

# Attachment 2

*Minutes of the Meeting with EPCglobal of  
September 27, 2007*



**California State Board of Pharmacy**

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STATE AND CONSUMERS AFFAIRS AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

**Meeting Summary  
September 27, 2007**

**California Board of Pharmacy Review of  
EPCglobal's Electronic Pedigree Standard**

Claremont Resort and Spa  
41 Tunnel Road  
Berkeley, CA 94705  
7 a.m. – 12:00 p.m.

Present: Bill Powers, Board President  
Stan Goldenberg, RPh, Board Member  
Virginia Herold, Executive Officer  
Judi Nurse, Supervising Inspector  
Joshua Room, Deputy Attorney General  
Robert Ratcliff, Supervising Inspector

From EPCglobal:

Ron Bone, CoChair, EPCglobal Healthcare & Life  
Sciences Industry Action Group  
Mike Rose, CoChair, EPCglobal Healthcare & Life  
Sciences Industry Action Group  
Eric Douglass, EPCglobal Retail Representative  
Grant Hodgkins, CoChair, EPCglobal Adoption Group  
John Howells, CoChair, EPCglobal Track & Trace  
Group  
Ted Ng, Industry Member  
Robert Celeste, Director, Healthcare, EPCglobal  
North America

The meeting was a follow-up to a March 2007 Meeting, and started at 7:15 a.m.

The meeting focused on a 10-page PowerPoint document (attached) in which the following topics were discussed in terms of whether the EPCglobal messaging standard was capable of handling specific situations. Input had been developed by EPCglobal from industry during periodic meetings on:

1. Unit Dose Serialization
2. Receipt of Partial Shipments
3. Drop Shipments

4. Sign and Certify Inbound (inference issue)
5. Resale of Returned Products
6. Intra-Company Transfers
7. Voided Pedigrees
8. Inference

The board may amplify some of these items into a question and answer framework, along with other questions submitted to the board's email address ([californiapedigree@pharmacy.ca.gov](mailto:californiapedigree@pharmacy.ca.gov)).

Another result of the September 27, 3007 discussion with EPCglobal representatives was the identification of certain topic areas in which the board would benefit from (and industry may wish to provide) additional input to the board regarding the prevalence, problems and possible preferred industry solutions in these areas. These topics may be scheduled as part of regularly scheduled Workgroup on E-Pedigree meetings or as stand alone meetings as topical workgroups as implementation issues arise.

It is anticipated that these presentations will come, at least initially, from industry associations or other representatives, so as to capture larger quantities of data or experience and focus the discussions on systemic rather than individual solutions. It is also anticipated that competing concerns of different industry players may need to be suspended to advance the presentation.

For each of these issue areas, the board would welcome written submissions regarding experience, difficulties, proposals, and other issues pertaining to implementation. Again, while the board is not precluding submissions by individual companies, it would be helpful for any written submission to be representative of more than an individual experience or preference.

To facilitate discussions of these topics, the board suggests the following "template" for written presentations to be submitted to the board in advance of such meetings.

- Submitted by:
- Problem/conflict with California's law:
- Background: Historical overview/framework of current practices in the industry, what are the different scenarios in which this practice or subject area has arisen already, and what are the processes employed to date, what members of the supply chain are involved?
- Frequency or prevalence of this practice or subject area:
- A specific discussion of the costs such implementation, on as many variables as possible (per-unit, per-store, per-facility, per-company)

- Can compliance with California's law be met? Why or why not?
- Desired Solution:
- Without the desired solution, what is the potential impact?

For each of these, the board would welcome written submissions regarding experience, difficulties, proposals, and other issues pertaining to implementation. While the Board is not precluding submissions by individual companies, it would be most helpful for any written submission to be representative of more than an individual experience or preference.

This proposal will be provided for the board at the October Board Meeting for discussion.

The meeting adjourned at 11:55 a.m.



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STATE AND CONSUMERS AFFAIRS AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

October 15, 2007

Notice:

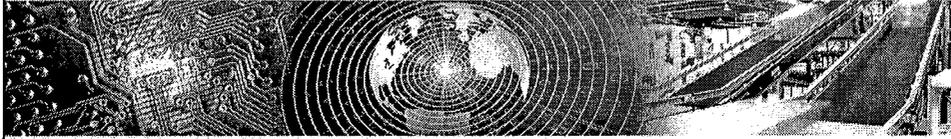
The following are slides prepared by EPCglobal that were used to frame and guide the discussion that occurred on September 27, 2007.

PLEASE NOTE: The following slides identify topics, issues, and/or responses pertaining to implementation of the EPCglobal electronic pedigree standard, and should not be relied upon as statements of California law. Though the board is satisfied that the EPCglobal standard enables compliance with the California pedigree law, the two are separate considerations. At all times, the law (of whatever jurisdiction, including California) should be separately consulted to determine its requirements and how the EPCglobal standard (or any other standard) may be relied upon or configured to ensure lawful compliance.

As EPCGlobal has articulated, its pedigree standard is designed to be flexible enough to enable compliance with several variations of pedigree laws, including for example those that (unlike California) only require serialization to the lot or case level, those that (unlike California) require paper pedigrees, and those that (unlike California) initiate the pedigree with the wholesaler/distributor rather than with the manufacturer. For that reason, some of what is in the following discussion of the capabilities of the standard may discuss outcomes and possibilities not compliant with California law. One example of this is on page 7 of the slides (Topic 5 - Resale of Returned Product): Though the EPCglobal standard has the capability to permit a manufacturer to "restart" with a new pedigree following a return, California law requires that every transaction resulting in change of ownership of a particular drug, including returns to a wholesaler or a manufacturer (and subsequent resale), be collected in a single pedigree record. (Business and Professions Code, § 4034(c) and (e).)

There may be other examples, and the failure to identify them here does not imply that the following slides are otherwise an accurate representation of California law. At all times, industry participants should consult the law itself to determine its requirements and how to configure their processes to come into compliance.

  
Virginia Herold  
Executive Officer



## EPCglobal Update

Follow up Items to the  
California Board of Pharmacy

Follow Up Items  
From  
March 8, 2007 Pedigree Workshop  
with  
Subset of California Board of Pharmacy

September 27, 2007

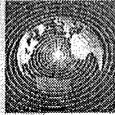


## Disclaimer

- Supply chain participants should rely upon their companies' legal interpretations of regulatory requirements.
  - GS1 US and EPCglobal North America do not interpret legislation nor recommend compliance postures.
  - Guidance presented in this presentation and associated documents is designed to provide a starting point for industry collaboration to drive towards common solutions.
  - Guidance and/or other team deliverables are not to be considered as legal advice and are not intended to substitute for competent legal counsel.

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## Follow Up Items - Summary Update Current Status

Weekly conference calls to work on follow up items

	Assign Responsibility	Document & Identify Item	Status	
1	Unit Dose Serialization	Individual company	Business Practice	On going
2	Receipt of Partial Shipments	Pedigree WG	Supported by Current Standard	Completed
3	Drop Shipments	Pedigree WG	Supported by Current Standard	Completed
4	Sign & Cert. Inbound	Industry Assoc	Supported by Current Standard	Completed
5	Resale of Returned Product	Pedigree WG	Supported by Current Standard	Completed
6	Intra-Company Transfers	Individual company	Business Practice	Completed
7	Voided Pedigrees	Industry Pedigree WG	Standard enhancement	Completed
8	Inference	Individual company	Supported by Current Standard	Completed

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## 1. Unit Dose Serialization

**Question:** Manufacturers SKUs comprised of sub-units (e.g. 10-pack pre-filled syringes), may be broken-down, where sub-units are sold as eaches. What are the implications re: serialization?

**Issues:**

- How are the eaches serialized
- What is the impact to Repackers
- How will Repackers continue the pedigree

**EPCglobal Response:**

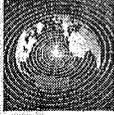
The current EPCglobal e-pedigree standard is capable of managing multiple levels of serialization, including serialized eaches. The standard does not contain a mechanism to manage items beyond the lowest level of unique identification, such as individual, unmarked or untagged, pills, tablets or syringes.

**Additional Comments:**

The original question was in reference to an item (syringe) that does not have a unique identifier, being sold from the lowest unit (a pack) that does have a unique identifier.

4





## 2. Receipt of Partial Shipments

**Question:** Orders are not always received complete & will likely have pedigree implications. How often does this occur? What pedigree /business process changes may be required?

**Issues:**

- How often does this occur
- What pedigree or business process
- changes may be required

**EPCglobal Response:**

The current EPCglobal e-pedigree standard is capable of managing orders that are separated in the delivery process. Pedigrees going forward will include the original pedigree denoting the entire shipment. As each partial receipt will cause a new pedigree to be created. Each partial receipt will result in a separate pedigree trail going forward.

**Additional comments:** none

**Reference:** EPCglobal Pedigree standard version 1.0, section 12.1.6. This is the guideline (non-normative) section of the standard.



## 3. Drop Shipments

**Question:** Manufacturers ship certain products to the end-customer, but billing goes through the Wholesaler. Where should the pedigree be sent and what transaction information should it reflect?

**Issues:**

- Where should the Pedigree be sent?
- What transaction information should it reflect?

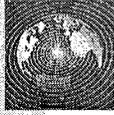
**EPCglobal Response:**

The current EPCglobal e-pedigree standard is capable of managing drop shipments. The standard provides guidance to the Wholesaler on how to indicate the direct shipment in the Pedigree.

**Additional comments:** none

**Reference:** EPCglobal Pedigree standard version 1.0, sections 12.1.11 and 12.1.12. These sections are contained in the guideline (non-normative) section of the standard.

Starting at line 1066 ... *"In this scenario, the manufacturer initiates the start of the drop ship pedigree documenting the sales transaction from the manufacturer to the wholesaler with the shipping information indicating the direct shipment to the pharmacy. The wholesaler adds only the second part of the drop ship transaction to the pedigree documenting the sales transaction from the wholesaler to the pharmacy."*



## 4. Sign & Certify Inbound

**Question:** The Law, as written, would require signature & certification of in-bound shipments, as well as out-bound. Use of inference on in-bound would be prohibited under strict interpretation of the Law.

**Issues:**

**EPCglobal Response:**

As this is not a Standards issue; the Industry Associations have decided to address this question. The Inference issue is responded in item 8.

**Additional comments:** None.

**Reference:** EPCglobal Pedigree standard version 1.0, section 6.



## 5. Resale of Returned Product

**Question:** If the product is returned to the manufacturer, can manufacturer initiate a new pedigree?

**Issues:**

- Customers may not want returned product if the pedigree must reflect the previous distribution of the product.
- How should a pedigree treat this transaction; reflect all previous movement of the product, or start anew when sold by the Manufacturer?
- What documents, processes, controls and enforcement would be required

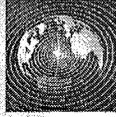
**EPCglobal Response:**

The current EPCglobal e-pedigree standard is capable of documenting the return and subsequent sale of items.

**Additional comments:** none

**Reference:** EPCglobal Pedigree standard version 1.0, section 12.1.9. This section is contained in the guideline (non-normative) section of the standard. The guideline does not read on the action of the Manufacturer after receiving the return and processing the received pedigree. The Standard allows for the continuation of this pedigree or the creation of a new pedigree when the item is shipped.

Starting at line 1052 ... *"The pedigree flow is described for a sale from a manufacturer to a wholesaler and then with a return from the wholesaler back to the manufacturer. The party making the return applies the return transaction to the pedigree."*



## 6. Intra-Company Transfers

**Question:** Pedigree status for intra-company transfers into CA: Can the EPCglobal pedigree standard support the product being shipped from an inter division location that isn't shown as the receiving location (e.g. the product is received in one location and shipped from a different location in the same entity)?

**Issues:**

- Product sold to a Wholesaler to an out-of-state location that does not require a Manufacturer originated pedigree may be intra-company transferred to CA,
- What are the CA pedigree implications

**EPCglobal Response:**

The current EPCglobal e-pedigree standard is capable of documenting the receipt of an item at one location and shipping from another. There is no requirement that the location information in the "received pedigree" be the same as the subsequent "shipped pedigree" when no change of ownership occurs.

**Additional comments:** none

**Reference:** EPCglobal Pedigree standard version 1.0.



## 7. Voided Pedigrees

**Question:** What is the process of voiding pedigrees where either an error in the pedigree has occurred (e.g. typographical error), or product has been returned?

**Issues:**

- What is the process of voiding pedigrees where an error has occurred, or a product has been returned
- How are pedigrees for products marked for destruction managed

**EPCglobal Response:**

The EPCglobal e-pedigree standard provides usage guidelines for voiding and altering pedigrees. The standard recommends that trading partners maintain a history (e.g., audit trail) of pedigree alterations and voids. Tracking of voided pedigrees is a combination of software and business processes. Future versions of the standard may provide some support for automating the communication of pedigree voids.

**Additional comments:** none

**Reference:** EPCglobal Pedigree standard version 1.0, section 12.2.

*"The current revision of the EPCglobal Pedigree Standard does not contain a mechanism to automate the notification of trading partners when a void or alteration occurs. However, some non-binding best practices are provided as recommendations to assist the industry in handling pedigree alterations and voids until a later revision of this standard may include a way to automate these activities.*

1. Pedigree voiding and alterations should be avoided if at all possible since they will create labor intensive activities at one or more trading partner sites.
2. The notification of trading partners that a pedigree has been altered or voided must be done manually (phone call, email, etc.) since there is no standard notification mechanism defined yet.
3. It is the responsibility of the trading partners to maintain a history of pedigree alterations and voids as specified by the various pedigree laws. Pedigree management software may assist with this.
4. Pedigree alterations and voids should be initiated only during the short window of time after the document has been transferred from one trading partner to another and prior to the inbound certification of the product received.
5. Recalls should typically never be used as a reason to void or alter a pedigree."



## 8. Inference

**Question:** Whether inference will be allowed at any step requiring "certification of the receipt", meaning that the receipt is positively affirming that they received all of the products specified in the pedigree without physically verifying all serial numbers.

**Issues:**

- Does the pedigree std allow two separate signature events for one receipt step (one to receive, one to certify at a later date).
- What is the Industry's view on inference and it's application
- Is there a time limit from inbound receipt inference until all unique ID numbers have been certified

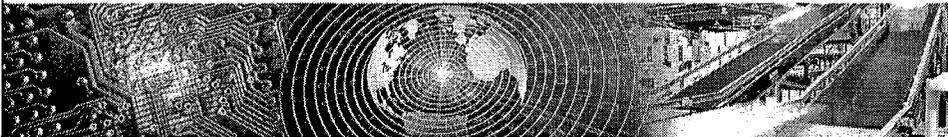
**EPCglobal Response:**

The current EPCglobal e-pedigree standard is capable of can supporting the use of inference but it is an individual company decision to implement an individual process.

**Additional comments:**

- **Infer (Inference): Conclude from evidence (Webster's Dictionary).**
- **EPCglobal Working Definition: To infer the serialized number based on information provided by the upstream supply chain partner and reasonable inspection of the package security features.**

**Reference:** EPCglobal Pedigree standard version 1.0, section 6.3.



# Questions?

# *Attachment 3*

*Federal Requirements for the FDA  
Regarding Drug Pedigrees*



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Summary of HR 3580

Analysis by Deputy Attorney General Joshua Room , September 28, 2007

This law is primarily about reauthorizing the FDA, and adding lots more post-approval auditing/enforcement of approved drugs. In the 422-page bill, only 3-4 pages (pages 355-358) are particularly relevant to recent activities of the Board of Pharmacy, and those are the pages that have to do with standards for serialization, track-and-trace, and pharmaceutical product security.

One thing that should be clear is that the federal legislation does NOT preempt or in any way limit the Board's authority to enact or enforce the pedigree law(s) (or any other authority of the Board). If anything, the timeline(s) given in the bill, and the "hands off" nature of the law, would appear to be an implicit blessing of the Board's activities with regard to electronic pedigree. If it in fact, as appears to be its aim, gets the federal government involved in ferreting/separating out the best technologies for serialization and track-and-trace, it may even significantly advance California electronic pedigree development.

\*\*\*\*\*

The bill/law amends the FFDCA (21 USC § 351 et seq.):

(1) to require that the Secretary (of HHS) "develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs."

(2) to require that the Secretary "develop standards for the identification, validation, authentication, and tracking and tracing of prescription drugs," in consultation with other (including state) agencies, and with manufacturers, distributors, pharmacies, etc.

(3) to require that within 30 months of enactment the Secretary develop "a standardized numerical identifier (which, to the extent practicable, shall be harmonized with international consensus standards for such an identifier) to be applied to a prescription drug at the point of manufacturing and repackaging (in which case the numerical identifier shall be linked to the numerical identifier applied at the point of manufacturing) at the package or pallet level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug."

(4) to require that such standards address "promising technologies, which may include" RFID, nanotechnology, encryption technologies, and other track-and-trace or authentication technologies.

(5) to require that the Secretary "expand and enhance the resources and facilities" of the FDA "to secure the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs "including biological products," and that the Secretary undertake "enhanced and joint" enforcement activities with other federal and state agencies, and "establish regional capacities for the validation of prescription drugs and the inspection of the prescription drug supply chain."

\*\*\*\*\*

So this is primarily a technology-development/standards-setting bill, which is something I would hope the industry would welcome.

Among other things, it is implicitly or explicitly supportive of the California legislation because (a) it responds to a perceived need to enhance the security of the pharmaceutical supply chain, the same need addressed by the California legislation (thus implicitly rejecting those who might claim current chain of custody, even through ADRs, is sufficiently secure), (b) the 30-month deadline for development of a standardized numerical identifier (by the way, many are assuming that this 30-month deadline also applies to the other standards required by the bill, but there is no explicit deadline on the others) would require that process to complete by April 2010, approximately - one might presume that this is intended to benefit from the work that will be done to get ready for the 2009 implementation in California, and (c) it is consistent with the California law in presuming the application of the numerical identifier (what we would call the "serialization") will take place at the manufacturer, and will therefore be tracked from the manufacturer. So it seems to call for an infrastructure consistent with that required by California law, where manufacturers initiate tracking.

One significant question that will need to be resolved about the law is what it means when it says that the numerical identifier is "to be applied to a prescription drug at the point of manufacturing and repackaging (in which case the numerical identifier shall be linked to the numerical identifier applied at the point of manufacturing) at the package or pallet level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug." Does this mean unit-level serialization, as is required by the California law? Or does it mean that serialization/tracking at the pallet, or perhaps case, level is sufficient? I believe it is more probable that this language envisions unit-level serialization. First, it says the identifier will be applied to "a" prescription drug; to me that would be an odd nomenclature to use to denote a case or pallet. Second, I believe that "package" will be read to mean the immediate container/saleable unit. Third, even though the law says the identifier standard could call for its application to the "package or pallet," I think ultimately the agency staff will push it toward unit-level serialization.

1           the date of the enactment of the Food and  
2           Drug Administration Amendments Act of 2007;  
3           or

4           “(4) the drug is a new animal drug whose use  
5           is not unsafe under section 512.”.

6           (b) CONFORMING CHANGES.—The Federal Food,  
7 Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amend-  
8 ed—

9           (1) in section 304(a)(1), by striking “section  
10          404 or 505” and inserting “section 301(l), 404, or  
11          505”; and

12          (2) in section 801(a), by striking “is adulter-  
13          ated, misbranded, or in violation of section 505,”  
14          and inserting “is adulterated, misbranded, or in vio-  
15          lation of section 505, or prohibited from introduction  
16          or delivery for introduction into interstate commerce  
17          under section 301(l),”.

18 **SEC. 913. ASSURING PHARMACEUTICAL SAFETY.**

19          Chapter V of the Federal Food, Drug, and Cosmetic  
20 Act (21 U.S.C. 351 et seq.), as amended in section 403,  
21 is amended by inserting after section 505C the following:

22 **“SEC. 505D. PHARMACEUTICAL SECURITY.**

23          “(a) IN GENERAL.—The Secretary shall develop  
24 standards and identify and validate effective technologies  
25 for the purpose of securing the drug supply chain against

1 counterfeit, diverted, subpotent, substandard, adulterated,  
2 misbranded, or expired drugs.

3 “(b) STANDARDS DEVELOPMENT.—

4 “(1) IN GENERAL.—The Secretary shall, in con-  
5 sultation with the agencies specified in paragraph  
6 (4), manufacturers, distributors, pharmacies, and  
7 other supply chain stakeholders, prioritize and de-  
8 velop standards for the identification, validation, au-  
9 thentication, and tracking and tracing of prescrip-  
10 tion drugs.

11 “(2) STANDARDIZED NUMERAL IDENTIFIER.—

12 Not later than 30 months after the date of the en-  
13 actment of the Food and Drug Administration  
14 Amendments Act of 2007, the Secretary shall de-  
15 velop a standardized numerical identifier (which, to  
16 the extent practicable, shall be harmonized with  
17 international consensus standards for such an identi-  
18 fier) to be applied to a prescription drug at the point  
19 of manufacturing and repackaging (in which case  
20 the numerical identifier shall be linked to the numer-  
21 ical identifier applied at the point of manufacturing)  
22 at the package or pallet level, sufficient to facilitate  
23 the identification, validation, authentication, and  
24 tracking and tracing of the prescription drug.

1           “(3) PROMISING TECHNOLOGIES.—The stand-  
2           ards developed under this subsection shall address  
3           promising technologies, which may include—

4                   “(A) radio frequency identification tech-  
5                   nology;

6                   “(B) nanotechnology;

7                   “(C) encryption technologies; and

8                   “(D) other track-and-trace or authentica-  
9                   tion technologies.

10           “(4) INTERAGENCY COLLABORATION.—In car-  
11           rying out this subsection, the Secretary shall consult  
12           with Federal health and security agencies, includ-  
13           ing—

14                   “(A) the Department of Justice;

15                   “(B) the Department of Homeland Secu-  
16                   rity;

17                   “(C) the Department of Commerce; and

18                   “(D) other appropriate Federal and State  
19                   agencies.

20           “(c) INSPECTION AND ENFORCEMENT.—

21                   “(1) IN GENERAL.—The Secretary shall expand  
22                   and enhance the resources and facilities of agency  
23                   components of the Food and Drug Administration  
24                   involved with regulatory and criminal enforcement of  
25                   this Act to secure the drug supply chain against

1 counterfeit, diverted, subpotent, substandard, adul-  
2 terated, misbranded, or expired drugs including bio-  
3 logical products and active pharmaceutical ingredi-  
4 ents from domestic and foreign sources.

5 “(2) ACTIVITIES.—The Secretary shall under-  
6 take enhanced and joint enforcement activities with  
7 other Federal and State agencies, and establish re-  
8 gional capacities for the validation of prescription  
9 drugs and the inspection of the prescription drug  
10 supply chain.

11 “(d) DEFINITION.—In this section, the term ‘pre-  
12 scription drug’ means a drug subject to section  
13 503(b)(1).”.

14 **SEC. 914. CITIZEN PETITIONS AND PETITIONS FOR STAY OF**  
15 **AGENCY ACTION.**

16 (a) IN GENERAL.—Section 505 of the Federal Food,  
17 Drug, and Cosmetic Act (21 U.S.C. 355), as amended by  
18 section 901(a), is amended by adding at the end the fol-  
19 lowing:

20 “(q) PETITIONS AND CIVIL ACTIONS REGARDING AP-  
21 PROVAL OF CERTAIN APPLICATIONS.—

22 “(1) IN GENERAL.—

23 “(A) DETERMINATION.—The Secretary  
24 shall not delay approval of a pending applica-  
25 tion submitted under subsection (b)(2) or (j)

# Attachment 4

*Development of an Ethics Course for  
Pharmacists*

**Registration & Attendance Fee:**

An application which includes a background assessment must be completed to register. This form is available at [www.imq.org](http://www.imq.org) click on Education Programs/"Professionalism Program."

**Resource Materials:**

Participants will be sent information about meeting location, the course schedule, a copy of the AMA Code of Medical Ethics and other reading materials that are required for the course.

**Fee:**

Registration fee \$1900 includes all three (3) components of the program, all required reading materials and continental breakfast and breaks at the two-day session.

**Refund:**

Cancellation must be received 21 calendar days prior to the reserved seminar date for registrants to receive a refund. The refund, less a \$500 service fee, will be mailed after the seminar. There is no refund if the cancellation notice is received at IMQ between 21 days before the seminar, and the date of the seminar. A registrant can transfer to another seminar date at no charge if the request is made at least 21 days prior to the reserved seminar.

Participants should phone (415) 882-3387 to reserve a place in one of the upcoming programs. Sessions are limited to 12 participants. Once a session has filled with pre-paid participants, others must choose an alternative date. A letter of confirmation will be mailed after receipt of the completed application with a copy of the Accusation and Decision and/or Stipulated Agreement and the program fee.

**Send the application and payment to:**

Institute for Medical Quality  
Medical Ethics Seminar  
221 Main Street, Suite 210  
San Francisco, CA 94105

**Learning Objectives:**

- Describe the ethics and law of medicine in California.
- Describe the foundations of the physician as a professional.
- Apply a variety of resources when future problems arise.
- Describe the legal and ethical dimensions of the practice of medicine in California.
- Identify and resolve ethical issues.



**INSTITUTE FOR MEDICAL  
QUALITY**

*A subsidiary of the California Medical Association*

Presents:

**IMQ  
Professionalism  
Program**

The Professionalism Program is designed to comply with the new requirements established by the Medical Board of California. The program centers on both the legal and ethical dimensions of medical practice in California. It introduces participants to a range of resources to address present or future problems.

The two-day portion of the Program will be held on Saturdays and Sundays at locations conveniently located to airports in Southern California

*The class shall not exceed a maximum of 12 participants.*

**Program Overview**

This Program consists of a Pre-Course Assessment and Testing component, a two-day Ethics Course and Longitudinal Follow-up after the Course.

Classes will include case presentations, break out groups, experiential exercises and role-playing. All class sessions must be attended. Full participation and fulfillment of all assignments are required for completion of the Program.

### Course Plan

#### Pre-Program Requirements:

- Background Assessment - Application
- Baseline Assessment of Knowledge Test
- Reading Assignment
- Participant Expectation of Program

#### Day One: Saturday

Introduction - Program Outline	8:00 - 8:30
What Ethical Issues are & when do they arise?	8:30 - 10:00
Break	10:00 - 10:15
Accessing legal resources, where to look and how to use	10:15 - 12:00
Lunch (on your own)	12:00 - 1:00
The physician as a Professional	1:00 - 2:00
Using sources to analyze a situation & an introduction to resources list	2:00 - 3:00
Break	3:00 - 3:15
Decision Making Model on how to resolve Ethical Decisions – Presentations	3:15 - 5:00
Break	5:00 - 5:15
Group Project Assignment	5:15 - 6:15

#### Day Two: Sunday

Group Reports	8:00 - 8:45
The Interplay of Law & Ethics	8:45 - 10:00
Break	10:00 - 10:15
Individual Work on Participant Violations	10:15 - 11:00
Small Group Application of Decision Model	11:00 - 12:00
Lunch (on your own)	12:00 - 1:00
Report out on Small Group Application	1:00 - 2:00
Role Play Exercise	2:00 - 3:00
Break	3:00 - 3:15
Concluding Session – review of seminar methods and concepts	3:15 - 4:00
Post Course Test	4:00 - 5:00

#### Longitudinal Follow-Up:

- 6 Month Follow-up
- 12 Month Follow-up

### Accreditation

The California Medical Association (CMA) is accredited by the Accreditation Council of Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians.

The CMA designates The Professionalism Program for a maximum of 22 *AMA PRA Category I Credits™*. Physicians should only claim credit commensurate with the extent of their participation in the activity. The credit may also be applied toward the CMA Certification in Continuing Medical Education.

### Faculty

**William May, PhD** is a faculty member at the University of Southern California where he specializes in medical ethics and business ethics. His primary teaching is on the main campus, but he participates in the bioethics program at the Medical School as well.

He has published books and articles on professional ethics. He has served on three hospital ethics committee and institutional review boards at LAC+USC Medical Center and the California State Human Subjects Committee from 1992 to 2004. Professor May taught an Ethics Seminar sponsored jointly by the CMA/IMQ and the Medical Board of California.

**Gregory M. Abrams, JD** received his Juris Doctor degree from University of California, Hastings College of Law in San Francisco.

Mr. Abrams is an attorney with California Medical Association and has worked on a variety of issues including professional liability and MICRA, physician reporting and warning requirements and Medical Board of California issues regarding physician discipline and unprofessional conduct. He is a contributing author of the *California Medical Association's California Physicians Legal Handbook*.



## Welcome to the online source for the California Code of Regulations

16 CA ADC § 1358.1

Term 

16 CCR s 1358.1

Cal. Admin. Code tit. 16, s 1358.1

BARCLAYS OFFICIAL CALIFORNIA CODE OF REGULATIONS  
TITLE 16. PROFESSIONAL AND VOCATIONAL REGULATIONS  
DIVISION 13. MEDICAL BOARD OF CALIFORNIA [FNA1]  
CHAPTER 2. DIVISION OF MEDICAL QUALITY  
ARTICLE 3. PROBATION AND REINSTATEMENT OF SUSPENDED OR REVOKED CERTIFICATES  
This database is current through 9/28/07, Register 2007, No. 39  
s 1358.1. Ethics Course Required as Condition of Probation.

A licensee who is required, as a condition of probation, to complete an ethics course shall take and successfully complete a professionalism program approved by the division that meets the requirements of this section.

(a) Approved Provider. The program provider shall be accredited by the Accreditation Council of Continuing Medical Education (ACCME), or by an entity qualified in Section 1337, to sponsor continuing medical education for physicians and surgeons and shall provide satisfactory written evidence that its professionalism program meets all of the requirements of this section.

(b) Criteria for Acceptability of Program.

(1) Duration. The course shall consist of a minimum of 22 hours, of which at least 14 are contact hours and at least 8 additional hours are credited for preparation, evaluation and assessment. The provider shall identify the number of continuing medical education hours that will be credited upon successful completion of the program.

(2) Faculty. Every instructor shall either possess a valid unrestricted California professional license or otherwise be qualified, by virtue of prior training, education and experience, to teach an ethics or professionalism course at a university or teaching institution. The provider shall submit with its application a curriculum vitae for each instructor for approval by the division or its designee.

(3) Educational Objectives. There are clearly stated educational objectives that can be realistically accomplished within the framework of the course.

(4) Methods of Instruction. The provider shall describe the teaching methods for each component of the program, e.g., lecture, seminar, role-playing, group discussion, video, etc.

(5) Content. The program shall contain all of the following components:

(A) A background assessment to familiarize the provider and instructors with the factors that led to the prospective candidate's referral to the class.

(B) A baseline assessment of knowledge to determine the participant's knowledge/awareness of ethical and legal issues related to the practice of medicine in California, including but not limited to those legal and ethical issues related to the specific case(s) for which the participant has been referred to the program.

(C) An assessment of the participant's expectations of the program, recognition of need for change, and commitment to change.

(D) Didactic presentation of material related to those areas that were problems for the participants based upon the results of the background assessments and baseline assessments of knowledge.

(E) Experiential exercises that allow the participants to practice concepts and newly developed skills they have learned during the didactic section of the class.

(F) A longitudinal follow-up component that includes (1) a minimum of two contacts at spaced intervals (e.g., 6 months and 12 months) within one year after course completion or prior to completion of the participant's probationary period if probation is less than one year, to assess the participant's status; and (2) a status report submitted to the division within 10 calendar days after the last contact.

(6) Class Size. A class shall not exceed a maximum of 12 participants.

(7) Evaluation. The program shall include an evaluation method that documents that educational objectives have been met - e.g. written examination or written evaluation - and that provides for written follow-up evaluation at the conclusion of the longitudinal assessment.

(8) Records. The provider shall maintain all records pertaining to the program, including a record of the attendance for each participant, for a minimum of 3 years and shall make those records available for inspection and copying by the division or its designee.

(9) Program Completion. The provider shall issue a certificate of completion to a participant who has successfully completed the program. The provider shall also notify the division or its designee in writing of its determination that a participant did not successfully complete the program. The provider shall fail a participant who either was not actively involved in the class or demonstrated behavior indicating a lack of insight (e.g., inappropriate comments, projection of blame). This notification shall be made within 10 calendar days of that determination and shall be accompanied by all documents supporting the determination.

(10) Change in Course Content or Instructor. The provider shall report to the division any change in course content or instructor within 30 calendar days after the date of that change.

## &lt;&lt;DIVISION 13. MEDICAL BOARD OF CALIFORNIA [FNA1]&gt;&gt;

[FNa1] For disposition of former Sections 1370-1375.45, see Table of Parallel Reference, Chapter 13.2, Title 16, California Code of Regulations.

## &lt;General Materials (GM) - References, Annotations, or Tables&gt;

Note: Authority cited: Section 2018, Business and Professions Code. Reference: Sections 2227, 2228 and 2229, Business and Professions Code.

## HISTORY

1. New section filed 3-7-2005; operative 4-6-2005 (Register 2005, No. 10).

16 CCR s 1358.1, 16 **←CA ADC s 1358.1→**  
1CAC

16 **←CA ADC s 1358.1→**

END OF DOCUMENT

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# Attachment 5

*Proposed Self Assessment Form for  
Veterinary Food Animal Drug Retailers*

# VETERINARY FOOD-ANIMAL DRUG RETAILER SELF ASSESSMENT

All legal references used throughout this self-assessment form are explained on Page 17  
All references to "drugs" throughout this self-assessment refer to dangerous drugs and  
dangerous devices as defined in Business & Professions Code (B&P) section 4022.  
([http://www.pharmacy.ca.gov/laws\\_regs/lawbook.pdf](http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf)) Dangerous drug or dangerous device  
means any drug or device unsafe for self-use in humans or animals.

## Definitions:

"Veterinary Food-Animal Drug Retailer" (vet retailer) is an area, place or premises, other than a pharmacy that holds a valid license from the California State Board of Pharmacy as a wholesaler and, in and from which veterinary drugs for food-producing animals are dispensed pursuant to a prescription from a licensed Veterinarian. It is a separate and additional license from a wholesaler license. Veterinary food-animal drug retailer includes but is not limited to any area, place or premises described in a permit issued by the board wherein veterinary food-animal drugs (as defined in Business & Professions Code section 4042) are stored, possessed, or repackaged, and from which veterinary drugs are furnished, sold, or dispensed at retail pursuant to a prescription from a licensed veterinarian.

"Veterinary Food-Animal Drugs" include any drug to be used in food-producing animals bearing the legend "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian" or words of similar import. Also included is any drug as defined in Section 14206 of the Food and Agriculture Code that is used in a manner that would require a veterinary prescription.

Veterinary Food-Animal Drug Retailer Name \_\_\_\_\_

Address \_\_\_\_\_

Phone \_\_\_\_\_

E-mail address (optional) \_\_\_\_\_

Ownership: Please mark one

- Sole owner       Partnership       Corporation       LLC  
 Non-licensed owner       other (please specify) \_\_\_\_\_

CA Veterinary Food-Animal Drug Retailer Permit # \_\_\_\_\_ Expiration Date \_\_\_\_\_

CA Wholesaler Permit # \_\_\_\_\_ Expiration Date \_\_\_\_\_

DEA Registration # \_\_\_\_\_ Expiration Date \_\_\_\_\_

Date of most recent DEA Inventory \_\_\_\_\_

Hours: Daily \_\_\_\_\_ Sat \_\_\_\_\_ Sun \_\_\_\_\_ 24 hours \_\_\_\_\_

Designated representative-in charge (DRIC) /pharmacist (RPH) \_\_\_\_\_

DRIC License # / RPH License # \_\_\_\_\_ Expiration Date \_\_\_\_\_

Licensed Veterinary Food-Animal Drug Retailer Staff (designated representative (DRep, pharmacist):

1. \_\_\_\_\_ DRep/RPH# \_\_\_\_\_ Exp. Date \_\_\_\_\_

2. \_\_\_\_\_ DRep/RPH# \_\_\_\_\_ Exp. Date \_\_\_\_\_

Please mark the appropriate box for each question. If "NO," enter an explanation on the "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, add additional sheets.

### 1. Ownership/Location

Yes No N/A

Review the current veterinary food-animal drug retailer permit for this business. Are the listed owners correct and is the listed address correct? If either is incorrect, notify the board in writing. (B&PC 4196 [a] [d])  
**Attach a copy of the notification letter to the board to this document.**

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_  
\_\_\_\_\_

### 2. Facility

Yes No N/A

Are only pharmacists, intern pharmacists, designated representatives, and authorized officers of the law, or a person authorized to prescribe, permitted in the area place or premises described in the permit as a veterinary food-animal drug retailer without supervision? (B&P 4196[c])

Is a pharmacist or designated representative responsible for any person who enters the premises for clerical, inventory control, housekeeping, delivery, maintenance, or similar functions related to the business of a veterinary food animal drug retailer? (B&P 4196[c])

Are all veterinary food-animal drugs stored in a secure, lockable area? (B&P 4197[a][1])

Premises, Fixtures and equipment: (B&P 4197[a][2])

Fixtures and equipment -Clean and orderly

Premises - dry

Premises - well ventilated

Premises - Adequately lighting

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_  
\_\_\_\_\_

**3. Designated Representative-in-Charge/Owner Responsibilities**

Yes No N/A

Are the owner and the designated representative-in-charge both equally responsible for maintenance of the records and inventory? (B&P 4081[b])

Is the designated representative-in-charge responsible for the veterinary food-animal drug retailer's compliance with all state and federal laws related to practice as a veterinary food-animal drug retailer? (B&P 4196[d]).

Has the owner notified the board within 30 days of the termination of the designated representative-in-charge or pharmacist? (B&P 4305.5[a])

Has the owner identified and notified the board of the appointment of a new designated representative-in-charge within 30 days of the termination of the former designated representative-in-charge? (B & P 4196[d], 4331[b]. The appropriate form for this notification is a "Change of Designated Representative-in-Charge", which is available on the board's web site.

Has any designated representative-in-charge who ends his or her employment at a wholesaler, notified the board within 30 days? (B & P 4305.5[c], 4101[b]. This notification is in addition to that required of the owner.

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

**4. Designated Representative/Pharmacist**

Yes No N/A

Does your veterinary food-animal drug retailer operate only when a pharmacist or veterinary designated representative is on the premises? (4053[c])

Is the address of the veterinary designated representative(s) current on their printed permit? (B&P4100,1704)

Yes No N/A

If a veterinary designated representative or pharmacist changes his/her name or personal address of record, he/she will notify the board in writing within 30 days? (B&P 4100, CCR 1704)

A pharmacist or veterinary retailer designated representative only dispenses drugs for use on food-producing animals on the basis of a written, electronically transmitted or oral order received from a licensed veterinarian? (CCR 1780.1[d])

Only a pharmacist or the veterinary designated representative receives an oral order for a veterinary food-animal drug from the veterinarian? (CCR 1780.1[d])

A written copy of any oral prescription is sent or electronically transmitted to the prescribing veterinarian within 72 hours? (CCR 1780.1[d])

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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### 5. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes No N/A

Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (B&P 4163[b], 4169)

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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### 6. Receipt of Drugs by this Business

Yes No N/A

When drugs are received by your business, are they delivered to the licensed wholesale premises, and received by and signed for only by a designated representative or a pharmacist? (B&P 4059.5[a])

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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### 7. Drug Stock

Yes No N/A

Is all drug stock open for inspection during regular business hours? (B&P 4081[a])

Do all drugs you sell conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (B&P 4342[a])

If dangerous drugs, legend drugs or extra label use drugs are returned to the veterinary food-animal drug retailer from a client are they treated as damaged or outdated prescription drugs and stored in the quarantine area specified in California Code of Regulations section 1780(3)(1) and are not returned to stock, or dispensed, distributed or resold? (CCR 1780.1)

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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### 8. Prescription Dispensing

Yes No N/A

Are dangerous drugs and extra label use drugs for use on food producing animals dispensed to clients pursuant to a prescription written by a veterinarian? (CCR 1780.1[a][d])

Are dangerous drugs, and extra label use drugs prepared and labeled by a pharmacist or designated representative only? (CCR 1781.1[d])

A veterinarian's prescription for a food-producing animal can only be refilled if the initial prescription issued indicated a specific number of refills. If no refills are indicated on the initial prescription, no refills may be dispensed. Instead a new prescription must be obtained from the veterinarian? (CCR 1780.1[g][1])

No veterinary food-animal drug prescriptions are refilled over six months from the date of issuance of the initial order? (CCR 1780.1[g][2])

Are prescriptions partially filled? If unable to fill the full quantity of drugs prescribed, fill and ship a portion of the order, so long as the full quantity is shipped within 30 days? (CCR 1780.1[j])

When partially filling a prescription, does the pharmacist or veterinary designated representative note the following information on the written prescription for each date the drugs are shipped: (CCR 1780.1[j])

Yes No N/A

Quantity shipped?

Date shipped?

Number of containers shipped?

If multiple containers, each container must be sequentially numbered?

If unable to fill the full quantity of a prescription within 30 days, has a new veterinarian's prescription been written to fill the remainder of the drugs originally prescribed? (CCR 1780.1[j])

**9. Prescription Labeling**

Yes No N/A

Does only a pharmacist or veterinary designated representative prepare and affix the label to a veterinary food-animal drug product?

Pursuant to a veterinarian's prescription, are prescription labels affixed to all drug containers that include: (CCR 1780.1[h][1-14])

- Active ingredients or the generic name(s) of the drug?
- Manufacturer of the drug?
- Strength of the drug dispensed?
- Quantity of the drug dispensed?
- Name of the client?
- Species of food-producing animal for which the drug is described?
- Condition for which the drug is prescribed?
- Directions for use?
- Withdrawal time?
- Cautionary statements, if any?
- Name of the veterinarian prescriber?
- Date dispensed?
- Name and address of the veterinary food-animal drug retailer?
- Prescription number or another means of identifying the prescription?

Yes No N/A

If an order is filled in multiple containers, a sequential numbering system to provide a means to identify multiple units if shipped to the same client from the same prescription? (container 1 of 6, container 2 of 6)

Manufacture's expiration date?

## 10. Repackaging

**Definition** - Repackaging within the meaning of B&P 4041 means that a veterinary food-animal drug retailer may break down case lots of dangerous drugs as described in 4022(a) or extra label use drugs, so long as the seals on the individual containers are not broken.

Yes No N/A

Are only sealed original manufacturer's containers labeled for distribution to clients? Veterinary retailers or wholesalers cannot open a container and count out or measure out any quantity of a dangerous legend or extra label use drug. (CCR 1780.1[b])

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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## 11. Sale or Transfer of Drugs by this Business

Yes No N/A

Are all dangerous drugs and extra label drugs that are sold, only sold pursuant to a prescription issued by a veterinarian to a veterinarian's client for use on food-producing animals? (CCR 1780.1[a])

No dangerous drugs or extra label drugs are sold, traded or transferred at wholesale by the veterinary retailers? (B&P 4041)

Are practices in place to prevent dangerous drugs from being sold, traded or transferred if the vet retailer or wholesaler knew or reasonably should have known the drugs were adulterated as defined by CA Health & Safety Code section 111250, misbranded as defined by CA Health & Safety Code section 111335, or beyond the use date on the label? (B&P 4169[a])

Yes No N/A

List any incidents where adulterated, misbranded or expired drugs were purchased, sold, traded or transferred by this business in the past 2 years.

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Do your advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (B&P 4341, 4651, CCR 1766)

Do you offer any rebates, refunds, commissions or preferences, discounts, or other considerations for referring clients? If your business has any of these arrangements, please list with whom? (B&P 650)

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If your business sells, transfers or delivers dangerous drugs outside of California, either to another state within the United States or a foreign country, do you comply with:

- All CA pharmacy and veterinary laws related to the distribution of drugs?
- The pharmacy law and veterinary laws of the receiving state within the United States?
- The statutes and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration?
- All laws of the receiving foreign country related to drugs for food producing animals?
- All applicable federal regulations regarding the exportation of dangerous drugs?

Describe how you determine a client in a foreign country is authorized to receive dangerous drugs or dangerous devices. (B&P 4059.5[e])

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CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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### 12. Delivery of Drugs

Yes No N/A

- Upon delivery of appropriately labeled prescription drugs or extra label drugs to a client, pursuant to a veterinarian's prescription, do you obtain the signature of the client, or the client's agent, on the invoice with notations of any discrepancies, corrections or damage? (CCR 1780.1[k])

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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### 13. Controlled Substances

Yes No N/A

- If a controlled substance is dispensed, are the labels on the containers countersigned by the prescribing veterinarian before being provided to the client? (CCR1780.1[e])

**Note:** Please refer to "Controlled Substances" section of the Wholesaler Self Assessment for additional controlled substance statutes, regulations, and requirements your business must follow

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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#### 14. Consultant Pharmacist

Yes No N/A

Does your consulting pharmacist assure compliance with all statutes and regulations governing veterinary food-animal drug retailers? (B&P 4198[e])

Does your consultant pharmacist visit routinely, but at least quarterly? (B&P 4198[e])

Does your consultant pharmacist: (B&P 4198[e])

Review and revise policies and procedures?

Assure compliance with state and federal statutes and regulations for labeling, storage and dispensing of veterinary food-animal drugs?

Provide a written report twice yearly certifying whether or not the veterinary food-animal drug retailer is operating in compliance with the requirements of this chapter?

Are these written reports readily available for inspection upon request?

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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#### 15. Designated Representative Training.

Yes No N/A

Does your business prepare and maintain records of training and demonstrated competence for each individual employed or retained by you? (B&P 4198[b])

Are records of training and demonstrated competence for each employee maintained for 3 years after the last date of employment? (B&P 4198[b])

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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## 16. Quality Assurance Program

Does your business have an ongoing, documented quality assurance program, which includes but is not limited to: (B&P 4198 [c])

Yes No N/A

Monitoring personnel performance?

Storage of veterinary food-animal drugs?

Maintenance of equipment?

Dispensing of veterinary food-animal drugs?

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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## 17. Policies and Procedures

Does your business maintain and adhere to policies and procedures for: (B&P 4198)

Yes No N/A

Handling of veterinary food animal drugs?

Dispensing of veterinary food animal drug?

Staff training records?

Cleaning of equipment?

Storage and maintenance of veterinary food –animal drugs?

Storage and maintenance of equipment?

Yes No N/A

Record keeping requirements?

Storage requirements?

Security requirements?

Quality assurance?

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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## 18. Record Keeping Requirements

### *Purchase and Sales Records*

Yes No N/A

Are all records of acquisition and disposition of dangerous drugs, retained on the premises, open for inspection, during regular business hours? (B&P 4081, 4332, CCR 1718)

Are all prescription documents and other disposition records for dangerous drugs or extra label use drugs dispensed by a vet food-animal drug retailer kept on file and maintained on the premises for 3 years? (B&P 4198[b])

Are all records of prescription refills retained by your business on the premises for 3 years? (CCR1780.1[I], B&P 4081[a], 4332)

Are all purchase and sales records retained in a readily retrievable form? (B&P 4105[a])

Are records of shipment of labeled dangerous drugs to clients (also known as an expanded invoice) included in the client's shipment? This document includes: (CCR1780.1[i])

Drug name?

Quantity shipped?

Manufacturer's name and lot number?

Date of shipment?

Name of the pharmacist or vet retailer exemptee who is responsible for the distribution?

Are copies of the records of shipment (also known as the expanded invoice) distributed to the prescribing veterinarian? (CCR 1780.1 [i])

Are copies of the records of shipment (also known as the expanded invoice) of labeled dangerous drugs retained by your business for 3years? (CCR 1780.1[I])

### ***Inventory***

Yes No N/A

Is a current, accurate inventory maintained for all dangerous drugs (B&P 4081[a], CCR 1718)

### ***Consultant Pharmacist***

Yes No N/A

Are consultant pharmacist semi-annual reports retained by your business for 3 years from the making? (B&P 4198 [e])

### ***Quality Assurance***

Yes No N/A

Is quality assurance documentation retained for 3 years from the making? (B&P 4198[d])

***Policies and Procedures***

Yes No N/A

Are all policies and procedures specified in section 4198(a) maintained for 3 years from the making? (B&P 4198(b))

Are all policies and procedures, documents related to the quality assurance program, and all records of employee training and demonstrated competency open for inspection by authorized officers of the law? (B&P 4198[b])

***Temporary removal of records***

Yes No N/A

If you temporarily remove purchase or sales records from your business, does your business retain, on your licensed premises at all times, a photocopy of each record temporarily removed? (B&P 4105[b])

***Off-site storage waiver***

Yes No N/A

Are required records stored off-site only if a board issued written waiver has been granted? (CCR 1707[a])

If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below: (CCR 1707[a])

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Yes No N/A

If an off-site written waiver is in place, is the storage area secure from unauthorized access? (CCR 1707[b][1])

If an off-site waiver is in place, are the records stored off-site retrievable within 2 business days? (1707[b][1])

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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## 19. Reporting Requirements to the Board

### *Ownership*

Yes No N/A

I understand this veterinary retailer license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted, in addition to an application for a permanent new permit, to the board, if the new owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval. (B&P 4201[h][I], 4196[b], CCR 1709[b])

Are transfers, in a single transaction or a series of transactions, of 10% or more of the beneficial interest in a business licensed by the board to a person who did not hold beneficial ownership interest at the time of the initial permit was issued, reported in writing to the board within 30 days of the transaction? (CCR 1709[b])

Any transfer of a beneficial interest in a business licensed by the board, in a single transaction or series of transactions, to a person or entity, which results in the transferee holding 50% or more shall constitute of change of ownership and an application must be submitted to the board for a change of ownership. (CCR 1709 [c])

When called upon by an inspector, can the business owner or manager, produce information indicating the names of the business owners, managers and employees and a brief statement of the capacity for each person employed by the business? (B&P 4082)

### *Veterinarian*

Yes No N/A

Whenever a veterinary designated representative dispenses to the same client for use on the same production class of food-animals, dangerous drugs, or extra label use drugs prescribed by multiple veterinarians, does the veterinary designated representative contact the prescribing veterinarians for authorization before dispensing any drugs? (CCR 1780.1[f])

Are copies of expanded invoices, documenting sales of dangerous drugs, distributed to the prescribing veterinarian within 72 hours of dispensing? (CCR 1780.1[I]).

Is a written copy of any oral prescription received by either a pharmacist or designated representative of the veterinary food-animal drug retailer sent or

electronically transmitted to the prescribing veterinarian within 72 hours? (CCR 1780.1[d])

***Consultant Pharmacist***

Yes No N/A

Does the consultant pharmacist provide written certification every 6 months that your business is or is not in compliance with all applicable statutes and regulation? (B&P 4198[e])

Does your business submit the most recent consultant pharmacist report with the annual application to renew the veterinary food-animal drug retailer license with this board? (B&P 4198[e])

***Designated Representative in Charge/ Designated Representative***

Yes No N/A

If a designated representative-in-charge terminates employment at this business, does the business notify the board within 30 days of the termination? (B&P 4101[b], 4305.5[c])

When a veterinary designated representative leaves the employ of a veterinary food-animal drug retailer, would the business owner immediately return the exemptee license to the Board of Pharmacy? (CCR 1780.1[l])

When a designated representative in charge terminates employment at this business, does the designated representative in charge notify the board within 30 days of the termination.? This requirement is in addition to the requirement for the owner to notify this board. (B&P 4101[c])

***Discontinuation of Business***

Yes No N/A

I understand if this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business? (CCR 1708.2).

I understand the owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs? (CCR 1705)

***Controlled substances (if applicable)***

Yes No N/A

Does the owner report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs? (CCR 1715.6)

Does the owner notify the DEA, on a DEA form 106, of any theft or significant loss of controlled substances upon discovery? (CFR 1301.74[c])

Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)

If the business holds a DEA registration, does the owner understand the requirement to notify the DEA promptly of the discontinuation of the business and all unused DEA 222 order forms must be returned to the DEA? (CFR1301.52[a], 1305.14)

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

**20. Additional Licenses/Permits Required**

List all licenses and permits required to conduct this business, including local business licenses, wholesaler licenses held in other states, permits or licenses required by foreign countries or other entities (B&P 4107, 4059[a], CFR 1305.11[a])

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## Designated Representative-in-Charge/Pharmacist Certification:

### DESIGNATED REPRESENTATIVE-IN-CHARGE CERTIFICATION:

I, (Please print) \_\_\_\_\_, RPH # \_\_\_\_\_ hereby certify that I have completed the self-assessment of this veterinary food-animal drug retailer of which I am the designated representative-in-charge. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature \_\_\_\_\_ Date \_\_\_\_\_  
(Designated Representative-in-Charge)

**Legal References** used in the self-assessment forms (California Code of Regulations [CCR], Title 16 and Title 24, and Business and Professions Code [B&P], Chapter 9, Division 2) can be found in the *California Pharmacy Law* (below) or visit the Board of Pharmacy Web site at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov) under *California Pharmacy Law and Index*.

The Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act is also in the *California Pharmacy Law* (below) or you can visit the Board of Pharmacy Web site at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov) under *California Pharmacy Law and Index*.

California Code of Regulations (CCR), Chapter 1, Division 5, Title 22, and other references can be found in the California State Law Library or county law libraries.

Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration, may be found at [www.dea.gov](http://www.dea.gov).

Fax: 877-508-6704

**California Board of Pharmacy**  
1625 N. Market Blvd., Suite N219  
Sacramento CA 95834  
(916) 574-7900  
fax: (916) 574-8618  
[www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)

**Bureau of Narcotic Enforcement**  
Security Prescription and CURES Programs  
1102 Q Street, 6<sup>th</sup> Fl.  
Sacramento, CA 95817  
(916) 319-9062  
Fax: (916) 319-9448  
<http://www.ag.ca.gov/bne>

*California Pharmacy Law* may be obtained by contacting:  
Law Tech  
1060 Calle Cordillera, Suite 105  
San Clements CA 92673  
(800) 498-0911 Ext. 5  
[www.lawtech-pub.com](http://www.lawtech-pub.com)

CURES Patient Activity Report Request Forms:  
<http://www.ag.ca.gov/bne/trips.php>

### PRESCRIBER BOARDS:

**Pharmacist Recovery Program**  
(800) 522-9198 (24 hours a day)

**Medical Board of California**  
1426 Howe Avenue, Suite 54  
Sacramento CA 95825  
(800) 633-2322  
(916) 263-2499  
Fax: (916) 263-2387  
<http://www.mbc.ca.gov>

**Atlantic Associates, Inc. (CURES)**  
Prescription Collection  
8030 S. Willow Street, Bldg. III, Unit 3  
Manchester NH 03103  
Phone: (888) 539-3370

**Dental Board of California**

1432 Howe Ave. #85  
Sacramento, CA 95825  
(916) 263-2300  
fax: (916) 263-2140  
<http://www.dbc.ca.gov>

**Board of Registered Nursing**

1625 N. Market Blvd., Suite N217  
Sacramento, CA 95834  
(916) 322-3350  
fax: (916) 574-8637  
<http://www.rn.ca.gov/>

**Board of Optometry**

2420 Del Paso Road, Suite 255  
Sacramento, CA 95834  
(916) 575-7170  
fax: (916) 575-7292  
<http://www.optometry.ca.gov/>

**Osteopathic Medical Board of California**

2720 Gateway Oaks Drive, #350  
Sacramento, CA 95833  
(916) 263-3100  
fax: (916) 263-3117  
<http://www.ombc.ca.gov>

**Physician Assistant Committee**

1424 Howe Avenue, #35  
Sacramento, CA 95825  
(916) 561-8780  
fax: (916) 263-2671  
<http://www.physicianassistant.ca.gov>

**Board of Podiatric Medicine**

1420 Howe Avenue, #8  
Sacramento, CA 95825  
(800) 633-2322  
(916) 263-2647  
fax: (916) 263-2651  
<http://www.bpm.ca.gov>

**Veterinary Medical Board**

1420 Howe Avenue, #6  
Sacramento, CA 95825  
(916) 263-2610  
fax: (916) 263-2621  
<http://www.vmb.ca.gov>

**FEDERAL AGENCIES:****Food and Drug Administration  
– Industry Compliance**

<http://www.fda.gov/oc/industry/centerlinks.html#drugs>

The **Drug Enforcement Administration** may be contacted at:

**DEA Website:**

<http://www.dea.gov>

**Online Registration – New Applicants:**

[http://www.dea.gov/drugreg/reg\\_apps/onlineforms\\_new.htm](http://www.dea.gov/drugreg/reg_apps/onlineforms_new.htm)

**Online Registration - Renewal:**

[www.dea.gov/drugreg/reg\\_apps/onlineforms.htm](http://www.dea.gov/drugreg/reg_apps/onlineforms.htm)

**Registration Changes (Forms):**

[http://www.dea.gov/drugreg/change\\_requests/index.html](http://www.dea.gov/drugreg/change_requests/index.html)

**DEA Registration Support (all of CA):**

(800) 882-9539

**Online DEA 106 Theft/Loss Reporting:**

<https://www.dea.gov/webforms/app106Login.jsp>

**Online DEA 222 Controlled Substance Ordering System (CSOS):**

<http://www.deacom.gov/>

**DEA - Fresno**

2444 Main Street, Suite 240  
Fresno, CA 93721  
Registration: (888) 304-3251 or  
(415) 436-7900  
Diversion or Investigation: (559) 487-5402

**DEA - Los Angeles**

255 East Temple Street, 20th Floor  
Los Angeles CA 90012  
(888) 415-9822 or (213) 621-6960 (Registration)  
(213) 621-6942 or 6952  
(Diversion or Investigation)

**DEA – Oakland**

1301 Clay Street, Suite 460N  
Oakland, CA 94612  
Registration: (888) 304-3251 or  
(415) 436-7900  
Diversion or Investigation: (510) 637-5600

**DEA – Redding**

310 Hensted Drive, Suite 310  
Redding, CA 96002  
Registration: (888) 304-3251 or  
(415) 436-7900  
Diversion or Investigation: (530) 246-5043

**DEA - Riverside**

4470 Olivewood Avenue  
Riverside, CA 92501-6210  
Registration: (888) 415-9822 or  
(213) 621-6960  
Diversion or Investigation: (909) 328-6000 or  
(909) 328-6200

**DEA - Sacramento**

4328 Watt Avenue  
Sacramento CA 95821  
Registration: (888) 304-3251 or  
(415) 436-7900  
Diversion or Investigation: (916) 480-7100 or  
(916) 480-7250

**DEA – San Diego and Imperial Counties**

4560 Viewridge Avenue  
San Diego, CA 92123-1637  
Registration: (800) 284-1152  
Diversion or Investigation: (858) 616-4100

# Attachment 6

## *Proposed Disciplinary Guidelines*

Memorandum

To: BOARD MEMBERS

Date: October 15, 2007

From: SUSAN CAPPELLO  
Enforcement Coordinator  
Board of Pharmacy

Subject: Proposed Revisions to the Disciplinary Guidelines

Enclosed is the proposed revision to the *Disciplinary Guidelines* for your review.

These guidelines are being revised to clarify language, ensure that terms and conditions are consistent for all license types (where appropriate), to define consequences for non-compliances and to include new terms of probation. Strikeouts indicate deleted language and underlines indicate new language.

Pharmacist/Intern Conditions; pages 34-56

Significant changes made to standard conditions are as follows:

- No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC) or Designated Representative-in-Charge (DRIC), or Serving as a Consultant (pg 36) – better defines the language for this provision. Restricts the pharmacist from serving as DRIC in a wholesaler or veterinary food-animal drug retailer.
- Tolling of Probation (pg 38) – allows for an option that would require a pharmacist to practice in a licensed pharmacy dispensing medications

Significant changes made to optional conditions:

- Pharmacist Examination (pg 40) – changed to reflect the new exam structure (CPJE & NAPLEX).
- Mental Health Examination (pg 41) – changes made to broaden the definition of the licensed health practitioner who can complete the mental health exam. Additionally, this term now better defines the condition under which the ongoing therapy must occur, if recommended.
- Psychotherapy (pg 43) - changes made to broaden the definition of the licensed health practitioner who can complete the mental health exam. Additionally, this term now better defines the condition under which the ongoing therapy must occur if recommended.
- Medical Evaluation (pg 44) – details more specifically the procedures to carry out this term.

- Pharmacists Recovery Program (pg 47) – this term now includes the automatic suspension for any confirmed positive test for drugs or alcohol under certain conditions and details the suspension provisions.
- Random Drug Screening (pg 49) - details more specifically the procedures to carry out this term.
- Abstain from Drugs and Alcohol Use (pg 49) – expands the definition of this term to include the prohibition of physical proximity to persons using illicit substances.
- Tolling of Suspension (pg 55) – details more specifically the procedures to carry out this term.

New optional terms and conditions of probation:

- Prescription Coordination and Monitoring of Prescription Use (pg 50) – this term will be recommended for individuals whose violations indicate chemical dependencies or psychiatric disorders. Designates a single health care practitioner to coordinate and monitor prescriptions. Also defines the procedures to carry out this term.
- Pharmacy Self-Assessment Mechanism (PSAM) (pg 52) – this term will be recommended to provide a self-assessment mechanism to aide the pharmacist in identifying deficient areas of practice. Options were included to allow the board to have access to the examination results for recommendation of remedial education if needed.
- Surrender of DEA Permit (pg 56) – this term will be recommended for pharmacists to prevent him or her from prescribing.

Pharmacy Technician Conditions; pages 63-72

Significant changes made to standard conditions are as follows:

- Obey All Laws (pg 63) – this term will be recommended to make consistent with other license types.
- License Surrender While on Probation/Suspension (pg 66) - this term was relocated within the standard terms to be consistent with the other license types.

Significant changes made to optional conditions:

- Random Drug Screening (pg 69) - details more specifically the procedures to carry out this term.
- Abstain from Drugs and Alcohol Use (pg 70) – expands the definition of this term to include the prohibition of physical proximity to persons using illicit substances.
- Tolling of Suspension (pg 72) – details more specifically the procedures to carry out this term.
- Restitution (pg 72) – this term will be recommended for those cases where drug diversion, theft fraudulent billing or patient harm resulting from negligence or incompetence occurred.

Designated Representative Conditions; pages 80-91

Significant changes made to standard conditions are as follows:

- Reexamination Prior to Resuming Work – this term was deleted because an exam is no longer a requirement for licensure.
- Obey All Laws (pg 80) – this term will be recommended to make consistent with other license types.
- No Being Designated Representative-in-Charge (pg 83) – this term is similar to the No Being PIC and will be recommended to prohibit a designated representative from serving as a designated representative-in-charge in a wholesaler or veterinary food-animal drug retailer.
- License Surrender While on Probation/Suspension (pg 84) - this term was relocated within the standard terms to be consistent with the other license types.

Significant changes made to optional conditions:

- Random Drug Screening (pg 89) - details more specifically the procedures to carry out this term.
- Abstain from Drugs and Alcohol Use (pg 90) – expands the definition of this term to include the prohibition of physical proximity to persons using illicit substances.
- Tolling of Suspension (pg 91) – details more specifically the procedures to carry out this term.
- Restitution (pg 91) – this term will be recommended for those cases where drug diversion, theft fraudulent billing or patient harm resulting from negligence or incompetence occurred.

Premises Conditions; pages 115-120

Significant changes made to standard conditions are as follows:

- Model language for Suspension modified - includes that failure to comply with the suspension term is a violation of probation.
- Model language for Revocation (pg 111), Surrender (pg 112) and standard condition License Surrender while on Probation/Suspension (pg 116) – requires pharmacy to notify its patients of the location of the transferred records
- Posted Notice of Probation (pg 118) – this term will be recommended for all premises to post to alert the consumer of the discipline imposed by the board.

**RONALD S. MARKS**  
**A Professional Law Corporation**  
21900 Burbank Boulevard, Suite 300  
Woodland Hills, California 91367  
Telephone: (818) 347-8112  
Facsimile: (818) 347-3834

June 15, 2007

Susan Cappello  
State Board of Pharmacy  
1625 North Market Blvd., Suite N 219  
Sacramento, CA 95834

***RE: PROPOSED DISCIPLINARY GUIDELINES***

Dear Susan:

I'm not able to make the Enforcement Committee meeting on June 20<sup>th</sup> in Sacramento but I have some concerns about the Proposed Disciplinary Guidelines that I hope you can pass on.

I believe it serves little public benefit for a pharmacy to have to post a notice of probation for the entire time of probation which is typically three years. It might tend to unduly alarm customers resulting in the failure of the business or significant financial loss. If a customer is concerned enough to check out a pharmacy, they can go to the Board's website.

I am concerned about the optional condition of automatic revocation for missing a cost payment deadline. Aside from raising due process issues that will no doubt be litigated, it is too draconian. There is no ability to present mitigating circumstances. Another issue that concerns me is that there are no factors to consider in when to impose that optional condition. In other words, under what circumstances should an ALJ or the Board decide that a particular licensee should be subject to an automatic revocation? Should it be based on the underlying violation, the amount of the costs, the financial ability of the licensee to pay costs? How can there be any uniformity between ALJ's when there are no guidelines or factors to base the optional condition on?

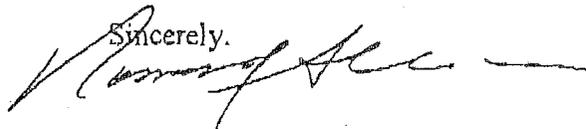
I am similarly concerned about a failed drug test. There should be some provision for having a drug sample re-tested. I have been apprised of so many instances of false positive drug tests. A more sophisticated (and, of course, costly) test which would be recognized as more reliable should be utilized to confirm or dispute a failed sample. And, of course, any type of automatic action would be subject to due process challenges.

I don't know why a licensee who is on a suspension cannot resume working until notified by the Board. Suspensions are usually weeks or months and waiting for formal notification will just serve to extend suspensions in a random fashion. This may also involve a due process issue if the Board declines to notify the licensee that the suspension is over because of a suspected violation. The licensee could be subjected to an unwarranted lengthy suspension without notice and opportunity to be heard in violation of his due process rights.

I have had concerns for some time now about the condition of probation that prohibits the supervision of pharmacy technicians. If a probationer cannot be a PIC or supervise technicians, coupled with the fact that he or she is on probation, he or she is precluded from about 99% of jobs in California. With such a condition, probation is tantamount to a revocation. Since a probationer is usually prohibited from being a PIC, then there would be a PIC in a supervisory role. Technicians also have their own license to protect and therefore can act as informal monitors of the pharmacist on probation. There is little public protection to be gained and the condition makes it almost impossible for a probationer to find employment.

Thank you for allowing me to offer my thoughts on the proposed guidelines. I have more but I think these are my main concerns that the committee might want to consider.

Sincerely,

A handwritten signature in black ink, appearing to read 'Ronald S. Marks', with a long horizontal flourish extending to the right.

RONALD S. MARKS

Summary of Written Comments Received from Ron Marks:

1. Posted Notice of Probation for Premises, page 118.

“... serves little public benefit for a pharmacy to post a notice of probation for the entire time of probation and would .....alarm customers resulting in the failure to the business or significant financial loss.....to check out a business customer can go to board’s website.”

Response

This term is recommended in order to provide another avenue in which to alert the consumer of the probationary status imposed by the board. The board currently requires a premise to post a notice of suspension, page 120.

2. Automatic Revocation of License for Missing Cost Recovery, pages 36-37.

“...concerned about the optional condition of automatic revocation for missing a cost payment deadline.”

Response

This is optional language that may be imposed either by the administrative law judge as part of a decision or by the board in cases of a settlement. The optional language is appropriate for this term, as compliance does not require judgment; probationer either is or is not making payments. Also, this option does not preclude the probationer from making a presentation of hardship or mitigating circumstances to the board’s probation monitor or to the executive officer.

3. Automatic Suspension for Confirmed Positive test, page 47.

“...concerned about a failed drug test. There should be some provision for having a drug sample re-tested. ...”

Response

A confirmed positive test for alcohol or any drug does mean that the “failed” drug test had been retested and may have been retested more than once through an appropriate and reliable process as directed by the Board’s Pharmacist Recovery Program (PRP). The board’s statutory mandate is the protection of the public, this term allows that protection to occur by the automatic suspension of the license and allows the PRP the time needed to confirm when a licensee may safely resume the practice of pharmacy.

4. Notification of the Resumption of Practice After Suspension, page 28

...."Don't know why a licensee who is on suspension cannot resume working until notified by the Board. "

Response

The language on page 28 currently reads "As part of probation, respondent is suspended from the practice of pharmacy for \_\_\_\_\_, beginning the effective date of this decision. Respondent shall not resume the practice of pharmacy until notified by the board."

Before the effective date of the penalty, the board does notify the respondent in writing when their suspension begins and ends. Board staff feels that this initial notification is sufficient. It is planned to eliminate this sentence from the proposed suspension language.

5. No Supervision of Technicians, page 53.

..."concerns about the condition of probation that prohibits the supervision of pharmacy technicians. If a probationer cannot be a PIC or supervise technicians...he or she is precluded from about 99% of the jobs in California."

Response

Currently the standard term and condition for pharmacist-in-charge restrictions (page 36) states that respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge..." The standard term does allow the respondent to supervise technicians.

The optional terms for pharmacist-in-charge, page 53, allows a respondent to be a PIC with a consultant. This term also allows the respondent to supervise technicians.

Optional term #31, page 53, does not allow a respondent to supervise ancillary personnel, including, but not limited to pharmacy technicians or designated representatives. This is an optional term, not a standard, and is employed by an ALJ or by the board in appropriate circumstances.

**RONALD S. MARKS**  
**A Professional Law Corporation**  
**21900 Burbank Boulevard, Suite 300**  
**Woodland Hills, California 91367**  
**Telephone: (818) 347-8112**  
**Facsimile: (818) 347-3834**

**FAX MESSAGE**

**DATE:** SEPTEMBER 14, 2007

**TO:** SUSAN CAPPELLO

**FROM:** RONALD S. MARKS

**RE:** PROPOSED DISCIPLINARY GUIDELINES

**NUMBER OF PAGES:** 2

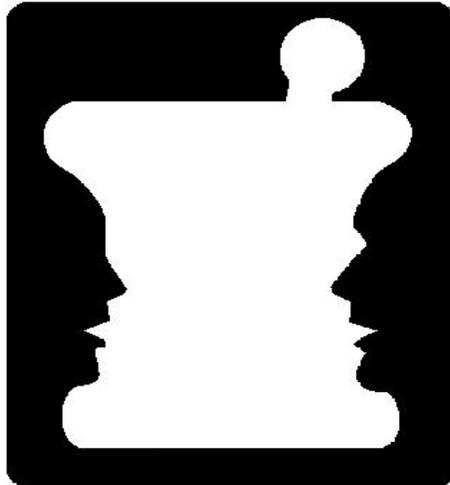
**MESSAGE:** *I would appreciate it if the enclosed letter and this fax could be provided to the committee for my input on proposed disciplinary guidelines since I am unable to attend unless my schedule changes.*

*Also, with respect to the proposed Ethics Course modeled after the Medical Board, I do a substantial amount of Medical Board cases. One of the problems is that Board staff seems to propose an Ethics course in settlement offers when the case has nothing to do with honesty or morality (it may just involve quality of care issues.) The problem it raises is that anyone reading the settlement agreement and seeing an Ethics course ordered, naturally assumes that there was some dishonest or immoral conduct involved. Often, a settlement cannot be reached for this reason. The guidelines should spell out that the condition is appropriate for dishonesty or similar conduct and should not be recommended or imposed indiscriminately.*

THE INFORMATION CONTAINED IN THIS MESSAGE IS CONFIDENTIAL AND IS INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR ENTITY NAMED ABOVE. IF THE READER OF THIS MESSAGE IS NOT THE INTENDED RECIPIENT, OR THE EMPLOYEE OR AGENT RESPONSIBLE TO DELIVER IT TO THE INTENDED RECIPIENT, OR IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, PLEASE NOTIFY US IMMEDIATELY BY TELEPHONE AND RETURN THE MESSAGE TO US BY MAIL OR FACSIMILE AT THE ADDRESS OR FACSIMILE NUMBER LISTED ABOVE.

# 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. [1/20016/2007](#))

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

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PRESIDENT

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~~8-467-6308~~www.pharmacy.ca.gov

Additional copies of these disciplinary guidelines  
may be ~~ordered from the~~ [downloaded from the board's website](#)  
~~address above~~

**BOARD OF PHARMACY**  
**DISCIPLINARY GUIDELINES**  
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# DEPARTMENT OF CONSUMER AFFAIRS STATE BOARD OF PHARMACY

## DISCIPLINARY GUIDELINES (Rev. ~~1/2004~~6/2007)

### INTRODUCTION

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

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

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

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

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

These guidelines are to be followed in Board of Pharmacy disciplinary actions. [Subject to judicial review, the](#) ~~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 violations are involved.

~~The board has found that accusations are rarely filed except in serious cases.~~ In general, the position of the board is that revocation should always be an option whenever grounds for

discipline are found to exist. Board policy is that revocation is generally an appropriate order where a respondent is in default, such as when he or she fails to file a notice of defense or fails to appear at a disciplinary hearing.

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

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

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

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

## FACTORS TO BE CONSIDERED IN DETERMINING PENALTIES

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

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

1. actual or potential harm to the public
2. actual or potential harm to any consumer
3. prior disciplinary record, including level of compliance with disciplinary order(s)
4. prior warning(s) ~~of record(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
- ~~7.8.~~ mitigating evidence
- ~~8.9.~~ rehabilitation evidence
- ~~9.10.~~ compliance with terms of any criminal sentence, parole, or probation
- ~~10.11.~~ overall criminal record
- ~~11.12.~~ if applicable, evidence of proceedings for case being set aside and dismissed pursuant to ~~section~~ Section 1203.4 of the Penal Code
- ~~12.13.~~ time passed since the act(s) or offense(s)
- ~~13.14.~~ 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
- ~~14.15.~~ financial benefit to the respondent from the misconduct.

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

## MITIGATING EVIDENCE

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

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

- a. Recent, dated written statements and/or performance evaluations from persons in positions of authority who have on-the-job knowledge of the respondent's current competence in the practice of pharmacy including the period of time and capacity in which the person worked with the respondent. Such reports must be signed under penalty of perjury and will be subject to verification by board staff.
- b. Recent, dated letters from counselors regarding the respondent's participation in a rehabilitation or recovery program, [which](#) should include at least a description and requirements of the program, a psychologist's diagnosis of the condition and current state of recovery, and the psychologist's basis for determining rehabilitation. [Such letters and reports will be subject to verification by board staff.](#)
- c. Recent, dated letters describing the respondent's participation in support groups, (e.g., Alcoholics Anonymous, Narcotics Anonymous, professional support groups, etc.). [Such letters and reports will be subject to verification by board staff.](#)
- d. Recent, dated laboratory analyses or drug screen reports, confirming abstention from drugs and alcohol. [Such analyses and reports will be subject to verification by board staff.](#)
- e. Recent, dated physical examination or assessment report by a licensed physician, confirming the absence of any physical impairment that would prohibit the respondent from practicing safely. [Such assessments and reports 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.](#)

## TERMS OF PROBATION – PHARMACIST/INTERN PHARMACIST

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

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

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

## CATEGORIES OF VIOLATIONS AND RECOMMENDED PENALTIES

The California Pharmacy Law ~~specifies the~~identifies offenses for which the board may take disciplinary action against the license. ~~The following are categories of violations used by the board in determining appropriate disciplinary penalties. 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.

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. Where a violation not included in these lists is a basis for disciplinary action, the appropriate penalty for that violation may be best derived by comparison to any analogous violation(s) that are included. Where no such analogous violation is listed, the category descriptions may be consulted.

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

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

## CATEGORY I

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

Maximum: Revocation

Category I discipline is recommended for:

- violations which are relatively minor but are potentially harmful
- repeated violations of a relatively minor nature:

| Violations [of the following](#) codes are ~~as follows~~ [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 Exempt Supervisor of Manufacturers, Wholesalers, and Licensed Laboratories; Veterinary Food-Animal Drug Retailers etc.: Requirements](#)
- [4054 Supplying Dialysis Drugs Supply by Manufacturer, etc. of Certain Dialysis Drugs and Devices](#)
- [4055 Sale of Devices to Licensed Clinics, etc.](#)
- [4056 Exempt Hospitals Purchase of Drugs at Wholesale – Hospital Containing 100 Beds or Less](#)
- [4057 Exempt Articles Exceptions to Application of this Chapter](#)
- [4058 License to be Displayed Display of Original License](#)
- [4062 Furnishing Drugs during Emergency Furnishing Dangerous Drugs During Emergency](#)
- [4064 Emergency Refills of Prescription Without Prescription Authorization](#)
- [4065 Administration through Injection Card System Injection Card System; Requirements of Administration](#)
- [4066 Furnishing to Ocean Vessel 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's Agent Transmitting Prescriptions Prescriber May Authorize Agent to Transmit Prescription; Schedule II Excluded](#)
- [4072 Transmitting Prescriptions from a Health Care Facility Oral or Electronic Transmission of Prescription – Health Care Facility](#)
- [4073 Drug Product Selection Substitution of Generic Drug – Requirements and Exceptions](#)
- [4074 Drug Warnings Drug Risk: Informing Patient; Providing Consultation for Discharge Medications](#)
- [4076 Prescription Label Requirements Prescription Container – Requirements for Labeling](#)
- [4077 Labeling Dispensing Dangerous Drug in Incorrectly Labeled Container](#)

### Article 5. Authority of Inspectors

- [4082 Information about Personnel Names of Owners, Managers and Employees Open for Inspection](#)

## Article 6. General Requirements

- 4100 Change of ~~Name or~~ Address ~~or Name~~ – Notification to Board
- ~~4102 Skin Puncture for Patient Training~~
- 4103 Blood Pressure ~~Measurement~~– Taking by Pharmacist

## Article 7. Pharmacies

- 4114 Intern Pharmacist ~~Activities:~~ Activities Permitted
- 4119 ~~Emergency Kit for Licensed Health Care Facilities~~ Furnish Prescription Drug to Licensed Health Care Facility – Secured
- ~~4119.1 Pharmacy May Provide Services to Health Facility~~
- 4119.5 ~~Transferring or Repacking Drugs~~ Transfer or Repackaging Dangerous Drugs by Pharmacy
- 4121 ~~Prescription Price Advertising~~ Advertisement for Prescription Drug: Requirements; Restrictions
- 4122 ~~Requests for Prescription Price Information~~ Required Notice at Availability of Prescription Price Information, General Product Availability, Pharmacy Services; Providing Drug Price Information; Limitations on Price Information Requests
- 4123 ~~Pharmacy contracts for Compounding of Parenteral Drugs~~ Compounding Drug for Other Pharmacy for Parenteral Therapy; Notice to Board
- 4124 ~~Contact Lens Dispensing~~ Dispensing Replacement Contact Lenses: Requirements; Patient Warnings; Registration with Medical Board; Application of Section to Nonresident Pharmacies

## Article 9. Hypodermic Needles and Syringes

- 4141 ~~License Required~~ Furnishing Without License
- 4142 Prescription Required
- 4143 Exemption: ~~Wholesale Sales~~ Sale to Other Entity, Physician, etc.
- 4144 ~~Exemption: Industrial Uses~~ Industrial Use Exception
- 4145 ~~Exemption: Human (Insulin; Adrenaline) or Animal Use~~ Exception: Furnishing for Administration of Insulin, Adrenaline, or Specified Animal Uses; Conditions
- ~~4146 Hypodermic Register~~
- 4148 Confiscation ~~if Found Outside Licensed Premises~~
- 4149 ~~Nonresident Sale by~~ Distributor

## Article 10. Pharmacy Corporations

- 4151 ~~Licensure~~ Requirements ~~for Shareholders, Directors, and Officers~~
- 4152 Corporate Name Requirements
- 4153 Shareholder Income While Disqualified
- 4156 Unprofessional Conduct ~~by Corporation~~

## Article 11. Wholesalers and Manufacturers

- 4161 ~~Out-of-State Manufacturer or Nonresident~~ Wholesaler: ~~When License Required;~~ Application
- 4162 ~~Registration -- Agent~~ Issuance or Renewal of Wholesaler License; Surety Bond
- 4163 ~~Sales to~~ Unauthorized Persons ~~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 [Responsibility Until Delivery Shipping of Dangerous Drugs or Devices – Wholesaler or Distributor](#)
- 4167 [Bar on Obtaining More Than Can Be Stored on Licensed Premises Wholesaler: Bar on Obtaining Dangerous Drugs or Devices It Cannot Maintain on Licensed Premises](#)

### Article 13. Non-Profit or Free Clinics

- 4180 [License Required \(Non-Profit, etc Clinics\)](#)[Purchase of Drugs at Wholesale Only with License: Eligible Clinics](#)
- 4181 [License Requirements; Policies and Procedures; Who May Dispense](#)
- 4182 [Application; Consulting Pharmacist](#)[Duties of Professional Director; Consulting Pharmacist Required](#)
- 4183 [No Medi-Cal Professional](#) Dispensing Fee
- 4184 [No Schedule II](#) Dispensing [Schedule II Substance Prohibited](#)
- 4186 [Professional Director](#)[Automated Drug Delivery Systems](#)

### Article 14. Surgical Clinics

- 4190 [Purchase of Drugs at Wholesale: Permitted Uses of Drugs; Required Records and Policies; License Required \(Surgical Clinic\)](#)
- 4191 [License Requirements](#)[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](#) [No Medi-Cal](#) Dispensing Fee; [Ban on Offering Drugs for Sale](#)
- 4194 [No Schedule II](#) 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;](#) [Security on Transfer of Ownership; Persons Authorized in Storage Area](#)
- 4197 [Minimum Standards; Waiver; Security; Sanitation; Board Regulations; Waivers](#)
- 4198 [Written Policies and Procedures Required;](#) [Contents; Training of Personnel;](#) [Quality Assurance; Consulting Pharmacist](#)

### Article 17. Continuing Education

- 4231 [Renewal](#) Requirements [for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee](#)
- 4232 [Course](#) Content [of Course](#)

### Article 18. Poisons

- 4240 Application of Act

### Article 20. Prohibitions and Offenses

- 4341 [Advertising in Compliance with Sections 651.3](#)[Advertisement of Prescription Drugs or Devices](#)
- 4343 [Use of Sign with "Pharmacy" or Similar Terms](#)[Buildings: Prohibition Against Use of Certain Signs Unless Licensed Pharmacy Within](#)

## CALIFORNIA CODE OF REGULATIONS, TITLE 16

- 1704 Change of ~~Address~~[address](#)—~~reporting a change of address~~
- 1705 Notification of Bankruptcy, Receivership or Liquidation—~~reporting the sale, inventory and location of records of dangerous drugs by a pharmacy, wholesaler or manufacturer in bankruptcy~~
- 1708.2 Discontinuance of ~~Business~~[business](#)—~~notification to board of a discontinuance of business and submission of appropriate forms~~
- 1708.4 Pharmacist ~~h~~[Handling](#) ~~r~~[Radioactive](#) ~~d~~[Drugs](#)—~~training of a nuclear pharmacist~~
- 1708.5 Pharmacy Furnishing Radioactive Drugs—~~nuclear pharmacy requirements~~
- 1709 Names of Owners and ~~Pharmacist in Charge~~[pharmacist in charge](#)—~~required information on a pharmacy permit, reporting PIC and owners on initial and renewal applications, and reporting of corporate officer changes~~
- 1712 Use of Pharmacist Identifiers
- 1714 Operational Standards and Security
- 1715.6 Reporting ~~d~~[Drug](#) ~~l~~[Loss](#)—~~reporting loss of controlled substances to the Board within thirty (30) day~~
- 1716 Variation ~~f~~[From](#) ~~p~~[Prescriptions](#)—~~prescription errors, deviation from prescription without consent of prescriber~~
- 1717 Pharmaceutical ~~p~~[Practice](#)—~~dispensing in new containers, pharmacist maintain on prescription record: date and initial of pharmacist, brand name of drug or device and indication if generic and manufacturer name, refill information, orally transmitted prescription requirements, depot of a prescription or a medication, prescription transfers, identification of pharmacist responsible for filling a prescription~~
- 1717.1 Common Electronic Files—~~establishing a common electronic file to maintain required dispensing information~~
- 1717.4 Electronic Transmission of Prescriptions—~~transmitting prescriptions by electronic means from prescriber to the pharmacy~~
- 1718.1 Manufacturer's Expiration Date—~~handling of prescription drugs not bearing a manufacturer's expiration date pursuant to federal law~~
- 1726 ~~Preceptor~~[Supervision of Intern Pharmacists](#)
- ~~1727~~ ~~Intern Pharmacist~~
- 1728 ~~Intern Experience~~—Requirements for ~~Licensure~~[Examination](#)
- 1732.1 Requirements for ~~Recognized Accredited~~ ~~Providers~~—~~requirements to provide continuing education courses as a recognized provider for California pharmacists~~
- 1732.3 ~~Coursework Approval for Providers~~[Requirements for Continuing Education Courses](#)
- 1732.4 Provider Audit Requirements
- 1732.5 Renewal Requirements for Pharmacist
- 1744 Drug ~~w~~[Warnings](#)—~~oral or written warnings when a drug should not be taken with alcohol or when a person should not drive~~
- 1746 Emergency Contraception
- ~~1751 to~~
- ~~1751.09 and~~
- ~~1751.11 to~~
- ~~1751.12~~ ~~Compounding Area for Parenteral Solutions~~—~~parenteral therapy requirements for pharmacists and pharmacies~~
- 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](#)
- [1751.7 Quality Assurance and Process Evaluation](#)
- [1751.9 Reference Materials](#)
- [1751.11 Furnishing to Home Health Agencies and Licensed Hospices](#)
- [1751.12 Obligations of a Pharmacy Furnishing Portable Containers](#)
- 1771 ~~Posting nNotice of sSuspension—suspended pharmacy must post a notice of suspension~~
- 1772 ~~Disciplinary eConditions of sSuspension—suspended pharmacist shall not enter a pharmacy prescription area or perform pharmacy related duties~~
- 1780 ~~Minimum sStandards for wWholesalers~~
- 1780.1 ~~Minimum Standards for Veterinary Food-Animal Drug Retailers~~
- 1781 ~~Exemption eCertificate—exemptee must be present in a manufacturer's or wholesaler's licensed premises~~
- 1786 ~~Exemptions—return of exemption certificate to board upon termination of employment~~
- 1787 ~~Authorization to Distribute Hemodialysis Drugs and Devices~~
- 1790 ~~Assembling and Packaging~~
- 1791 ~~Labeling~~
- 1792 ~~Receipt of for Shipment~~

## HEALTH AND SAFETY CODE, ~~TITLE 22~~

- 11100 ~~Report of Certain Chemical: Chemicals Included; Exclusions; Penalties eControlled substance transaction—reporting sales of restricted chemicals to Department of Justice~~
- 11100.1 ~~Report of Chemicals Received eControlled substances received from eOutside sState; Penalties—reporting Purchases of restricted chemicals from outside California~~
- ~~11124 Inventory of Controlled Substances~~
- 11151 ~~Limitation on Filling Prescriptions From Medical Students Issued By Unlicensed Person Lawfully Practicing Medicine~~
- 11158 ~~Prescription rRequired for Schedule I, II, III, or IV, or V eControlled sSubstance; Exception for Limited Dispensing, Administrations—prescriptions for controlled substances must comply with requirements prior to dispensing~~
- 11159 ~~Chart Order Exemption for pPatient in eCounty or lLicensed hHospital; Maintaining Record for Seven Years—controlled substance orders in hospitals~~
- 11159.1 ~~Chart Order Exemption for Clinic Records Patient; Maintaining Record for Seven Years~~
- 11159.2 ~~Exception to Triplicate Prescription Requirement Terminally III Exception~~
- 11167 ~~Emergency dDispensing of Schedule II sSubstance: Circumstances and Requirements—emergency oral Schedule II prescriptions; must receive a triplicate within seventy-two (72) hours~~
- 11167.5 ~~Emergency eOral or Electronic pPrescriptions for Scheduled II Controlled Substances for Specified iIn-patients, Residents, and Home Hospice Patients; Requirements—oral orders for Schedule II drugs in a skilled nursing facility, intermediate care facility, or a home health care agency providing hospice care; pharmacy to obtain special triplicates from Dept. of Justice; facility must forward all~~

- [signed order to the pharmacy](#)
- 11171 Prescribing, ~~etc. administering, or furnishing~~ ~~e~~Controlled ~~s~~Substance Only as Authorized—~~furnishing controlled substances must be consistent with law~~
- 11172 Antedating or ~~p~~Postdating ~~p~~Prescription Prohibited
- 11175 Prohibition on Obtaining ~~and or~~ ~~p~~Possession ~~and~~ ~~n~~Nonconforming ~~p~~Prescription; Prohibition on ~~e~~Obtaining ~~e~~Controlled ~~s~~Substance by ~~n~~Nonconforming ~~p~~Prescription
- 11180 Prohibition on Controlled ~~s~~Substance ~~e~~Obtained or ~~p~~Possessed by ~~n~~Nonconforming ~~p~~Prescription ~~—possession of a controlled substance obtained from noncomplying prescriptions~~
- 11200 Restrictions on ~~e~~Dispensing or ~~r~~Refilling; Refill of Schedule II Prescription Barred—refill restrictions of controlled substances
- 11201 Emergency Refill by Pharmacist of Schedule III, IV, or V Prescription; Circumstances; Requirements
- 11205 Maintenance and ~~r~~Retention of Records in Separate fFile—~~separate prescription file for Schedule II prescriptions~~
- 11206 Required ~~information~~information on Prescription—~~information required on a prescription for controlled substances~~
- 11209 Delivery and Receiving Requirements for Schedule II, III, and IV of Controlled Substances; Violation
- 11210 Issuing Prescription: By Whom; For What Purpose; Quantity to Be Prescribed—~~under authorized project— a prescriber may not prescribe controlled substances to treat addiction~~
- 11250 Authorized Retail Sale by Pharmacists to Physicians, etc.; Required Order Form
- 11251 Authorized Wholesale Sale by Pharmacists
- 11252 Preservation of ~~f~~Federally ~~r~~Required ~~f~~Forms—~~a wholesaler or manufacturer must maintain records of sales~~
- 11253 Duration of ~~r~~Retention
- 11255 Actions ~~e~~Constituting ~~s~~Sale—~~orders for future delivery constitutes a sale of a controlled substance~~
- 11256 Required Report of Order bBy or Sale to Out-of-State Wholesaler or Manufacturer
- [1111225 to 111655 Adulterated or Misbranded Drugs or Devices](#)

## CODE OF FEDERAL REGULATIONS, TITLE 21

- 1301.11 Persons Rrequired to Rregister.
- 1301.12 Separate Rregistrations for Sseparate 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 Ssecurity 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 Rrequirements.
- 1302.06 Sealing of controlled substances.
- 1302.07 Labeling and packaging requirements for imported and exported substances.
- ~~1302.07 Labeling and packaging requirements for imported and exported substances~~
- ~~1304.18 Inventories of importers and exporters~~
- ~~1304.31 Reports from manufacturers importing opium~~
- ~~1304.32 Reports of manufacturers importing medicinal coca leaves~~
- ~~1304.33 Reports to ARCOS~~
- ~~1305.03 to~~
- ~~1305.06 and~~
- ~~1305.08 to~~
- ~~1305.12 and~~
- ~~1305.14 to~~
- ~~1305.16 Distributions requiring order forms; persons entitled to obtain and execute order forms; procedure for obtaining order forms; procedure for executing order forms; persons entitled to fill order forms; procedure for filling order forms; procedure for endorsing order forms; unaccepted and defective order forms; lost and stolen order forms; return of unused order forms~~
- 1304.11 Inventory requirements.
- 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.—~~Schedule II.~~
- 1306.24 Labeling of substances and filing of prescriptions.—~~Schedule III and IV~~
- 1306.25 Transfer between pharmacies of prescription information for ~~of~~ Schedules III, IV, and V controlled substances for refill purposes.Prescriptions
- 1306.26 Dispensing Without a Prescription.
- 1307.11 Distribution by dispenser to another practitioner or reverse distributor.—
- 1307.12 Distribution to supplier or Manufacture and distribution of narcotic solutions and compounds by a pharmacist
- 1307.13 Incidental manufacture of controlled substances.Distribution to supplier
- 1307.21 Procedure for disposaling of controlled substances.
- 1700.1 to
- 1707.15 Child-resistant containers.

## **MISCELLANEOUS - HEALTH AND SAFETY CODE, TITLE 22**

411225 to

~~111655 — Adulterated or misbranded drugs or devices~~

## ~~MISCELLANEOUS - FEDERAL REGULATIONS~~

~~16 CFR 1700.1 to~~

~~1707.15 — Child-resistant containers~~

## **CATEGORY II**

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

Maximum: Revocation

Category II discipline is recommended for:

- violations with 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 as follows representative of this category:

## BUSINESS AND PROFESSIONS CODE

- [650](#) [Rebates or Discounts for Referral Prohibited](#)
- [650.1](#) [Lease Prohibition – Hospitals or Prescribers](#)
- [651](#) [Professional Advertising Requirements](#)

### Article 3. Scope of Practice and Exemptions

- 4051(b) [Conduct Authorized by Pharmacist ~~from Outside Pharmacy~~](#)
- 4052 [conduct Authorized by Pharmacist ~~Furnishing to Prescriber; Permissible Procedures by Pharmacist in Health Care Facility or Clinic or for Other Health Care Provider~~](#)
- 4060 [Possession of ~~Controlled Substance – Prescription Required; Exceptions~~](#)
- 4061 [Distribution of ~~Drug as Sample; Written Request Required~~ ~~Drugs~~](#)
- 4063 [Refills of ~~Prescription for Dangerous Drug or Device; Prescriber Authorization~~](#)
- 4067 [Prescription ~~Dispensing over the Internet; Dispensing Dangerous Drugs or Devices without Prescription~~](#)
- 4075 [Proof of Identity ~~Required – Oral or Electronic Prescription of Recipient for Controlled Substance Prescriptions~~](#)
- 4078 [False or Misleading Labeling ~~on Prescription~~](#)

### Article 6. General Requirements

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

### Article 7. Pharmacies

- 4112 [Non-Resident 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 – Pharmacy~~](#)
- 4117 [Security – ~~Hospital Pharmacy Admission to Area Where Narcotics are Stored, etc. – Who May Enter~~](#)
- 4120 [Non-Resident Pharmacy: ~~Registration Required~~](#)
- 4125 [Pharmacy Quality Assurance Program Required; Records Considered Peer Review Documents](#)

### Article 9. Hypodermic Needle and Syringes

- 4140 [Unlawful Possession](#)
- 4147 [Disposal ~~of Needle or Syringe~~](#)

## Article 11. Wholesalers and Manufacturers

4160 [Wholesaler:](#) License Required

4163 ~~Sales to Unauthorized Persons~~ [Furnishing by Manufacturer or Wholesaler](#)

4164 ~~Reporting by Manufacturer and Wholesalers~~ [Reports Required](#)

[4169\(a\)\(1\) Prohibited Acts](#)

## Article 13. Non-Profit of Free Clinics

4185 Inspections [Permitted](#)

## Article 14. Surgical Clinics

4195 Inspections [Permitted](#)

## Article 19. Disciplinary Proceedings

4301 ~~General Unprofessional eConduct and~~ subsections (a)-(h), (j), and (l) through (q)  
4302 ~~Pharmacy Corporation~~ [Discipline of Corporate Licensee for Conduct of Officer, Director, Shareholder](#)  
4303 Nonresident Pharmacy: [Grounds for Discipline](#)  
4304 Out-of-~~S~~state Distributors: [Authority to Discipline](#)  
4305 [Disciplinary Grounds: Failure of Pharmacy, Pharmacist to Notify Board of Termination of Pharmacist in Charge; Continuing to Operate Operation of Pharmacy wWithout a 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 to Keep Pharmacist in Charge or Exemptee in Charge; Failure to Notify Board of Termination of Same](#)  
4306 Violation of ~~Mescene-Knox~~ Professional Corporation Act [as Unprofessional Conduct](#)  
4306.5 ~~Pharmacist~~ Misuse of Education, etc. [by Pharmacist Outside Course of Practice of Pharmacy as Unprofessional Conduct](#)

## Article 20. Prohibitions and Offenses

4326 ~~Hypodermics: Obtaining Falsely; Misuse~~ [Misdemeanor: Obtaining Needle or Syringe by Fraud, etc.; Unlawful Use of Needle or Syringe Obtained from Another](#)  
4328 ~~Allowing Compounding by Non-pharmacist~~ [Misdemeanor: Permitting Compounding, Dispensing, or Furnishing by Non-pharmacist](#)  
4330 ~~Pharmacy; Failure to Place Pharmacist in Charge-, Subverting Compliance with Law by Pharmacist in Charge~~ [Misdemeanor: Non-pharmacist Owner Failing to Place Pharmacist in Charge, Dispensing or Compounding Except by Pharmacist, Interfering with Pharmacist in Charge](#)  
4331 ~~Veterinary Food-Animal Drug Retailer; Dispensing by Other than Pharmacist or Exemptee; Failure to Place Pharmacist or Exemptee in Charge~~ [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 ~~Failure to Maintain Prescription Files~~ [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 ~~Advertisement of Pharmacy Services by Unregistered Non-Resident Pharmacy~~ [Unlawful Advertising by Nonresident Pharmacy Not Registered with Board](#)

## Article 22. Unfair Trade Practices

4380 Resale of Preferentially Priced Drugs; ~~Emergency Exception: Prohibition; Exceptions~~

4381 — ~~Violation of Section 4380 as Unfair Competition; Right of Private Action to Enforce~~  
4382 ~~Authority of Board to Audit for Compliance~~ Board May Audit Sales to Walk-in  
Customers

## CALIFORNIA CODE OF REGULATIONS, TITLE 16

- 1707.1 Duty to ~~m~~Maintain ~~m~~Medication ~~p~~Profiles (~~p~~Patient ~~m~~Medication ~~r~~Records)–  
~~requirements for maintenance of patient medication profiles~~
- 1707.2 Notice to ~~e~~Consumers and ~~d~~Duty to ~~e~~Consult–~~requirements of pharmacist to consult; posting of notice to consumers~~
- 1707.3 ~~Reviewing the patient profile prior to consultation~~Duty to Review Drug Therapy and Patient Medication Record Prior to Delivery
- 1709.1 Designation of ~~p~~Pharmacist in ~~e~~Charge
- 1714.1 Pharmacy Operations ~~d~~During the Temporary Absence of ~~a~~ Pharmacist
- 1715 Self-Assessment of a Pharmacy by the Pharmacist-in-Charge
- 1715.5 ~~Transmitting Schedule II Prescription Information to CURES~~Implementation of Electronic Monitoring of Schedule II Prescriptions
- 1716.1 Compounding ~~U~~napproved ~~d~~Drugs for ~~p~~Prescriber ~~e~~Office ~~u~~Use
- 1716.2 Record ~~r~~Requirements ~~when e~~Compounding for ~~f~~uture ~~f~~urnishing
- ~~1717.2~~ ~~Notice of Electronic Prescription Files~~
- 1717.3 Preprinted, ~~m~~Multiple ~~e~~Check-off ~~p~~Prescription ~~b~~Blanks
- 1723.1 Confidentiality of Examination Questions
- 1745 Partial ~~f~~illing of Schedule II ~~p~~Prescriptions
- 1751.10 Furnishing to ~~p~~Parenteral ~~p~~Patient at ~~h~~Home–~~carrying and furnishing dangerous drugs to parenteral patients~~
- 1761(a) Erroneous or Uncertain Prescriptions–
- 1764 Unauthorized ~~d~~Disclosure of ~~p~~Prescriptions–~~revealing the contents of a prescription to unauthorized persons~~
- 1765 Commissions, ~~g~~Gratuities, and ~~r~~ebates–~~commission, gratuity or rebate to a health care facility~~
- 1766 False or ~~m~~Misleading ~~a~~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 to~~
- ~~1793.7~~ ~~Ancillary personnel–pharmacy technician requirements and tasks~~
- ~~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, ~~TITLE 22~~

- 11103 Report of ~~t~~Theft, ~~l~~oss, or ~~s~~hipping ~~d~~iscrepancy–~~reporting losses of restricted chemicals to Department of Justice~~
- ~~11123~~ ~~Warehouseman License~~
- ~~11124~~ ~~Warehouse Inventory~~
- ~~11125~~ ~~Warehouseman Bond~~
- ~~11128~~ ~~Nontransferability of Warehouse License~~
- ~~11129~~ ~~Discipline or Denial of Warehouse License~~
- ~~11130~~ ~~Disciplinary Grounds for Warehouse License~~
- ~~11131~~ ~~Disciplinary Grounds for Warehouse License~~
- 11150 ~~Issuing Controlled Substance~~ Persons Authorized to Write or Issue a Prescription

- 11152 Nonconforming ~~p~~Prescriptions ~~Prohibited~~—filling a prescription that does not conform to the requirements of the code
- 11154 ~~Prescription, etc, Must Be for Treatment; Knowingly Issuing Prescriptions; Solicitation of Unlawful Prescription, etc.~~
- 11156 ~~Prescribing, etc. Administering or dispensing eControlled sSubstances to aAddict Only as Authorized~~—prohibition on administering or dispensing a controlled substance to an addict or a habitual user
- 11164 ~~Completion of pPrescriptions for Schedule II, III, IV and V eControlled sSubstances: Form and Content; Record of Practitioner Dispensing Schedule II Controlled Substances~~—prescription requirements for controlled substances
- 11166 Time ~~Limit F~~For Filling Schedule II Prescriptions; ~~Knowingly Filling Mutilated, Forged, or Altered Prescriptions Prohibited~~
- 11170 Prohibition on ~~Prescribing, etc. eControlled sSubstance for sSelf use~~—prohibition on prescribing, administering or furnishing controlled substance to self
- 11179 Retention of Controlled Substance Prescription ~~period~~—prescription file to be maintained for three (3) years
- 11207 ~~Filling prescription eOnly by pPharmacist or iIntern Authorized to Fill Prescription pharmacist~~—dispensing, compounding, filling by pharmacist or intern pharmacist only
- 11209 Delivery and Receiving Requirements for Schedule II, III, ~~&and~~ IV Substances; ~~Violation~~
- 11350 Possession of ~~sSpecified eControlled sSubstance~~—illegal possession of a narcotic
- 11377 Unlawful ~~p~~Possession of ~~sSpecified sSubstance~~—illegal possession of a non-narcotic controlled substance
- 11165(d) CURES Transmission
- 150204 Surplus Medication Collection and Distribution Program

## CODE OF FEDERAL REGULATIONS, TITLE 21

- 1304.03 Persons required to keep records and file reports.
- 1304.04 Maintenance of records and inventories.
- 1304.11 ~~General Inventory~~ requirements ~~for inventories.~~
- 1304.21 General requirements for continuing records.
- 1304.22 Records for manufacturers.
- 1305.07 ~~Power of attorney~~Special procedure for filling certain orders.
- 1305.13 ~~Preservation of order forms~~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 ~~Schedule II P~~prescriptions.
- 1306.12 Refilling prescriptions—~~Schedule II.~~
- 1306.13 Partial filling of prescriptions—~~Schedule II.~~
- 1306.21 Requirement of prescription—~~Schedule III and IV.~~
- 1306.22 Refilling of prescriptions—~~Schedule III and IV.~~
- 1306.23 Partial filling of prescriptions—~~Schedule III and IV.~~

## CATEGORY III

Minimum: Revocation; Revocation stayed, 90 days actual suspension, three to five years

probation (five years probation where self-administration or diversion of controlled substances is involved). All standard terms and conditions and optional terms and conditions as appropriate.

Maximum: Revocation

Category III discipline is recommended for:

- 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 ~~as follows~~ representative of this category:

## BUSINESS AND PROFESSIONS CODE

### Article 3. Scope of Practice and Exemptions

- [4034 Pedigree](#)
- 4051(a) Conduct Limited To Pharmacist
- 4059 Furnishing [Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions](#)
- 4059.5 [Who May Ordering Dangerous Drugs or Devices: Exceptions](#)

### Article 5. Authority of Inspectors

- 4080 Stock [of Dangerous Drugs and Devices Kept Open for Inspection](#)
- 4081 Records of [Acquisition and Dispensing; Inspection 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 [Requirement of License; Temporary Licenses Licensed Required; Temporary Permit Upon Transfer of Ownership](#)
- 4111 [Ownership by Prescribers Prohibited 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, [Recordkeeping Requirements; Maintaining Prescription Records](#)

### Article 19. Disciplinary Proceedings

- 4301 [Unprofessional Conduct - Ssubsections \(i\) and \(k\) and \(o\)](#)
- 4307 Prohibition [Against Association with a Licensee of Association of Individual with Entity License by Board: Length of Prohibition; Individuals Covered; Imposition of Prohibition Through Administrative Act Proceeding](#)
- 4308 [Notification of Licensee Person is Prohibited from Association; Replacement Prohibited Association: Notification of Affected Licensees Known to Board](#)

### Article 20. Prohibitions and Offenses

- 4322 [False Representation to Obtain Licensure Misdemeanor or Infraction: False Representations to Secure License for Self or Others; False Representation of Licensure; Penalties](#)
- 4323 [False Representation by Telephone or Electronic Transmission to Obtain a Drug Misdemeanor: False Representation of Self as Physician, Agent of Physician, etc. to Obtain Drug](#)
- 4324 [Forgery or Alteration Felony or Misdemeanor: Forgery of Prescription; Possession of Drugs Obtained Through Forged Prescription](#)
- 4325 [Producing Prescription Blanks Without Authorization Misdemeanor: Manufacture, Possession, etc. of False Prescription Blank](#)
- 4327 [Use of Alcohol or Drugs while on Duty Misdemeanor: Sale, Dispensing, or Compounding While Under the Influence of Drugs or Alcoholic Beverages](#)
- 4329 [Nonpharmacist Taking Charge Misdemeanor: Non-pharmacist Acting as Manager, Compounding, Dispensing or Furnishing Drugs](#)
- 4332 [Failure or Refusal to Produce or Provide Records Misdemeanor: Failure or Refusal to Maintain or Produce Required Drug or Device Records; Willful Production of False Records](#)
- 4335 [4335 Failure to Arrange for Transfer of Stock after Closure Voided License: Knowing Failure to Arrange for Disposition of Stock as Misdemeanor](#)
- 4336 [4336 Use of Minor as Agent to Violate Pharmacy Law 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 – audit accountability of dangerous drugs](#)
- 1761(b) [Controlled substance prescription – professional judgment Erroneous or Uncertain Prescriptions](#)
- 1771 to
- 1774 [Disciplinary conditions of suspension and probation](#)
- 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, TITLE 22**

- 11104 [Providing Chemical for Illicit Manufacturing; Evasion of Reporting Requirements; Penalties controlled substances for manufacturing](#)
- 11105 [False Statement in Report](#)
- 11122 [Storage of controlled substances](#)
- 11150 [Persons Authorized to Write or Issue a Prescription](#)
- 11153 [Responsibility for Legitimacy of controlled substance Prescription; – eCorresponding Responsibility of a Pharmacist; Knowing Violation](#)
- 11153.5 [Wholesaler or Manufacturer Furnishing a Controlled Substance for Other Than](#)

	<a href="#">for a Legitimate Medical Purpose; Knowing Violation; Factors in Assessing Legitimacy—corresponding responsibility of a wholesaler or manufacturer</a>
11157	<a href="#">No False or Fictitious Prescriptions—issuing a false or fictitious prescription</a>
11162.5	<a href="#">Counterfeiting or Possession of Counterfeit Triplicate Prescription Blank; Penalty</a>
11173	<a href="#">Fraud, Deceit, Misrepresentation or False Statement; False Representation; False Label—obtaining controlled Substances by fraud or deceit</a>
11174	<a href="#">Prohibition on Providing False Name or Address in Connection with Prescription, etc.—false name or address on prescription</a>
11351	<a href="#">Possession or Purchase for Sale of Specified Controlled Substance—illegal possession for sale of a narcotic</a>
11368	<a href="#">Forged or Altered Prescriptions—forging a narcotic prescription</a>
11375	<a href="#">Possession for Sale or Selling Specified Substance</a>
11378	<a href="#">Possession for Sale—illegal possession for sale of a nonnarcotic</a>
11550	<a href="#">Using or Being Under the Influence of Controlled Substance</a>
11167.5	<a href="#">Pharmacy Generated Prescription for Schedule II Controlled Substances in a Skilled Nursing Facility</a>
111295	<a href="#">Manufacturing, Selling, or Offering for Sale an Adulterated Drug or Device</a>
111300	<a href="#">Unlawful to Adulterate a Drug</a>
111305	<a href="#">Unlawful to Receive in Commerce an Adulterated Drug</a>
111440	<a href="#">Unlawful Manufacturer, Selling a Misbranded Drug</a>
111445	<a href="#">Unlawful for a Person to Misbrand</a>
111450	<a href="#">Unlawful to Receive into Commerce a Drug that is Misbranded</a>

## CATEGORY IV

Penalty: Revocation

Revocation is recommended for violations of the Uniform Controlled Substance Act (Heath and Safety Code 11000 et seq.) [when involving](#):

- possession for sale
- transportation
- importation
- sale
- use of a minor for the unlawful sale of controlled substances

Revocation is also recommended when:

- 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 [as follows](#) representative of this category:

HEALTH AND SAFETY CODE, ~~TITLE 22~~

- 11352 Importing, ~~s~~Selling, ~~f~~Furnishing ~~e~~Controlled ~~s~~Substance—~~illegal sale of a narcotic~~  
11353 Adult ~~i~~nducing ~~m~~Minor to ~~v~~iolate ~~controlled substances p~~rovisions  
11379 Transporting, ~~i~~mporting, ~~s~~Selling ~~e~~Controlled ~~s~~Substances—~~illegal sale of a non-~~  
~~narcotic~~  
11380 Adult ~~u~~Using, ~~s~~Soliciting or ~~i~~ntimidating ~~m~~Minor for ~~v~~iolation—~~violation of non-~~  
~~narcotic provisions or the use of a minor~~

## MODEL DISCIPLINARY LANGUAGE – PHARMACIST/INTERN PHARMACIST

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

### Revocation – Single Cause

License number \_\_\_\_\_, issued to respondent \_\_\_\_\_, is revoked.

Respondent shall relinquish his or her wall license and pocket renewal license to the board within 10 days of the effective date of this decision. Respondent may not reapply or petition the board for reinstatement of his or her revoked license for three years from the effective date of this decision.

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

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

### Revocation – Multiple Causes

License number \_\_\_\_\_, issue to respondent \_\_\_\_\_ is revoked pursuant to Determination of Issues \_\_\_\_\_, separately and together.

~~Respondent shall relinquish his or her wall license and pocket renewal license to the board within 10 days of the effective date of this decision. Respondent may not petition the board for reinstatement of his or her revoked license for three years from the effective date of this decision. Respondent shall pay to the board its costs of investigation and prosecution in the amount of \$ \_\_\_\_\_ within 15 days of the effective date of this decision.~~

**Option:** ~~Upon~~ reinstatement of his or her revoked license, respondent shall reimburse the board for its costs of investigation and prosecution in the amount of \$ \_\_\_\_\_. Said amount shall be paid in full prior to the reinstatement of his or her license. ~~If respondent fails to pay the amount specified, his or her license shall remain revoked.~~

## **Suspension – Single Cause**

License number \_\_\_\_\_, issued to respondent \_\_\_\_\_ is suspended for a period of \_\_\_\_\_.  
As part of probation, respondent is suspended from the practice of pharmacy 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 which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.

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 this suspension shall be considered a violation of probation.

## **Suspension – Multiple Causes**

License number \_\_\_\_\_, issued to respondent is suspended for a period of \_\_\_\_\_ pursuant to Determination of Issues \_\_\_\_\_, separately and together. All suspensions shall run concurrently.

Respondent is suspended from the practice of pharmacy for \_\_\_\_\_ beginning the effective date of this decision.

## 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.)

~~The application for licensure of respondent is hereby granted, on the following terms and conditions:~~

- ~~1. That, respondent first meet all statutory and regulatory requirements for the issuance of a license to \_\_\_\_\_.~~
- ~~2. That, following the satisfaction of #1, respondent's license be issued and immediately revoked, the order of revocation being stayed and respondent placed on probation for a period of \_\_\_\_\_ years on the following terms and conditions:~~

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

### Surrender

Respondent surrenders license number \_\_\_\_\_ as of the effective date of this decision. Respondent shall relinquish his or her wall license and pocket renewal license to the board within ten (10) days of the effective date of this decision.

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

Respondent understands and agrees that if he or she 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 ~~re~~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 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 the California Pharmacist Licensure Examination prior to the issuance of a new license. Respondent is obligated-required to report this surrender as disciplinary action.

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

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

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## Public Reprimand

It is hereby ordered that a public reprimand be issued against licensee, \_\_\_\_\_.  
[Respondent is required to report this reprimand as a disciplinary action.](#)

## 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 ~~Attorney General's 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.

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

~~Term Number: (Numbers reflect actual term and condition numbers as listed beginning with page \_\_\_\_\_.)~~

1. Obey ~~a~~All Laws
2. Reporting to the Board
3. Interview with the Board
4. Cooperation with Board Staff
5. Continuing Education
6. Notice to Employers
7. No ~~Preceptorships~~, Supervision of Interns, ~~Being~~Serving as Pharmacist-In-Charge (PIC), or Serving as a Consultant
8. Reimbursement of Board Costs
9. Probation Monitoring Costs
10. Status of License
11. License Surrender While on Probation/Suspension
12. Notification of ~~a Change in Name, Residence Address, Employment/Mailing Address or Employment Change~~
13. Tolling of Probation
14. Violation of Probation
15. Completion of Probation

## OPTIONAL CONDITIONS

~~Term Number: (Numbers reflect actual term and condition numbers as listed beginning with page \_\_\_\_\_.)~~

- ~~1.~~Actual Suspension
- ~~2.~~16. Restricted Practice
- ~~3.~~17. Pharmacist Examination
- ~~4.~~18. Mental Health Examination
- ~~5.~~19. Psychotherapy
- ~~6.~~20. Medical Evaluation
- ~~7.~~21. ~~Rehabilitation Program~~Pharmacists Recovery Program (PRP)
- ~~8.~~22. Random Drug Screening
- ~~9.~~23. Abstain from Drugs and Alcohol Use
24. Prescription Coordination and Monitoring of Prescription Use
- ~~10.~~25. Community Service Program
- ~~11.~~26. Restitution
- ~~12.~~27. Remedial Education
28. Pharmacy Self-Assessment Mechanism (PSAM)
- ~~13.~~29. ~~Pharmacy~~Intern Pharmacist Experience
- ~~14.~~30. Supervised Practice
- ~~15.~~31. No Supervision of Ancillary Personnel
- ~~16.~~32. No Ownership of Licensed Premises
- ~~17.~~33. Separate File of Records
- ~~18.~~34. Report of Controlled Substances
- ~~19.~~35. No Access to Controlled Substances
- ~~20.~~36. Criminal Probation/Parole Reports
- ~~21.~~37. Consultant for Owner or Pharmacist-In-Charge

- [22.38. Tolling of Suspension](#)
- [39. Surrender of DEA Permit](#)
- [40. Ethics Course](#)

## STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS

### 4.1. Obey All Laws

Respondent shall obey all state and federal laws and regulations ~~substantially related to or governing the practice of pharmacy.~~

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

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

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

### 2.2. Reporting 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, Rrespondent 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~~ is not made as directed, probation shall be automatically extended ~~automatically~~ until such time as the final report is made and accepted by the board.

### 3.3. 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 upon request at various intervals and at a locations as are to be 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.

### 4.4. Cooperation with Board Staff

Respondent shall cooperate with the board's inspectional program and in-with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to comply-cooperate shall be considered a violation of probation.

### 5.5. Continuing Education

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

## **6. Notice to Employers**

During the period of probation, Respondent shall notify all present and prospective employers of the decision in case number \_\_\_\_\_ and the terms, conditions and restrictions imposed on respondent by the decision, as follows:-

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his or her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and/or owner to report to the board in writing acknowledging that the listed individual(s) has/have employer has 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 acknowledgment(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify ~~the his or her~~ direct supervisor, pharmacist-in-charge, and/or owner at every pharmacy entity licensed by the board of the ~~and~~ terms and conditions of the decision in case number \_\_\_\_\_ in advance of the respondent commencing work at each ~~pharmacy~~ licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his or her direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he or she has read the decision in case number \_\_\_\_\_ and the terms and conditions imposed thereby. It shall be 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 acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or 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 ~~considered~~ an employee, ~~or~~ independent contractor or volunteer.

## **7.7. No Preceptorships, Supervision of Interns, Being Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant**

During the period of probation, Respondent shall not supervise any intern pharmacist, ~~or perform any of the duties of a preceptor, nor shall respondent~~ be the pharmacist-in-charge or designated representative-in-charge 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.

## **8.8. 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.

Option: If respondent fails to make any payment by the directed deadline(s), the stay shall terminate and the license shall be revoked without further notice or opportunity to be heard.

### **9.9. Probation Monitoring Costs**

Respondent shall pay ~~the 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 ~~at the end of each year of probation 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.

### **10.10. Status of License**

Respondent shall, at all times while on probation, maintain an active, current 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 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.

### **11. License Surrender ~~w~~While on Probation/Suspension**

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her 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 pocket and wall license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

## 12. Notification of a Change in Name, Residence Address, Employment/Mailing Address or EmploymentChange

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/or~~ the address of the new employer, the name of the supervisor or 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.

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.~~13. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacist 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 practicing pharmacy as a pharmacist for a minimum of \_\_\_\_\_ hours per calendar month in California, respondent must notify the board in writing within ten (10) days of the cessation of the practice of pharmacy or, and must further notify the board in writing within ten (10) days of the resumption of the practice of pharmacy. ~~Such periods of time shall not apply to the reduction of the probation period. 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 three years thirty-six (36) months.

"Cessation of practice" means any period of time exceeding 30 days calendar month in during which respondent is not practicing as a pharmacist for at least \_\_\_\_\_ hours, as defined by Business and Professions Code section 4000 et seq engaged in the practice of pharmacy as defined in Section 4052 of the Business and Professions Code. "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: 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: Respondent shall work at least 40 hours in each calendar month as a pharmacist and at least an average of 80 hours per month in any six consecutive months. Failure to do so will be a violation of probation. If respondent has not complied with this condition during the probationary term, and respondent has presented sufficient documentation of his or her good

~~faith efforts to comply with this condition, and if no other conditions have been violated, the board, in its discretion, may grant an extension of respondent's probation period up to one year without further hearing in order to comply with this condition.~~

#### **14-14. 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 ~~which 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.

~~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 which was stayed.~~

#### **15-15. 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**

#### **1. Actual Suspension**

~~As part of probation, respondent is suspended from the practice of pharmacy 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 which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.~~

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

**2-16. Restricted Practice** ~~(Where this condition is imposed, optional condition #7 should also be imposed)~~

Respondent's practice of pharmacy shall be restricted to [specify setting or type of practice] for the first \_\_\_\_\_ years of probation. Respondent shall submit proof satisfactory to the board of compliance with this term of probation.

**Option:** Respondent shall not prepare, oversee or participate in the preparation of injectable sterile products during the first \_\_\_\_\_ year(s) of probation. Respondent shall submit proof satisfactory to the board of compliance with this term of probation. Failure to abide by this restriction or to timely submit proof to the board of compliance therewith shall be considered a violation of probation.

**3-17. Pharmacist Examination**

Respondent shall take and pass the \_\_\_\_\_ section(s) of the pharmacist licensure examination as scheduled by the Board after the effective date of this decision at respondent's own expense [California Pharmacist Jurisprudence Examination (CPJE) and/or the North American Pharmacist Licensure Examination (NAPLEX)] within six (6) months of the effective date of this decision. If respondent fails to take and pass the examination(s) within six (6) months after the effective of this decision, respondent shall be automatically suspended from practice ~~upon written notice~~. Respondent shall not resume the practice of pharmacy until he or she takes and passes the same section(s) at a subsequent examination [CPJE and/or NAPLEX] and is notified, in writing, that he or she has passed the examination(s) and may resume practice. Respondent shall bear all costs of the examination(s) required by the board.

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 which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, ~~or~~ be a consultant to any licensee of the Board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

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 ~~an exemptee~~ 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 pharmacy-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.

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. Failure to complete coursework as required shall be considered a violation of probation. Failure to take and pass the examination(s) within one (1) year of the effective date of this decision shall be considered a violation of probation. ~~Suspension and probation shall be extended until respondent passes the examination and is notified in writing.~~

**4.18. Mental Health Examination** (Appropriate for those cases where evidence demonstrates that mental illness or disability was a contributing cause of the violations.)

Within thirty (30) days of the effective date of this decision, and on a periodic basis as may be required by the board or its designee, respondent shall undergo, at his or her own expense, psychiatric evaluation(s) by a board-appointed or board-approved ~~psychiatrist or psychologist licensed mental health practitioner~~. The approved evaluator shall be provided with a copy of the board's [accusation or petition to revoke probation] 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 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 ~~psychiatrist or psychotherapist evaluator~~ recommends, and the board or its designee directs, respondent shall undergo psychotherapy. ~~Respondent shall, within 30 days of written notice of the need for psychotherapy, submit to the board for its prior approval, the recommended program for ongoing psychotherapeutic care. Respondent shall undergo and continue psychotherapy, at respondent's own expense, until further notice from the board. Respondent shall have the treating psychotherapist or psychiatrist submit written quarterly reports to the board as directed. 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 ~~determined to be~~ 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, upon notification, respondent shall ~~immediately cease practice~~ be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.

**Option:** Commencing on the effective date of this decision, respondent shall not engage in the practice of pharmacy until notified in writing by the board that respondent ~~is~~ has been deemed psychologically fit to practice pharmacy safely, and the board or its designee approves said recommendation.

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 which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, ~~or~~ 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 controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, Rrespondent 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 ~~an exemptee 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 pharmacy-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.

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

**Option:** If recommended by the ~~evaluating psychiatrist or psychotherapist~~ evaluating psychiatrist or psychotherapist licensed mental health practitioner and approved by the board, respondent shall be suspended from practicing pharmacy until ~~the respondent's~~ the respondent's treating ~~psycho~~therapist recommends, in writing, stating the basis therefor, that respondent can safely practice pharmacy, and the board or its designee approves said recommendation.

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 which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act

involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, ~~or~~ be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

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 ~~an exemptee 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 pharmacy-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.

**5-19. Psychotherapy** (Appropriate for those cases where the evidence demonstrates mental illness or alcohol or drug abuse was involved in the violations.)

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board or its designee, for ~~its~~ 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.

Therapy Psychotherapy shall be at least once a week unless otherwise ~~determined~~ 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 ~~to provide~~ such other information as may be required by the board or its designee.

If at any time the treating therapist ~~finds~~ determines that respondent cannot practice safely or

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

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 this suspension shall be considered a violation of probation. Upon approval of the licensed mental health practitioner, respondent shall undergo and continue treatment with that therapist and at respondent's own expense, until the board deems that no further psychotherapy is necessary. The board may require respondent to undergo a mental health evaluation(s) by a board-appointed or board-approved licensed mental health practitioner.

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

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

If respondent is required by the board the physician recommends, and the board or its designee directs, that respondent to 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. for its prior approval, the name and qualifications of a physician of respondent's choice. Upon board approval of the treating physician, respondent shall undergo and continue medical treatment, with that physician and at

respondent's own expense, until further notice from the board. Respondent shall have the treating physician submit written quarterly reports to the board. Should respondent, for any reason, cease treatment with the approved physician, respondent shall notify the board immediately and, within 30 days of ceasing treatment, submit the name of a replacement physician 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 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, 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 suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

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 this suspension shall be considered a violation of probation.

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

**Option:** ~~Upon Commencing on~~ the effective date of this decision, respondent shall not engage in the practice of pharmacy until notified in writing by the board ~~of its determination~~ that respondent ~~has been deemed is~~ medically fit to practice safely and independently, and the board ~~or its designee~~ approves said recommendation.

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 which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, ~~or~~ be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs or controlled substances. Respondent shall not resume practice until notified by the board.

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 ~~an exemptee~~ 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 pharmacy-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.

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

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

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 an exemptee 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 pharmacy 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.

**7.21. Rehabilitation Program--Pharmacists Recovery Program (PRP)** (Appropriate for chemical dependency (alcohol, drugs), or psychiatric disorders (mental illness, emotional disturbance, gambling)

Within thirty (30) days of the effective date of this decision, respondent shall 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. 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 43634362(c)(2), ~~as of the effective date of this decision~~. Respondent shall successfully participate in and complete his or her current contract and any subsequent addendums with the PRP.

Failure to timely contact or enroll in the PRP, or successfully participate in and complete the treatment contract and/or any addendums, shall be considered a violation of probation.

Probation shall be automatically extended until respondent successfully completes ~~his or her treatment contract~~ the PRP. Any person terminated from the PRP program shall be automatically suspended ~~upon notice~~ by the board. Respondent may not resume the practice of pharmacy until notified by the board in writing.

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

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

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 this suspension shall be considered a violation of probation.

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

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

**Option:** Respondent shall work in a pharmacy setting with access to controlled substances for six (6) consecutive months before successfully completing probation. 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.

~~The board shall retain jurisdiction to institute action to terminate probation for any violation of this term.~~

**8.22. Random Drug Screening** (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.)

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 a other drug screening program approved as directed by the board or its designee. The length of time shall be for the 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 constitute 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 drug test shall result in the immediate-automatic suspension of practice of pharmacy by respondent. Respondent may not resume the practice of pharmacy 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 which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

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 this suspension shall be considered a violation of probation.

### **9.23. Abstain from Drugs and Alcohol Use**

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. 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. 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.

**24. Prescription Coordination and Monitoring of Prescription Use** (Appropriate for chemical dependency (alcohol, drugs), or psychiatric disorders (mental illness, emotional disturbance, gambling))

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board, for its prior approval, the name and qualifications of a single physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice, who shall be aware of the respondent's history [with the use of alcohol, controlled substances, and/or dangerous drugs, and/or of mental illness, and/or of gambling addiction] and who will coordinate and monitor any prescriptions for respondent for dangerous drugs, controlled substances or mood-altering drugs. The approved practitioner shall be provided with a copy of the board's [accusation or petition to revoke probation] and decision. A record of this notification must be provided to the board upon request. Respondent shall sign a release authorizing the practitioner to communicate with the board 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 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 immediately and, within thirty (30) days of ceasing treatment, submit the name of a replacement physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice to the board or its designee for its prior approval. Failure to timely submit the selected practitioner or replacement practitioner to the board for approval, or to ensure the required reporting thereby on the quarterly reports, shall be considered a violation of probation.

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

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 which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the

board.

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 this suspension shall be considered a violation of probation.

#### **40.25. Community Services Program**

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

#### **11.26. Restitution (For Pharmacist and Premises)**— (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)

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

#### **12.27. 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 ~~its~~ 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. The period of probation shall be extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board.—All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

Failure to timely submit or complete the approved remedial education ~~as set forth hereinabove is grounds for the filing of a petition to revoke probation~~ 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 ~~may administer or its designee may require~~

the respondent, at his or her own expense, to take an approved an 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.

## **13.29. Pharmacy Intern Pharmacist Experience (For Intern Pharmacist)**

Within ninety (90) days of the effective date of this decision, respondent shall submit to the board or its designee, for ~~its~~ 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 from the effective date of this decision, submit ~~a~~ "Pharmacy Intern Experience Affidavit" and "Pharmacy Intern Hours Affidavit" signed by a currently licensed pharmacist not on probation with the board 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.

## **14.30. Supervised Practice**

During the period of probation, rRespondent 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, rRespondent shall not practice pharmacy and his or her license shall be automatically suspended until ~~the a~~ supervisor is approved by the board or its designee. The supervision shall be, as required by the board or its designee, either:

Continuous — ~~At least 75% to 100%~~ 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

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

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

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

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

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 this suspension shall be considered a violation of probation.

#### **15.31. No Supervision of Ancillary Personnel**

During the period of probation, Respondent shall not supervise any ancillary personnel,

including, but not limited to, ~~registered~~ pharmacy technicians or ~~exemtees~~ designated representatives; ~~of~~ any entity licensed by the board.

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

### **16.32. 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 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.

### **17.33. Separate File of Records (For pharmacist owners and pharmacists-in-charge)**

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

### **18.34. Report of Controlled Substances (For 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 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. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period. Failure to timely prepare or submit such reports shall be considered a violation of probation.

### **19.35. 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 Schedule II, III, IV or V (Health and Safety Code sections 11055-11058 inclusive). Respondent shall not order, receive or retain any triplicate-security prescription forms. Failure to comply with this restriction shall be considered a violation of probation.

### **20.36. 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 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.

### **21.37. 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, ~~perform any of the duties of a preceptor~~ 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 ~~its~~ 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 documentation documented mitigating evidence to warrant this option.)**

During the period of probation, Respondent shall not supervise any intern pharmacist, ~~perform the duties of a preceptor~~ 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 ~~its~~ 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.

### **22.38. 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.

~~If respondent leaves California to reside or practice outside this state, for any period exceeding 10 days (including vacation), respondent must notify the board in writing of the dates of departure and return. Periods of residency or practice outside the state – or any absence exceeding a period of 10 days shall not apply to the reduction of the suspension period.~~

~~Respondent shall not practice pharmacy upon returning to this state until notified by the board that the period of suspension has been completed.~~

### **39. Surrender of DEA Permit**

Within thirty (30) days of the effective date of this decision, respondent shall surrender his or 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 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:** Respondent may obtain a DEA permit restricted to Schedule(s) \_\_\_\_\_ controlled substance(s).

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

### **40. Ethics Course**

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. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, 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.

## 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 ~~of a~~ 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 ~~from the Pharmacy Technician Certification Board (PTCB)~~ [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 [registration license](#) is disciplined but not revoked.

Pharmacy technicians are issued a [registration license](#) based on minimal education, ~~or~~ 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 TECHNICIAN

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~~ [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

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

#### Revocation-- Single Cause

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

A condition of reinstatement shall be that the respondent is certified as defined in Business and Professions Code section 4202(a)(4) by the Pharmacy Technician Certification Board (PTCB) 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 ~~Upon~~ reinstatement of his or her revoked technician registration license respondent shall reimburse the board for its costs of investigation and prosecution in the amount of \$ \_\_\_\_\_, ~~and s~~ 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 of his or her technician registration. If the respondent fails to pay the amount specified, his or her technician registration shall remain revoked.

#### Revocation-- Multiple Causes

Technician registration number \_\_\_\_\_, issued to respondent \_\_\_\_\_ is revoked pursuant to Determination of Issues \_\_\_\_\_, separately and together. Respondent shall relinquish his or her ~~poCKET~~ technician registration to the board within 10 days of the effective date of this decision. Respondent may not petition the board for reinstatement of his or her revoked technician registration for three years from the effective date of this decision. A condition of reinstatement shall be that the respondent is certified by the Pharmacy Technician Certification Board (PTCB) 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 15 days of the effective date of this decision.

**Option:** Upon reinstatement of his or her technician registration respondent shall reimburse the board for its costs of investigation and prosecution in the amount of \$\_\_\_\_\_, and said amount shall be paid in full prior to the reinstatement of his or her technician registration. If the respondent fails to pay the amount specified, his or her technician registration shall remain revoked.

### **Suspension – Single Cause**

As part of probation, Technician registration number \_\_\_\_\_, issued to respondent \_\_\_\_\_ is suspended from working as a pharmacy technician for a period of \_\_\_\_\_ beginning the effective date of this decision.

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

### **Suspension – Multiple Causes**

Technician registration number \_\_\_\_\_, issued to respondent is suspended for a period of \_\_\_\_\_ pursuant to Determination of Issues \_\_\_\_\_, separately and together. All suspensions shall run concurrently. Respondent is suspended from the duties of a pharmacy technician for \_\_\_\_\_ beginning the effective date of this decision.

### **Standard Stay/Probation Order**

Pharmacy Technician registration license number \_\_\_\_\_ issued to \_\_\_\_\_ is revoked; however, the revocation is stayed and respondent is placed on probation for \_\_\_\_\_ years upon the following terms and conditions:

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

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

## Surrender

Respondent surrenders pharmacy technician registration-license number \_\_\_\_\_ as of the effective date of this decision. Respondent shall relinquish his or her ~~poeket-pharmacy~~ technician registration-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 ~~re~~apply for any license, permit, or technician-registration ~~of from~~ the board for three (3) years from the effective date of this decision. Respondent stipulates that should ~~respondent he or she~~ apply for any technician-registration-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. Should respondent apply for any new license, respondent will be subject to all terms and conditions not previously satisfied.

~~Respondent shall meet all requirements applicable to that technician registration 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 registration.~~

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

**Option:** Respondent stipulates that should he or she apply for any technician registration license from the board on or after the effective date of this decision, ~~that~~ investigation and prosecution costs in the amount of \$\_\_\_\_\_ shall be paid to the board prior to issuance of the technician registration 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 ~~Attorney General's 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.

~~Term Number: (Numbers reflect actual term and condition numbers as listed beginning with page \_\_\_\_\_.)~~

1. Certification Prior to Resuming Work
2. Obey ~~a~~All Laws
3. Reporting to the Board
4. Interview with the Board
5. Cooperation with Board Staff
6. Notice to Employers
7. Reimbursement of Board Costs
8. Probation Monitoring Costs
9. Status of License
10. License Surrender While on Probation/Suspension
- ~~10.11.~~ Notification of a Change in Name, Residence Address, Employment/Mailing Address or Employment Change
- ~~11.12.~~ Tolling of Probation
- ~~12.13.~~ Violation of Probation
- ~~13.14.~~ Completion of Probation
- ~~14.~~ License Surrender While on Probation/Suspension

**OPTIONAL CONDITIONS**

~~Term Number: (Numbers reflect actual term and condition numbers as listed beginning with page \_\_\_\_\_.)~~

- ~~1.~~ Actual Suspension
- ~~2.15.~~ No Ownership of Licensed Premises
- ~~3.16.~~ Attend Substance Abuse Recovery Relapse Prevention and Support Groups
- ~~4.17.~~ Random Drug Screening
- ~~5.18.~~ Work Site Monitor
- ~~6.19.~~ Notification of Departure
- ~~7.20.~~ Abstain from Drugs and Alcohol Use
- ~~8.21.~~ Tolling of Suspension
- ~~22.~~ Restitution

## STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS

### 1.1. Certification Prior to Resuming Work

Respondent shall be automatically suspended from working as a pharmacy technician until he or she is certified by the Pharmacy Technician Certification Board (PTCB) 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 the licensed premises of a (wholesaler, veterinary food-animal drug retailer or any other distributor of drugs) which is licensed by the board, or any 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 be a consultant to or assist any licensee of the board, Respondent shall not ~~or~~ 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 ~~entity~~ 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.

### 2.2. Obey All Laws

Respondent shall obey all state and federal laws and regulations ~~substantially related to or governing the practice of pharmacy.~~

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

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

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

### 3.3. Reporting 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 automatically until such time as the final report is made and accepted by the board.

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

#### **5.5. Cooperatione with Board Staff**

Respondent shall cooperate with the board's inspectional program and in-with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to comply-cooperate shall be considered a violation of probation.

## **6.6. Notice to Employers**

During the period of probation, Respondent shall notify all present and prospective employers of the decision in case number \_\_\_\_\_ and the terms, conditions and restrictions imposed on respondent by the decision, as follows:-

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his or her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner employer to report to the board in writing acknowledging that the listed individual(s) has/have employer 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 acknowledgement(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify the his or her direct supervisor, pharmacist-in-charge and/or owner at every pharmacy of the terms and conditions of the decision in case number \_\_\_\_\_ in advance of the respondent commencing work at each pharmacy. A record of this notification must be provided to the board upon request.

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

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgements to the board shall be considered a violation of probation.

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

## **7.7. 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.

**Option:** If respondent fails to make any payment by the directed deadline(s), the stay shall

terminate and the license shall be revoked without further notice or opportunity to be heard.

### **8.8. Probation Monitoring Costs**

Respondent shall pay ~~the 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 ~~at the end of each year of probation 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.

### **9.9. Status of License**

Respondent shall, at all times while on probation, maintain an active, current pharmacy technician registration/certification 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 registration/certification 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.

### **10.11. Notification of a Change in Name, Residence Address, Employment/Mailing Address or Employment Change**

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/or~~ the address of the new employer, the name of the supervisor or 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.

## **11.12. 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.

It is a violation of probation for respondent to work less than \_\_\_\_\_ hours per month as a pharmacy technician/exemptee. Should respondent, regardless of residency, for any reason (including vacation) cease practicing working as a pharmacy technician or an exemptee for a minimum of \_\_\_\_\_ hours per calendar month in California, respondent must notify the board in writing within ten (10) days of cessation of practice work and must further notify the board in writing within ten (10) days of or the resumption of the practice work. Such periods of time shall not apply to the reduction of the probation period. 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 three consecutive years thirty-six (36) months.

"Cessation of practicework" means any period of time exceeding 30 days calendar month during in which respondent is not engaged in the practice of working for at least \_\_\_\_\_ hours as a pharmacy technician, as defined in section \_\_\_\_\_ of the 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.

## **12.13. 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 ~~which 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.

~~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 which was stayed.

### **13.14. Completion of Probation**

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

### **14. License Surrender While on Probation/Suspension**

~~Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her license to the board for surrender. The board 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.~~

~~Upon acceptance of the surrender, respondent shall relinquish his or her pocket license to the board within 10 days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three 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.~~

## **OPTIONAL CONDITIONS OF PROBATION**

### **1. Actual Suspension**

~~As part of probation, respondent is suspended from the duties of a pharmacy technician 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 which is licensed by the board, or any manufacturer, or 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 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 or controlled substances.~~

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

~~During suspension, respondent shall not perform any of the duties of a pharmacy technician as provided by Section 1793.2 of the California Code of Regulations.~~

### **2.15. 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.

### **3.16. 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 ~~board-approved~~ recognized and established substance abuse recovery support group in California, (e.g., Alcoholics Anonymous, ~~Cocaine-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.

### **4.17. 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 ~~a other~~ drug screening program ~~approved as directed~~ by the board or its designee. ~~The length of time shall be for the 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 ~~constitute 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 ~~drug-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 ~~immediate-automatic~~ suspension of ~~practice-work~~ by respondent. Respondent may not resume ~~the practice of pharmacy-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.

**5.18. 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. The Respondent shall be responsible for ensuring that the work site monitor shall report 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.

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

~~If respondent leaves~~ 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, prior to leaving. Failure to comply with this provision shall be considered a violation of probation.

**7.20. 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. Additionally, respondent shall cause the prescribing practitioner to notify the board in writing, indicating their awareness of the chemical dependency. Additionally, respondent shall cause the prescribing physician to notify the board in writing, indicating their awareness of the chemical dependency. 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.

## **8.21. 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.

If respondent leaves California to reside or practice outside this state, or for any period exceeding 10 days (including vacation), respondent must notify the board in writing of the dates of departure and return. Periods of residency or practice outside the state or any absence exceeding a period of 10 days shall not apply to the reduction of the suspension period.

Respondent shall not act as a pharmacy technician upon returning to this state until notified by the board that the period of suspension has been completed.

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

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

## EXEMPTEE DESIGNATED REPRESENTATIVE

The board files cases against exemptees 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 ~~of a~~ Category III level of discipline be imposed on the exemptee designated representative. This would include suspension and probation.

~~An exemptee would be required to be reexamined by the board prior to resuming work as an exemptee.~~

## **TERMS OF PROBATION -- EXEMPTEE 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

## **MODEL DISCIPLINARY LANGUAGE -- EXEMPTEE DESIGNATED REPRESENTATIVE**

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

### **Revocation -- Single Cause**

Designated Representative license Certification number \_\_\_\_\_, issued to respondent \_\_\_\_\_ is revoked. Respondent shall relinquish his or her designated representative pocket certification 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 certification designated representative license for three (3) years from the effective date of this decision.

~~A condition of reinstatement shall be that the respondent retake the exemption certification examination.~~

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~~ Upon reinstatement of his or her revoked designated representative license certification respondent shall reimburse the board for its costs of investigation and prosecution in the amount of \$ \_\_\_\_\_, ~~and~~ said amount shall be paid in full prior to the reinstatement of his or her certification revoked designated representative license, unless otherwise ordered by the board. ~~If the respondent fails to pay the amount specified, his or her certification shall remain revoked.~~

### **Revocation -- Multiple Causes**

~~Certification number \_\_\_\_\_, issued to respondent \_\_\_\_\_ is revoked pursuant to Determination of Issues \_\_\_\_\_, separately and together. Respondent shall relinquish his or her pocket certification to the board within 10 days of the effective date of this decision. Respondent may not petition the board for reinstatement of his or her revoked certification for three years from the effective date of this decision. A condition of reinstatement shall be that the respondent retake the exemption certification examination.~~

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

**Option:** ~~Upon reinstatement of his or her certification respondent shall reimburse the board for its costs of investigation and prosecution in the amount of \$ \_\_\_\_\_, and said amount shall be paid in full prior to the reinstatement of his or her certification. If the respondent fails to pay the amount specified, his or her certification shall remain revoked.~~

### **Suspension -- Single Cause**

As part of probation, Certification number \_\_\_\_\_, issued to respondent \_\_\_\_\_ is suspended from working as a designated representative for \_\_\_\_\_ beginning the effective date of this decision a period of \_\_\_\_\_.

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.

## **Suspension – Multiple Causes**

Certification number \_\_\_\_\_, issued to respondent is suspended for a period of \_\_\_\_\_ pursuant to Determination of Issues \_\_\_\_\_, separately and together. All suspensions shall run concurrently. Respondent is suspended from the duties of an exemptee for \_\_\_\_\_ beginning the effective date of this decision.

## **Standard Stay/Probation Order**

Designated representative license Certification number \_\_\_\_\_ issued to \_\_\_\_\_ is revoked; however, the revocation is stayed and respondent is placed on probation for \_\_\_\_\_ years upon the following terms and conditions:

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

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

## **Surrender**

Respondent surrenders certification-designated representative license number \_\_\_\_\_ as of the effective date of this decision. Respondent shall relinquish his or her pocket certification-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 reapply for any certification-of-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 respondent apply for any certification-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. Should respondent apply for any new license, respondent will be subject to all terms and conditions not previously satisfied.

Respondent shall meet all requirements applicable to that certification as of the date the application is submitted to the board, including, but not limited to exemptee reexamination prior to the issuance of a new registration or certification.

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

**Option:** Respondent stipulates that should he or she apply for any certification license from the board on or after the effective date of this decision, ~~that~~ investigation and prosecution costs in the amount of \$\_\_\_\_\_ shall be paid to the board prior to issuance of the ~~certification 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 ~~Attorney General's 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.

Term Number: (~~Numbers reflect actual term and condition numbers as listed beginning with page \_\_\_\_\_~~)

- ~~1.~~ Certification Prior to Resuming Work
- ~~5.1.~~ Obey aAll Laws
- ~~6.2.~~ Reporting to the Board
- ~~7.3.~~ Interview with the Board
- ~~5.~~ 4. Cooperatione with Board Staff
- ~~6.~~ 5. Notice to Employers
- ~~6.~~ No Being Designated Representative-in-Charge
- ~~9.7.~~ Reimbursement of Board Costs
- ~~10.8.~~ Probation Monitoring Costs
- ~~15.9.~~ Status of License
- ~~10.~~ License Surrender While on Probation/Suspension
- ~~16.11.~~ Notification of a Change in Name, Residence Address, Employment/Mailing Address or Employment Change
- ~~17.12.~~ Tolling of Probation
- ~~18.13.~~ Violation of Probation
- ~~19.14.~~ Completion of Probation
- ~~20.~~ License Surrender While on Probation/Suspension

**OPTIONAL CONDITIONS**

Term Number: (~~Numbers reflect actual term and condition numbers as listed beginning with page \_\_\_\_\_~~)

- ~~1.~~ Actual Suspension
- ~~2.15.~~ No Ownership of Licensed Premises
- ~~3.16.~~ Attend Substance Abuse Recovery Relapse Prevention and Support Groups
- ~~4.17.~~ Random Drug Screening
- ~~5.18.~~ Work Site Monitor
- ~~6.19.~~ Notification of Departure
- ~~7.20.~~ Abstain from Drugs and Alcohol Use
- ~~8.21.~~ Tolling of Suspension
- ~~22.~~ Restitution

## STANDARD CONDITIONS - TO BE INCLUDED IN ALL PROBATIONS

### 1. ~~Reexamination Prior to Resuming Work~~

~~Respondent shall be suspended from working as an exemptee until he or she takes and passes the exemption examination as scheduled by the board after 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 which is licensed by the Board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving wholesaling, or repackaging or manufacturing, 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 or controlled substances. Respondent shall not direct or control any aspect of the practice of pharmacy.~~

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

### 2.1. Obey All Laws

~~Respondent shall obey all state and federal laws and regulations substantially related to or governing the practice of pharmacy.~~

~~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 contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment~~
- ~~▪ a conviction of any crime~~
- ~~▪ discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's \_\_\_\_\_ license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling 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.~~

### 3.2. Reporting 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~~

~~automatically~~ until such time as the final report is made and accepted by the board.

#### **4.3. 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 ~~various~~such intervals ~~at and~~ locations ~~to be 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.

#### **5.4. Cooperatione with Board Staff**

Respondent shall cooperate with the board's inspection~~al~~ program and ~~in~~with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to comply~~comply~~ shall be considered a violation of probation.

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## **6.5. Notice to Employers**

During the period of probation, Respondent shall notify all present and prospective employers of the decision in case number \_\_\_\_\_ and the terms, conditions and restrictions imposed on respondent by the decision, as follows:-

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his or her direct supervisor, designated representative-in-charge (including each new designated representative-in-charge employed during respondent's tenure of employment) and owner employer to report to the board in writing acknowledging that the listed individual(s) has/have employer has 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 the pharmacist-in-charge his or her direct supervisor, designated representative-in-charge and/or owner at every pharmacy each entity licensed by the board of the terms and conditions of the decision in case number \_\_\_\_\_ in advance of the respondent commencing work at each pharmacy licensed entity. A record of this notification must be provided to the board upon request.

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

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgements to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary or relief service or pharmacy management service as a pharmacy technician 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.

**Option:** If respondent fails to make any payment by the directed deadline(s), the stay shall terminate and the license shall be revoked without further notice or opportunity to be heard.

## **8.       –Probation Monitoring Costs**

Respondent shall pay ~~the 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 ~~at the end of each year of probation 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 certification 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 certification 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.

## **10.11.        Notification of a Change in Name, Residence Address, Employment/Mailing Address or Employment Change**

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 ~~or~~ the address of the new employer, supervisor ~~or~~ 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.

#### **41.12. Tolling of Probation**

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a designated representative in California for a minimum of \_\_\_\_\_ hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

It is a violation of probation for respondent to work less than \_\_\_\_\_ hours per month as an exemptee. Should respondent, regardless of residency, for any reason (including vacation) cease practicing working as an exemptee designated representative for a minimum of \_\_\_\_\_ hours in California, respondent must notify the board in writing within ten (10) days of cessation of practice work and must further notify the board in writing within ten (10) days of or the resumption of the practice work. Any failure to provide such notification(s) shall be considered a violation of probation. Such periods of time shall not apply to the reduction of the probation period.

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 three consecutive years thirty-six (36) months.

"Cessation of practicework" means any period of time exceeding 30 days calendar month during in which respondent is not engaged in the practice of a pharmacy technician working as a designated representative for at least \_\_\_\_\_ hours as a designated representative as defined in section \_\_\_\_\_ of the by Business and Professions Code section 4053 or as an exemptee as defined in section \_\_\_\_\_ of the Business and Professions Code. "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.

#### **42.13. 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 which 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.

~~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 which was stayed.~~

### **13-14. Completion of Probation**

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

### **14. License Surrender while on Probation/Suspension**

~~Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her license to the board for surrender. The board 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.~~

~~Upon acceptance of the surrender, respondent shall relinquish his or her pocket license to the board within 10 days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three 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.~~

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## OPTIONAL CONDITIONS OF PROBATION

### 1. Actual Suspension

~~As part of probation, respondent is suspended from the duties of a pharmacy technician 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 which is licensed by the board, or any manufacturer, or 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 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 or controlled substances.~~

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

~~During suspension, respondent shall not perform any of the duties of a pharmacy technician as provided by Section 1793.2 of the California Code of Regulations.~~

### 2.15. 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.

### 3.16. 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 ~~board-approved~~ recognized and established substance abuse recovery support group in California, (e.g., Alcoholic Anonymous, ~~Cocaine-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.

**4.17. 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 ~~a other~~ drug screening program ~~approved as directed~~ by the board or its designee. ~~The length of time shall be for the 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 ~~constitute 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 ~~drug~~-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 ~~immediate-automatic~~ suspension of practice work by respondent. Respondent may not resume ~~the practice of pharmacy 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.

**5.18. 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 shall report 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.

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

~~If respondent leaves~~ 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, ~~prior to leaving~~. Failure to comply with this provision shall be considered a violation of probation.

**7.20. 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. ~~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. Additionally, respondent shall cause the prescribing practitioner to notify the board in writing, indicating their awareness of the chemical dependency. Additionally, respondent shall cause the prescribing physician to notify the board in writing, indicating their awareness of the chemical dependency.~~ 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.

## **8.21. 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.

~~If respondent leaves California to reside or practice outside this state, or for any period exceeding 10 days (including vacation), respondent must notify the board in writing of the dates of departure and return. Periods of residency or practice outside the state or any absence exceeding a period of 10 days shall not apply to the reduction of the suspension period.~~

~~Respondent shall not act as a pharmacy technician upon returning to this state until notified by the board that the period of suspension has been completed.~~

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

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

## TERMS OF PROBATION – PREMISES

A minimum three-year probation period has been established by the board as 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~~ has occurred at a licensed premises. 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~~ 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 ~~specifies the~~ identifies offenses for which the board may take disciplinary action against a license. ~~The following are categories of violations used by the board in determining appropriate disciplinary penalties. 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.

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. Where a violation not included in these lists is a basis for disciplinary action, the appropriate penalty for that violation may be best derived by comparison to any analogous violation(s) that are included. Where no such analogous violation is listed, the category descriptions may be consulted.

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

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

## CATEGORY I

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

Maximum: Revocation

Category I discipline is recommended for:

- violations which are relatively minor but are potentially harmful
- repeated violations of a relatively minor nature:

Violations of the following codes are as follows representative of this category:

## BUSINESS AND PROFESSIONS CODE

### Article 3. Scope of Practice and Exemptions

4053	<u>Exemptee Supervisor</u> of Manufacturers, <u>etc.: Requirements</u> <u>Wholesalers, and Licensed Laboratories; Veterinary Food-Animal Drug Retailers</u>
4054	<u>Supplying Dialysis Drugs</u> <u>Supply by Manufacturer, etc. of Certain Dialysis Drugs and Devices</u>
4056	<u>Exempt Hospitals</u> <u>Purchase of Drugs at Wholesale – Hospital Containing 100 Beds or Less</u>
4057	<u>Exempt Articles</u> <u>Exceptions to Application of this Chapter</u>
4058	<u>License to be Displayed</u> <u>Display of Original License</u>
4062	<u>Furnishing Drugs during Emergency</u> <u>Furnishing Dangerous Drugs During Emergency</u>
4064	<u>Emergency Refills</u> <u>of Prescription Without Prescriber Authorization</u>
4065	<u>Administration through Injection Card System</u> <u>Injection Card System; Requirements for Administration</u>
4066	<u>Furnishing to Ocean</u> <u>Dangerous Drugs to Master or First Officer of Vessel</u>

### Article 4. Requirements for Prescription

4070	<u>Reduction of Oral or Electronic Prescription to Writing</u>
4071	<u>Prescriber's May Authorize Agent to Transmitting Prescriptions; Schedule II Excluded</u>
4072	<u>Oral or Electronic Transmitting Transmission of Prescriptions from a - Health Care Facility</u>
4073	<u>Substitution of Generic Drug Product Selection- Requirements and Exceptions</u>
4074	<u>Drug Warnings</u> <u>Risk: Informing Patient; Providing Consultation for Discharge Medications</u>
4076	<u>Prescription Container - Label</u> <u>Requirements for Labeling</u>
4077	<u>Labeling</u> <u>Dispensing Dangerous Drug in Incorrectly Labeled Container</u>

### Article 5. Authority of Inspectors

4082	<u>Information about Personnel</u> <u>Names of Owners, Managers and Employees Open for Inspection</u>
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## Article 6. General Requirements

- 4100 Change of ~~Name or~~ Address ~~or Name~~ – Notification to Board
- ~~4102~~ ~~Skin Puncture for Patient Training~~
- 4103 Blood Pressure ~~Measurement-~~ Taking by Pharmacist

## Article 7. Pharmacies

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

## Article 9. Hypodermic Needles and Syringes

- 4141 Furnishing Without License Required
- 4142 Prescription Required
- 4143 Exemption: Wholesale Sales to Other Entity, Physician, etc.
- 4144 ~~Exemption: Industrial Uses~~ Exception
- 4145 ~~Exemption: Human (Insulin; Adrenaline) or Animal Use~~ Exception: Furnishing for Administration of Insulin, Adrenaline, or Specified Animal Uses; Conditions
- ~~4146~~ ~~Hypodermic Register~~
- 4148 Confiscation if Found Outside Licensed Premises
- 4149 ~~Nonresident Sale by~~ Distributor

## Article 10. Pharmacy Corporations

- 4151 Licensure Requirements for Shareholders, Directors, and Officers
- 4152 Corporate Name Requirements
- 4153 Shareholder Income ~~w~~ While Disqualified
- 4156 Unprofessional Conduct by Corporation

## Article 11. Wholesalers and Manufacturers

- 4161 ~~Out-of-State Manufacturer or Nonresident~~ Wholesaler: When License Required; Application
- 4162 ~~Registration~~ ~~Agent~~ Issuance or Renewal of Wholesaler License; Surety Bond
- 4164 ~~Sales to Unauthorized Persons~~ 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 ~~Responsibility until Delivery~~ Shipping of Dangerous Drugs or Devices – Wholesaler

- 4167 [or Distributor](#)  
[Wholesaler: Bar on Obtaining Dangerous Drugs or Devices It More Than Cannot Maintain Be Stored](#) on Licensed Premises

### Article 13. Non-Profit or Free Clinics

- ~~4182 License Required (Non-Profit, etc Clinics)~~  
~~4183 License Requirements~~  
4180 [Purchase of Drugs at Wholesale Only with License: Eligible Clinics](#)  
4181 [License Requirements; Policies and Procedures; Who May Dispense](#)  
4182 ~~Application~~ [Duties of Professional Director; Consulting Pharmacist Required](#)  
4183 ~~No Medi-Cal~~ [Professional Dispensing Fee](#)  
4184 ~~No Schedule II~~ [Dispensing Schedule II Substance Prohibited](#)  
4186 ~~Professional Director~~ [Automated Drug Delivery Systems](#)

### Article 14. Surgical Clinics

- 4190 [Purchase of Drugs at Wholesale: Permitted Uses of Drugs; Required Records and Policies; License Required \(Surgical Clinic\)](#)  
4191 [License Compliance with Department of Health Services Requirements; Who May Dispense Drugs](#)  
4192 [Duties of Professional Director; Providing Information to Board](#)  
4193 ~~No Medi-Cal~~ [Clinic Not Eligible for Professional Dispensing Fee; Ban on Offering Drugs for Sale](#)  
4194 ~~No Schedule II~~ [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; Security](#)  
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

- ~~4233 Renewal Requirements~~  
~~4234 Course Content~~  
4231 [Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee](#)  
4232 [Content of Courses](#)

### Article 18. Poisons

- 4240 [Application of Act](#)

## Article 20. Prohibitions and Offenses

- 4341 [Advertising in Compliance with Sections 651.3](#) [Advertisement of Prescription Drugs or Devices](#)
- 4343 [Use of Sign with "Pharmacy" or Similar Terms](#) [Buildings: Prohibition Against Use of Certain Signs Unless Licensed Pharmacy Within](#)

## CALIFORNIA CODE OF REGULATIONS, TITLE 16

- 1704 Change of [a](#)Address ~~—reporting a change of address~~
- 1705 Notification of Bankruptcy, Receivership or Liquidation ~~—reporting the sale, inventory and location of records of dangerous drugs by a pharmacy, wholesaler or manufacturer in bankruptcy~~
- 1708.2 Discontinuance of [b](#)Business ~~—notification to board of a discontinuance of business and submission of appropriate forms~~
- 1708.4 Pharmacist [h](#)Handling [r](#)Radioactive [d](#)Drugs ~~—training of a nuclear pharmacist~~
- 1708.5 Pharmacy Furnishing Radioactive Drugs ~~—nuclear pharmacy requirements~~
- 1709 Names of Owners and [p](#)Pharmacist in [c](#)Charge ~~—required information on a pharmacy permit, reporting PIC and owners on initial and renewal applications, and reporting of corporate officer changes~~
- 1714 [Building Operational](#) Standards and Security
- 1715.6 Reporting [d](#)Drug [l](#)Loss ~~—reporting loss of controlled substances to the Board within thirty (30) day~~
- 1716 Variation from [p](#)Prescriptions ~~—prescription errors, deviation from prescription without consent of prescriber~~
- 1717 [Pharmaceutical](#) [Pharmaceutical](#) [p](#)Practice ~~—dispensing in new containers, pharmacist maintain on prescription record: date and initial of pharmacist, brand name of drug or device and indication if generic and manufacturer name, refill information, orally transmitted prescription requirements, depot of a prescription or a medication, prescription transfers, identification of pharmacist responsible for filling a prescription~~
- 1717.1 Common Electronic Files ~~—establishing a common electronic file to maintain required dispensing information~~
- 1717.4 Electronic Transmission of Prescriptions ~~—transmitting prescriptions by electronic means from prescriber to the pharmacy~~
- 1718.1 Manufacturer's Expiration Date ~~—handling of prescription drugs not bearing a manufacturer's expiration date pursuant to federal law~~
- 1726 [Preceptor](#)Supervision of Intern Pharmacists
- ~~1727~~ [Intern Pharmacist](#)
- 1728 [Intern Experience](#)—Requirements for [Licensure](#)[Examination](#)
- 1732.1 Requirements for [Recognized Accredited](#) Providers ~~—requirements to provide continuing education courses as a recognized provider for California pharmacists~~
- 1732.3 [Coursework Approval for Providers](#)[Requirements for Continuing Education Courses](#)
- 1732.4 Provider Audit Requirements

- 1732.5 Renewal Requirements for Pharmacist
- 1744 Drug ~~w~~arnings—~~oral or written warnings when a drug should not be taken with alcohol or when a person should not drive~~
- ~~1751 to~~  
~~1751.09 and~~  
~~1751.11 to~~  
1751.12 ~~Compounding Area for Parenteral Solutions—parenteral therapy requirements for pharmacists and pharmacies~~  
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 n~~Notice of ~~s~~Suspension—~~suspended pharmacy must post a notice of suspension~~
- 1772 Disciplinary ~~e~~Conditions of ~~s~~Suspension—~~suspended pharmacist shall not enter a pharmacy prescription area or perform pharmacy related duties~~
- 1780 Minimum ~~s~~Standards for ~~w~~Wholesalers
- 1780.1 Minimum Standards for Veterinary Food-Animal Drug Retailers
- 1781 Exemption ~~e~~Certificate—~~exemptee must be present in a manufacturer's or wholesaler's licensed premises~~
- 1786 Exemptions—~~return of exemption certificate to board upon termination of employment~~
- 1787 Authorization to Distribute Hemodialysis Drugs and Devices
- 1790 Assembling and Packaging
- 1791 Labeling
- 1792 Receipt ~~of for~~ Shipment

## HEALTH AND SAFETY CODE, ~~TITLE 22~~

- 11100 Report of ~~Certain Chemical: Chemicals Included; Exclusions; Penalties~~ ~~controlled substance transaction—reporting sales of restricted chemicals to Department of Justice~~
- 11100.1 Report of ~~Chemicals controlled substances r~~Received from ~~e~~Outside ~~s~~State; ~~Penalties—reporting Purchases of restricted chemicals from outside California~~
- ~~11124—Inventory of Controlled Substances~~
- 11151 ~~Limitation on Filling Prescriptions From Medical Students Issued By Unlicensed Person Lawfully Practicing Medicine~~
- 11158 Prescription ~~r~~Required for Schedule I, II, III, ~~or IV, or V~~ ~~e~~Controlled ~~s~~Substances—~~prescriptions for controlled substances must comply with requirements prior to dispensing; Exception for Limited Dispensing, Administration~~
- 11159 ~~Chart Order Exemption for p~~Patient in ~~e~~County or ~~l~~Licensed ~~h~~Hospital; ~~Maintaining Record for Seven Years—controlled substance orders in hospitals~~
- 11159.1 ~~Chart Order Exemption for~~ Clinic ~~Records~~Patient; ~~Maintaining Record for Seven Years~~
- 11159.2 ~~Exception to Triplicate Prescription Requirement~~Terminally III-Exception
- 11167 Emergency ~~d~~Dispensing of Schedule II ~~s~~Substance: ~~Circumstances and Requirements—emergency oral Schedule II prescriptions; must receive a triplicate within seventy-two (72) hours~~
- 11167.5 Emergency ~~e~~Oral or Electronic ~~p~~Prescriptions for ~~Schedule II Controlled Substance~~

- for Specified in-patients, Residents, and Home Hospice Patients; Requirements—oral orders for Schedule II drugs in a skilled nursing facility, intermediate care facility, or a home health care agency providing hospice care; pharmacy to obtain special triplicates from Dept. of Justice; facility must forward all signed order to the pharmacy
- 11171 Prescribing, etc. Controlled Substance Only as Authorized administering, or furnishing controlled substance—furnishing controlled substances must be consistent with law
- 11172 Antedating or pPostdating pPrescription Prohibited
- 11175 Prohibition on Obtaining and or pPossession g nNonconforming pPrescription
- 11180 Prohibition on eObtaining eControlled sSubstance by nNonconforming pPrescription
- 11180 Prohibition on Controlled sSubstance eObtained or pPossessed by nNonconforming pPrescription —possession of a controlled substance obtained from noncomplying prescriptions
- 11200 Restrictions on eDispensing or rRefilling; Refill of Schedule II Prescription Barred—refill restrictions of controlled substances
- 11201 Emergency Refill by Pharmacist of Schedule III, IV, or V Prescription; Circumstances; Requirements
- 11205 Maintenance and rRetention of Records in Separate fFile—separate prescription file for Schedule II prescriptions
- 11206 Required iInformation on Prescription—information required on a prescription for controlled substances
- 11209 Delivery of Controlled and Receiving Requirements for Schedule II, III, and IV Substances; Violation
- 11210 Issuing Prescription: By Whom; For What Purpose; Quantity to Be Prescribed under authorized project—a prescriber may not prescribe controlled substances to treat addiction
- 11250 Authorized Retail Sale by Pharmacists to Physicians, etc.; Required Order Form
- 11251 Authorized Wholesale Sale by Pharmacists
- 11252 Preservation of fFederally rRequired fForms—a wholesaler or manufacturer must maintain records of sales
- 11253 Duration of rRetention
- 11255 Actions eConstituting sSale—orders for future delivery constitutes a sale of a controlled substance
- 11256 Required Report of Order bBy 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 Persons Required to Register Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.
- 1301.14 Separate Registration for Separate Locations 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 ~~Physical s~~Security controls for ~~practitioners~~freight forwarding facilities.
- ~~1301.78 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 ~~D~~ates of ~~L~~abeling ~~R~~requirements.
- 1302.06 Sealing of controlled substances.
- 1302.07 Labeling and packaging requirements for imported and exported substances.
- ~~1304.18 Inventories of importers and exporters~~
- ~~1304.11 Inventory requirements.~~
- 1304.31 Reports from manufacturers importing ~~opium~~narcotic raw material.
- 1304.32 Reports of manufacturers importing ~~medicinal~~-coca leaves.
- 1304.33 Reports to ARCOS.
- ~~1305.03 to~~
- ~~1305.06 and~~
- ~~1305.08 to~~
- ~~1305.12 and~~
- ~~1305.14 to~~
- ~~1305.16 Distributions requiring order forms; persons entitled to obtain and execute order forms; procedure for obtaining order forms; procedure for executing order forms; persons entitled to fill order forms; procedure for filling order forms; procedure for endorsing order forms; unaccepted and defective order forms; lost and stolen order forms; return of unused order forms~~
- ~~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. ~~— Schedule II.~~
- 1306.24 Labeling of substances and filing of prescriptions. ~~— Schedule III and IV~~
- ~~1306.26 Transfer of Schedule III, IV, and V Prescriptions~~
- ~~1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.~~
- 1306.26 Dispensing ~~W~~without a ~~P~~rescription.
- 1307.11 Distribution by dispenser to another practitioner or reverse distributor. ~~—~~
- 1307.12 ~~Manufacture and d~~Distribution ~~of narcotic solutions and compounds by a pharmacist~~to supplier or manufacturer.
- 1307.13 ~~Distribution to supplier~~Incidental manufacture of controlled substances.
- 1307.21 Procedure for disposaling of controlled substances.
- ~~1700.1 to~~
- ~~1707.15 Child-resistant containers.~~

## ~~MISCELLANEOUS - HEALTH AND SAFETY CODE, TITLE 22~~

~~111225 to  
111655 — Adulterated or misbranded drugs or devices~~

## ~~MISCELLANEOUS-FEDERAL REGULATIONS~~

~~16 CFR 1700.1 to  
1707.15 — Child-resistant containers~~

## CATEGORY II

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

Maximum: Revocation

Category II discipline is recommended for:

- violations with 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 as follows representative of this category:

## **BUSINESS AND PROFESSIONS CODE**

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

### **Article 3. Scope of Practice and Exemptions**

- 4051(b)    Conduct Authorized by Pharmacist ~~from Outside Pharmacy~~
- 4052        conduct Authorized by Pharmacist ~~Furnishing to Prescriber; Permissible Procedures~~  
by Pharmacist in Health Care Facility or Clinic or for Other Health Care Provider
- 4060        ~~Possession of~~ Controlled Substance – Prescription Required; Exceptions
- 4061        Distribution of ~~Sample~~ Drugs as Sample; Written Request Required
- 4064        Emergency Refills of Prescription Without Prescriber Authorization
- 4067        ~~Internet; Prescription~~ Dispensing over the Internet ~~Dangerous Drugs or Devices~~  
without Prescription
- 4076 ~~Proof of Identity of Recipient for Controlled Substance Prescriptions~~
- 4079 ~~False or Misleading Labeling~~
- 4075        Proof of Identity Required – Oral or Electronic Prescription
- 4078        False or Misleading Label on Prescription

### **Article 6. General Requirements**

- 4101        ~~Termination as~~ Pharmacist in Charge, ~~Exemptee: Termination of Employment; ;~~  
Notice-Notification to Board
- 4106 ~~Licensed Employee: Theft or Impairment~~
- 4107 ~~Retaining Records on Premises~~
- 4104        Licensed Employee, Theft or Impairment: Pharmacy Procedures
- 4105        Retaining Records of Dangerous Drugs and Devices on Licensed Premises;  
Temporary Removal; Waivers; Access to Electronically Maintained Records

### **Article 7. Pharmacies**

- 4113 ~~Non-Resident Pharmacy Registration~~
- 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
- 4116 ~~Pharmacy Technician Activities~~
- 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        Security — Hospital Pharmacy Admission to Area Where Narcotics are Stored, etc. –  
Who May Enter
- 4120        Non-Resident Pharmacy: Registration Required
- 4125        Pharmacy Quality Assurance Program Required; Records Considered Peer Review

## Documents

### **Article 9. Hypodermic Needle and Syringes**

- 4140 Unlawful Possession
- 4147 Disposal of Needle or Syringe

### **Article 11. Wholesalers and Manufacturers**

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

### **Article 13. Non-Profit of Free Clinics**

- 4185 Inspections Permitted

### **Article 14. Surgical Clinics**

- 4195 Inspections Permitted

### **Article 19. Disciplinary Proceedings**

- 4301 General Unprofessional Conduct and - subsections (a)-(h), (j), and (l) through - (q)
- 4302 Pharmacy Corporation Discipline of Corporate Licensee for Conduct of Officer, Director, Shareholder
- 4303 Nonresident Pharmacy: Grounds for Discipline
- 4304 Out-of-State Distributor: s Authority to Discipline
- 4307 Failure to Notify Board of Termination of Pharmacist in Charge; Operation of Pharmacy without a Pharmacist
- 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 to Keep Pharmacist in Charge or Exemptee in Charge; Failure to Notify Board of Termination of Same Pharmacist in Charge or Exemptee; Continuing to Operate Without Pharmacist or Exemptee
- 4308 Violation of Moscone-Knox Professional Corporation Act
- 4306 Violation of Professional Corporation Act as Unprofessional Conduct
- 4306.5 Pharmacist-Misuse of Education, etc. by Pharmacist Outside Course of Practice of Pharmacy as Unprofessional Conduct

### **Article 20. Prohibitions and Offenses**

- 4326 Hypodermics: Obtaining Falsely; Misuse Misdemeanor: Obtaining Needle or Syringe by Fraud, etc.; Unlawful Use of Needle or Syringe Obtained from Another
- 4328 Allowing Compounding by Non-pharmacist Misdemeanor: Permitting Compounding, Dispensing, or Furnishing by Non-pharmacist
- 4330 Pharmacy; Failure to Place Pharmacist in Charge-, Subverting Compliance with Law by Pharmacist in Charge Misdemeanor: Non-pharmacist Owner Failing to Place

- 4331 [Pharmacist in Charge, Dispensing or Compounding Except by Pharmacist, Interfering with Pharmacist in Charge](#)  
~~Veterinary Food-Animal Drug Retailer; Dispensing by Other than Pharmacist or Exemptee; Failure to Place Pharmacist or Exemptee in Charge~~  
[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 [Failure to Maintain Prescription Files](#)  
[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 [Advertisement of Pharmacy Services by Unregistered Non-Resident Pharmacy](#)  
[Unlawful Advertising by Nonresident Pharmacy Not Registered with Board](#)

## Article 22. Unfair Trade Practices

- 4380 [Resale of Preferentially Priced Drugs](#); ~~Emergency Prohibition~~; [Exceptions](#)  
~~4381 Violation of Section 4380 as Unfair Competition; Right of Private Action to Enforce~~  
 4382 ~~Authority of Board to May Audit for Compliance~~ [Sales to Walk-in Customers](#)

## CALIFORNIA CODE OF REGULATIONS, TITLE 16

- 1707.1 [Duty to mMaintain mMedication pProfiles \(pPatient mMedication rRecords\)](#) ~~requirements for maintenance of patient medication profiles~~
- 1707.2 [Notice to eConsumers and dDuty to eConsult](#) ~~requirements of pharmacist to consult; posting of notice to consumers~~
- 1707.3 [Reviewing the patient profile prior to consultation](#)  
[Duty to Review Drug Therapy and Patient Medication Record Prior to Deliver](#)
- 1709.1 [Designation of pPharmacist in eCharge](#)
- 1714.1 [Pharmacy Operation dDuring Temporary Absence of a Pharmacist](#)  
~~1716 Self-Assessment of a Pharmacy by the Pharmacist in Charge~~  
 1715 [Self-Assessment of a Pharmacy by the Pharmacist-in-Charge](#)
- 1715.5 [Transmitting Schedule II Prescription Information to CURES](#)  
[Implementation of Electronic Monitoring of Schedule II Prescriptions](#)
- 1716.1 [Compounding Unapproved dDrugs for pPrescriber eOffice uUse](#)
- 1716.2 [Record rRequirements -when eCompounding for fFuture fFurnishing](#)
- 1717.2 [Notice of Electronic Prescription Files](#)
- 1717.3 [Preprinted, mMultiple eCheck-off pPrescription bBlanks](#)
- 1723.1 [Confidentiality of Examination Questions](#)
- 1745 [Partial fFilling of Schedule II pPrescriptions](#)
- 1751.10 [Furnishing to pParenteral pPatient at hHome](#) ~~carrying and furnishing dangerous drugs to parenteral patients~~
- 1761(a) [Erroneous or Uncertain Prescriptions](#) ~~revealing the contents of a prescription to unauthorized persons~~
- 1764 [Unauthorized dDisclosure of pPrescriptions](#) ~~revealing the contents of a prescription to unauthorized persons~~
- 1765 [Commissions, gGratuities, and rRebates](#) ~~commission, gratuity or rebate to a health care facility~~
- 1766 [False or mMisleading aAdvertising](#)
- 1775.3 [Compliance with Orders of Abatement](#)
- 1782 [Reporting Sales of Drugs Subject to Abuse](#)
- 1783 [Manufacturer or Wholesaler Furnishing Drugs or Devices](#)

~~1775.4 Compliance with Orders of Abatement~~  
~~1784 Reporting Sales of Drugs Subject to Abuse~~  
~~1785 Manufacturer or Wholesaler Furnishing~~  
~~1793.1 to~~  
~~1793.7 Ancillary personnel – pharmacy technician requirements and tasks~~  
~~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, ~~TITLE 22~~

- 11103 Report of ~~t~~Theft, ~~l~~Loss, or ~~s~~Shipping ~~e~~Discrepancy—~~reporting losses of restricted chemicals to Department of Justice~~
- ~~11123 Warehouseman License~~
- ~~11124 Warehouse Inventory~~
- ~~11125 Warehouseman Bond~~
- ~~11128 Nontransferability of Warehouse License~~
- ~~11129 Discipline or Denial of Warehouse License~~
- ~~11130 Disciplinary Grounds for Warehouse License~~
- ~~11131 Disciplinary Grounds for Warehouse License~~
- 11150 ~~Issuing Controlled Substance Prescription~~ Persons Authorized to Write or Issue a Prescription
- 11152 Nonconforming ~~p~~Prescriptions Prohibited—~~filling a prescription that does not conform to the requirements of the code~~
- 11154 ~~Issuing Prescriptions, etc. Must Be for Treatment; Knowing Soliciting of Unlawful Prescription, etc.~~
- 11156 Prescribing, etc. Administering or dispensing eControlled sSubstances to aAddict Only as Authorized—~~prohibition on administering or dispensing a controlled substance to an addict or a habitual user~~
- 11164 Completion of pPrescriptions for Schedule II, III, IV and V eControlled sSubstance; Form and Content; Record of Practitioner Dispensing Schedule II Controlled Substance—~~prescription requirements for controlled substances~~
- 11165(d) CURES Transmission
- 11166 Time Limit For Filling Schedule II Prescriptions; Knowingly Filling Mutilated, Forged, or Altered Prescriptions Prohibited
- 11170 Prohibition on Prescribing, etc. eControlled sSubstance for sSelf-use—~~prohibition on prescribing, administering or furnishing controlled substance to self~~
- 11179 Retention of Controlled Substance Prescription period—~~prescription file to be maintained' for three (3) years~~
- 11207 Filling prescription eOnly by pPharmacist or iIntern Authorized to Fill Prescription pharmacist—~~dispensing, compounding, filling by pharmacist or intern pharmacist only~~
- 11209 Delivery and Receiving Requirements for Schedule II, III, and IV Substances; Violation
- 11350 Possession of ~~s~~Specified ~~e~~Controlled ~~s~~Substance—~~illegal possession of a narcotic~~
- 11377 Unlawful ~~p~~Possession of ~~s~~Specified ~~s~~Substance—~~illegal possession of a non-narcotic controlled 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 General Inventory requirements for inventories
- 1304.21 General requirements for continuing records.
- 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers and exporters.
- 1305.07 Power of attorney Special procedures for filling certain orders.
- 1305.13 Preservation of order forms Procedure for filling DEA Forms 222.
- 1306.04 Purpose of issue of prescription.

- 1306.06 Persons entitled to fill prescriptions.
- ~~1306.08 Administering or dispensing of narcotic drugs~~
- 1306.11 ~~\_\_\_\_\_~~ - Requirement of ~~Schedule II P~~ prescriptions.
- 1306.12 Refilling prescriptions. ~~— Schedule II~~
- 1306.13 Partial filling of prescriptions. ~~— Schedule II~~
- 1306.21 Requirement of prescription. ~~— Schedule III and IV~~
- 1306.22 Refilling of prescriptions. ~~— Schedule III and IV~~
- 1306.23 Partial filling of prescriptions. ~~— Schedule III and IV~~

## 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 occurred at the licensed premises). All standard terms and conditions and optional terms and conditions as appropriate.

For a licensed premises, a minimum 14-28 days actual suspension.

Maximum: Revocation

Category III discipline is recommended for:

- 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 as follows representative of this category:

## BUSINESS AND PROFESSIONS CODE

### Article 3. Scope of Practice and Exemptions

4051(a) Conduct Limited ~~To~~ Pharmacist

~~4060~~ Furnishing without prescription

4059 Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions

4059.5 Ordering-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 ~~Acquisition and Dispensing~~; 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 ~~Requirement of~~ License Required; Temporary ~~Licenses~~ Permit Upon Transfer of Ownership

4111 Restrictions on Prescriber Ownership ~~by Prescribers Prohibited~~

### Article 11. Wholesalers and Manufacturers

4169(a)(2) to

4169(a)(5) Prohibited Acts

## Article 15. Veterinary Food-Animal Retailers

4199 [Labeling, Recordkeeping Requirements; Maintaining Prescription Records](#)

## Article 19. Disciplinary Proceedings

4301 [Unprofessional Conduct - Subsections \(i\) and \(k\) and \(o\)](#)  
4307 [Prohibition against Association with Individual with Entity License by Board: Length of Prohibition; Individuals Covered; Imposition of Prohibition Through Administrative Act Proceeding](#)  
4308 [Notification of Licensee Person is Prohibited from Association; Replacement Notification of Affected Licensees Known to Board](#)

## Article 20. Prohibitions and Offenses

4322 [Misdemeanor or Infraction: False Representations to Obtain Secure License for Self or Others; False Representation of Licensure; Penalties](#)  
4323 [Misdemeanor: False Representation of Self as Physician, Agent of Physician, etc. by Telephone or Electronic Transmission to Obtain a Drug](#)  
4324 [Felony or Misdemeanor: Forgery of Prescription; Possession of Drugs Obtained Through Forged Prescriptioner Alteration](#)  
4325 [Misdemeanor: Manufacture, Possession, etc. of False Producing Prescription Blanks Without Authorization](#)  
4327 [Misdemeanor: Sale, Dispensing, or Compounding While Under the Influence Use of Alcohol or Drugs while on Duty or Alcoholic Beverages](#)  
4329 [Misdemeanor: Non-pharmacist Taking Charge Acting as Manager, Compounding, Dispensing or Furnishing Drugs](#)  
4332 [Misdemeanor: Failure or Refusal to Maintain or Produce or Provide 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](#)  
4337 [Failure to Arrange for Transfer of Stock after Closure](#)  
4338 [Use of Minor as Agent to Violate Pharmacy Law](#)

## Article 22. Unfair Trade Practices

4380 [Resale of Preferentially Priced Drugs: Prohibition; Exceptions](#)

## CALIFORNIA CODE OF REGULATIONS, TITLE 16

1718 [Current Inventory Defined - audit accountability of dangerous drugs](#)  
1761(b) [Controlled substance prescription - professional judgment Erroneous or Uncertain Prescriptions](#)  
1771 to  
1774 [Disciplinary conditions of suspension and probation](#)  
1771 [Posting of Notice of Suspension](#)  
1772 [Disciplinary Condition of Suspension](#)  
1773 [Disciplinary Conditions of Probation of Pharmacist](#)

**HEALTH AND SAFETY CODE, ~~TITLE 22~~**

- 11104 Providing [Chemical for Illicit Manufacturing; Evasion of Reporting Requirements; Penalties](#)~~controlled substances for manufacturing~~
- 11105 False Statement in Report
- ~~11122 Storage of Controlled Substances~~
- 11150 Persons ~~a~~Authorized to ~~w~~Write or ~~i~~Issue a ~~p~~Prescription
- 11153 Responsibility for [Legitimacy of](#)~~controlled substance~~ ~~p~~Prescription; [Corresponding Responsibility of Pharmacist](#)~~—corresponding responsibility of a pharmacist~~
- 11153.5 [Wholesaler or Manufacturer](#) ~~Furnishing a~~ ~~c~~Controlled ~~s~~Substance ~~for e~~Other ~~t~~han ~~for a~~ ~~H~~Legitimate ~~m~~Medical ~~p~~Purpose; [Knowing Violation; Factors in Assessing Legitimacy](#)~~—corresponding responsibility of a wholesaler or manufacturer~~
- 11157 ~~No~~ False or ~~f~~Fictitious ~~p~~Prescriptions~~—issuing a false or fictitious prescription~~
- 11162.5 Counterfeiting or ~~p~~Possession of ~~e~~Counterfeit [TriPLICATE](#) ~~p~~Prescription ~~b~~Blank; [Penalty](#)
- ~~11167.5 Pharmacy Generated Prescription for Schedule II Controlled Substance in a Skilled Nursing Facility~~
- 11173 Fraud, ~~d~~Deceit, ~~m~~Misrepresentation or ~~f~~False ~~s~~Statement; [False Representation; False Label](#)~~—obtaining controlled Substances by fraud or deceit~~
- 11174 [Prohibition on Providing False n](#)Name or ~~a~~Address [in Connection with Prescription, etc.](#)~~—false name or address on prescription~~
- 11351 Possession or ~~p~~Purchase for ~~s~~Sale of ~~s~~Specified ~~e~~Controlled ~~s~~Substance~~—illegal possession for sale of a narcotic~~
- 11368 Forged or ~~a~~Altered ~~p~~Prescriptions~~—forging a narcotic prescription~~
- 11375 Possession for ~~s~~Sale or ~~s~~Selling ~~s~~Specified ~~s~~Substance
- 11378 Possession for ~~s~~Sale~~—illegal possession for sale of a nonnarcotic~~
- 11550 Use~~ing~~ or ~~b~~Being ~~u~~nder ~~the i~~nfluence of ~~e~~Controlled ~~s~~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

Revocation is recommended for violations [of](#) the Uniform Controlled Substance Act (Health and Safety Code 11000 et seq.) [involving](#):

- possession for sale
- transportation
- importation
- sale
- use of a minor for the unlawful sale of controlled substances

Revocation is also recommended when:

- 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 ~~as follows~~ representative of this category:

**HEALTH AND SAFETY CODE, ~~TITLE 22~~**

- 11352 Importing, sSelling, fFurnishing eControlled sSubstance ~~—illegal sale of a narcotic~~
- 11353 Adult iInducing mMinor to vViolate ~~controlled substances p~~rovisions
- 11379 Transporting, iImporting, sSelling eControlled sSubstances ~~—illegal sale of a non-narcotic~~
- 11380 Adult uUsing, sSoliciting or iIntimidating mMinor for vViolation ~~—violation of non-narcotic provisions or the use of a minor~~

## MODEL DISCIPLINARY LANGUAGE - PREMISES

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

### **Revocation – Single Cause**

License number \_\_\_\_\_, issued to respondent \_\_\_\_\_, is revoked.

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

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.

### **Revocation – Multiple Causes**

License number \_\_\_\_\_, issue to respondent \_\_\_\_\_ is revoked pursuant to Determination of Issues \_\_\_\_\_, separately and together.

~~**For premises:** Respondent 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 controlled substances and dangerous drugs and devices. Respondent shall provide written proof of such disposition to the board within five days of disposition.~~

### **Suspension – Single Cause**

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

Respondent shall cease all pharmacy operations during the period of suspension. Failure to comply with this suspension shall be considered a violation of probation.

### **Suspension – Multiple Causes**

Respondent is suspended from \_\_\_\_\_ operations for \_\_\_\_\_ beginning the effective date of this decision.

## 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.)

~~The application for licensure of respondent is hereby granted, on the following terms and conditions:~~

- ~~1. That, respondent first meet all statutory and regulatory requirements for the issuance of a license to \_\_\_\_\_.~~
- ~~2. That, following the satisfaction of #1, respondent's license be issued and immediately revoked, the order of revocation being stayed and respondent placed on probation for a period of \_\_\_\_\_ years on the following terms and conditions:~~

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

### Surrender

Respondent owner surrenders license number \_\_\_\_\_ as of the effective date of this decision. Respondent owner shall relinquish his or her the premises wall license and pocket renewal license to the board within ten (10) days of the effective date of this decision.

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

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

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

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

Respondent owner may not reapply for any license, permit, or registration from the board for three (3) years from the effective date of this decision. Respondent owner 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 taking and passing the California Pharmacist Licensure Examination prior to the issuance of a new license.~~ Respondent is obligated required to report this surrender as disciplinary action.

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

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

### **Public Reprimand**

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

### **Adoption of Stipulation**

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

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

~~Term Number: (Numbers reflect actual term and condition numbers as listed beginning with page \_\_\_\_\_.)~~

1. Obey ~~a~~All laws
2. Reporting to the Board
3. Interview with the Board
4. Cooperation with Board Staff
5. Reimbursement of Board Costs
6. Probation Monitoring Costs
7. Status of License
8. License Surrender ~~w~~While on Probation/Suspension
9. Notice to Employees
10. Owners and Officers: Knowledge of ~~the~~ Law
11. Posted Notice of Probation
- ~~11.12.~~ Violation of Probation
- ~~12.~~ 13. Completion of Probation

**OPTIONAL CONDITIONS**

~~Term Number: (Numbers reflect actual term and condition numbers as listed beginning with page \_\_\_\_\_.)~~

- ~~1.~~ Actual Suspension
- ~~2.~~ 14. Community Services Program
- ~~3.~~ 15. Restitution
- ~~4.~~ 16. Separate File of Records
- ~~5.~~ 17. Report of Controlled Substances
- ~~6.~~ 18. Surrender of DEA Permit
- ~~7.~~ 19. Posted Notice of Suspension

## STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS

### 1.1. Obey All Laws

Respondent owner shall obey all state and federal laws and regulations ~~substantially related to or governing the practice of pharmacy.~~

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

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

### 2.2. Reporting to the Board

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

### 3.3. Interview with the Board

Upon receipt of reasonable prior notice, respondent owner shall appear in person for interviews with the board or its designee, upon request at ~~various such~~ intervals ~~at and~~ locations ~~to be 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.

### 4.4. Cooperation with Board Staff

Respondent owner shall cooperate with the board's inspectional program and in-with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to comply-cooperate shall be considered a violation of probation.

## **5.5. Reimbursement of Board Costs**

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

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

Option: If respondent owner fails to make any payment by the directed deadline(s), the stay shall terminate and the license shall be revoked without further notice or opportunity to be heard.

## **6.6. Probation Monitoring Costs**

Respondent owner shall pay ~~the 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 ~~at the end of each year of probation 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.

## **7.7. Status of License**

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

If respondent 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.

## **8.8. License Surrender ~~w~~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~~ owner ~~discontinue business,~~ respondent owner may tender ~~his or her 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.

Upon acceptance of the surrender, respondent owner shall relinquish ~~his or her pocket 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.

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

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

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

### **9.9. Notice to Employees**

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

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

## **10-10. Owners and Officers: Knowledge of the Law**

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

## **11. Posted Notice of Probation**

Respondent owner shall prominently post a probation notice provided by the board in a place conspicuous and readable to the public. 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.

## **11-12. Violation of Probation**

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

If respondent owner violates probation in any respect, the board, after giving respondent owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order which-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.

~~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 which was stayed.~~

## **12-13. 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

### **1. Actual Suspension**

~~As part of probation, respondent pharmacy is suspended from the operation of pharmacy for \_\_\_\_\_ days beginning the effective date of this decision.~~

~~During suspension, respondent pharmacy may not order, maintain or dispose of any dangerous drugs and devices or controlled substances. The pharmacy may not make demand or bill for any drugs or services during the period of suspension and may not process any claims for pharmacy services during the period of suspension, except as to services rendered prior to the effective date of the suspension period. The pharmacy shall not receive or transmit any prescription, new or refill, during the period of suspension. Where the pharmacy does not maintain dangerous drugs and devices or controlled substances in an area which can be closed off from the rest of the pharmacy and locked, the entire pharmacy must be closed during the period of suspension.~~

### **2.14. 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 ~~its~~ prior approval, a community service program in which respondent shall provide free health-care related services on a regular basis to a community or charitable facility or agency for at least \_\_\_\_\_ hours per \_\_\_\_\_ for the first \_\_\_\_\_ of probation.

Within thirty (30) days of board approval thereof, respondent 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.

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

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

### **4.16. Separate File of 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.

### **5.17. Report of Controlled Substances**

Respondent owner shall submit quarterly reports to the board detailing the total acquisition and

disposition of such controlled substances as the board 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. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period. Failure to timely prepare or submit such reports shall be considered a violation of probation.

#### **6.18. 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 within 30 days of the effective date of this decision. 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 222 forms, for controlled substances.

#### **7.19. 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. The suspension notice shall remain posted during the entire period of ~~actual~~ suspension ordered by this decision.

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

2/27/2004/2007

# Attachment 7

*CMS Security Forms for Written  
Medicaid Prescriptions*

## Update on Medicaid Tamper Proof Prescriptions...

On Saturday, September 29, 2007, President Bush signed the TMA, Abstinence Education, and QI Programs Extension Act of 2007 delaying the implementation date for all paper Medicaid prescriptions to be written on tamper-resistant paper. Under the new law, as of April 1, 2008, all written Medicaid prescriptions must be on tamper-resistant prescription pads.

CMS' guidance on the tamper-resistant law, set forth in an August 17, 2007 State Medicaid Director letter, contains two phases. For the first, a prescription must contain at least one of the three tamper-resistant characteristics in order to be considered "tamper resistant." For the second, prescriptions must contain all three characteristics. The two-phased approach will still be in effect. At least one of the three tamper-resistant characteristics is required on April 1, 2008. All three characteristics are required on October 1, 2008.

All other guidance that CMS has issued on this requirement contained in the State Medicaid Director letter and Frequently Asked Questions will still apply once it is implemented. More info on the CMS guidance to States can be found on our website.

Chris Worrall  
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The following is a comparison of the new Medicare/MediCal prescription requirements and the corresponding California controlled substance prescription form's tamper resistant requirements:

<b>CMS Requirements</b>	<b>Corresponding California Protection</b>
1) One or more industry-recognized features designed to prevent the unauthorized copying of a completed or blank prescription.	1) <b>Repetitive Void pattern appears across face of prescription when the prescription is copied.</b> 2) Opaque feature, such as Rx, which fades or disappears with repeated attempts to lighten a prescription on a copier.
2) One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber.	1) <b>Repetitive Void Pattern or stain appears where attempts have been made to chemically alter the prescription.</b> 2) 6 quantity checkboxes allows quick confirmation of the quantity ordered. 3) Prescription not valid without the number of drugs prescribed written in by the prescriber.
3) One or more industry – recognized features designed to prevent the use of counterfeit prescription forms.	1) <b>California watermark</b> 2) Thermochromic Ink changes color or disappears temporarily with hot breath or when rubbed briskly. 3) Preprinted prescriber name, DEA and State License number by approved printer. 4) Use of a Dept. of Justice approved security prescription vendor. 5) Unique batch and lot number assigned by the approved vendor when printed.

**Note: The thermochromic ink feature is the most effective in preventing counterfeit prescription forms; however, the ink is expensive and very costly to apply.**



**Center for Medicaid and State Operations**

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August 17, 2007

SMDL #07-012

Dear State Medicaid Director:

The purpose of this letter is to offer guidance to State Medicaid agencies on section 7002(b) of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007, regarding use of tamper-resistant prescription pads, which was signed into law on May 25, 2007.

Section 7002(b), which amends section 1903(i) of the Social Security Act (the Act) (42 U.S.C. section 1936b(i)) by adding new paragraph (23), states that payment shall not be made for "... amounts expended for medical assistance for covered outpatient drugs (as defined in section 1927(k)(2)) for which the prescription was executed in written (and non-electronic) form unless the prescription was executed on a tamper-resistant pad." This provision becomes effective on October 1, 2007. The tamper resistant pad requirement of section 7002(b) applies to all outpatient drugs, including over-the-counter drugs in States that reimburse for prescriptions for such items. Section 1927(k)(3) of the Act provides exceptions to section 1927(k)(2) for drugs provided in nursing facilities, intermediate care facilities for the mentally retarded, and other specified institutional and clinical settings. Such drugs in these settings (to the extent that they are not separately reimbursed) are exceptions to section 1927(k)(2), and, therefore, are not subject to the tamper-resistant pad requirement of section 7002(b). Section 7002(b) is applicable regardless of whether Medicaid is the primary or secondary payor of the prescription being filled.

The tamper-resistant pad requirement does not apply to refills of written prescriptions presented at a pharmacy before October 1, 2007. In addition, the payment limitation does not apply to e-prescriptions transmitted to the pharmacy, prescriptions faxed to the pharmacy, or prescriptions communicated to the pharmacy by telephone by a prescriber. The Centers for Medicare & Medicaid Services (CMS) particularly encourages the use of e-prescriptions as an effective and efficient method of communicating prescriptions to pharmacists. Please note, however, that Drug Enforcement Administration regulations regarding controlled substances may require a written prescription.

Paragraph (23) of section 1903(i) is not included among the payment limitations in the last paragraph of the section that are applicable "to items or services furnished and amounts expended by or through a managed care entity." Therefore, the requirement for the use of a tamper-resistant prescription pad does not apply when a managed care entity pays for the prescription.

To the extent permissible under State and Federal law and regulation, our guidance does not restrict emergency fills of non-controlled or controlled dangerous substances for which a prescriber provides the pharmacy with a verbal, faxed, electronic, or compliant written prescription within 72 hours after the date on which the prescription was filled.

To be considered tamper resistant on October 1, 2007, a prescription pad must contain at least one of the following three characteristics:

- 1) one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;
- 2) one or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber;
- 3) one or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

No later than October 1, 2008, to be considered tamper resistant, a prescription pad must contain all of the foregoing three characteristics. Failure of a State to enforce the tamper-resistant pad requirement of section 7002(b) may result in the loss of Federal financial participation.

States are free to exceed the above baseline standard as to what constitutes a tamper-resistant prescription pad. States should make their own determination whether to allow pharmacists to accept an out-of-State prescription that meets the tamper-resistant requirements of another State. Several States have laws and regulations concerning mandatory, tamper-resistant prescription pad programs, which were in effect prior to the passage of section 7002(b). CMS deems that the tamper-resistant prescription pad characteristics required by these States' laws and regulations meet or exceed the baseline standard, as set forth above.

The payment limitation set forth in section 1903(i)(23) of the Act does not impose additional requirements on States regarding retention of hard copy prescriptions. States may follow current State and Federal laws and regulations for record retention.

The CMS strongly supports State program integrity measures and wants States to be aware that both e-prescribing and use of tamper-resistant prescription pads may reduce instances of unauthorized, improperly altered, and counterfeit prescriptions. If a State elects to purchase compliant prescription pads for Medicaid prescriptions and provide them to prescribers at no cost or at a discounted rate, the cost of the prescription pads is reimbursable as an administrative expense.

States are not required to file a State plan amendment in connection with actions taken to comply with section 1903(i)(23). It is up to each State to establish its own enforcement plan for ensuring compliance with the payment restrictions contained in section 1903(i)(23).

If you have any questions regarding this guidance, please contact Mr. David Frank, Director, Medicaid Integrity Group, at 410-786-8874.

Sincerely,

/s/

Dennis G. Smith  
Director

cc:

CMS Regional Administrators

CMS Associate Regional Administrators  
Division of Medicaid and Children's Health

Martha Roherty  
Director, Health Policy Unit  
American Public Human Services Association

Joy Wilson  
Director, Health Committee  
National Conference of State Legislatures

Matt Salo  
Director of Health Legislation  
National Governors Association

Debra Miller  
Director for Health Policy  
Council of State Governments

Christie Raniszewski Herrera  
Director, Health and Human Services Task Force  
American Legislative Exchange Council

Jacalyn Bryan Carden  
Director of Policy and Programs  
Association of State and Territorial Health Officials

# Attachment 8

*Request for Waiver of 16 CCR 1717(e)  
by University Specialty Pharmacy*



RECEIVED BY CALIF.  
BOARD OF PHARMACY

September 2007-5 AM 11:10

Virginia Herold, Executive Officer  
California Board of Pharmacy  
1625 N. Market Blvd., Suite N-219  
Sacramento, CA 95834

Dear Ms. Herold:

We are sending you this request at the direction of Bob Ratcliff, Pharm.D. Supervising Inspector, with whom we originally spoke with regarding our request.

We hereby request a waiver of California Code of Regulations, title 16, section 1717, subdivision (e), to deliver dispensed Synagis<sup>®</sup> prescriptions to a licensed home health agency (HHA) for the administration by the HHA to the patient at his/her residence. We would like to note the following highlights of our proposed program:

1. The medication involved requires refrigeration, and as a result, the medications will, at all times be stored either in a refrigerator or in a cooler to maintain its integrity. By allowing these medications to be delivered to the administering professional nurses rather than direct delivery to patients, we believe that better such control can be maintained, by avoiding the accidental and unattended delivery of the drugs (e.g. being left on a doorstep) and the mishandling of the drugs once in the residence.
2. Transportation of the prescriptions to the designated nurses will be either delivery driver (our employee) or via overnight courier. The nurses will, in turn, directly deliver the prescriptions to the patients' homes upon receipt. At all times following its delivery, the prescribed medication will be under the *direct supervision* of the nurse(s) who receive it.
3. If consultation is needed regarding the delivered prescriptions, it will be available primarily through written drug information (provided in English and Spanish) and a pharmacist will be available at all times for further consultation via phone.

We are currently working closely with Marcia Ehinger, M.D. & Barry Handon, M.D. with the Medi-Cal Policy Division to develop a comprehensive Medication Therapy Management (MTM) program for Synagis<sup>®</sup> (by MedImmune) including immunizations of the serviced infants, which will not only improve this medication's coverage within the State, but also improve the effectiveness of the medication therapy for each patient and drastically increase the recorded immunization rates statewide. In conjunction with the Policy Division, we are beginning an informal pilot program to develop checks and balances for the delivery and care of covered patients.

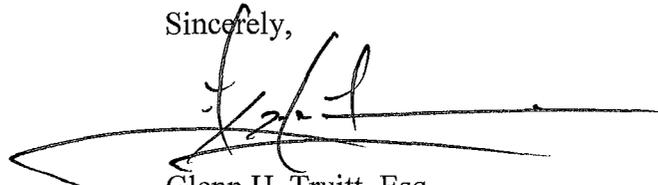
Although we understand that a waiver of the type we are requesting is extraordinary and unique, there is precedent for such waiver under similar circumstances, and it is imperative to the success of the State's pilot program that we obtain one. The season for Synagis commences in the early

autumn (late September/early October), and patient intake picks up sharply in the month prior to the start of the season. We expect that the majority of the infants we will service will be dosed in their homes, so the receipt of the subject waiver becomes of paramount importance to this program in the coming year.

We have recently received our Medi-Cal and Medicare provider numbers, and are in the final stages of developing a web-based patient information system which will give referral sources unprecedented real-time access to patient status, and the State a way of accessing overview statistics on demand. If there is anything we can do to help expedite the waiver approval process for our pharmacy, please don't hesitate to contact us.

We look forward to working with you and the entire staff at the California Board of Pharmacy in the future.

Sincerely,

A handwritten signature in black ink, appearing to read 'G. Truitt', is written over a horizontal line. The signature is stylized and somewhat cursive.

Glenn H. Truitt, Esq.  
Chief Operating Officer/General Counsel

Cc: Bob Ratcliff, Pharm.D., Supervising Inspector  
Marcia Ehinger, M.D.  
Barry Handon, M.D.

# Attachment 9

*Enforcement Statistics  
First Quarter 2007-08*

# Board of Pharmacy Enforcement Statistics

## Fiscal Year 2007/2008

**Workload Statistics**                      July-Sept    Oct-Dec    Jan-Mar    Apr-June    Total 07/08

**Complaints/Investigations**

Initiated	299				299
Closed	447				447
Pending (at the end of quarter)	803				803

**Cases Assigned & Pending (by Team)**

Compliance Team	55				55
Drug Diversion/Fraud	73				73
Mediation Team	146				146
Probation/PRP	71				71
Enforcement	216				216

**Application Investigations**

Initiated	69				69
Closed					
Approved	26				26
Denied	14				14
Total*	41				41
Pending (at the end of quarter)	216				216

**Citation & Fine**

Issued	196				196
Citations Closed	141				141
Total Fines Collected	\$143,070.00				\$143,070.00

\* This figure includes withdrawn applications.

\*\* Fines collected and reports in previous fiscal year.

# Board of Pharmacy Enforcement Statistics

## Fiscal Year 2007/2008

**Workload Statistics**                      **July-Sept**   **Oct-Dec**   **Jan-Mar**   **Apr-June**   **Total 07/08**

**Administrative Cases** (by effective date of decision)

Referred to AG's Office*	25				25
Pleadings Filed	20				20
<b>Pending</b>					
Pre-accusation	64				64
Post Accusation	62				62
Total	141				141
<b>Closed**</b>					
<b>Revocation</b>					
Pharmacist	2				2
Pharmacy	1				1
Other	4				4
<b>Revocation, stayed; suspension/probation</b>					
Pharmacist	4				4
Pharmacy	0				0
Other	0				0
<b>Revocation, stayed; probation</b>					
Pharmacist	2				2
Pharmacy	1				1
Other	0				0
<b>Suspension, stayed; probation</b>					
Pharmacist	0				0
Pharmacy	0				0
Other	0				0
<b>Surrender/Voluntary Surrender</b>					
Pharmacist	0				0
Pharmacy	1				1
Other	1				1
<b>Public Reproval/Reprimand</b>					
Pharmacist	0				0
Pharmacy	0				0
Other	0				0
Cost Recovery Requested	\$54,145.50				\$54,145.50
Cost Recovery Collected	\$52,838.60				\$52,838.60

\* This figure includes Citation Appeals

\*\* This figure includes cases withdrawn

# Board of Pharmacy Enforcement Statistics Fiscal Year 2007/2008

**Workload Statistics**                      July-Sept    Oct-Dec    Jan-Mar    Apr-June    Total 07/08

**Probation Statistics**

Licenses on Probation

Pharmacist	108				108
Pharmacy	5				5
Other	16				16
Probation Office Conferences	18				18
Probation Site Inspections	44				44
Probationers Referred to AG for non-compliance	1				1

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

**Pharmacists Recovery Program (as of 9/30/07)**

Program Statistics

In lieu of discipline	0				0
In addition to probation	5				5
Closed, successful	3				3
Closed, non-compliant	0				0
Closed, other	3				3
Total Board mandated Participants	54				54
Total Self-Referred Participants*	18				18
Treatment Contracts Reviewed	53				53

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, diversion program manager and supervising inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

\* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

As of September 30, 2007.

# California State Board of Pharmacy

## Citation and Fine Statistics

### July 1, 2007 – October 1, 2007

**198 Citations have been issued so far this fiscal year**

Total dollar amount of fines issued this fiscal year  
\$ 389,600.00

Total dollar amount of fines collected  
\$143,070.00\*

\*This amount also reflects payment of the citations issued before July 1, 2007.

The average number of days from date case is  
opened until a citation is issued is **156**

Average number of days from date citation is  
issued to date citation is closed is **48**

#### Citation Breakdown by license type

Total issued	RPH with fine	RPH no fine	PHY with fine	PHY no fine	PIC with fine	PIC no fine	TCH with fine	TCH no fine
198	64	2	50	23	25	0	7	0

#### Citation Breakdown by Miscellaneous license type

Wholesalers	Exemptee's	Clinics	Drug room	Exempt Hosp.	Hosp. pharmacy	Misc.	Unlicensed Premises	Unlicensed person
8	6	0	2	0	3	2	1	0

\*Licensed Correctional Facilities, Exempt Pharmacies, Non-Resident Pharmacies, and Vet Retailers

## Top Ten Violations for the first quarter of 2007/2008 by license type

Pharmacists	%	Pharmacies	%	Pharmacists in charge	%
1716 - Variation from prescription	35%	1716 - Variation from prescription	35%	1716 - Variation from prescription	20%
1707.2 - Duty to consult	11%	1707.2 - Duty to consult	10%	1715 - Self-assessment of a pharmacy by the pharmacist-in-charge	10%
1716/1761(a) - Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	5%	1715 - Self-assessment of a pharmacy by the pharmacist-in-charge	8%	1707.3 - Duty to review drug therapy	10%
4342 - Actions by board to prevent sales of preparations or drugs lacking quality or strength; Penalties for knowing or willful violation of regulations governing those sales	5%	1716/1761 - Variation from Rx / Erroneous Rx	8%	4115(e) - Pharmacy technician license required	10%
1715 - Self-assessment of a pharmacy by the pharmacist-in-charge	5%	4342 - Actions by board to prevent sales of preparations or drugs lacking quality or strength; Penalties for knowing or willful violation of regulations governing those sales	7%	4127.1(a) - A pharmacy shall not compound injectable sterile drug products...unless the pharmacy has obtained a license from the board.	5%
1707.3 - Duty to review drug therapy	4%	1707.3 - Duty to review drug therapy	6%	1304.11- Inventory requirements	5%
1711(d) - Quality assurance program finding shall be used to develop systems to prevent medication errors...	4%	1301.52(e)(1)/1304.11 - Controlled Substance inventory/Inventory requirements	6%	1714(b)- Operational standards and security; pharmacy responsible for pharmacy security	5%
1714(d) - Operational standards and security; pharmacist responsible for pharmacy security	4%	1714(b) - Operational standards and security; pharmacy responsible for pharmacy security	6%	1707.2 - Duty to consult	5%
4115(f) - Pharmacy Technician: Activities Permitted; Required Supervision; Activities Limited to Pharmacist; Registration; Requirements for Registration; Ratios; Supervision by Pharmacist, verification of prescription by initialing; Exceptions	4%	4125-1711 - Pharmacy quality assurance program required/Quality assurance program	6%	4105 - Retaining records of dangerous drugs and devices on licensed premises	5%
4125-1711 - Pharmacy quality assurance program required/Quality assurance program	4%	1711(d) - Quality assurance program finding shall be used to develop systems to prevent medication errors...	4%	4125-1711 - Pharmacy quality assurance program required/Quality assurance program	5%

# Contested Citations Office Conference

(These statistics also include contested Letters of Admonishment)

There were three office conferences held this quarter

Number of requests	37
--------------------	----

Number scheduled	37
------------------	----

Number appeared	22
-----------------	----

Number Postponed	12**
------------------	------

\*\*Please note these are added back into the number of requests and scheduled case totals above.

Total number of requests withdrawn	3
Failed to appear	0

## Office Conference between July 1, 2007 and September 17, 2007

Total number of citations affirmed	17
------------------------------------	----

Decision	Total citations	Total dollar amount reduced
Modified	6	\$4,500.00
Dismissed	4	\$3,850.00
Reduced to Letter of Admonishment	0	\$0.00

# Attachment 10

*First Quarterly Update on the  
Enforcement Committee Goals for  
2007/08*

# GOALS, OUTCOMES, OBJECTIVES, AND MEASURES

## ENFORCEMENT COMMITTEE

Goal 1: Exercise oversight on all pharmacy activities.

Outcome: Improve consumer protection.

Objective 1.1	Achieve 100 percent closure on all cases within 6 months.						
Measure:	Percentage of cases closed.						
Tasks:	1. Mediate all complaints within 90 days (for cases closed during quarter).						
		<u>N</u>	<u>&lt; 90 days</u>	<u>&lt; 120 days</u>	<u>&lt; 180 days</u>	<u>Longer</u>	<u>Average Days</u>
	Qtr 1	211	171	25	12	2	57
			(81%)	(12%)	(6%)	(1%)	
	Qtr 2						
	Qtr 3						
	Qtr 4						
	2. Investigate all cases within 120 days (for cases closed during quarter).						
		<u>N</u>	<u>&lt; 120 days</u>	<u>&lt; 180 days</u>	<u>&lt; 270 days</u>	<u>Longer</u>	<u>Average Days</u>
	Qtr 1	235	167	20	37	11	91
			(71%)	(8%)	(16%)	(5%)	
	Qtr 2						
	Qtr 3						
	Qtr 4						

3. Close (e.g., no violation, issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.

Qtr 1	N	< 180	< 270	< 365	> 365
Closed, no additional action	184	171	11	2	0
Cite and/or fine letter of admonishment	237	209	21	7	0
Attorney General's Office	24	15	7	2	0
Qtr 2	N	< 180	< 270	< 365	> 365
Closed, no additional action					
Cite and/or fine letter of admonishment					
Attorney General's Office					
Qtr 3	N	< 180	< 270	< 365	> 365
Closed, no additional action					
Cite and/or fine letter of admonishment					
Attorney General's Office					
Qtr 4	N	< 180	< 270	< 365	> 365
Closed, no additional action					
Cite and/or fine letter of admonishment					
Attorney General's Office					

Objective 1.2	Manage enforcement activities for achievement of performance expectations.						
Measure:	Percentage compliance with program requirements.						
Tasks:	1. Administer the Pharmacists Recovery Program.						
		Voluntary Participants	Participants Mandated Into Program	Noncompliant, Terminated From Program	Successfully Completed Program		
	Qtr 1	18	54	0	3		
	Qtr 2						
	Qtr 3						
	Qtr 4						
	2. Administer the Probation Monitoring Program.						
		Qtr 1	Qtr 2	Qtr 3	Qtr 4		
	Individuals	123					
	Sites	6					
	Tolled	25					
	Inspections Conducted	44					
	Successfully Completed	2					
	Petitions to Revoke Filed	2					
	3. Issue all citations and fines within 30 days.						
		<u>N</u>	30 days	60 days	90 days	> 90 days	<u>Average Days</u>
Qtr 1	188	1	11	77	99	94	
		(.5%)	(6%)	(41%)	(53%)		
Qtr 2							
Qtr 3							
Qtr 4							
4. Issue letters of admonishment within 30 days.							
	<u>N</u>	30 days	60 days	90 days	> 90 days	<u>Average</u>	
Qtr 1	50	20	24	4	2	38	
		(40%)	(48%)	(8%)	(4%)		
Qtr 2							
Qtr 3							
Qtr 4							

5. Obtain immediate public protection sanctions for egregious violations.

	Interim Suspension Orders	Automatic Suspension Based on Conviction	Penal Code 23 Restriction
Qtr 1	0	0	0
Qtr 2			
Qtr 3			
Qtr 4			

6. Submit petitions to revoke probation within 30 days for noncompliance with terms of probation.

	30 days	60 days	> 60 days	N
Qtr 1	0	0	1	1
Qtr 2				
Qtr 3				
Qtr 4				

Objective 1.3

Achieve 100 percent closure on all administrative cases within 1 year.

Measure:

Percentage of administrative cases closed within 1 year.

	N	1 Year	1.5 Year	2 Year	2.5 Year	>2.5 Years	Average
Qtr 1	13	5 (39%)	3 (23%)	4 (31%)	1 (8%)	0 (0%)	448 days
Qtr 2							
Qtr 3							
Qtr 4							

Objective 1.4	Inspect 100 percent of all facilities once every 3 year inspection cycle ending 6/30/08.																																																							
Measure:	Percentage of licensed facilities inspected once every 3 year cycle.																																																							
Tasks:	<p>1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.</p> <table border="1" data-bbox="365 283 1485 493"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Aggregate Inspections This Cycle</th> <th>Percent Complete</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>387</td> <td>3,648</td> <td>50%</td> </tr> <tr> <td>Qtr 2</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Qtr 3</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p>2. Inspect sterile compounding pharmacies initially before licensure and annually before renewal.</p> <table border="1" data-bbox="365 619 1161 829"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Number Inspected Late</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>60</td> <td>0</td> </tr> <tr> <td>Qtr 2</td> <td></td> <td></td> </tr> <tr> <td>Qtr 3</td> <td></td> <td></td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> </tr> </tbody> </table> <p>3. Initiate investigations based upon violations discovered during routine inspections.</p> <table border="1" data-bbox="365 913 1485 1123"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Number of Investigations Opened</th> <th>Percent Opened</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>387</td> <td>14</td> <td>4%</td> </tr> <tr> <td>Qtr 2</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Qtr 3</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Qtr 4</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		Number of Inspections	Aggregate Inspections This Cycle	Percent Complete	Qtr 1	387	3,648	50%	Qtr 2				Qtr 3				Qtr 4					Number of Inspections	Number Inspected Late	Qtr 1	60	0	Qtr 2			Qtr 3			Qtr 4				Number of Inspections	Number of Investigations Opened	Percent Opened	Qtr 1	387	14	4%	Qtr 2				Qtr 3				Qtr 4			
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Objective 1.5	Initiate policy review of 25 emerging enforcement issues by June 30, 2011.
Measure:	The number of issues.
Tasks:	<p>1. Monitor the implementation of e-pedigree on all prescription medications sold in California.</p> <p><i>Sept. 28, 2006: Board convenes third Workgroup on Implementation of E-Pedigree Meeting. Presentations provided by EPCglobal, McKesson, Supervising Inspector Nurse and Johnson and Johnson.</i></p> <p><i>Sept. 30, 2006: Governor signs SB 1476 which delays implementation of e-pedigree requirements until 2009, requires serialization and interoperability and notification to the board whenever counterfeit drugs are discovered.</i></p> <p><i>Oct. 6, 2006: FDA provides presentation on federal pedigree requirements at board-hosted NABP District 7 &amp; 8 Meeting.</i></p> <p><i>Dec. 2006: Board convenes fourth Workgroup on Implementation of E-Pedigree Meeting. Presentations made by EPCglobal, McKesson, AmerisourceBergen and Cardinal. Pilot testing e-pedigree systems underway at each of the three large wholesalers. Standards for electronic pedigree to be finalized by January 2007 by EPCglobal.</i></p> <p><i>Jan. 2007: EPCglobal finalizes electronic messaging standards for electronic pedigrees.</i></p> <p><i>Feb. 2007: EPCglobal convenes regional meeting with hospitals to discuss implementation issues of e-pedigree in these facilities. Hospitals are encouraged to join the board's Workgroup on Implementation of E-Pedigree Meetings.</i></p> <p><i>March 2007: Two board members and executive staff meet with nine EPCglobal representatives to walk through EPCglobal's messaging standards and business scenarios. The standard complies with California's e-pedigree requirements although some questions remain about situation-specific criteria.</i></p> <p><i>Board convenes fifth Workgroup on Implementation of E-pedigree Meeting. Presentations are made by EPCglobal, AmerisourceBergen and SupplyScape.</i></p> <p><i>May 2007: Board presents information at the National Association of Boards of Pharmacy annual meeting on California's electronic pedigree requirements in both a poster session and a full presentation to the full assembly.</i></p> <p><i>June 2007: Board convenes sixth Workgroup on E-pedigree Meeting, with the largest attendance of any prior meeting. Presentations were made by EPCglobal, Pfizer, Walgreens and PhRMA. Hospital pharmacies were specifically invited to attend this meeting.</i></p> <p>2. Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products.</p> <p><i>Sept. 2006: Final phase-in of federal requirements takes effect on September 30. Board newsletter provides information for licensees.</i></p> <p><i>Oct. 2006: Board adds Consumer friendly materials regarding sales of these drugs to its Website.</i></p> <p><i>July 2007: Board hears presentations on EPCglobal standards.</i></p>

*Sept. 2007: Enforcement Meeting has large audience (200 people). Presentations by PhRMA, GSK, Bracco, CPhA, EPCglobal, Walgreens, Rite Aid, CVS, rfxcel, and HDMA. Federal legislation enacted for the FDA supports California requirements. Major presentations made on California's standards to LogiPharma (Philadelphia) and HDMA Subcommittee of board meets with EPCglobal representatives on standards.*

*Oct. 2007: Major presentations at EPCglobal Conference in Chicago. At Board Meeting, presentations made by IBM/Amerisource Bergen, Alien Technology and EPCglobal on readiness of technology.*

3. Monitor the efforts of the DEA and DHHS to implement electronic prescribing for controlled substances.

*Sept. 2006: DEA releases proposed rule to allow prescribers to issue 90 days' worth of Schedule II prescriptions at one time.*

*Oct. 2006: Board considers proposed rule.*

*Nov. 2006: Board submits letter supporting change in DEA policy allowing prescribers to write multiple prescriptions for Schedule II drugs with "Do not fill before (date)" at one time, eliminating the need for patients to revisit prescribers merely to obtain prescriptions.*

4. Evaluate establishment of an ethics course as an enforcement option.

*June 2007 Subcommittee meets with ethicist trainer for Dental Board.*

*Aug. 2007: Subcommittee meets with Medical Boards Ethics course provider (Institute for Medical Quality).*

*Oct. 2007: Institute for Medical Quality provides information to board about program; recommendation of committee is to move forward with the specialized program.*

5. Participate in emerging issues at the national level affecting the health of Californians regarding their prescription medicine.

*May 2007: Board staff provides presentation at National Association of Boards of Pharmacy annual meeting on California's pedigree requirements.*

*June 2007: Board works with Center for Medicare and Medicaid Services on security prescription forms that will be required in only four months for all written Medicaid and Medicare prescriptions.*

6. Provide information about legal requirements involving e-prescribing to support the Governor's Health Care Initiative and its promotion of e-prescribing.

*Sept. 2007: Provided comments on proposed statutory requirements.*

7. Implement in California the Center for Medicare and Medicaid Service requirements for security prescription forms that will be required in only four months for all written Medicaid and Medicare prescriptions.

*June - Oct. 2007: Board works with the Department of Health Care Services to implement security forms until subsequent federal legislation delays implementation until April 2008.*