or a board referral. However, the disclosure shall not contain information that the restrictions are a result of the licensee's participation in a diversion program.

Licensee's name;

Whether the licensee's practice is restricted, or the license is on inactive status;

A detailed description of any restriction imposed.

#15 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, a schedule for external independent audits of the vendor's performance in adhering to the standards adopted by the committee.

#15 Uniform Standard

- If a board uses a private-sector vendor to provide monitoring services for its licensees, an external independent audit must be conducted at least once every three (3) years by a qualified, independent reviewer or review team from outside the department with no real or apparent conflict of interest with the vendor providing the monitoring services. In addition, the reviewer shall not be a part of or under the control of the board. The independent reviewer or review team must consist of individuals who are competent in the professional practice of internal auditing and assessment processes and qualified to perform audits of monitoring programs.
- 2. The audit must assess the vendor's performance in adhering to the uniform standards established by the board. The reviewer must provide a report of their findings to the board by June 30 of each three (3) year cycle. The report shall identify any material inadequacies, deficiencies, irregularities, or other non-compliance with the terms of the vendor's monitoring services that would interfere with the board's mandate of public protection.
- 3. The board and the department shall respond to the findings in the audit report.

#16 SENATE BILL 1441 Requirement

Measurable criteria and standards to determine whether each board's method of dealing with substance-abusing licensees protects patients from harm and is effective in assisting its licensees in recovering from substance abuse in the long term.

#16 Uniform Standard

Each board shall report the following information on a yearly basis to the Department of Consumer Affairs and the Legislature as it relates to licensees with substance abuse problems who are either in a board probation and/or diversion program.

Number of intakes into a diversion program

Number of probationers whose conduct was related to a substance abuse problem

Number of referrals for treatment programs

Number of relapses (break in sobriety)

Number of cease practice orders/license in-activations

Number of suspensions

Number terminated from program for noncompliance

Number of successful completions based on uniform standards

Number of major violations; nature of violation and action taken

Number of licensees who successfully returned to practice

Number of patients harmed while in diversion

The above information shall be further broken down for each licensing category, specific substance abuse problem (i.e. cocaine, alcohol, Demerol etc.), whether the licensee is in a diversion program and/or probation program.

If the data indicates that licensees in specific licensing categories or with specific substance abuse problems have either a higher or lower probability of success, that information shall be taken into account when determining the success of a program. It may also be used to determine the risk factor when a board is determining whether a license should be revoked or placed on probation. The board shall use the following criteria to determine if its program protects patients from harm and is effective in assisting its licensees in recovering from substance abuse in the long term.

At least 100 percent of licensees who either entered a diversion program or whose license was placed on probation as a result of a substance abuse problem successfully completed either the program or the probation, or had their license to practice revoked or surrendered on a timely basis based on noncompliance of those programs.

At least 75 percent of licensees who successfully completed a diversion program or probation did not have any substantiated complaints related to substance abuse for at least five (5) years after completion.

Attachment 5



California State Board of Pharmacy 1625 N. Market Blvd, N219, Sacramento, CA 95834 Phone: (916) 574-7900 Fax: (916) 574-8618 www.pharmacy.ca.gov

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

DATE:	June 19, 2015
LOCATION:	University of Southern California – Orange County Center 2300 Michelson Drive Irvine, CA 92612
COMMITTEE MEMBERS	
PRESENT:	Stanley C. Weisser, Committee Chair
	Victor Law, RPh Amy Gutierrez, PharmD. President
COMMITTEE MEMBERS	Discusts Courstson, Dublic Manshow
NOT PRESENT:	Ricardo Sanchez, Public Member
STAFF	
PRESENT:	Virginia Herold, Executive Officer
	Anne, Sodergren, Assistant Executive Officer
	Desiree Kellogg, Deputy Attorney General
	Laura Hendricks, Staff Analyst

Call to Order

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Proposed changes:

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

Committee Discussion:

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

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

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

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

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

M/S: Gutierrez/Law Support: 0 Oppose: 0 Abstain: 0

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

Proposed Changes:

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

Committee Discussion:

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

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

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

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

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

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

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

M/S: Law/Gutierrez

Support: 3 Oppose: 0 Abstain: 0

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

Proposed Changes:

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

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

Committee Discussion:

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

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

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

M/S: Law/Gutierrez Support: 3 Oppose: 0 Abstain: 0

Standard Conditions – Pages 28-35

Proposed Changes:

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

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

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

Committee Discussion:

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

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

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

M/S: Gutierrez/Law

Support: 3 Oppose: 0 Abstain: 0

Optional Conditions of Probation – Pages 35-59

Proposed Changes:

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

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

- Option 1 is being added to include that the respondent is suspended from practice until specified conditions are met including:
 - Completion of the evaluation,
 - Submission of the evaluator's report, demonstrating that the respondent is safe to return to practice,
 - The board has determined that respondent is safe to return to practice and under what conditions.
 - Respondent received written notice that practice may resume.
- Option 2 is being renumbered and recast to facilitate consolidation of the probationary terms for each of the individual license types. Further, the suspension language is being modified to clarify those activities that are prohibited during any such suspension.
- Option 3 is being renumbered and recast to facilitate consolidation of the probationary terms for each of the individual license types. The optional term is to be rewritten to better define each of the criteria that must be satisfied prior to a respondent being allowed to return to work. The suspension language is being modified to clarify those activities that are prohibited during any such suspension.
- Psychotherapy: This term is being renumbered and the guidance provided to the guideline users is being updated to clarify the conditions when inclusion of this term is appropriate. The suspension language is being modified to clarify those activities that are prohibited during any such suspension.
- Medical Evaluation: This term is being renumbered and modified to facilitate consolidation of the probationary terms for each of the individual license types. The suspension language is being modified to clarify those activities that are prohibited during any such suspension. The same types of changes are being made to the two options provided in this term.
- Pharmacists Recovery Program (PRP): The guidance provided to the users of these guidelines is being updated to clarify the conditions when inclusion of this term is appropriate. This term is also being modified to clarify what actions a respondent must take to comply with the term as well as the timeline for completion. (Currently the board has received complaints that this term lacks specificity and has caused confusion for licensees on the board's expectations for compliance.) The term is also clarifying that the respondent must comply with the treatment contracts established

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

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

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

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

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

Committee Discussion:

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

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

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

M/S: Law/Gutierrez

Terms of Probation – Premises (Pages 84-88)

Proposed Changes:

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

Committee Discussion:

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

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

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

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

M/S: Gutierrez/Law

Support: 3 Oppose: 0 Abstain: 0

Model Disciplinary Language: Premises – Pages 99-102

Proposed Changes:

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

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

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

Committee Discussion:

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

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

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

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

M/S: Gutierrez/Law

Support: 3Oppose: 0Abstain: 0

Standard Conditions – Pages 103-107

Proposed Changes:

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

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

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

Committee Discussion:

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

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

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

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

M/S: Law/Gutierrez

Support: 3 Oppose: 0 Abstain: 0

Optional Conditions – Pages 107-108

Proposed Changes:

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

Committee Discussion:

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

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

M/S: Gutierrez/Law

Support: 3 Oppose: 0 Abstain: 0

General Policy Discussion

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

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

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

M/S: Law/Gutierrez

Support: 3 Oppose: 0 Abstain: 0

3. Public Comment for Items Not on the Agenda, Matters for Future Meetings The committee scheduled the next SB 1441 Uniform Standards Implementation Committee meeting for July 27, 2015.

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