

XVI. Consideration of Proposed Changes to the Board's Disciplinary Guidelines and Title 16, California Code of Regulations Section 1760

SB 1441 Ad Hoc Committee

Victor Law, Professional Member, Chair Ricardo Sanchez, Public Member Stan Weisser, Professional Member

Relevant Sections

Title 16, 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 (B&PC) 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 substance-abusing licensees.

Chapter 9, Division 2, Chapter 19 (B&PCsections 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.

During the June Board meeting, an ad hoc committee was established to allow a complete review of the proposed implementation strategy. The ad hoc committee met on two occasions and made recommendations.

Following the work of the ad hoc committee, during the July Board meeting, the board was presented with recommended changes to the 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.

After discussion, the board voted to initiate the 45-day comment period.

Recent Update

On September 4, 2015 the board initiated the 45-day comment period. Since that time the board received further input from counsel regarding the proposal as well as comments from two individuals.

Based on the feedback received, staff is recommending several changes to Section 1760 language itself as well as to the guidelines. The changes presented for board consideration include nonsubstantive changes as well as substantive changes intended strengthen and/or clarify the understanding of the guidelines as well as to clarify the intent of some of the language. As part of this process, some policy questions have arisen.

During the meeting board staff request that the board review the changes being presented in the guidelines, consider the public comments received during the comment period as well as provide clarification on some policy issues.

The following items have been included for board consideration:

- Attachment 1 includes the proposed revisions to Section 1760 as well as the draft disciplinary guidelines. Items in double underline and double strikeout highlight the proposed changes.
- Attachment 2 includes a brief description of all of the proposed substantive changes.
- Attachment 3 includes some policy questions for the board.
- Attachment 4 includes the comments received in response to the initial comment period

During the meeting the board has the opportunity to take actions including:

- 1. Adopt the amendments to the regulation and Disciplinary Guidelines as presented at the July 2015 Board meeting
- 2. Further amend the proposed regulation and Disciplinary Guidelines and modify the text for a 15-day comment. If not negative comments are received adopt the proposed regulation at Section 1760 and Disciplinary Guidelines as approved by the board. Direct staff to take all necessary steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative law. Delegate to the Executive Officer to authority to make any nonsubstantive changes to the proposed regulations.

Attachment 1

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 10/2015), 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 315, 315.2, 315.4 and 4005, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 315, 315.2, 315.4, 4300 - 4313 and 4301, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

DISCIPLINARY GUIDELINES

A Manual of Disciplinary Guidelines and Model Disciplinary Orders



BE AWARE & TAKE CARE: Talk to your pharmacist!

California State Board of Pharmacy Department of Consumer Affairs (Rev. 10/2007 7/2015 <u>10/2015</u>)

STATE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS

William Powers
Amy Gutierrez
PRESIDENT

Virginia K. Herold EXECUTIVE OFFICER

1625 N. Market Blvd, Suite N-219 Sacramento, CA 95834 (916) 574-7900 (916) 574-8618 Fax www.pharmacy.ca.gov

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

BOARD OF PHARMACY

DISCIPLINARY GUIDELINES

TABLE OF CONTENTS

Introduction	1
Factors to be Considered in Determining Penalties	3
Mitigating Evidence	
Pharmacist/Intern Pharmacist Individual Licensees	5
Terms of Probation – Pharmacist/Intern Pharmacist Individual Licensees	5
Categories of Violation and Recommended Penalties	5
Category I – Penalty	6
Category II – Penalty	11
Category III - Penalty	15
Category IV – Penalty	
Model Disciplinary Language - Pharmacist/Intern Pharmacist Individual Licensees	19
Standard Conditions	23
Optional Conditions	27
Pharmacy Technician	
Terms of Probation – Pharmacy Technician	43
Category III - Penalty	
Model Disciplinary Language – Pharmacy Technician	44
Standard Conditions	48
Optional Conditions	52
Designated Representative	
Terms of Probation –Designated Representative	
Category III - Penalty	
Model Disciplinary Language - Designated Representative	
Standard Conditions	
Optional Conditions	64
Premises	
Terms of Probation – Premises	
Category I – Penalty	
Category II – Penalty	
Category III – Penalty	
Category IV – Penalty	79
Model Disciplinary Language – Premises	
Standard Conditions	-
Optional Conditions	87

DEPARTMENT OF CONSUMER AFFAIRS STATE BOARD OF PHARMACY

DISCIPLINARY GUIDELINES (Rev. 10/2007 7/2015)

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 ensures 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 or devices 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, <u>and the provisions contained in Sections 1771-1774</u>, 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, <u>defense</u> attorneys, <u>board licensees</u>, 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 personnel.

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.
- 16. consideration of other licenses held by the respondent and license history of those licenses.
- 17. Uniform Standards Regarding Substance-Abusing Healing Arts Licensees (see <u>Business</u> and Professions Code Section 315)

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, she, or it 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/or assessment report(s) by a licensed physician, confirming the absence of any physical impairment that would prohibit the respondent from practicing safely. Such assessments and report(s) will be subject to verification by board staff.
- f. Recent, dated, letters from probation or parole officers regarding the respondent's participation in and/or compliance with terms and conditions of probation or parole, which should include at least a description of the terms and conditions, and the officer's basis for determining compliance. Such letters and reports will be subject to verification by board staff.
- g. Recent, dated, letters from persons familiar with respondent in either a personal or professional capacity regarding their knowledge of: the respondent's character; the respondent's rehabilitation, if any; the conduct of which the respondent is accused; or any other pertinent facts that would enable the board to better decide the case. Such letters must be signed under penalty of perjury and will be subject to verification by board staff.
- 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 uses 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, designated representatives-3PL, and advanced practice pharmacists), 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; ene 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 that are less serious that than Category 2 through 4 but are potentially harmful. These may include:</u></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
- <u>violation(s) resulting from the misuse of education or licensing privileges</u> 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
4400	Chairma of Adduses on News - Netitiontian to Doord
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;
	Bioponoling replacement contact concess requirements, rations warnings,
	Registration with Medical Board; Application of Section to Nonresident Pharmacies
Article 9.	
	Registration with Medical Board; Application of Section to Nonresident Pharmacies Hypodermic Needles and Syringes
4141	Registration with Medical Board; Application of Section to Nonresident Pharmacies Hypodermic Needles and Syringes Furnishing Without License
4141 4142	Registration with Medical Board; Application of Section to Nonresident Pharmacies Hypodermic Needles and Syringes Furnishing Without License Prescription Required
4141	Registration with Medical Board; Application of Section to Nonresident Pharmacies Hypodermic Needles and Syringes Furnishing Without License

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

//221	Requirements for Renewal of Pharmacist License: Clock Hours: Evention for	· NIOW
120 i	Requirements for Kerlewar or Fharmacist Electise. Clock Hours, Exemption for	1404
	Licensee	
4000		

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
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
1712	Use of Pharmacist Identifiers
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
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
1751.2	Labeling Requirements
1751.3	Recordkeeping Requirements
1751.4	Attire
1751.5	Training of Staff, Patient, and Caregiver
1751.6	Disposal of Waste Material

Quality Assurance and Process Evaluation
Reference Materials
Furnishing to Home Health Agencies and Licensed Hospices
Obligations of a Pharmacy Furnishing Portable Containers
Posting Notice of Suspension
Disciplinary Condition of Suspension
Minimum Standards for Wholesalers
Minimum Standards for Veterinary Food-Animal Drug Retailers
Exemption Certificate
Exemptions
Authorization to Distribute Hemodialysis Drugs and Devices
Assembling and Packaging
Labeling
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.
1301.12	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.
1301.75	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.
1302.07	Labeling and packaging requirements for imported and exported substances.
1304.11	Inventory requirements.
1304.21	Inventories of importers and exporters
1304.31	Reports from manufacturers importing narcotic raw materials.
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 manufacture.
	Incidental manufacture of controlled substances.
	Procedure for disposing of controlled substances.
1700.1 to	
1707 15	Child-registant 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>violation(s)</u> with serious potential for harm, as well as for violations involving disregard for public safety or for the laws or regulations pertaining to pharmacy and/or to dispensing or distributing of dangerous drugs and/or dangerous devices or controlled substances, violations that reflect on ethics, competence, or diligence, and criminal convictions not involving alcohol, dangerous drugs and/or dangerous devices, or controlled substances. Violations in this category may include:

- <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;
- <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;
- smaller 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 dangerous drug(s) and/or dangerous device(s) to or from unauthorized person(s);
- failure(s) to make required reports to the board or other regulatory agencies, including CURES obligations and reporting to DEA;
- violation(s) of quality assurance and self-assessment obligations, failure(s) to clarify erroneous or uncertain prescription(s);
- gross immorality, incompetence, gross negligence, elearly excessive furnishing of controlled substances, moral turpitude, dishonesty, or fraud;
- <u>criminal conviction(s) not involving alcohol, dangerous drugs and/or</u> dangerous devices, or controlled substances;
- 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
000	Repaired of Discounts for Referral Frombited
650.1	Lease Prohibition – Hospitals or Prescribers
000	•
651	Professional Advertising Requirements
001	Troicessional 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

Pharmacist in Charge, Exemptee: Termination of Employment; Notification to Board
Licensed Employee, Theft or Impairment: Pharmacy Procedures
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 -	Halawful Passassian	
+ 1 + 0	Official in 0000000001	
		_

4147 Disposal of Needle or Syringe

Article 11. Wholesalers and Manufacturers

/1160		Licanca Required
T 100	Willowsalci.	License rreadired

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

Unprofessional Conduct - subsections (a)-(h), (j), and (l)-(q)
Discipline of Corporate Licensee for Conduct of Officer, Director, Shareholder
Nonresident Pharmacy: Grounds for Discipline
Out-of-state Distributor: Authority to Discipline
Disciplinary Grounds: Failure of Pharmacy, Pharmacist to Notify Board of
Termination of Pharmacist in Charge; Continuing to Operate Without Pharmacist
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
Violation of Professional Corporation Act as Unprofessional Conduct
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 Non-
	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

4380	Resale of Preferentially Priced Drugs: Prohibition; Exceptions
1000	Tresaile of Frederitially Fried Brags. Fromblion, Exceptions
4381	Violation of Section 4380 as Unfair Competition; Right of Private Action to Enforce
1001	Violation of Occiton 4000 as official Competition, right of 1 hvate retion to Emolec
4382	Board May Audit Sales to Walk-in Customers
1002	- Doard May Addit Gales to Walk-III Gustomers

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 Delivery
1709.1	Designation of Pharmacist in Charge
1714.1	Pharmacy Operations During the 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
1717.3	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
1793.7	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
15020À	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.
	Partial filling of prescriptions.
	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 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 track and trace, pedigree, transaction history Drug Supply Chain Security Act requirements, 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;

- dispensing or furnishing without valid prescription, dispensing or furnishing to unauthorized person(s):
- violation(s) involving fraudulent acts committed in connection with the licensee's practice:
- repeat or serious violation(s) of controlled substance secure prescription requirements, inventory controls, or security requirements;
- violation(s) of laws governing 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 create 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);
- failing to maintain record(s) of acquisition and disposition of dangerous drug(s) 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 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

4034	Pedigree
	Conduct Limited To Pharmacist
4050 ´	Furnishing Dangerous Drugs or Davisos Prohibited Without Proscription: Exceptions
	Who May Order Dangerous Drugs or Devices Frombited Without Frescription. 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	<u> Unprofessional Conduct - subsections (i) - (k) and (o)</u>
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

Voided License: Knowing Failure to Arrange for Disposition of Stock as
 Misdemeanor

 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
	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 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:</u>

- possession for sale violations involving possession for sale, transportation, importation, and/or use of a minor for unlawful sale of controlled substances;
- transportation <u>criminal convictions involving the above, or repeat convictions</u> <u>involving diversion or abuse of alcohol, dangerous drugs and/or dangerous devices,</u> 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 create a potential infection control risk.
- <u>→ importation</u>
- - sale
- use of a minor for the unlawful sale of controlled substances

Revocation is also recommended when: where a respondent fails to file a notice of defense to an Accusation or 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
11000	radit osing, conditing of intimidating willor for violation

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

The following standardized language shall be used in every decision where the order or condition is imposed. Where brackets appear, drafters should choose the appropriate term or consider the text instructional.

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 [his/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 [his/her] revoked license, respondent shall reimburse the board for its costs of investigation and prosecution in the amount of
\$ Said amount shall be paid in full prior to the reapplication or reinstatement of his or her license unless otherwise ordered by the board.
Option: Respondent shall pay to the board its costs of investigation and prosecution in the amount of \$ within fifteen (15) days of the effective date of this decision.
Suspension
As part of probation, respondent is suspended from the practice as a [insert license type] for [day(s)/month(s)/year(s)] of pharmacy forbeginning 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

<u>During suspension</u>, Rrespondent 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

devices or controlled substances.

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

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.

Revocation, stayed, Standard Stay/Probation Order
License number, issued to respondent is revoked; however, the revocation is stayed and respondent is placed on probation for years upon the following terms and conditions:
Issuance of Probationary License (In cases where a Statement of Issues has been filed.)
Upon satisfaction of all statutory and regulatory requirements for issuance of a [insert license type] license, a [insert license type] license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for years upon the following terms and conditions:
Should the board subsequently issue a license to practice as a pharmacist to respondent during the period of probation, the intern license shall be cancelled and the pharmacist 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 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 numberas of the effective date of this decision. Respondent shall relinquish his or her [his/her]wall license, including any indicia of licensure issued by the board, and/or pocket renewal license to the board within ten (10) days of the effective date of this decision.
The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board.

23

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 is required to report this surrender as disciplinary action.	
Respondent further stipulates that he or she [he/she] shall reimburse the board for its convestigation and prosecution in the amount of \$withindays of the effective date of this decision.	
Option: Respondent stipulates that should he or she [he/she] apply for any license from board on or after the effective date of this decision the investigation and prosecution commount of \$shall be paid to the board prior to issuance of the new license.	
Public Reprimand Reproval	
It is hereby ordered that a public reprimand reproval be issued against licensee,	

<u>License Reinstatement with Conditions Precedent (Pharmacists and Pharmacy Technicians Only)</u>

Respondent is required to report this reprimand reproval as a disciplinary action.

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:

OPTION (Pharmacists Only)

- 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 the examination(s) 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(s) in place at the time for [this/these] examinations.
- c. Petitioner must pay a reinstatement fee all applicable application and licensing fees as well as any cost recovery owed from the prior action in the amount of \$.

Option (Pharmacy Technicians Only)

a. Petitioner shall take and pass the Pharmacy Technician Certification Board

exam] within one (1) year of the effective date of this order. Failure to take and pass the 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(s) in place at the time for [this/these] examinations.
- c. Petitioner must pay a reinstatement fee all applicable application and licensing fees as well as any cost recovery owed from the prior action 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 <u>GRANTED granted</u> and Petitioner's license shall be <u>REINSTATED reinstated</u>. 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
- Interview with the Board
- 4. Cooperate with Board Staff
- 5. Continuing Education
- 6. Reporting of Employment and Notice to Employers
- 7. Notification of Change(s) in Name, Employment, Address(es), or Phone Number(s)
- 7.8. No Supervision of Interns, Serving as Pharmacist-In-Charge (PIC), or Serving as a Consultant Restrictions on Supervision and Oversight of Licensed Facilities
- & 9. Reimbursement of Board Costs
- 9-10. Probation Monitoring Costs
- 10 11. Status of License
- 41 12.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 Extension of Probation
- 14. 16. Violation of Probation
- 15. 17. 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. 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 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 contender contender, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other the filing of a disciplinary pleading, issuance of a citation, or initiation of another 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 completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

5. Continuing Education (Pharmacists Only)

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

6. Reporting of Employment and Notice to Employers (Standard 3)

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:
Toopendent by the decicient, de reneme.
Within thirty (30) days of the effective date of this decision, and within fifteen (15) ten (10) days of undertaking any new employment, respondent shall report to the board in writing the name, physical address, and mailing address of all each 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) and the work schedule, if known. Respondent shall also include the reason(s) for leaving the prior employment. 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 [his/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 of the decision in case number in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy an employment service, respondent shall cause the person(s) described in (a), (b), and (c) above his or her direct supervisor with the pharmacy at the employment service to report to the board in writing acknowledging that he or she has read the decision in case number ______, and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or <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)¹

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

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

78. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant Restrictions on Supervision and Oversight of Licensed Facilities²
(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(To be included along with standard language when appropriate): 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

_

This term was renamed and renumbered from previous term 12.

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

<u>unauthorized ancillary personnel supervision responsibilities shall be considered a violation of probation.</u>

Option 2 (To be used in place of standard language when appropriate): During the period of probation, respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge, designated representative-in-charge, 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 [his/her] 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 [his/her] supervisory position. Respondent may serve in such a position at only one entity licensed by the board, only upon approval by the board or its designee and at only one entity licensed by the board. This Any such approval shall be 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 or prior to assumption of duties allowed in this term. Assumption of any unauthorized supervision responsibilities shall be considered a violation of probation. In addition, failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall be considered a violation of probation.

89. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, responder	nt 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 [insert license type] license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current [insert license type] license shall be considered a violation of probation.

If respondent's [insert license type] license expires or is cancelled by operation of law or

otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's <u>finsert license typel</u> license shall be subject to all terms and conditions of this probation not previously satisfied.

1112. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender [his/her] [insert license type] license to the board for shall may relinquish [his/her] license, including any indicia of licensure issued by the board, along with a request to surrender the license for surrender. The board or its designee shall have the discretion whether to grant accept the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the finsert 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, including any indicia of licensure not previously provided to the board within ten (10) days of notification by the board that the surrender is accepted if not already provided. 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.

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

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 <u>License Practice Requirement – Tolling Extension of Probation</u>

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 tell the period of probation, i.e., extend 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 telling of probation insufficient employment, respondent must nonetheless comply with all terms and conditions of probation, unless respondent is notified otherwise receives a waiver in writing by from 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 at the minimum number 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 reduction 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 at the 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 be extended pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months. The board or its designee may post a notice of the extended probation period on its website.

"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 the board shall provide notice to respondent that 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. The board or its designee may post a notice of the extended probation period on its website

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 that 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 this suspension shall be considered a violation of probation.

Option 4: 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 as a [insert license type	<u>oe</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 or its designee	of compliance with this term of probation.

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

submit proof to the board <u>or its designee</u> of compliance therewith shall be considered a violation of probation.

17.20. Pharmacist Examination (Pharmacists Only)

Respondent shall take and pass the [California Pharmacist Jurisprudence Examination (CPJE) [and/or] the North American Pharmacist Licensure Examination (NAPLEX)] within six (6) months of the effective date of this decision. If respondent fails to take and pass the examination(s) within six (6) months after of 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 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.

Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.</u>

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. 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. Failure to complete coursework or provide proof of such completion as required shall be considered a violation of probation.

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

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

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

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

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

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

designee that practice may be resumed.

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

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];
- The board or its designee is satisfied that respondent is safe to return to practice as a [insert license type];
- Respondent receives written notice from the board or its designee that practice may resume.

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.

<u>Failure to comply with any requirement, including any suspension or deadline stated by this term shall be considered a violation of probation.</u>

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

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

During <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 <u>or controlled substances</u>. 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 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 is 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, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or 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, or of the manufacturing, <u>distributing</u>, <u>wholesaling</u>, 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 <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, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or and controlled substances. Respondent shall not resume practice until notified by the board.

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs 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 a pharmacist [insert license type] with safety to the public. Respondent shall comply with all the recommendations of the physician if directed by the board or its designee. If the physician recommends

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 any such restrictions or conditions as additional probation terms and conditions, violation of which shall be considered a violation of probation.

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, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or and controlled substances. Respondent shall not resume practice untilnotified by the board.

During any such 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 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 <u>when suspension is warranted</u> <u>until the evaluation is completed.</u>)

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-this</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, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances. Respondent shall not resume practice until notified by the board.

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

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

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

During <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 <u>[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 <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 those cases where evidence demonstrates substance abuse chemical dependency (alcohol, drugs), or psychiatric disorders (mental illness, emotional disturbance, gambling addiction) (Pharmacists and Pharmacist Interns Only)

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

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

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.

Any of the following shall result in the automatic suspension of practice by respondent and shall be considered a violation of probation:

- Failure to contact, complete enrollment, and execute and return the treatment contract with the PRP, including any addendum(s), within ten (10) days of the effective date of the decision as directed by the PRP:
- Failure to complete registration for any drug or alcohol testing mandated by the treatment contract and/or by the PRP, and begin compliance with the testing protocol(s), within ten (10) days of the effective date of the decision as directed by the PRP:
- Failure to comply with testing protocols regarding daily check-in and/or failure to complete a mandated test as directed by the PRP:
- Any report from the PRP of material non-compliance with the terms and conditions of the treatment contract and/or any addendum(s); or
- <u>Termination by the PRP for non-compliance, failure to derive benefit, or as a public risk.</u>

Respondent may not result the practice of pharmacy until notified by the board in writing.

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. The board will provide notice of any such suspension or extension 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 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 <u>pharmacy 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 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 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, <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.

(Option language to be used in addition to standard language when appropriate to ensure licensee works in an access position while being monitored.)

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. 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 shallbe 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 an illicit drug, 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 an illicit drug, 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, an illicit drug, 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. <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 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.

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 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>, <u>or and</u> their associated <u>paraphernalia</u>, <u>except when possessed</u>

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 supported by 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, illicit drugs, 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 or its designee 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

<u>designee</u> 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 <u>or its designee</u> immediately and, within thirty (30) days of ceasing <u>treatment</u> <u>supervision</u>, 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 <u>or its designee</u> for approval, or to ensure the <u>required reporting thereby on the quarterly reports required quarterly reporting thereby</u>, shall be considered a violation of probation.

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

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, 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 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>, <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.

25.27. Community Services Program

Within sixty (60) days of the effective date of this deci-	sion, respondent shall submi	t to the board
or its designee, for prior approval, a community service	e program in which responde	ent shall
provide free [insert type of service, e.g., health-care re	elated 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	d approval thereof, responde	ent shall
submit documentation to the board or its designee de		
community service program. A record of this notificat	ion must be provided to the <mark>k</mark>	ooard upon
request. Respondent shall report on progress with the	e community service progran	n in the
quarterly reports and provide satisfactory documentar	y evidence of such progress	to the board

<u>or its designee upon request</u>. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

26. 28.	Restitution (Appropriate in case harm resulting from negligence o	es of drug diversion, theft, fraudulent billing, or patient r incompetence.)
Within	days of the effective datein the amount of \$	of this decision, respondent shall pay restitution to Failure to make restitution by this deadline shall be
consid	ered 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 and ten (10) days from the effective date of this decision, submit proof satisfactory to the board of completion of this experience signed under penalty of perjury by both the respondent and supervising pharmacist. Failure to timely complete or document the required intern experience shall be considered a violation of probation.

30. 31. Supervised Practice (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's replacement practice supervisor. As part of the documentation submitted, respondent shall cause the proposed replacement practice supervisor to report to the board in writing acknowledging that he or she has read the decision in case number [insert case number], and is familiar with the terms and conditions imposed thereby, including the level of supervision required.

Any of the following shall result in the automatic suspension of practice by a respondent and shall be considered a violation of probation:

- <u>Failure to nominate an initial practice supervisor, and to have that practice supervisor report to the board in writing acknowledging the decision, terms and conditions, and supervision level, within thirty (30) days;</u>
- Failure to nominate a replacement practice supervisor, and to have that practice supervisor report to the board in writing acknowledging the decision, terms and conditions, and supervision level, within ten (10) days:
- Practicing in the absence of an approved practice supervisor beyond the initial or

replacement nomination period; or

Any failure to adhere to the required level of supervision.

Respondent shall not resume practice until notified in writing by the board or its designee.

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-incharge 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 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]of a pharmacist</u>. Respondent shall not direct or control any aspect of the practice of pharmacy <u>or of the manufacture</u>, <u>distribution</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 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 nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

Option (To be used in place of the standard language in those circumstances where respondent is permitted to continue existing ownership of a licensed entity): 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 pharmacist <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 Pharmacist owners and pharmacists-in-charge)

Respondent shall submit quarterly reports to the board detailing the total acquisition and disposition of such controlled substances as the board <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 <u>I</u>, II, III, IV or V (Health and Safety Code sections <u>11055</u> <u>11054</u>-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.

Within ten (10) days of the effective date of this decision, or within ten (10) days of the issuance or assignment/replacement of same, whichever is earlier, respondent shall provide the board or its designee in writing: a copy of the conditions of any criminal probation/parole applicable to respondent; and the name and contact information of any probation, parole or similar supervisory officer assigned to respondent. On an following the effective date, respondent shall provide a copy of all criminal probation/parole reports to the board within ten (10) days after such report is issued. 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 1: Respondent may obtain a DEA permit restricted to Schedule(s) _____controlled substance(s).

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

40 38. 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.

39. Facilitated Group Recovery and/or Support Meetings (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 quarterly 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 the number of group meetings per week or month unless otherwise directed by the board or its designee, which shall typically be at least one per week. 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.

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.)⁴ (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.

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:

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

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

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

Option (Alternate language that is appropriate 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 which shall be followed by written notification within two (2) business days of the occurrence. If, for any reason, including change of employment, respondent is not longer able to be monitored by the approved work site monitor, within ten (10) days of commencing new employment for prior approval by the PRP. Failure to identify an acceptable initial or replacement work site monitor, or to ensure monthly reports are submitted to the PRP by the work site monitor, shall be considered a violation of probation.

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.

⁴This probationary term is not new, but is being moved from the previous section "Pharmacy Technician — Standard Terms and Conditions" for purposes of consolidation. The language of this term is also changing from the previous version.

The 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 TECHNICIAN ⁵
The following standardized language shall be used in every decision where the order of condition is imposed.
Revocation
Pharmacy technician license number
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 \$within fifteen (15) days of the effective date of this decision.
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 forbeginning 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 numberis revoked; however the revocation is stayed and respondent is placed on probation foryears 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 foryears upon the following terms and conditions:
Surrender
Respondent surrenders pharmacy technician license numberas 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 \$withindays of the effective date of this decision.

Ontion:	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
<u>\$</u>	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
- Cooperate with Board Staff
- 6. Notice to Employers
- 7. Reimbursement of Board Costs
- 8. Probation Monitoring Costs
- 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 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
- 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.

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.

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.

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.

acknowledgment(s) to the board.

6	Notice to Employers
the de	g the period of probation, respondent shall notify all present and prospective employers of ecision in case numberand the terms, conditions and restrictions imposed on ndent by the decision, as follows:
respo super respo that the terms	n thirty (30) days of the effective date of this decision, and within fifteen (15) days of ndent undertaking any new employment, respondent shall cause his or her direct visor, pharmacist-in-charge (including each new pharmacist-in-charge employed during ndent's tenure of employment) and owner to report to the board in writing acknowledging ne listed individual(s) has/have read the decision in case number and the and conditions imposed thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgement(s) to the board.
respo pharn the re	pendent works for or is employed by or through a pharmacy employment service, and and an independent must notify his or her direct supervisor, pharmacist-in-charge and owner at every enacy of the terms and conditions of the decision in case number in advance of spondent commencing work at each pharmacy. A record of this notification must be led to the board upon request.
days	ermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) of respondent undertaking any new employment by or through a pharmacy employment e. respondent shall cause his or her direct supervisor with the pharmacy employment

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.

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

"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

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.

to provide such notification(s) shall be considered a violation of probation.

"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 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.

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.

Restitution (Appropriate in cases of drug diversion, theft, fraudulent billing, or	patient
harm resulting from negligence or incompetence.)	
Withindays of the effective date of this decision, respondent shall pay restitutionin the amount of \$ Failure to make restitution by this deadline	
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 REPRESENTATIVE

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

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

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

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

⁶ All information specific to Designated Representative is being removed and consolidated into Terms of Probation – Individual Licensees.

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
As part of probation, respondent is suspended from working as a designated representative for 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, 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 numberis revoked; however, the revocation is stayed and respondent is placed on probation foryears 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 foryears upon the following terms and conditions:
Surrender
Respondent surrenders designated representative license numberas 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 \$withindays 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
- 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 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
- 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 numberand 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 numberin 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 numberand 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 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 car harm resulting from negligence	ses of drug diversion, theft, fraudulent billing, or patient or incompetence.)
Within	days of the effective date	te of this decision, respondent shall pay restitution to - Failure to make restitution by this deadline shall be
consid	ered 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 least 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 respondent 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 the disciplinary order may include 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 harmful:

- violation(s) of recordkeeping requirements, scope of practice requirements, or inventory control requirements;
- smaller or isolated failure(s) to abide by or enforce prescription or refill requirements, drug-substitution requirements, or labeling requirements;
- violation(s) of obligations to supply or update information to the board, or to other enforcement or regulatory agencies;
- failure(s) to adequately supervise staff to ensure security and sanitation of premises, dangerous drugs and/or dangerous devices or controlled substances;
- violation(s) of packaging requirements, security control requirements, or reporting requirements; and
- failure(s) to display original license(s), or to supply name(s) of owner(s), manager(s), or employee(s).
- 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	<u>Exemptee Supervisor of Manufacturer, etc.: Requirements</u>
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
	5 5

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;
7127	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
	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
	Elochood Fromisoo
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	· · · · · · · · · · · · · · · · · · ·
4100	Automated Drug Delivery Systems
Article 14	. Surgical Clinics
4190	Purchase of Drugs at Wholesale: Permitted Uses of Drugs; Required Records and
1100	Policies; License Required
4191	Compliance with Department of Health Services Requirements; Who May Dispense
1101	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
1100	Authorized in Storage Area
4197	Minimum Standards: Security; Sanitation; Board Regulations; Waivers
4198	Written Policies and Procedures Required: Contents; Training of Personnel; Quality
4130	
	Assurance; Consulting Pharmacist
Article 17. Continuing Education	
4231	Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New
0.	Licensee
4232	Content of Courses
7202	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
10 10	Within
	vvicini.

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
1751.11	Furnishing to Home Health Agencies and Licensed Hospices
1751.12	Obligations of a Pharmacy Furnishing Portable Containers
1771	Posting of 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	<u>Exemptions</u>
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.
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> may include optional terms and conditions, as appropriate.

Maximum: Revocation

Category II discipline is recommended for violations with serious potential for harm, as well as for violations involving disregard for public safety or for laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs and/or dangerous 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 controlled substances. Violations in this category may include:

- failure(s) to abide by prohibitions on referral rebates or discounts (kickbacks) and/or volume or percentage-based lease agreements;
- violation(s) of advertising or marketing limitations, including use of false or misleading advertising or marketing;
- repeat or serious violation(s) of recordkeeping requirements, scope of practice requirements, or inventory control requirements;

- violation(s) of controlled substance secure prescription requirements, inventory controls, or security requirements;
- <u>failure(s) to meet compliance requirements, including pharmacist-in-charge or designated representative-in-charge designation and duties;</u>
- 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;
- smaller scale dispensing or furnishing of dangerous drugs and/or dangerous devices via the internet, without a valid prescription;
- purchasing, trading, selling, or transferring dangerous drugs and/or dangerous devices to or from unauthorized person(s);
- <u>failure(s)</u> 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;
- <u>criminal conviction(s) not involving alcohol, dangerous drugs and/or dangerous</u> 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
000	repairs of biscounts for referral frombited
650.1	Lease Prohibition - Hospitals or Prescribers
000.1	Loade i formenteri - freepitale et i federibere
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

4060	Facility or Clinic or for Other Health Care Provider 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— 4104—	Pharmacist in Charge, Exemptee: Termination of Employment; Notification to Board
-	Licensed Employee, Theft or Impairment: Pharmacy Procedures Pataining Records of Dangarous Drugs and Davises on Licensed Promises:
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 1	1. Wholesalers and Manufacturers
	Nonresident Wholesaler: When License Required; Application
	Unauthorized Furnishing by Manufacturer or Wholesale
	Reports Required
4169(a)(1) Prohibited Acts
Article 1	3. Non-Profit of Free Clinics
4185	Inspection Permitted
Article 1	4. Surgical Clinics
4195	Inspection Permitted
Article 1	9. 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 Non-
	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

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.

- 1306.13 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 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
- 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
 - 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

4 051(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
1 110	Election Required, Temperary Ferritt Open Transier of Ownership
4111	Restrictions on Prescriber Ownership
	- Restrictions on Frescriber 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
1001	· · · · · · · · · · · · · · · · · · ·
	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	
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

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

- violation(s) involving possession for sale, transportation, importation, and/or use of a minor for unlawful acquisition of sale, of controlled substances;
- criminal conviction(s) involving the above, or repeat convictions involving diversion or abuse of alcohol, dangerous drugs 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
- sale
- use of a minor for the unlawful sale of controlled substances

Revocation is also recommended when where a respondent fails to file a notice of defense to 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 ewner 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 dangerous devices or</u> controlled substances and dangerous drugs and/ <u>or dangerous</u> devices. Respondent shall further arrange for the transfer of all records of acquisition and disposition of dangerous drugs to premises licensed and approved by the board. Respondent ewner 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 <u>(5)</u> days of disposition.		
Option: Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five (5) days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.		
Suspension		
License number, issued to respondentis suspended for a period ofdays beginning the effective of this decision.		
Respondent shall cease all pharmacy operations as a [insert license type] during the period of suspension. Failure to comply with this 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 foryears 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 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 foryears <u>upon on the following terms</u> and conditions:		

Surrender

Respondent ewner surrenders license number ______as of the effective date of this decision. Respondent ewner 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 ewner 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 and approved by the board of all controlled substances and dangerous drugs and/or dangerous devices. Respondent shall further arrange for the transfer of all records of acquisition and disposition of dangerous drugs to premises licensed and approved by the board. Respondent ewner shall further provide written proof of such disposition and submit a completed Discontinuance of Business form according to board guidelines.

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

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

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

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

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

Public Reprimand Reproval

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

Adoption of Stipulation

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

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

- 1. Definition: Respondent
- 1 2. Obey All laws
- 23. Report to the Board
- 3 4. Interview with the Board
- 4 <u>5</u>. Cooperate with Board Staff
- 5 6. Reimbursement of Board Costs
- 6-7. Probation Monitoring Costs
- 78. Status of License
- 8 9. License Surrender While on Probation/Suspension
- 10. Sale or Discontinuance of Business
- 9 11. Notice to Employees
- 10 12. Owners and Officers: Knowledge of the Law
- 13. Premises Open for Business
- 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
- 46. 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.

4 2. Obey All Laws

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

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

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;
- a plea of guilty, or nolo contender contender, no contest, or similar, in any state or federal

- criminal proceeding to any criminal complaint, information or indictment;
- a conviction of any crime; or
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's _____license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any dangerous drug, and/or dangerous device or controlled substance.

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

23. Report to the Board

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

3 4. Interview with the Board

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

4 <u>5</u>. Cooperate with Board Staff

Respondent <u>owner</u> 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 <u>his or her the</u> 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 <u>timely</u> cooperate shall be considered a violation of probation.

5 6. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent ewner shall pay to the board its costs of investigation and prosecution in the amount of \$______. Respondent ewner 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 ewner 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 ewner shall, at all times while on probation, maintain current [insert license type] 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 within five (5) days. Respondent shall further arrange for the transfer of all records of acquisition and disposition of dangerous drugs and/or devices to premises licensed and approved by the board.

Respondent ewner 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 ewner 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 ewner may not apply for any new licensure license from the board for three (3) years from the effective date of the surrender. Respondent ewner 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 <u>it</u> 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 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 of the new owner.

9 11. Notice to Employees

Respondent ewner 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 ewner 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 ewner 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 timely provide such notification to employees, or to timely 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 all of its 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	<u>hours per calend</u>	dar month. Any month during which this
minimum is not met shall toll th	e period of probation,	, i.e., the period of probation shall be
extended by one month for each	ch month during with the	this minimum is not met. During any such
period of tolling of probation, re	spondent must nonet	theless comply with all terms and conditions
of probation, unless responden	t is informed otherwis	se in writing by the board or its designee. If
respondent is not open and en	gaged in its ordinary b	business as a [insert license type] for a
minimum of hours	n any calendar month	h, for any reason (including vacation),
respondent shall notify the boa	rd in writing within ten	n (10) days of the conclusion of that
calendar month. This notificati	on shall include at mir	nimum all of the following: the date(s) and
hours respondent was open; th	e reason(s) for the int	terruption or why business was not
conducted; and the anticipated	date(s) on which resp	pondent will resume business as required.
Respondent shall further notify	the board in writing w	with ten (10) days following the next
calendar month during which re	espondent is open and	d engaged in its ordinary business as a
[insert license type] in Californi	a for a minimum of	hours. Any failure to timely provide
such notification(s) shall be cor	nsidered a violation of	f probation.

11_14. Posted Notice of Probation

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

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

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

12 15. Violation of Probation

If a respondent owner has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent <u>license</u>, 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's 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 within two (2) days of receipt thereof from the board or its designee. The suspension notice shall remain posted during the entire period of suspension ordered by this decision. Failure to timely post such notice, or to maintain the posting during the entire period of suspension, shall be considered a violation of probation.

Respondent ewner 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.

44. 19. Community Services Program

Within sixty (60) days of the effective date of this decision, respondent owner shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free health-care related services to a community or charitable facility or agency for at leasthours perfor the firstof probation.
Within thirty (30) days of board approval thereof, respondent owner shall submit documentation to the board demonstrating commencement of the community service program. Respondent owner shall report on progress with the community service program in the quarterly reports.
Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.
15. 20. Restitution (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)
Withindays of the effective date of this decision, respondent owner shall pay restitution toin 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 ewner 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.

6/2007 <u>7/2015</u> 10/2015

Attachment 2

<u>Brief Description of Suggested Changes for Possible 15-Day Comment</u>

Many of the changes proposed are to provide clarification and allow for easier reading and consistency. Nonsubstantive changes are made throughout the document as well. The nonsubstantive changes are not detailed within this attachment, but are properly reflected in the draft guidelines.

Title Page

The board proposes to update the revision date on the title page to 10/2015.

Introduction (page 1)

The board proposes to include reference to California Code of Regulations sections 1771-1774 relating to requirements for disciplinary actions.

Factors to Be Considered in Determine Penalties (page 3)

The board is proposing to include a reference to Business and Professions Code Section 315, which establishes the requirements for the uniform standards.

Table of Contents

The table of contents will need to be renumbered and conforming changes made throughout the document. This will be done before the 15-day notice is released if necessary and is nonsubstantive.

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 remove the last sentence of the first paragraph as it is unnecessary.

Categories of Violations and Recommended Penalties

The board is proposing to include all of the individual license categories to conform with other areas of the guidelines. This change includes including the designated representative-3PL and the advanced practice pharmacists, which were inadvertently not incorporated during the initial notice period.

Category II

The board is proposing to remove the word "clearly" from the term "clearly excessive furnishing" as appropriate for a category II violation.

Category III

The board is proposing to specifically include reference to federal law establishing the traceability/pedigree requirements for the drug supply chain. Specific reference to the Drug Supply Chain Security Act is now included..

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 provide guidance to the user by including instructional language in the opening paragraph.

Revocation, Stayed, Probation Order

The proposed change in the title is more reflective of the provisions contained within the model language

Option: Intern Pharmacy Only)

The board is proposing to language to clarify the process used to effectuate this condition.

Public Reproval

The board is proposing to replace the word "reprimand" with "reproval" to ensure consistency with the title of the model language.

<u>License Reinstatement Order with Conditions Prior to Issuing License</u>

The board is proposing to update this section to include two separate options to facilitate ease of use in the guidelines. Specifically, the guidelines will include an option specific to pharmacists only as well as an option specific to pharmacy technicians. The requirements themselves are not new.

The board is proposing to remove the optional language requiring payment of cost recovery owed as that requirement is the prior two options.

Standard Conditions Listing (Page 27)

The board is proposing to renumber several provisions. (This will be done is if necessary in advance of the 15-day notice and is nonsubstantive.)

The board is proposing minor changes in the titles of some terms to ensure consistency within the document.

Optional Conditions Listing (Page 27)

The board is proposing to renumber several provisions. (This will be done is if necessary in advance of the 15-day notice and is nonsubstantive.)

Standard Conditions: To Be Included in All Probations (Page 29 – 35)

The board is proposed the following changes:

- Obey All Laws: Proposed changes will correct grammatical errors as well as clarify the items that must be reported to the board, providing guidance to the respondent.
- Reporting of Employment and Notice to Employers: The board is proposing to changes to
 incorporate some of the employment related requirements from term 7. This will centralize
 the employment requirements into a single term making it easier for a respondent to
 understand the requirements. Further, the language is modified to ensure consistency with
 timeframes used in term 7.

- Notification of Change(s) in Name, Address(es) or Phone Number(s): This term is being renamed to better reflect the requirements of the term. Also, this term modified to remove the employment reporting requirements that are now contained in term 6 and to include reporting changes in e-mail addresses.
- Restrictions on Supervision and Oversight of Licensed Facilities: The board is proposing
 modifications to this term to provide instructional language to users on how to use the
 options included within this term.

Option 2 is also being modified to clarify the requirement.

- License Surrender While of Probation: The board is proposing modifications to clarify the term as well as process a respondent must follow to surrender his or her license.
- Certification Prior to Resuming Work: The board is proposing modification to remove redundant requirements.
- Notification of Departure: This term will need to be discussed during the policy discussion and may require changes.
- Practice Requirement Extension of Probation: This term is being renamed to better reflect the
 provisions contained therein. Further, this term is being modified to clarify the requirements
 and specify that the board will provide notice if probation is extended.

Option 1 is also being removed as the optional language is inconsistent with the intent of the term

 Violation of Probation: This term is being modified to specify that the board will provide notice to the respondent and that the notice may posted.

Optional Conditions of Probation (Page 36 - 59)

The board is proposed the following changes:

• Clinical Diagnostic evaluation: This term is being modified to clarify that failure to comply with the provisions of the term will be considered a violation of probation.

Option 2 is being modified to provide guidance to the user about when inclusion of the option is appropriate. Redundant language is also being removed from this option.

Option 3 is being modified to remove redundant language.

- Psychotherapy: This term is being modified to remove redundant language.
- Medical Evaluation: The language is this term is being modified to mirror the language in similar terms. Proposed modifications clarify that recommendations for the physician may be included as part of the probation monitoring order if notice is provided by the board.

Option 1 is being modified to provide guidance to the user about when inclusion of the option is appropriate and redundant language is also being removed.

Option 2 is being removed as the provisions contained within the option are redundant with the previous option.

Pharmacists Recovery Program (PRP): The term is being modified to clearly detail what
actions must be taken as well as clearly details violations of the term that will result in
the automatic suspension of the license. Further language regarding the consequences
for testing positive is being removed as it is duplicate language also contained in the
Drug and Alcohol Testing term.

Option language is being modified to provide guidance to the user about when inclusion of the option is appropriate.

- Drug and Alcohol Testing: This term is being modified to clarify that the respondent will also be screened for the use of illicit drugs which is consistent with the provisions contained in the Abstain from Drugs and Alcohol term.
- Abstain from Drugs and Alcohol: This term is being modified to clarify the language and restore language that was inappropriately deleted during the 45-day comment period.
- Prescription Coordination and Monitoring of Prescription Use: This term is being modified to clarify the provision and to include illicit drugs. Redundant language is also being removed.
- Supervised Practice: The term is being modified to clearly detail what actions must be taken as well as clearly details violations of the term that will result in the automatic suspension of the license.
- No Ownership or Management of Licensed Premises: Option language is being modified to provide guidance to the use about when inclusion of the option is appropriate
- Criminal Probation/Parole Reports: This term is being modified to more clearly detail what information needs to be provided to the board.
- Facilitated Group/Recovery and/or Support Meetings: This term is being modified to remove redundant requirements.
- Attend Substance Abuse Recovery Relapse Prevention and Support Groups.
 This term is being modified to clarify the requirements of the term and to remove redundant language.
- Work Site Monitor: This term is being modified to clarify the notification requirement to mirror the language in similar terms to ensure consistency within the guidelines. Option language is being modified to provide guidance to the use about when inclusion of the option is appropriate

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.

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

The board is proposed the following changes:

Public Reproval

Replace the word "reprimand" with "reproval" to ensure consistency with the title of the model language.

Standard Conditions: To Be Included in All Probations (Pages 102-105)

The board is proposed the following changes:

- Obey All Laws: Proposed changes will correct grammatical errors as well as clarify the items that must be reported to the board, providing guidance to the respondent.
- Report to the Board: This term is being modified to clarify the requirement.
- 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.
- Status of License: This term is being modified to allow for the insertion of the appropriate license type in the order.
- License Surrender While on Probation: The option language is this term is being modified to remove the directional language as the option is language is appropriate for all business licenses issued by the board.
- Notice to Employees: This term is being modified to clarify the requirements of the term.

Conforming Changes

To ensured consistent use of the suspension provisions, the following language proposed to be used in all areas of the guidelines where suspension provisions currently exist. The language below is the language is its final format.

During suspension, respondent shall not enter any secured 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 that 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. 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 this suspension shall be considered a violation of probation.

This change will be incorporated if the board prefers the above language.

Attachment 3

Crosscutting Policy Issues

Reimbursement of Board Costs: The guidelines currently provide optional language
that allows the respondent to pay costs in a payment plan approved by the board or its
designee, as long as full payment is completed no later than one year prior to the end of
probation.

Question: Would the board like to convert this optional language into the standard term?

Staff Recommendation: Board staff recommends this change.

• Reapplication versus Petitioning the Board for Reinstatement: A currently drafted, a respondent that surrenders a license must reapply if a license is surrendered.

Question: Does the board wish to continue with this current policy or change it to treat it as for a petition for reinstatement?

Staff Recommendation: Board staff does not recommend a change to the board's current policy at this time.

Policy Issues Specific to Individual Licensees

• **Term 20 Pharmacist Examination**: Current guidelines provide that a respondent pharmacist is automatically suspended if he or she fails to take the exam within 6 months of the effective date of the decision. The term also specifies that failure to pass within 6 month is a violation of probation.

Question: Does the board agree with this change, or should we revert back to the two different time frames.

Staff Recommendation: Board staff recommends retaining the change to six months for both events.

Discuss with Giny. Move sentence and consolidate if they keep at six and six.

• **Term 29 Remedial Education**: The board's current guidelines establish the requirement for remedial education, including a provision that at the request of the board, respondent may be required to take an approved examination to test respondent's knowledge of the course. The term further states that failure of respondent to receive a passing score on the exam will be considered a violation of probation.

Question: Does the board wish to reconsider this provision to specify that respondent shall take another course approved by the board in the same subject area if he or she fails the examination? Below is language to establish this requirement if the board elects to change its current policy on this issue. (Change is reflected in strikeout.)

Remedial Education

. . .

Following the completion of each course, the board or its designee may require the respondent, at [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 that course shall not count towards satisfaction of this term. Respondent shall take another course approved by the board in the same subject area.

...

Staff Recommendation: Board staff recommends this change.

• **Term 30 Intern Pharmacist Experience**: The board's current guidelines include a term specific to intern pharmacist experience to require an intern to complete a training program under specified conditions.

Question: Does the board believe that this term is still appropriate? Staff notes that this term has not been used in at least the last seven years.

Staff Recommendation: Board staff recommends removal of this term.

• **Term 31 Supervised Practice**: As drafted, this term does not apply to pharmacy technicians, who by law must always perform duties under the direct supervision of a pharmacist in a pharmacy.

Question: Does the board want a pharmacy technician to be supervised only by a supervisor approved by the board? If so, the below language could be incorporated into the draft guidelines

Option (For Pharmacy Technicians Only)

Agenda Item XVI
Attachment 3

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 pharmacist 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 her 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. Respondent may have multiple supervisors approved by the board if necessary to meet respondent's work requirements.

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 prohibited from practice as a [insert license type] and may not resume such practice until notified by the board or its designee in writing.

Staff Recommendation: Board staff recommends this change

Policy Issues Specific to Premises

Model Language Revocation and Model Language Surrender: The model language for both the revocation and surrender of a premises license includes optional language that requires a respondent to arrange for the continuity of patient care and specifies how that should be done.

Question: Does the board believe that this optional language should be included in all orders calling for the revocation or surrender of a license?

Staff Recommendation: Board staff recommends this change

Attachment 4

RONALD S. MARKS

A Professional Law Corporation

Westlake Corporate Plaza 2625 Townsgate Road, Suite 330 Westlake Village, California 91361 Telephone: (818) 347-8112 Facsimile: (805) 445-0071

September 14, 2015

Lori Martinez State Board of Pharmacy 1625 North Market Blvd, Suite N 219 Sacramento, CA 95834 SOARD OF PHARMACY

RE: PROPOSED DISCIPLINARY GUIDELINES REVISIONS

Dear Ms. Martinez:

In reviewing the proposed revisions to the disciplinary guidelines, I felt compelled to provide some input based on a quick review.

- 1. Initial Statement of Reasons. I think it is error to fail to address the Economic Impact and merely assert that the revisions will not eliminate jobs. In practice for 44 years, I can tell you that imposing more stringent conditions of probation will affect jobs for licensees on probation. It is very difficult for probationers to find employment currently for the simple reason that pharmacies are aware that having a pharmacist on probation means that a board inspector will be visiting the pharmacy on a routine basis. I have heard it over and over that even pharmacies that are doing their best to follow the law do not want inspectors in their pharmacy. Unemployed pharmacists could result in a financial drain on State or other public resources. Additionally, the Board is proposing to carry over probation terms on interns after they are licensed. Just how many pharmacies are going to want to hire a brand new pharmacist who is also on probation? An analysis or study should be done on how many probationers are unemployed and what the likely impediment would be on newly graduated interns on probation before the Board makes the statement that the revised guidelines will not eliminate jobs.
- 2. The board should eliminate other license history from Factors to be Considered in Determining Penalty. It is vague as to what licenses should be considered since it does not even mention professional licenses. If the conduct is substantially related to the practice of pharmacy, it should be alleged as such in the Accusation. It could then be considered under the substantial relationship requirement.
- 3. Supervised Practice. The Board should allow more than 10 days to replace a practice supervisor. In my experience, finding a practice supervisor is extremely difficult. To have to find another one in 10 days if the first one is no longer able to serve or be automatically suspended is too harsh and could severely impact the operation of the pharmacy resulting in

probationers with this condition to be effectively unemployable. The allowable length of time should be increased. Also, to penalize the pharmacist for failure to "cause the practice supervisor to timely report to the board in writing" etc. is too vague. How do you fail to cause someone to do something?

- 4. Violation of Probation. The Board should not add the provision that probation will continue if the board staff requests the Office of the Attorney General to prepare an accusation or petition to revoke probation. I speak from experience. Without any deadline, such cases will be placed on the "back burner" and there will be an unconscionable delay inconsistent with due process. In addition, depending on the deputy's work load, there could be a great disparity between cases as to when accusations are filed. This new provision should be eliminated.
- 5. Notification of Departure. I cannot believe it is workable to have a probationer notify the board verbally and in writing every time he/she is leaving the "probationary geographic area" for more than 24 hours. Also, there is no definition of what constitutes the probationary geographic area.
- 6. Category IV violations. The proposed guidelines recommend revocation where prior discipline has been imposed. Without any discussion as to reasons, the proposed guidelines eliminate the qualification "unless the respondent can demonstrate satisfactory evidence of rehabilitation." This is either a drafting error or purely draconian to imply that rehabilitation is not relevant. The previous language should be restored.
- 7. Category III grounds. To add that knowingly or willfully violating laws or regulations constitutes a Category III level of discipline is vague and ambiguous. "Knowingly" and "willfully" are not consistently defined in the law and as to some definitions would make almost every act by a pharmacist done either "knowingly" or "willfully" thus making irrelevant Categories I and II. This phrase should be either modified to be more specific or eliminated altogether.

In June 2007, I shared some thoughts about those proposed guidelines but never received any response or feedback which led me to wonder whether the time spent is worthwhile. I am an optimist so I am again submitting some of my opinions which I hope will make a difference and that they will be seriously considered.

Sincerely,

RONALDS MARKS

cc: CPHA

John Cronin, Esq.

From: Megan B. Harwood <megan.harwood@gmail.com>

Sent: Monday, October 19, 2015 4:59 PM

To: Martinez, Lori@DCA

Subject: Proposed Changes to Title 16, California Code of Regulations Sections 1760

Good Afternoon Ms. Martinez,

I am in favor of providing less ambiguous terms and further clarifying the specifics of what is expected of a probationee in order to be compliant per the Board of Pharmacy. I myself have experienced difficulty with this and am highly in favor of improved definitions & clarifications on expectations, as well as methods of submission and potentially request the addition of a confirmation of receipt from the BOP for the probationer's records.

One proposed change I noticed stated "Business and Professions Code section 315.2 generally authorizes the board to suspend a licensee on probation from the practice of pharmacy if the licensee tests positive for any substance that is prohibited under the terms of the licensee's probation or diversion program."

Recommendation:

I recommend this term only be instituted for probationees who have been found to be substance abusing pharmacists or technicians.

It can appear confusing as to where the line is drawn, if at all it is, between those in treatment vs. probationees who have a term of drug testing, but are not substance abusers themselves, but perhaps are merely being monitored. I do not feel it within the best interest of the public nor the professional to suspend them without first giving timely notice if there is no history of substance abuse.

Thank you very much for your time. Sincerely, Megan

Megan B. Harwood, PharmD mobile 631-948-5508 email megbpharmd@gmail.com

• www.linkedin.com/pub/megan-b-harwood-pharmd/16/b93/14