



California State Board of Pharmacy
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www.pharmacy.ca.gov

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

Date: June 9, 2010

To: Enforcement Committee

**Subject: DEA Proposal Interim Final Rule for the E-Prescribing of
Controlled Substances**

The federal Drug Enforcement Administration (DEA) released on March 22 proposed requirements to enable e-prescribing of controlled drugs. Until June 1, 2010, federal law did not allow the electronic prescribing of written prescriptions for controlled drugs. The comment period on the proposed interim final rule ended on May 31, 2010.

At the April Board Meeting, the board was led in a discussion of the proposed, highly technical requirements by Deputy Attorney General Joshua Room. After a short discussion, the board agreed to send a request to the DEA to extend the comment period another 120 days so that the board and others could carefully read and consider the more than 330 pages of requirements and policy statements released by the DEA. A copy of the board's comments is in the letter on the following pages.

E-prescribing of controlled substances is an important and significant change for prescribers, for pharmacy and for patients. The volume of material released by the DEA for this regulation is extensive – 334 pages, and fortunately, not all these pages are text of the requirements. However, the regulation is very technical and is difficult to readily digest.

The committee may wish to recommend to the board the formation of an ad hoc workgroup to develop guidelines for pharmacies and perhaps prepare comments to the DEA on behalf of the board (in which case the workgroup or subcommittee will need to be appointed and meet). Or the committee may want to dedicate a portion of a future meeting on discussion of the requirements, and not proceed with comments to the DEA during the short time-frame available for comment.



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

May 7, 2010

Drug Enforcement Administration
Attn: DEA Federal Register Representative/ODL
8701 Morrisette Drive
Springfield, VA 22152

RE: COMMENTS OF THE CALIFORNIA STATE BOARD OF PHARMACY
Request for 120-day Extension of the Comment Period, to October 1, 2010
Docket No. DEA—218I: *Electronic Prescriptions for Controlled Substances*

To Whom It May Concern:

I write on behalf of the California State Board of Pharmacy (Board). We are pleased to respond to Docket No. DEA—218I, an Interim Final Rule (IFR) and Request for Comment titled *Electronic Prescriptions for Controlled Substances*. As we remarked in our September 15, 2008 comments on the initial Notice of Proposed Rulemaking (NPRM), we are encouraged that the Drug Enforcement Administration (DEA) is actively moving to permit electronic prescribing (e-prescribing) for controlled substances. We believe that widespread adoption of e-prescribing has significant potential to reduce medication errors and associated outcomes, and that the ability to use e-prescribing for controlled substances is necessary to encourage widespread adoption. In our prior comments, we urged you to consider the value of widespread adoption, and to balance that interest against our shared interest in maintaining a secure drug delivery system. We thank you for the effort you have put into reviewing and responding to all of the comments received.

We have so far conducted only a preliminary review of the IFR, and have not yet had the opportunity to either engage in extensive analysis or receive and review analyses of the IFR from the affected industries, the public, or other stakeholders. Our comments on the NPRM benefited from the input of affected and interested parties. We would like any comments we might submit on the IFR to have that same benefit. However, the present deadline for response (June 1, 2010) does not provide us with enough time to review any such input in aid of meaningful comments. In particular, it may take some time for industry members and/or third-party vendors to assess or assimilate the technical requirements imposed by the IFR, and for us to understand based on their input and our own analysis the magnitude and necessity of any burden(s) imposed thereby.

To ensure that both we and other persons that might wish to submit comments on the IFR have an adequate opportunity to do so, we are requesting that you extend your own deadline¹ for submission of comments by 120 days, to October 1, 2010. This will provide a total of 180 days in which to submit comments. We believe that is a more appropriate comment period.

¹ We understand that this deadline may also be separately extended by congressional review.

Again, we applaud your efforts in proposing the draft regulations, and emphasize that we view ourselves as joined with you in this task of ensuring a safe and secure prescription delivery system for controlled substances. We are greatly encouraged that the DEA has taken the step of defining an appropriate system for e-prescribing controlled substances. The document you have produced is impressive in its scope and its complexity. We would like to be of assistance in this project, and request additional time to be sure that any further input we provide is well-informed.

Thank you for your attention to these matters, and for your willingness to hear our input. We look forward to continuing to work together, on this and on other matters. Please feel free to contact the Board at any time if we can be of assistance to you. The best route for contact is via Executive Officer Virginia Herold, at (916) 574-7911, or Virginia_Herold@dca.ca.gov.

Sincerely,

A handwritten signature in cursive script that reads "Kenneth H. Schell".

KENNETH H. SCHELL
President, California State Board of Pharmacy



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

Date: June 9, 2010

To: Enforcement Committee

Subject: Request to Modify 16 CCR 1713(d) Regarding the Requirement That Automated Dispensing Machines Be Adjacent to the Secure Pharmacy Area

At the January 2010 Board Meeting, Phil Burgess representing Asteres made a presentation to board seeking a waiver from 1713(d) to allow automated dispensing machines to be located in areas other than the requirements of this section that the automated dispensing machine be adjacent to the secure pharmacy area. At the meeting (excerpt of meeting minutes follow this memorandum), the board asked Mr. Burgess to refine his request and return to the board so the board would more fully understand the proposal.

Background:

In 2005 and 2006, the board discussed and eventually promulgated a regulation to allow automated dispensing machines in pharmacies to dispense refill medications -- if requested by the patient and approved by the pharmacist. This was a use of emerging technology and several pharmacies had sought the board's authority to install such machines in their pharmacies to provide patients with afterhours access (as well as access during times when the pharmacy was open) to refills. Basically, a patient could pick up refill medication, if approved by the pharmacy, from a vending-like machine using a credit card for payment and not specifically deal with the pharmacy staff. The machine was to be located near -- specifically adjacent -- to the physical area of the pharmacy.

A number of conditions were built into the regulations to provide for assurance patients would not be required to use these machines for refills if they were not supportive. A copy of the final regulation is provided below.

This regulation was promulgated cautiously. Throughout 2006, the board modified and adopted the regulation now in effect as section 1713. In January 2007, the regulation actually took effect.

Update for this Meeting

During the December 2009 Enforcement Committee Meeting and the subsequently January 2010 Board Meeting, Phil Burgess requested a waiver to the requirements

in 1713 (d)(6) which requires that the delivery device be located adjacent to the secure pharmacy area. In making the request, Mr. Burgess stated that his client Asteres would like to place the device in a secure area that is readily accessible to the patient and that a telephone would be placed adjacent to the device for patients that wished to speak with a pharmacist. Whereas the initial proposal was to place the device in a hospital waiting room for refills for employees, at the board meeting, the request was far broader and would allow the machines to be placed anywhere and could be used for patient delivery of refill medications as well.

A written copy of the draft waiver request, the PowerPoint presentation from the Board Meeting, January Board Meeting Minutes and a copy of CCR 1713 is provided f on the following pages.

At this Enforcement Committee Meeting, the committee needs to determine how it wishes to proceed with the proposal.

Regulation Section 1713
(relevant portion highlighted in bold)

1713. Receipt and Delivery of Prescriptions and Prescription Medications Must be to or from Licensed Pharmacy

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.

(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) A pharmacy may use an automated delivery device to deliver previously dispensed prescription medications provided:

(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.

(2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication to that patient.

(3) The device has a means to identify each patient and only release that patient's prescription medications.

(4) The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).

(5) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

(6) The device is located adjacent to the secure pharmacy area.

(7) The device is secure from access and removal by unauthorized individuals.

(8) The pharmacy is responsible for the prescription medications stored in the device.

(9) Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

(10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).

(e) Any pharmacy making use of an automated delivery device as permitted by subdivision (d) shall maintain, and on an annual basis review, written policies and procedures providing for:

(1) Maintaining the security of the automated delivery device and the dangerous drugs within the device.

(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.

- (3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device.**
- (4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the automated delivery device.**
- (5) Orienting participating patients on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring that patient use of the device does not interfere with delivery of prescription medications.**
- (6) Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.**
- (f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.**
- (g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.**

Ms. Herold:

On behalf of Asteres, we hereby request an appearance before the California Board of Pharmacy at the January 20/21 meeting in Sacramento.

The purpose of our appearance will be to seek approval for the installation of an automated prescription "pick up" system in a hospital environment whereby the unit is not directly attached to the pharmacy.

Upon review of Section 1713, we feel that the Board has regulatory authority to grant this request based upon Paragraph 1713 (b) which states in part:

"In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause. Subdivision (a) contains the language prohibiting the picking up of prescriptions from "any place not licensed as a retail pharmacy". We will be prepared to justify this action by the Board demonstrating how that the unit will be in a high-traffic, secure area on the hospital campus and that a telephone installation immediately adjacent to the unit will allow readily available access by the patient to a pharmacist for counseling.

Failing this argument, then we would request a specific waiver from Section 1713 (d) (6) requiring that "the device is located adjacent to the secure pharmacy area". We are prepared to have representatives appear from California hospitals to represent to the Board that by allowing flexibility in the placement of these "pick-up" devices on their campuses, that the net result will be to improve patient compliance and thereby improve patient care. Asteres will present past history to show to the Board that these devices can be installed in an area not adjacent to the pharmacy, yet in a secure manner..as well as in a manner where counseling by a pharmacist to the patient will be equally if not more readily available than in a standard retail environment.

Thank you for your consideration.

Phil

Philip P. Burgess, RPh, MBA
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**CALIFORNIA STATE BOARD OF PHARMACY
WAIVER APPLICATION
REVIEW FORM**

*CALIFORNIA CODE OF REGULATIONS
DIVISION 17, TITLE 16, SECTION 1713*

Date: XX/XX /2010

Facility/Firm Name: ABC City/Firm of _____

Telephone /Fax: _____

Pharmacy License(s) : _____

Responsible PHARMACIST IN CHARGE: _____
 Address: _____
 Telephone: _____
 Facsimile: _____

The submitted waiver request includes the following:

	Yes	No	Comments
Contains a signed statement/letter from the facility administrator, and names the program responsible manager, and requests acceptance of the waiver..			
The sites are all California State licensed Pharmacies. The waiver describes the Pharmacy, and the location(s) of automated deliver devices. The pharmacy may anticipate additional delivery devices but would so notify the Board PRIOR to any installation.			
There are waiver policies and procedures that cover the topics that follow: <ul style="list-style-type: none"> • The waiver approval documents contains a time period for the agreement, not to exceed three years. Program must re-apply after three years. 			

<ul style="list-style-type: none"> • The waiver states that law enforcement and/or Board officers have unlimited access to review operations and/or records. 			
<p>Policies and Procedures clearly define/describe:</p> <ul style="list-style-type: none"> • Securing procedures. • Location of secure automated delivery system • Periodic system QA assessment and reporting: <ul style="list-style-type: none"> ▪ provides for a program assessment within 90 days of implementation and at least annually thereafter ▪ QA plan provides for notifying the BOP of identified problems or discrepancies within 72 hours, <i>(the idea is to be sure that the BOP was at least notified of incidents)</i> including a correctional plan. ▪ Provides a report any losses to local police and the BOP. 			
<ul style="list-style-type: none"> • The system prevents unauthorized access to the secure container or removal of the container? • Describes the 24 hour security in-place for the automated delivery system. 			
<p>Instructions/training:</p> <ul style="list-style-type: none"> • All staff are trained in the use of the delivery system prior to implementation. • Training includes specifics (in written form) on what can and can not be done within California regulations and how to deal with problematic items or issues. • Consumer instruction and/or training aids are provided as part of the plan for implementation. 			

Comments: _____

FOR STAFF USE ONLY

Staff Recommendation: Acceptance _____	Revision Needed _____	Board Agenda _____
Date Approved by Board _____	Investigator Notified _____	

Revised 5/22/2010

Excerpt of the Minutes of January 22, 2010 Board Meeting:

Presentation - Phil Burgess and Mike de Bruin, Asteres

Phil Burgess, representing Asteres, provided an overview of ScriptCenter, a 24/7 automated pharmacy prescription pick-up machine including the registration and authorization process. He reviewed patient safety and security benefits and added that ScriptCenter has successfully delivered over 450,000 prescriptions without one delivery error.

Mr. Burgess requested that the board waive regulation Section 1713(d)(6) regarding the placement of automated medication dispensing machines in hospitals.

Board Discussion

Mr. Brooks sought clarification regarding how a pharmacy obtains a ScriptCenter machine.

Mike de Bruin provided that there are multiple methods of acquisition strategies.

Burgess provided that each machine will have a phone located adjacent to the machine to allow the patient to immediately contact the pharmacist.

Mr. Lippe asked if the patient will be charged a transaction fee.

Mr. Burgess provided that no transaction fee is charged.

Mr. de Bruin provided that the machine will collect the patient's insurance co-pay.

Ms. Herold sought clarification regarding if it is intended for the machine to be made available to both hospital staff and patients.

Mr. Burgess indicated that Asteres would like the machine to be available to both hospital staff and patients. He provided that only refill prescriptions would be filled and the machine would only be located on the hospital campus in a secure environment, not necessarily in a hospital.

Mr. Room asked if any machines have been installed outside of a hospital campus.

Mr. de Bruin provided that machines have been installed in other areas in other states.

Mr. Room provided that this request may not be granted under a Section 1713 waiver.

Discussion continued regarding the ScriptCenter system and its applicability to pharmacy law and Section 1713. Advantages and disadvantages of the system were evaluated. Concern was expressed that this process may depersonalize the pharmacist and prescription service. It was clarified that in the event a waiver is granted, the waiver would be granted to the licensed facility and not to Asteres.

Public Comment

Dr. Allan Schaad, representing Catholic Healthcare West (CHW), provided that CHW would like to provide ScriptCenter as a service to their employees.

Dr. Castellblanch sought clarification regarding why the waiver is also being requested for patients.

Mr. Burgess provided that the machine can benefit the spouses of employees and children of employees.

Discussion continued regarding the request and the placement of the machine in a secure area on the hospital campus. Concern was expressed that the request does not specify placement of the machine.

Dr. Steve Gray, representing Kaiser Permanente, offered support for the ScriptsCenter concept. He encouraged the board to grant a waiver under Section 1713 (b) for employees and to consider further discussion of a waiver for other patients.

Mr. Weisser sought clarification regarding mail order prescriptions and patient requests for phone consultations with a pharmacist.

Dr. Gray provided that in the rare event that a patient does have a question, they can often get their questioned answered faster by calling a pharmacist than if they were to wait in line at a pharmacy.

Mr. Burgess provided that the ScriptsCenter machine allows for a pharmacist to be available to the patient when the adjacent pharmacy is closed during off hours.

Ms. Herold provided that pharmacies using such a device are required to provide immediate access to a telephone for patients to contact a 24-hour pharmacy in the event their pharmacy is closed.

Ms. Herold indicated that board staff will provide some guidelines to assist Asteres with providing the required clarification regarding their request.

There was no additional board discussion or public comment.

California State Board of Pharmacy- January 2010 Meeting

Respectfully Submitted



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Agenda

- Introduction
- Pharmacy Benefit
- Patient Safety & Security
- Pharmacy Process
- Convenience
- Experience
- Questions?

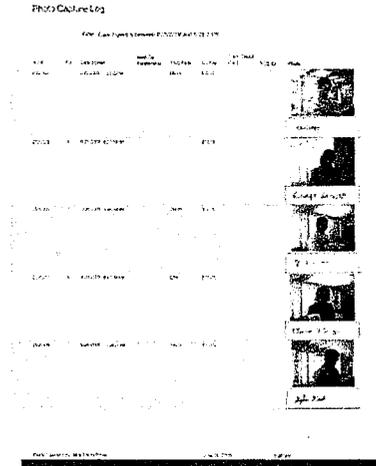
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Benefits to Pharmacy

24/7 Automated Pharmacy Services™

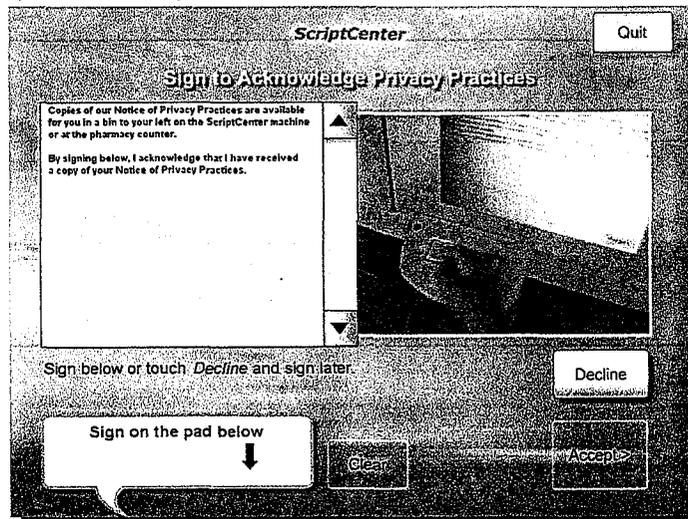
- ▶ Will call security system
- ▶ Photo & signature audit trail
- ▶ Automated Return To Stock compliance
- ▶ Auto check-in from Central Fill
- ▶ Right Rx → Right Patient



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ScriptCenter captures the signature electronically to recognize HIPAA requirements which can also be forwarded to a 3rd party (PBM) for claim adjudication if needed.



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Safety & Security Features

- ▶ Rx tracking from fill to delivery
- ▶ Bar code assures patient/Rx match
- ▶ Automated return to stock
- ▶ Photo & signature audit trail
- ▶ Equipped with floor bolts and door locks
- ▶ Alarm interface



Rx 2500302 7/19/09 9:46:09AM \$10.00



Biometric
Staff Login
& Tracking

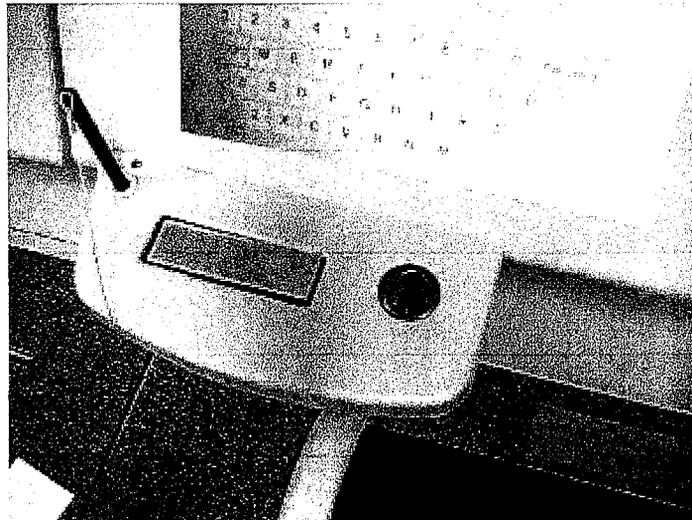


Barcode Rx
Tracking

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ScriptCenter Fingerprint Login



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ScriptCenter Pharmacy Process



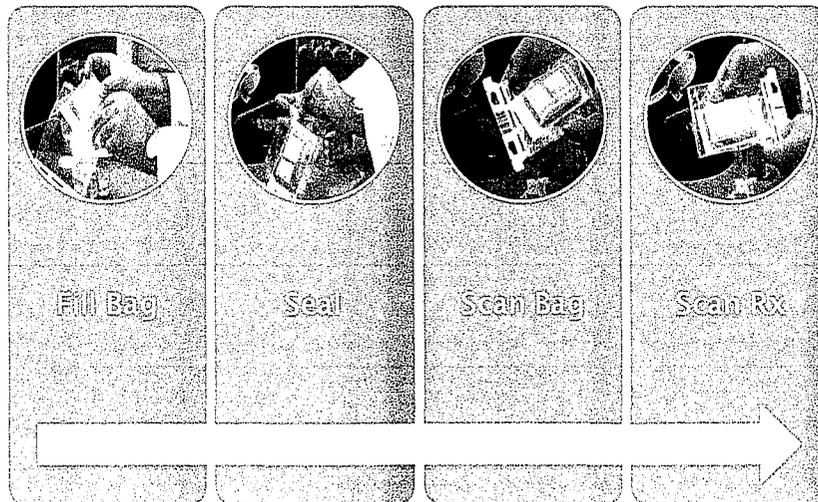
- ▶ Customer orders prescription as usual
- ▶ Pharmacist fills prescription as usual
- ▶ Prescriptions put in ScriptCenter bag and scanned
- ▶ Bags individually or batch loaded



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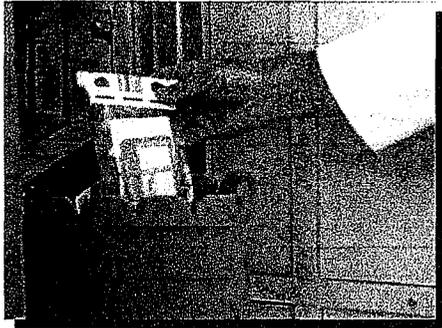
Pharmacy Workflow Process



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Pharmacy Workflow Process Cont.



Single or Batch Loads as desired

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ScriptCenter Prescription Pickup



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Patient Convenience

Very few patients using APDS or the regular counter asked to speak to a pharmacist about their refill medications, although almost all patients believed that they could speak to a pharmacist if they had wanted to do so. Because the majority of patients agreed that their wait time was not long and that the overall prescription pick-up process was convenient, no perceived barriers to pharmacist access appear to exist; patients simply did not perceive the need to ask the pharmacist questions about their refill.

"Patient request for pharmacist counseling and satisfaction: Automated prescription delivery system versus regular pick-up counter" JAPhA • 49 :1 • Jan / Feb 2009 pgs. 73-78

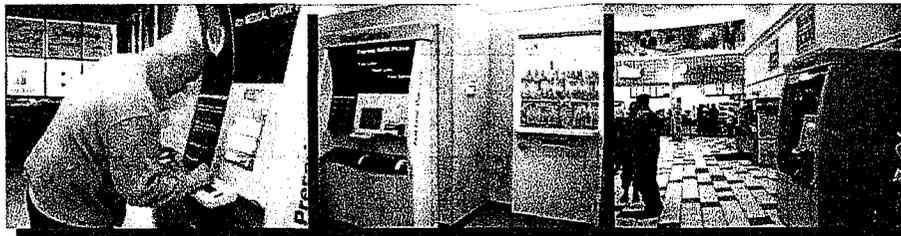
-Jan D. Hirsch, Austin Oen, Suzie Robertson,
Nancy Nguyen, and Charles Daniels

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ScriptCenter Installations



Military (Commissary)

Rite Aid

Military (BX)



Safeway

Ahold (Giant)

Hospital Outpatient

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ScriptCenter Facts & Figures

32,719 = customers that have used ScriptCenter

468,738 = total prescription refill deliveries

48,261 = total prescription refill deliveries after hours

11% = % of ScriptCenter refills delivered after hours



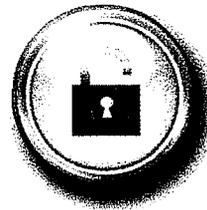
Experience



ScriptCenter has successfully delivered over 450,000 prescriptions without one delivery error!



Safety:



ScriptCenter has never
been accessed by
unauthorized persons or
had an attempted break-in.

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Questions?

Thank You
Respectfully Submitted

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

Date: June 9, 2010

To: Enforcement Committee

Subject: Proposed Drug Distribution Model

Recently the board was asked to review a drug distribution model currently being pilot tested in several eastern states. The model is being advanced by Medco. The initial proposal was to be presented to the Licensing Committee in December, but Medco requested a postponement. The proposal is now being brought to the Enforcement Committee. This is the board's first review.

Documents showing and describing the workflow are attached.

Under this proposal, a patient comes into a community pharmacy and receives medication adjudicated by Medco. The prescription is then either filled by the community pharmacy, or filled by Medco and shipped to the community pharmacy for dispensing. (At one point, Medco indicated that in some cases it could mail the medication directly to the patient, bypassing the community pharmacy dispensing entirely. This latter proposal is not described in the current proposal.)

Representatives of Medco Health, Dennis McAllister and Rich Palumbo, will attend this meeting and provide a presentation to the committee.

California has a regulation for pharmacies that refill medications for other pharmacies. The requirements are in 16 CCR section 1707.4. A copy of the section is provided below:

1707.4. Procedures for Refill Pharmacies.

- (a) A pharmacy licensed by the board may process a request for refill of a prescription received by a pharmacy within this state, provided:
- (1) The pharmacy that is to refill the prescription either has a contract with the pharmacy which received the prescription or has the same owner as the other pharmacy.
 - (2) The prescription container:
 - (A) is clearly labeled with all information required by Section 4076 of the Business and Professions Code; and

(B) clearly shows the name and address of the pharmacy refilling the prescription and/or the name and address of the pharmacy which receives the refilled prescription for dispensing to the patient.

(3) The patient is provided with written information, either on the prescription label or with the prescription container, that describes which pharmacy to contact if the patient has any questions about the prescription or medication.

(4) Both pharmacies maintain complete and accurate records of the refill, including:

(A) the name of the pharmacist who refilled the prescription;

(B) the name of the pharmacy refilling the prescription; and

(C) the name of the pharmacy that received the refill request.

(5) The pharmacy which refills the prescription and the pharmacy to which the refilled prescription is provided for dispensing to the patient shall each be responsible for ensuring the order has been properly filled.

(6) The originating pharmacy is responsible for compliance with the requirements set forth in Section 1707.1, 1707.2 and 1707.3 of the California Code of Regulations.

(b) Nothing in this section shall be construed as barring a pharmacy from also filling new prescriptions presented by a patient or a patient's agent or transmitted to it by a prescriber.

Authority cited: Section 4005, Business & Professions Code. Reference: Sections 4063, 4076,

Overview: Medco intends to participate in agreements whereby it provides services to community pharmacies in a Central Fill/Central Processing arrangement. These services will generally be the filling of the prescription; however, when circumstances warrant may include, but not limited to prescriber and patient contact, Drug Utilization Review, data entry and dispensing.

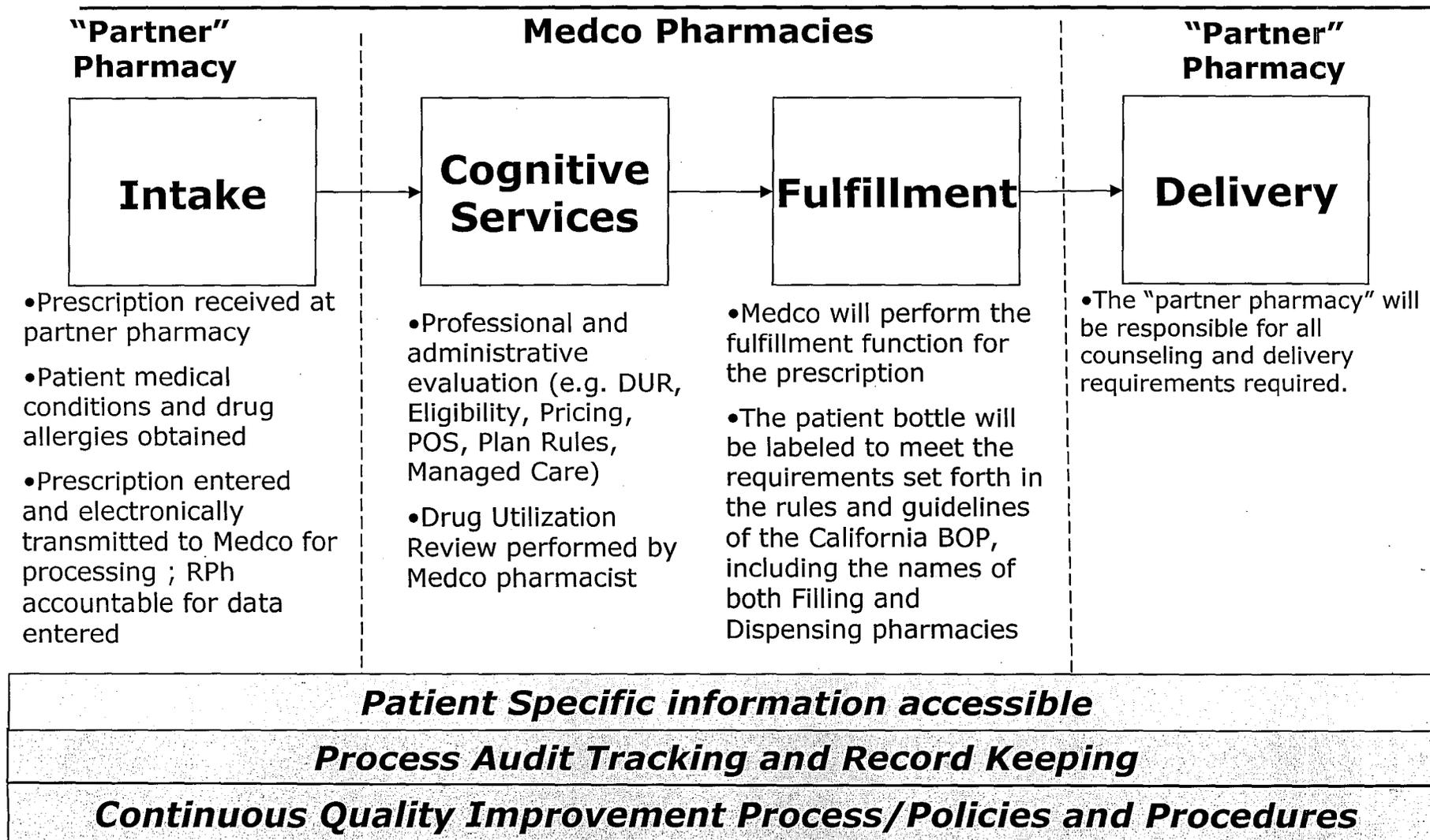
California Resident Community Pharmacies: Medco intends to enter into Central Fill/Central Processing arrangements with community pharmacies resident in the state of California and licensed by the Board. The prescriptions will be filled at Medco pharmacies in states other than California and returned back to the California community pharmacy for delivery. It is understood that as the delivery pharmacy will be located in California, the rules of the California Board of Pharmacy will prevail.

The following describes specific situations:

1. In those instances where the medication is not picked up by the patient, the pharmacy will destroy the medication through a reverse distributor. All documentation will be available for the Board for inspection.
2. The community pharmacy will have access to the patient's medication history dating back one year. The active prescriptions (those dispensed in the last six months) will be available through an active process. The remaining six months will be available to the pharmacist through a retrieval process.
3. Medco will perform DUR prior to dispensing the prescription. The results of the DUR and any interventions will be communicated to the community pharmacy.
4. The community pharmacy will provide the necessary patient counseling consistent with California rules upon delivering the prescription to the patient.

Since, it is Medco's desire to enter into this arrangement with multiple partners in the state, Medco will utilize a Medco assigned number on the prescription bottle so as to eliminate the possibility of duplicate prescription numbers. As part of a participation agreement the community pharmacy will have a system in place that will cross reference this unique number to the original prescription number and this functionality can be demonstrated to the Board. Such a system will prevent the assignment of duplicate prescription numbers, which could result in errors when prescription refills are requested.

California Community Pharmacy Centralized Prescription Processing Workflow





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

Date: June 9, 2010

To: Enforcement Committee

Subject: Update on the Board's Efforts to Implement Components of the Department of Consumer Affairs' Consumer Protection Enforcement Initiative.

Since July 2009, the Department of Consumer Affairs has been working with the health care boards to upgrade their capabilities to investigate and discipline errant licensees to protect the public. The proposed changes have taken various forms. The goal is to ensure the average case closure time for formal discipline, from receipt of the complaint to final vote of the board, occurs within 12 to 18 months. Formal discipline means those cases which are the most serious, and for which license removal or restriction is being sought.

In addition to the additional staff resources being sought, board staff completed a comprehensive review of our internal processes to identify ways to streamline our processes, reduce timelines and improve our effectiveness. Board staff identified 18 improvements and is working towards full implementation. Below is a summary of changes initiated to date as well as the status.

1. Complete case assignments on line.
Status: Completing testing of the new process. Staff is working to finalize written procedures.
2. Complete review of draft accusations on line
Status: Accusations are now reviewed on line by field staff. Staff will finalize written procedures.
3. Prescreen complaints at assignment with an AGPA - AGPA would follow up to ensure that complaints are assigned. Screen out non-jurisdictional and close or refer as appropriate.
Status: Training is complete and this provision is implemented. As indicated in previous months, this is a temporary solution, and full implementation cannot be achieved without staff resources.
4. AGPA to complete license history instead of board inspector including past CI's, assignments, violations and outcomes of those. Past inspections, date and who completed them.
Status: A draft template is developed, however p&p's are not yet in place. Initiated pilot with limited investigator staff.
5. Develop a method to automatically populate information on the investigation report instead of using expensive inspector time.
Status: A draft template is developed, however p&p's are not yet in place. Initiated pilot with limited investigator staff.

6. Train non-attorney staff to prepare default decisions to speed investigation closures.
Status: Training completed. Board staff preparing some default decisions in-house.
7. Secure automated fingerprint background checks and criminal record information from the Department of Justice.
Status: Implemented and staff trained.
8. Begin drafting some Petitions to Revoke Probation in house.
Status: Internal staff completed first PTR. Draft is currently undergoing review.



California State Board of Pharmacy

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

Date: June 9, 2010

To: Enforcement Committee

Subject: Update on California's Drug Take Back Programs from Patients

In the February 2010 *The Script*, the board promoted the take-back guidelines developed by the California Integrated Waste Management Board pursuant to SB 966 (Simitian, Chapter 542, Statutes of 2007) with the assistance of the Board of Pharmacy.

Since April, board inspectors have been directed to take pictures of drug take back programs in place in pharmacies, and to encourage compliance with the state's guidelines.

The Drug Enforcement Administration continues to be concerned about these programs nationally, and is working with counties that are establishing principally short-term take back programs for controlled drugs. In some communities, law enforcement is working with the DEA to take back controlled drugs at law enforcement facilities.

On July 20, the CalRecycle Program, which took the place of components of the California Integrated Waste Management Board, will hold a workshop on home-generated pharmaceutical waste collection and disposal. The purpose is to generate data that will be included in a report to the Legislature by the end of 2010.

Below is information about this workshop:

Date: July 20, 2010

Time: 10am-5pm

Location: Cal/EPA building; 1001 I Street, Sacramento, California

Webcast: The meeting will also be webcast

This is your opportunity to comment on the survey results, analysis methodology, initial findings and to provide information on effective model programs in California that collect and dispose of home-generated pharmaceutical waste. These findings and your input will be addressed in a report to the California Legislature.

Please RSVP by **July 6** to PharmaSharps@CalRecycle.ca.gov or call Sangeeta Hegde at (916) 341-6486.

Background:

Senate Bill 966 required CalRecycle to work with agencies including the Department of Toxic Substances Control, the State Water Resources Control Board, and the California State Board of Pharmacy to develop criteria and procedures for model pharmaceutical waste collection programs by December 2008. SB 966 also requires CalRecycle to analyze model programs for effectiveness, cost, accessibility, and safety. These findings must be included with recommendations in a report to the Legislature by December 2010.



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

Date: June 9, 2010

To: Enforcement Committee

Subject: Questions Concerning the Board's Compounding Regulations

On July 6, the board's regulation for compounding requirements for pharmacies will take effect. Over the following six months, the board has directed that educational compliance be encouraged to implement the requirements.

In recent days, the board has been asked a number of questions about specific requirements during speaking presentations. At this meeting, board staff will provide an opportunity to address questions of the board about the requirements.

Questions have been requested in advance of the meeting, but will also be taken during the meeting.

A copy of the regulations and the related self assessment form follows.

Order of Adoption

Board of Pharmacy California Code of Regulations

To Repeal Division 17 of Title 16 CCR §1716.1 and §1716.2 and To Adopt Division 17 of Title 16 CCR §1735 and §1735.1 – §1735.8, and To Amend Division 17 of Title 16 CCR §1751 and §1751.1 -- §1751.8 Requirements for Compounding and Sterile Injectable Compounding

Repeal Section 1716.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1716.1. Compounding Unapproved Drugs for Prescriber Office Use.

~~As used in Business and Professions Code Section 4052(a)(1), the following terms have the indicated meaning concerning the compounding of unapproved drugs for prescriber office use:~~

- ~~(a) "Reasonable quantity" means that quantity of an unapproved drug which:~~
- ~~(1) is sufficient for that prescriber's office use consistent with the expiration date of the product as set forth in section 1716.2(a)(3); and~~
 - ~~(2) is reasonable considering the intended use of the compounded medication and nature of the prescriber's practice; and~~
 - ~~(3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality and purity of the compounded medication.~~
- ~~(b) "Compounded medication" means medications actually compounded by the pharmacy supplying them to a prescriber.~~
- ~~(c) "Prescriber office use" means application or administration in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients as estimated by the prescriber.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4027, 4033, 4050, 4051, 4052, 4059, 4170 and 4171, Business and Professions Code.

Repeal Section 1716.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1716.2. Record Requirements--Compounding for Future Furnishing.

~~(a) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:~~

- ~~(1) The date of preparation.~~
- ~~(2) The lot numbers. These may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If the lot number is assigned by the pharmacy, the pharmacy must also record the original manufacturer's lot numbers and expiration dates, if known. If~~

~~the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components.~~

~~(3) The expiration date of the finished product. This date must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.~~

~~(4) The signature or initials of the pharmacist performing the compounding.~~

~~(5) A formula for the compounded product. The formula must be maintained in a readily retrievable form.~~

~~(6) The name(s) of the manufacturer(s) of the raw materials.~~

~~(7) The quantity in units of finished products or grams of raw materials.~~

~~(8) The package size and the number of units prepared.~~

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, 4059, 4081 and 4332, Business and Professions Code.

Article 4.5. Compounding

Add Section 1735 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735. Compounding in Licensed Pharmacies.

- (a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:
- (1) Altering the dosage form or delivery system of a drug
 - (2) Altering the strength of a drug
 - (3) Combining components or active ingredients
 - (4) Preparing a drug product from chemicals or bulk drug substances
- (b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.
- (c) "Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.
- (d) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile injectable compounding are stated by Article 7 (Section 1751 et seq.).

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.1. Compounding Definitions.

- (a) "Integrity" means retention of potency until the expiration date noted on the label.
- (b) "Potency" means active ingredient strength within +/- 10% of the labeled amount.
- (c) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.
- (d) "Strength" means amount of active ingredient per unit of a compounded drug product.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

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

§1735.2. Compounding Limitations and Requirements.

- (a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.
- (b) A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.
- (c) A "reasonable quantity" as used in Business and Professions Code section 4052(a)(1) means that amount of compounded drug product that:
 - (1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and
 - (2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and
 - (3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with

pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.

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

issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.3. Records of Compounded Drug Products.

- (a) For each compounded drug product, the pharmacy records shall include:
- (1) The master formula record.
 - (2) The date the drug product was compounded.
 - (3) The identity of the pharmacy personnel who compounded the drug product.
 - (4) The identity of the pharmacist reviewing the final drug product.
 - (5) The quantity of each component used in compounding the drug product.
 - (6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.
 - (7) The equipment used in compounding the drug product.
 - (8) A pharmacy assigned reference or lot number for the compounded drug product.
 - (9) The expiration date of the final compounded drug product.
 - (10) The quantity or amount of drug product compounded.
- (b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.
- (c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.
- (d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

Note: Authority cited: Sections 4005, 4127 and 4169, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.4. Labeling of Compounded Drug Products.

- (a) In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).
- (b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.
- (c) Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight, pharmacy reference or lot number, and expiration date.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

Add Section 1735.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.5. Compounding Policies and Procedures.

- (a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.
- (b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.
- (c) The policy and procedure manual shall include the following
 - (1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.
 - (2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.
 - (3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

- (4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.
- (5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.6. Compounding Facilities and Equipment.

- (a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.
- (b) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications.
- (c) Any equipment used to compound drug products for which calibration or adjustment is appropriate shall be calibrated prior to use to ensure accuracy. Documentation of each such calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.7. Training of Compounding Staff.

- (a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.
- (b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.
- (c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.8. Compounding Quality Assurance.

- (a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.
- (b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.
- (c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.
- (d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Article 7 Sterile Injectable Compounding

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

§1751. Sterile Injectable Compounding; Compounding Area.

- (a) Any pharmacy engaged in compounding sterile injectable drug products shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile injectable compounding.
- (b) The Any pharmacy doing sterile injectable compounding shall have a designated area for the preparation of sterile injectable products which shall meet the following standards:

- (1) Clean Room and Work Station Requirements, shall be in accordance with Section ~~490A.3.4~~ 1250 of Title 24, Part 2, Chapter 4A 12, of the California Code of Regulations.
- (2) Walls, ceilings and floors shall be constructed in accordance with Section ~~490A.3.4~~ 1250 of Title 24, Part 2, Chapter 4A 12, of the California Code of Regulations.
- (3) Be ventilated in a manner in accordance with Section 505.12, of Title 24, ~~Part 4~~, Chapter 5 of the California Code of Regulations.
- (4) Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years.
- (5) The pharmacy shall be arranged in accordance with Section ~~490A.3.4~~ 1250 of Title 24, Part 2, Chapter 4A 12, of the California Code of Regulations. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.
- (6) A sink shall be included in accordance ~~in~~ with Section ~~490A.3.4~~ 1250 of Title 24, Part 2, ~~Chapter 4A~~ of the California Code of Regulations.
- (7) There shall be a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.

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

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4127 and 4127.7, Business and Professions Code; and Section 18944(a), Health and Safety Code.

Renumber section 1751.3 to new section 1751.1 and amend section 1751.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§~~1751.3~~. 1751.1. Sterile Injectable Recordkeeping Requirements.

- (a) Pharmacies compounding sterile injectable products for future use pursuant to section ~~1716.1~~ 1735.2 shall, in addition to those records required by section ~~1716.2~~ 1735.3, ~~have~~ make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.
- (b) In addition to the records required by section 1735.3 and subdivisions (a), for sterile products compounded from one or more non-sterile ingredients, the following records must be ~~maintained for at least three years~~ made and kept by the pharmacy:
 - (1) The training and competency evaluation of employees in sterile product procedures.
 - (2) Refrigerator and freezer temperatures.

- (3) Certification of the sterile compounding environment.
- (4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).
- (5) Inspection for expired or recalled pharmaceutical products or raw ingredients.
- (6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

(c) ~~Pharmacies shall maintain records of validation processes as required by Section 1751.7 (b) for three years~~ Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Amend Section 1751.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.2. Sterile Injectable Labeling Requirements.

~~In addition to existing labeling requirements to the labeling information required under Business and Professions Code section 4076 and section 1735.4,~~ a pharmacy which compounds sterile injectable products shall include the following information on the labels for those products:

- (a) Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.
- (b) Name and concentrations of ingredients contained in the sterile injectable product.
- (c) Instructions for storage and handling.
- (d) All cytotoxic agents shall bear a special label which states "Chemotherapy -Dispose of Properly."

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

Renumber section 1751.02 to new section 1751.3 and amend section 1751.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~§1751.02.~~ 1751.3. Sterile Injectable Policies and Procedures.

- (a) ~~Written policies and procedures associated with the pharmacy's preparation and dispensing of sterile injectable products shall include, but not be limited to~~ Any pharmacy engaged in compounding sterile injectable drug products shall maintain a written policy

and procedure manual for compounding that includes, in addition to the elements required by section 1735.5, written policies and procedures regarding the following:

- (1) Compounding, filling, and labeling of sterile injectable compounds.
 - (2) Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.
 - (3) Equipment and supplies.
 - (4) Training of staff in the preparation of sterile injectable products.
 - (5) Procedures for handling cytotoxic agents.
 - (6) Quality assurance program.
 - (7) Record keeping requirements.
- (b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.
- (c) Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.
- (d) Pharmacies compounding sterile injectable products from one or more non-sterile ingredients must have written policies and procedures that comply with the following:
- (1) All written policies and procedures shall be immediately available to all personnel involved in these activities and board inspectors.
 - (2) All personnel involved must read the policies and procedures before compounding sterile injectable products, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.
 - (3) Policies and procedures must address at least the following:
 - (A) Competency evaluation.
 - (B) Storage and handling of products and supplies.
 - (C) Storage and delivery of final products.
 - (D) Process validation.
 - (E) Personnel access and movement of materials into and near the controlled area.
 - (F) Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).
 - (G) Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.
 - (H) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.

- (I) For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.
- (J) Sterilization.
- (K) End-product evaluation and testing.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Renumber section 1751.01 to new section 1751.4 and amend section 1751.4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.01. 1751.4. Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients.

- (a) No sterile injectable product shall be ~~prepared~~ compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.
- (b) During the preparation of sterile injectable products, access to the designated area or cleanroom must be limited to those individuals who are properly attired.
- (c) All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected.
- (d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.
- (e) Pharmacies preparing parenteral cytotoxic agents shall do so in accordance with Section 505.12.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a laminar air flow hood. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code; and Section 18944 Health and Safety Code.

Repeal Section 1751.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.1. Laminar Flow Biological Safety Cabinet.

~~Pharmacies preparing parenteral cytotoxic agents shall be in accordance with Section 4-1106(b) of Title 24 of the California Administrative Code. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.~~

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code; and Section 18944(a), Health and Safety Code.

Repeal Section 1751.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.3. Recordkeeping Requirements.

~~(a) Pharmacies compounding sterile injectable products for future use pursuant to section 1716.1 1735.2 shall, in addition to those records required by section 1716.2 1735.3, have records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.~~

~~(b) In addition to the records required by subdivisions (a), for sterile products compounded from one or more non-sterile ingredients the following records must be maintained for at least three years:~~

- ~~(1) The training and competency evaluation of employees in sterile product procedures.~~
- ~~(2) Refrigerator and freezer temperatures.~~
- ~~(3) Certification of the sterile compounding environment.~~
- ~~(4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).~~
- ~~(5) Inspection for expired or recalled pharmaceutical products or raw ingredients.~~
- ~~(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.~~

~~(c) Pharmacies shall maintain records of validation processes as required by Section 1751.7 (b) for three years.~~

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

Renumber section 1751.4 to new section 1751.5 and amend section 1751.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.4. 1751.5. Sterile Injectable Compounding Attire.

- (a) When preparing cytotoxic agents, gowns and gloves shall be worn.
- (b) When compounding sterile products from one or more non-sterile ingredients the following standards must be met:
 - (1) Cleanroom garb consisting of a low-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times.
 - (2) Cleanroom garb must be donned and removed outside the designated area.
 - (3) Hand, finger, and wrist jewelry must be eliminated. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.
 - (4) Head and facial hair must be kept out of the critical area or be covered.
 - (5) Gloves made of low-shedding materials are required.
- (c) The requirements of this subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Renumber section 1751.5 to new section 1751.6 and amend section 1751.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.5. 1751.6. Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.

- (a) Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.
- (b) The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have training and demonstrated competence in the safe handling and compounding of sterile injectable products, including cytotoxic agents if the pharmacy compounds products with cytotoxic agents.
- (c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.
- (d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile injectable products.
- (e) Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:

- (1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:
 - (A) Aseptic technique.
 - (B) Pharmaceutical calculations and terminology.
 - (C) Sterile product compounding documentation.
 - (D) Quality assurance procedures.
 - (E) Aseptic preparation procedures.
 - (F) Proper gowning and gloving technique.
 - (G) General conduct in the controlled area.
 - (H) Cleaning, sanitizing, and maintaining equipment used in the controlled area.
 - (I) Sterilization techniques.
 - (J) Container, equipment, and closure system selection.

- (2) Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Repeal Section 1751.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.6. Disposal of Waste Material.

~~Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The procedures shall include cleanup of spills and shall be in conformance with local health jurisdiction.~~

Note: Authority cited: Section 4005 Business and Professions Code. Reference: Section 4005 Business and Professions Code.

Amend 1751.7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:
§1751.7. Sterile Injectable Compounding Quality Assurance and Process Validation.

- (a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, ~~There shall be~~ a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:
- (1) Cleaning and sanitization of the parenteral medication preparation area.
 - (2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.
 - (3) Actions to be taken in the event of a drug recall.
 - (4) Written justification of the chosen expiration dates for compounded sterile injectable products.
- (b) Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials are must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.
- (c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.
- (d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Renumber section 1751.9 to new section 1751.8 and amend section 1751.8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.9. 1751.8. Sterile Injectable Compounding Reference Materials.

In any pharmacy engaged in compounding sterile injectable drug products. There shall be current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.



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

Date: June 9, 2010

To: Enforcement Committee

Subject: Pharmacies Filling Internet Prescriptions for Web Site Operators

At the December Enforcement Committee, the committee was advised that the board's inspectors have investigated a number of cases where California pharmacies are filling prescriptions from Internet Web sites in situations where patients are in a number of states, a prescriber is writing prescriptions for the patients from a single state, and the California pharmacy is filling the prescription.

Many times these prescriptions are not valid because an appropriate exam by a prescriber has not occurred. California law allows the board to issue citations at \$25,000 per invalid prescription delivered to patients in California. Often these drugs are controlled drugs or other non-controlled drugs of abuse (e.g., Soma, Tramadol).

Over the last 18 months, the board has issued multiple million dollar fines to California pharmacies for filling such false prescriptions. The Drug Enforcement Administration is also involved in some of these Web site investigations and has fined California pharmacies for their participation.

Pharmacies are facilitating the illegal distribution of prescription drugs from the Internet. From discussion with the owners of several of these pharmacies investigated by the board, the pharmacies receive an offer via a faxed notice offering amounts as low as between \$3 and \$6 per prescription plus drug costs to fill these orders. However the economics greatly benefit the Web site operator. The patient may pay \$100 to \$200 purchase a prescription from the Internet – the pharmacy may get \$6 or \$10 from such a sale.

At the Enforcement Meeting, the executive officer will provide a listing of the huge fines issued in the last year to California pharmacies aiding Internet providers in distributing prescription drugs without a valid prescription.

The *July 2008 The Script* reminded pharmacies not to participate in such scams. A copy of the article is attached. At public speaking events, this is one area touched on by board speakers.

One project recently initiated by board staff is the development of a short video on the dangers of purchasing drugs online. We are working with the Department of

Consumer Affairs on this video, which we plan to have completed by the end of the summer.

A copy of California Business and Professions Code section 4067 is provided below page.

4067. Internet; Dispensing Dangerous Drugs or Devices without Prescription

(a) No person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination of a human or animal for whom the prescription is meant if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination of a human or animal, or if the person or entity did not act in accordance with Section 1761 of Title 16 of the California Code of Regulations.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to either a fine of up to twenty-five thousand dollars (\$25,000) per occurrence pursuant to a citation issued by the board or a civil penalty of twenty-five thousand dollars (\$25,000) per occurrence.

(c) The Attorney General may bring an action to enforce this section and to collect the fines or civil penalties authorized by subdivision (b).

(d) For notifications made on and after January 1, 2002, the Franchise Tax Board, upon notification by the Attorney General or the board of a final judgment in an action brought under this section, shall subtract the amount of the fine or awarded civil penalties from any tax refunds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.

(e) Nothing in this section shall be construed to permit the unlicensed practice of pharmacy, or to limit the authority of the board to enforce any other provision of this chapter.

(f) For the purposes of this section, "good faith prior examination" includes the requirements for a physician and surgeon in Section 2242 and the requirements for a veterinarian in Section 2032.1 of Title 16 of the California Code of Regulations.



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

Date: June 9, 2010

To: Enforcement Committee

Subject: Post Implementation Review of the Board's Criminal Conviction Unit

Included as part of last year's budget, was a staff augmentation for the board to establish the Criminal Conviction Unit within the board. This specialized unit was created to address the significant increase in the number of subsequent arrest notifications that the board receives, in part because of an increase in our licensing population, but mainly because of the transition the Department of Justice made to an automated system.

We initiated recruitment the beginning of last year, and the unit was fully staff beginning in the new fiscal year, when funding was provided. We are pleased to report the following accomplishments of this unit.

As of July 1, 2009, there were 1708 investigations pending. As of June 1, 2010, that number was reduced 629 investigations pending. Additionally over 1900 cases have been completed. Below is a snapshot of the final disposition of those cases.

Referred for Formal Discipline	190
Citation and Fine Issued	112
Letter of Admonishment Issued	152
B&PC 4301 Letter Issued	633
Closed No Further Action	785
Closed Referred to PRP	2
Closed Other	30
Closed No Violation	<u>1</u>
	1905

This unit was envisioned to be a "beginning to end" unit, meaning that the staff would not only complete the investigation, but also complete the final processing as well, e.g. issue the citation and fine, refer the matter to the Office of the Attorney General, etc. (This workload is currently being processed by other staff but is impacting other workload priorities.) As we continue to reduce the number of pending investigations, staff will begin training in these other functions to ensure the final resolution is achieved timely, consistent with our consumer protection mandate.



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

Date: June 9, 2010

To: Enforcement Committee

Subject: Strategic Plan Update 2010-11

At the July Board Meeting, the board will update its 2010-11 Strategic Plan. The board truly manages its operations by its strategic plan. All activities undertaken by the board are reported in the plan -- in the component committee reports provided quarterly to the board (in the board packets).

Each fiscal year, the board updates its strategic plan. The current plan was developed in 2006-07 with the assistance of a consultant. Since then, each year the board has reviewed and as necessary revised its strategic plan. These are typically minor adjustments and additions.

The revision is done by each strategic committee by reviewing its portion of the strategic plan, making recommendations and then recommendations to the full board for review and approval at the board meeting.

The Enforcement Committee's strategic goals, objectives and tasks are being updated and will be provided at the meeting. The committee needs to review the plan to ensure its activities are current and reflect projects underway.

Enforcement unit managers reviewed the plan in advance of this meeting and are recommending inclusion of the following task:

Identify investigative and enforcement internal processes improvement.



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STATE AND CONSUMER SERVICES AGENCY
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ARNOLD SCHWARZENEGGER, GOVERNOR

Date: June 9, 2010

To: Enforcement Committee

Subject: Enforcement Statistics

Enforcement statistics will be compiled at the end of the fiscal year and will be provided for the July Board Meeting along with a three year fiscal comparison.