Agenda Item C2

Regulation Proposal for 2006

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State of California | Department of Consumer Affairs

Memorandum

To: Legislation & Regulation Committee | Date: January 20, 2006

From: Jan E. Perez
Legislation and Regulation Coordinator

Subject: Regulation Proposals for 2006

FOR ACTION

Action Item 1: Request from the California Association of Health-System Pharmacists to amend 16 CCR section 1793.7 and 1793.8, to allow the use of pharmacy technicians in hospital inpatient pharmacies to check other pharmacy technicians filling floor stock, ward stock and unit dose cassettes.

Discussion: At the October committee meeting Maria Serpa, California Society of Health-System Pharmacists (CSHP) representative, presented proposed language for a regulation that would permit general acute care hospitals to employ specially trained pharmacy technicians to check the work of other pharmacy technicians (TCT) filling floor stock, ward stock, and unit dose cassettes. The proposed regulation is similar to CSHP's sponsored Senate Bill 592 (Aanestead, 2005); SB 592 is a two-year bill that is currently in the Assembly Health Committee. At the October 2005 committee meeting, the committee directed staff to review SB 592 and the proposed regulation, and to bring an analysis of each to the next committee meeting so board members could discuss the issue.

A copy of the proposed regulation and analysis, SB 592 analysis, board history on the issue of TCT, a determined the board has the authority to promulgate TCT regulations, and results from two studies conducted on effectiveness of TCT are in Attachment 1.

Action Item 2. Proposal to repeal 16 CCR section 1786 - An outdated provision related to exemptees.

Discussion: CCR section 1786 requires a supplier to immediately return a certificate of exemption to the board if a person, on the basis of whose qualifications a certificate of exemption was granted under B&P section 4054, leaves the employment of a supplier. This regulation is base on past Pharmacy Law that required certificate of exemptions to be linked to a specific licensed wholesaler location, not to the designated representative as current law requires. Consequently, CCR section 1786 is no longer a meaningful regulation and should be repealed.

A copy of the CCR 1786 is in Attachment 2.

Action Item 3. Revised language incorporating comments from the October 2005 public hearing to repeal 16 CCR section 1717(e) and to add 16 CCR section1713 Prescription Drop Boxes and Automated Self-Use Delivery Device for Refill Prescriptions.

Discussion: The Legislation and Regulation Committee is considering a proposed regulation for prescription drop boxes and automated delivery devices. This proposed regulation is based on public comment and board discussion received at the board's October 25, 2006 meeting, on the October 19, 2005 version of the regulation. The January 26, 2006 version of the regulation further strengthens consumer protections from earlier versions of the regulation. Specifically, the new language would require:

1) a consumer to sign a consent form stating that the consumer has chosen to use the delivery device;
2) a pharmacy to provide a means for each patient to obtain an immediate consultation with a pharmacist via phone or in person if the patient request a consultation;
3) complaints received from patients to be reviewed as part of a pharmacy's quality assurance program;
4) pharmacies to have procedures in place to notify patients when expected prescriptions are not available in the device; and
5) pharmacies to have producers in place to ensure the delivery of prescriptions to patients in the event that a device is disabled or malfunctions.

The intent of staff is to bring this revised language to the committee and for the board to consider whether it wishes to move forward with a revised regulation and start the rulemaking process anew.

A copy of the new, January 26, 2006 version, of the proposed language for the regulation, a summary of comments heard at the October 2005 regulation hearing, and comment letters received since the posting of this item on the committee's January 2006 agenda are in Attachment 3. .

NO ACTION

Item 4. At the Legislation and Regulation Committee meeting in October, the Committee approved five regulation proposals. At the February board meeting, the board needs to approve each of the regulation proposals. These proposals are provided for your information, in Attachment 4.

Regulation Proposals for 2006

Attachment 1

SUBMITTED BY CSHP

PROPOSED AMENDMENTS & ADDITION
TITLE 16 CCR SECTION 1793.7 & 1793.8

1793.7 Requirements for Pharmacies Employing Pharmacy Technicians.

(a) ~~a.~~ Any pharmacy which employs a pharmacy technician shall do so in compliance with applicable federal and state laws and regulations governing pharmacy.

(b) ~~b.~~ Except as otherwise provided in section 1793.8, any ~~Any~~ function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, the pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient.

(c) ~~c.~~ Pharmacy technicians must work under the direct supervision of a registered pharmacist and in such a relationship that the supervising pharmacist is on the premises at all times and is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records. Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, a pharmacy technician may perform the duties, as specified in subdivision 1793.2, only under the immediate, personal supervision and control of a registered pharmacist and within the pharmacist's view.

(d) ~~d.~~ A pharmacy technician must wear identification clearly identifying him or her as a pharmacy technician.

(e) ~~e.~~ Any pharmacy employing or using a pharmacy technician shall develop a job description and written policies and procedures adequate to ensure compliance with the provisions of Article 12 of this Chapter, and shall maintain, for at least three years from the time of making, records adequate to establish compliance with these sections and written policies and procedures.

(f) ~~f. Except as otherwise provided herein, the ratio of pharmacists to pharmacy technicians performing the duties specified in subsection 1793.2 shall not be less than one pharmacist on duty for each pharmacy technician on duty.~~ For the preparation of a prescription for an inpatient of a licensed health facility and for a patient of a licensed home health agency, the ratio shall not be less than one pharmacist on duty for a total of two pharmacy technicians on duty. Pursuant to Business and Professions Code section 4115(g)(1), these ratios shall not apply to the preparation of a prescription for an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

Authority cited: Sections 4005, 4115 Business and Professions Code.
Reference cited: Sections 4007 and 4115 Business and Professions Code.

1793.8 Technicians in Hospitals with Clinical Pharmacy Programs.

(a) Notwithstanding any other provision of law, general acute care hospitals, as defined in Health and Safety Code 1250 (a), that have an ongoing clinical pharmacy program may allow pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed and approved by a licensed pharmacist.

(b) Compounded or repackaged products must have been previously checked by a pharmacist and then may be used by the technician to fill unit dose distribution systems, and floor and ward stock.

(c) To ensure quality patient care and reduce medication errors, programs that use pharmacy technicians to check the work of other pharmacy technicians pursuant to this section must include the following components:

(1) The overall operation of the program shall be the responsibility of the pharmacist in charge;

(2) The program shall be under the direct supervision of a pharmacist and the parameters for the direct supervision shall be specified in the facility's policies and procedures;

(3) The pharmacy technician who performs the checking function has received specialized and advanced training as prescribed in the policies and procedures of the facility;

(4) To ensure quality, there shall be ongoing evaluation of programs that use pharmacy technicians to check the work of other pharmacy technicians.

Authority cited: Sections 4005, 4115, Business and Professions Code.
Reference cited: Sections 4007 and 4115, Business and Professions Code.

REGULATION ANALYSIS

AMEND CCR 1793.7 ADD CCR 1793.8 **January 19, 2006**

SUBJECT: TECHNICIAN CHECKING TECHNICIAN

SPONSOR: CALIFORNIA SOCIETY OF HEALTH-SYSTEM PHARMACISTS (CSHP)

Existing Law:

1) Requires pharmacy technicians to be licensed by the board. (B&P 4115)

2) Permits pharmacy technicians to perform packaging, manipulative, repetitive, or other nondiscretionary tasks under the direct supervision of a pharmacist as follows:

a. Removing drugs from stock.
b. Counting, pouring, or mixing pharmaceuticals
c. Placing product in a container.
d. Affixing a label or labels to the container.
e. Packaging and repackaging.

(CCR 1793.2)

3) Requires pharmacy technicians to possess a high school education and fulfill one of the following requirements to be licensed:

a. Associate degree in pharmacy technology.
b. Complete a training course approved by the board.
c. Is eligible to take the board examination for licensure as a pharmacist.

(CCR 1793.5, 1793.6)

This Regulation:

1) Amends CCR 1793.7 to allow pharmacy technicians to check the work of other pharmacy technicians (TCT) in accordance with CCR 1793.8. (CCR 1793.7 Amended)

2) Permits general acute care hospitals that have an ongoing clinical pharmacy program to use TCT in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed and approved by a licensed pharmacist.

3) Requires compounded or repackaged products to be checked by a pharmacist prior to a technician filling unit dose distribution systems, and floor and ward stock.

4) Requires TCT programs to include the following components:

a. The overall operation of the program shall be the responsibility of the pharmacist in charge;
b. The program shall be under the direct supervision of a pharmacist and the parameters for the direct supervision shall be specified in the facility's policies and procedures;

c. The pharmacy technician who performs the checking function has received specialized and advanced training as prescribed in the policies and procedures of the facility;
d. To ensure quality, there shall be ongoing evaluation of programs that use pharmacy technicians to check the work of other pharmacy technicians.

(CCR 1793.8 Added)

Comment:

1) Sponsor's Intent. For over ten years the California Society of Health-System Pharmacists (CSHP) has supported both regulation and legislative attempts that would permit TCT programs. Most recently CSPH sponsored SB 393 (2003) and SB 592 (2005) to permit TCT. Both bills met with opposition from labor and failed to make it out of the Assembly.

2) Board Authority. In 1995, the board initiated a rulemaking process for TCT. At the time some questioned whether the board had the authority to promulgate TCT regulations. Bion Gregory, Legislative Counsel, determined the board has the authority to promulgate TCT regulations.

3) Accuracy and Usefulness of TCT. Two studies have been conducted by Long Beach Memorial Medical Center, Cedar-Sinai Medical Center, and the UCSF School or Pharmacy to determine the accuracy and usefulness of TCT.

The first study, "Evaluating the Accuracy of Technicians and Pharmacists in Checking Unit Dose Medication Cassettes" was conducted from 1998-2000. The study determined that certified technicians had an accuracy rate of 99.88% compared with pharmacists who had an accuracy rate of 99.52% for checking unit-dose cassettes.

The second study, will evaluate the impact of pharmacists in preventing medication errors associated with prescribing and administering medications as a result of pharmacists being re-deployed form unit-dose medication cassette checking to clinical and professional functions. The study began in 2004 and will be completed in 2006.

Interim results presented at the board's July 2005 meeting, show that redeploying a pharmacist for 1.5 hours a day over 48 weeks resulted in pharmacists intercepting 1,296 medication errors, and allowed 27,450 medication related encounters including the dosing of medications per doctors' requests, participation in codes, and rounds and drug information questions. Overall these interceptions prevented temporary harm to 387 patients, permanent harm to 11 patients, and one death. Results from the complete study will be presented to the board in late summer or fall of 2006.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 592 | **VERSION: AMENDED MARCH 29, 2005**

AUTHOR: AANESTEAD | **SPONSOR: CALIFORNIA SOCIETY OF HEALTH SYSTEMS PHARMACISTS**

RECOMMENDED POSITION: SUPPORT

SUBJECT: TECHNICIAN CHECKING TECHNICIAN

Existing Law:

1) Requires pharmacy technicians to be licensed by the board. (B&P 4115)

2) Permits pharmacy technicians to perform packaging, manipulative, repetitive, or other nondiscretionary tasks under the direct supervision of a pharmacist as follows:

a. Removing drugs from stock.
b. Counting, pouring, or mixing pharmaceuticals
c. Placing product in a container.
d. Affixing a label or labels to the container.
e. Packaging and repackaging.

(CCR 1793.2)

3) Requires pharmacy technicians to possess a high school education and fulfill one of the following requirements to be licensed:

a. Associate degree in pharmacy technology.
b. Complete a training course approved by the board.
c. Is eligible to take the board examination for licensure as a pharmacist.

(CCR 1793.5, 1793.6)

This Bill:

1) Permits general acute care hospitals to employ specially trained pharmacy technicians to check the work of other pharmacy technicians (TCT) filling floor stock, ward stock, and unit dose cassettes. (B&P 4128 Added)

2) Requires hospitals implementing TCT to do the following:

a. Conduct ongoing training for technicians.
b. Conduct continuous quality improvement programs to audit the performance of technicians in TCT programs.
c. Remove any technician in TCT programs whose accuracy rate falls below 99.8 percent.

d. Possess a current accreditation from the Joint Commission on the Accreditation of Health Care Organizations (JCAHO), or another nationally recognized accrediting organization.
e. Be inspected by the Board of Pharmacy.
f. Establish a program using pharmacists to provide clinical services.

(B&P 4128 Added)

3) Requires training for pharmacy technicians to include both didactic and practical elements, and to be completed prior to technicians commencing participation in the checking program.

a. The didactic component of the training shall consist of at least four hours of education covering the following topics:
   i. Information required to be on the label of unit dose or extemporaneous packaging.
   ii. Identification of expired or contaminated medications.
   iii. The product characteristics that need to be checked for each drug dispensed from the pharmacy.
   iv. Special packaging or handling requirements, including refrigeration for certain medications.
   v. Generic names for common name-brand medications.
   vi. Recognition and identification of various dosage forms.
   vii. Common medical abbreviations and symbols used in pharmacy.
   viii. Basic mathematical principles used in pharmacy calculations, including conversions between and within metric, avoirdupois, and apothecary systems.

b. The practical component of the training shall consist of at least two hours of supervised practice in which the trainee both observes proper checking procedures and performs proper checking procedures under the direct observation of the supervisor.

(B&P 4128 Added)

4) Permits the board to adopt other rules related to TCT. (B&P 4128 Added)

5) Permits the board to order a hospital to cease a TCT program. (B&P 4128 Added)

6) Requires that data and records for TCT programs be retained for three years.

(B&P 4128 Added)

7) Specifies that legal responsibility for errors in the TCT process is that of the pharmacy and the pharmacist-in-charge. (B&P 4128 Added)

8) Requires hospitals to have a list of technicians in TCT programs available for inspection by the board. (B&P 4128.1Added)

9) Requires pharmacy technicians participating in TCT programs by certified by the Pharmacy Technician Certification Board. (B&P 4128.1 Added)

Comment:

1) Author's Intent. The author is seeking to apply the model TCT program evaluated in a study project at Cedars Sinai Medical Center and Long Beach Memorial Hospital. The results of that study were published in the American Journal of Health System Pharmacy, June 2002, and found the practice to be safe and that TCT allowed staff pharmacists to spend more time addressing clinical issues with patients and prescribers.

2) Legislative History. In 2003 the author introduced SB 393, a bill similar to SB 592. SB 393 was opposed by the United Food and Commercial Workers Union. The measure failed to make it beyond its second committee hearing.

The sponsor of SB 592 is engaging labor in discussions in hopes labor will either support or remain neutral on the bill.

3) Board History. At its October 2001 meeting, the board voted to support legislation that would allow a pharmacy technician to check another pharmacy technician filling unit-dose cassettes in an inpatient hospital pharmacy. At that meeting the board expressed a desire for TCT programs to emulate those operated by Cedars-Sinai and Long Beach Memorial under the board waiver.

In April 2003, the board voted to support SB 393.

At the April 2004 board meeting the board approved a two-year pilot program at UCSF / Cedars to allow TCT to continue while documentation of duties preformed by pharmacists continue. This pilot program will end in April 2006.

4) Amended on March 29, 2005. The amendments 1) detail training for pharmacy technicians who participate in the program, and 2) specified requirements for the quality improvement program required by the measurer. This version of the bill is similar to AB 393, as amended on July 16, 2003.

5) History.

2005	
June 14	Set, first hearing. Failed passage in committee. Reconsideration granted.
May 26	To Com. on HEALTH.
May 9	In Assembly. Read first time. Held at Desk.
May 9	Read third time. Passed. (Ayes 23. Noes 8. Page 972.) To Assembly.
May 3	Read second time. To third reading.
May 2	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
Apr. 21	Set for hearing May 2.
Apr. 18	From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 4. Noes 1. Page 625.) Re-referred to Com. on APPR.
Mar. 30	Set for hearing April 18.
Mar. 29	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 3	To Com. on B., P. & E.D.
Feb. 19	From print. May be acted upon on or after March 21.
Feb. 18	Introduced. Read first time. To Com. on RLS. for assignment. To print.

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Board History: Technicians Checking Technicians (TCT) 1995 to 2006

July 1993	Board Meeting – Board appoints a committee to research hospital practices with regards to the possible use of TCT. The committee recommended that the board adopt proposed regulations.
May 1995	Board Meeting – Board members discuss pharmacy technicians' duties and their concern that some employees may be asking techs to perform illegal activities. It was estimated that 50% of all hospitals in Southern California use TCT.
July 1995	Board Meeting - Board members discuss TCT. Washington and Minnesota allow TCT. In 1995 California law did not require hospital techs to be licensed. California Society of Health-System Pharmacists (CSHP) supports TCT, the California Pharmacist Association (CPhA) opposes TCT. There is general agreement among the board members that hospital techs should be licensed if TCT moves forward. The board approves a motion to notice CCR 1793.8.
October 1995	Regulation Hearing to amend CCR 1793.7 and adopt 1793.8. The regulation would establish requirements for a class of pharmacy tech authorized to participate in TCT. Discussion. Does the Board have the authority to adopt this regulation? Staff Counsel Chris Grossgart stated that the board has the authority. Board votes to reject the regulation and refers this issue to the board's Pharmacy Technician Committee.
July 1996	Pharmacy Technician Committee – Brief discussion on TCT. One proposal would be to require hospitals to apply to the board to have a TCT program and impose reporting requirements to the board to evaluate effectiveness. Also discussed was SB 1553 (1996) which would require the registration of techs working for hospitals and correction facilities.
January 1997	Board Meeting – Board members approve a motion to pursue a regulation authorizing a waiver program for techs to be able to check the filling of unit dose cassettes in an inpatient setting.
May 2, 1997	Notice published for to amend CCR 1793.7 and adopt 1793.8 to allow hospitals to apply for a waiver to allow techs to be able to check the filling of unit dose cassettes in an inpatient setting. Comment period ends June 16, 1997.
May 1997	Board Meeting - Board members discuss proposed TCT regulation. The board approves a motion to cancel the regulation hearing scheduled for July 1997, and moves the technician issue to the board's Licensing Committee.
May 1998	Board Meeting - Long Beach Memorial Medical Center, Cedar-Sinai Medical Center, and the UCSF School or Pharmacy request a waiver from CCR 1731 to conduct a two-year study to evaluate TCT. Waiver granted until November 2000.
October 2000	Board Meeting – UCSF request a waiver to continue TCT study until February 1, 2001. Board grants waiver.

January 2001	Board Meeting - Dr. Peter Ambrose, UCSF, presented results of the study. Pharmacist checking unit-dose cassettes had an accuracy rate of 99.52% compared with **99.88% for certified technicians** performing the same task. The board approves a motion to move forward with legislation or regulation to allow TCT. The Board approves a motion to extend UCSF's waiver until the end of the 2002 Legislative Session (December 2002) to allow for passage of legislation or regulation.
June 2002	The results of UCSF's TCT study are published in the June 15, 2002 issue of the American Journal of Health-System Pharmacists.
October 2002	Board Meeting - UCSF request and the board grants a continuation of UCSF's waiver until December 2004. CSHP will sponsor legislation in January 2003 to allow TCT.
April 2003	Board Meeting – Board approves a position of Support if Amended on SB 393 (Aanestead 2003) TCT. The amendment would delete the requirement for the board approve regulations in association with TCT and instead place the criteria directly into the law. Note: SB 393 died in the Senate.
January 2004	Board Meeting - Dr. Peter Ambrose, UCSF, presented the final results of the UCSF study that ended in December 2003. He states that no medication errors were reported as a result of TCT. The board asked the Licensing Committee to review the issue of TCT and report back to the board.
April 2004	Board Meeting - Dr. Peter Ambrose, UCSF, request a two year waiver for TCT to evaluate the impact of pharmacists in preventing medication errors associated with prescribing and administering medications as a result of pharmacists being re-deployed form unit-dose medication cassette checking to clinical and professional functions. The Board approves a two-year waiver with the understanding that an interim report will be provided after one year.
February 2005	SB 592 (Aanestead) TCT introduced, based on SB 393 (Aanestead 2003) TCT. SB 592 is currently in the Assembly Health Committee and is likely to die in the Assembly on January 31, 2006. The board has a position of support on the measure.
July 2005	Board Meeting - Dr. Rita Shane, Director of Pharmacy Services, Cedar-Sinai Medical Center, presented interim results of his latest study. The results demonstrate that having specially trained pharmacy techs performing the non-discretionary task of checking technician filled unit-dose medication carts frees up time for pharmacists to play a role in intercepting potential medication errors and preventing harm to patients.
October 2005	Legislation Committee Hearing - Maria Serpa, CSHP representative, presented proposed language for TCT. Committee directs staff to compare the regulation with SB 592 (2005) and report back to the committee.

STATE OF CALIFORNIA

Memorandum

To: PATRICIA F. HARRIS
Executive Officer
Board of Pharmacy

Date: October 13, 1994

Telephone: (916) 445-4216
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From: **Department of Consumer Affairs**
Legal Office

Subject: Direct Supervision of Pharmacy Technicians

I. BACKGROUND.

As you are aware, the Hospital Pharmacy Committee is proposing regulations ("the Proposed Regulations") which would allow pharmacy technicians employed in inpatient hospitals, skilled nursing facilities and correctional facilities (referred to collectively as "Inpatient Pharmacy Technicians" or "IPTs") to "check" certain tasks performed by other IPTs. Specifically, the Committee proposes to authorize IPTs to check unit dose cassettes and floor and ward stocks filled by other IPTs. An IPT would perform this "check" in lieu of the supervising pharmacist.

You asked whether the Proposed Regulations would be inconsistent with, and thus precluded by, existing statute which requires IPTs to work under the "direct supervision and control" of pharmacists.

Subject to the discussion below, I conclude that, although existing statute requires the supervising pharmacist to be present in the facility at the time the IPT is performing his or her duties, the pharmacist is not required to personally check unit dose cassettes and floor and ward stocks filled by an IPT. Instead, the pharmacist may authorize another IPT to perform such checks.

II. DISCUSSION.

The functions performed by pharmacy technicians, and the supervision required in the performance of those functions, are governed by Business and Professions Code Section 4008.5 and

regulations promulgated under that statute.[1] Subdivision (b) of Section 4008.5 requires IPTs to work under the direct supervision and control of pharmacists. It provides:

> (b) Notwithstanding any other provision of law, a pharmacy technician may perform packaging, manipulative, repetitive, and other nondiscretionary tasks, while assisting, and under the direct supervision and control of, a registered pharmacist. (Emphasis added.)[2]

Under Section 4008.5, an IPT may fill unit dose cassettes and floor stocks under a pharmacist's direct supervision and control. As indicated, the Proposed Regulations would authorize a pharmacist to delegate the responsibility of checking the filled cassettes and floor stock to another IPT. The Pharmacy Board may not adopt the Proposed Regulations without statutory amendment if the "direct supervision and control" standard requires the supervising pharmacist to personally check such tasks. In order to resolve this question, we must determine what is required under "direct supervision and control".

The term "direct supervision and control" is not defined in the Pharmacy Law. Nor has any court defined this term for purposes of Section 4008.5. Therefore, I have looked to other

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[1]Unless otherwise specifically stated, all references herein are to the Business and Professions Code.

[2]Note that Section 4008.5 creates two levels, or standards, of supervision. Subdivision (f)(2) creates a second standard which is more stringent than that set forth in Subdivision (b). It provides, in relevant part:

> . . . A pharmacy technician may perform the duties, as specified in subdivision (b) only under the immediate, personal supervision and control of, a registered pharmacist. (Emphasis added.)

This second standard, "immediate, personal supervision and control", does not apply to pharmacy technicians who are employed in inpatient hospitals or correctional facilities. (See § 4008.5(f)(5).) Hence, the first standard of supervision, namely "direct supervision and control", is applicable to IPTs.

statutes in the Business and Professions Code for guidance. Although the term "direct supervision and control" does not appear in other practice acts, the term "direct supervision" is used several times.[3]

Under other practice acts, the terms "direct supervision" means that the supervisor must be present in the facility at the time the supervised trainee or employee is performing duties which require supervision. I have found no statutes in the Business and Professions Code which define "direct supervision" to require the supervisor to personally check all tasks completed by supervised employees.

For example, under the Dental Practice Act, dental auxiliaries are required to perform many of their duties under the direct supervision of a dentist. "Direct supervision" under the Dental Practice Act is defined as:

> supervision of dental procedures based on instructions given by a licensed dentist, <u>who must be physically present in the treatment facility during the performance of those procedures</u>. (<u>Emphasis added</u>; B&P Code § 1741.)

Thus, Section 1741 provides only that the supervising dentist must be present in the treatment facility at the time the auxiliary is performing assigned tasks. The statute does not require the dentist to personally review an auxiliary's work product.

Similarly, under the Medical Practice Act, student and intern perfusionists must work under the direct supervision of a perfusionist who has met certain statutory requirements. (B&P Code § 2593.) For purposes of section 2593, "direct supervision" means that the supervising perfusionist is on duty and

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[3]Other practice acts are not binding on the Pharmacy Board. However, a review of other statutes in the Business and Professions Code which define the term "direct supervision" may aid us in determining legislative intent behind Section 4408.5.

immediately available in the assigned patient care area. Again, the supervising perfusionist is not required to personally check all tasks completed by students and interns under his or her supervision.

Also under the Medical Practice Act, student respiratory care practitioners are required to work under direct supervision. Section 3742 provides:

> During the period of any clinical training, a student respiratory care practitioner shall be under the direct supervision of a person holding a valid and current license issued under this chapter. "Under the direct supervision" means assigned to a respiratory care practitioner who is on duty and immediately available in the assigned patient care area. (Emphasis added.)

The fact that the Legislature, in regulating other health professions, has not defined "direct supervision" to require licensees to personally check the work of employees under their supervision, suggests that the Legislature did not intend to impose such requirements under the Pharmacy Law.

Moreover, had the Legislature intended to require Pharmacists to personally check the work product of IPTs, it would have expressly so stated. As we have seen, community pharmacy technicians must work under the immediate, personal supervision and control of a pharmacist. Although this term is not defined, the words "immediate" and "personal" suggest that there is no intermediate supervision between the supervisior and the pharmacy technician. Also, logic dictates that in the community pharmacy setting, where drugs are supplied directly to the consumer rather than to an intermediary medical professional, the pharmacist must closely scrutinize, and presumably personally check, the work of pharmacy technicians. Had the Legislature intended to impose similar requirements on IPTs, it would not have exempted IPTs from the standard of "immediate, personal supervision and control".

III. CONCLUSION.

Based on the preceding discussion, I conclude that the Proposed Regulations, which would authorize a pharmacist in an inpatient hospital, skilled nursing facility or correctional

institution to delegate to a pharmacy technician the task of "checking" unit dose cassettes and ward stocks filled by another pharmacy technician, is consistent with Section 4008.5.

DERRY L. KNIGHT
Deputy Director
Legal Affairs

By CHRISTOPHER GROSSGART
Staff Counsel

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REPORTS

Evaluating the accuracy of technicians and pharmacists in checking unit dose medication cassettes

PETER J. AMBROSE, FRANK G. SAYA, LARRY T. LOVETT, SANDY TAN, DALE W. ADAMS, AND RITA SHANE

Abstract: The accuracy rates of board-registered pharmacy technicians and pharmacists in checking unit dose medication cassettes in the inpatient setting at two separate institutions were examined.

Cedars-Sinai Medical Center and Long Beach Memorial Medical Center, both in Los Angeles county, petitioned the California State Board of Pharmacy to approve a waiver of the California Code of Regulations to conduct an experimental program to compare the accuracy of unit dose medication cassettes checked by pharmacists with that of cassettes checked by trained, certified pharmacy technicians. The study consisted of three parts: assessing pharmacist baseline checking accuracy (Phase I), developing a technician-training program and certifying technicians who completed the didactic and practical training (Phase II), and evaluating the accuracy of certified technicians checking unit dose medication cassettes as a daily function (Phase III).

Twenty-nine pharmacists and 41 technicians (3 of whom were pharmacy interns) participated in the study. Of the technicians, all 41 successfully completed the didactic and practical training, 39 successfully completed the audits and became certified checkers, and 2 (including 1 of the interns) did not complete the certification audits because they were reassigned to another work area or had resigned. In Phase II, the observed accuracy rate and its lower confidence limit exceeded the predetermined minimum requirement of 99.8% for a certified checker. The mean accuracy rates for technicians were identical at the two institutions ($p = 1.0$). The difference in mean accuracy rates between pharmacists (99.52%; 95% confidence interval [CI] 99.44–99.58%) and technicians (99.89%; 95% CI 99.87–99.90%) was significant ($p < 0.0001$).

Inpatient technicians who had been trained and certified in a closely supervised program that incorporated quality assurance mechanisms could safely and accurately check unit dose medication cassettes filled by other technicians.

Index terms: Administration; Dispensing; Drug distribution systems; Personnel, pharmacy; Pharmacists, hospital; Pharmacy, institutional, hospital; Professional competence

Am J Health-Syst Pharm. 2002; 59:1183-8

The rapidly changing health care environment necessitates that health care organizations optimize limited resources while improving the quality of care provided. Medication-related complications cost the American health care system as much as $177 billion annually.[1] Pharmacist expertise in drug therapy has repeatedly demonstrated improved patient outcomes, fewer complications, and better control of the cost of medication use.[2-4] However, there currently is a critical shortage of pharmacists, as documented in the Department of Health and Human Services report to Congress on the pharmacist workforce.[5] This shortage is especially acute in California, where the ratio of 58 pharmacists to 100,000 people in the population is well below the national average of 71 pharmacists to 100,000 people in the population. In this same report, the Pharmacy Manpower Project Aggregate Demand Index for California indicated a high

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level of demand for pharmacists. The current shortage of pharmacists poses a significant challenge to providing and maintaining the desired level of pharmaceutical care.[6]

The importance of pharmacy technicians in ensuring the efficient operation of hospital pharmacies is widely recognized. By reassigning nondiscretionary drug distribution tasks to pharmacy technicians, pharmacists can be redeployed to prevent adverse drug events and ensure optimal medication use. In California, unit dose medication cassettes that are filled by pharmacy technicians must be checked by a pharmacist. Pharmacists spend one hour per day checking technician-filled medication cassettes, which competes with the increasing demands on pharmacists to provide clinical services and become more involved in medication safety initiatives, in addition to dealing with the increased complexity of hospitalized patients and the pharmacist shortage. Expanding the role of technicians by implementing a structured training program with ongoing quality assurance measures may ease the impact of the pharmacist shortage through the judicious and appropriate use of skilled support personnel and increase the time available to pharmacists to perform clinical functions.

Background

In 1997, the California State Board of Pharmacy was petitioned to authorize board-registered pharmacy technicians to check unit dose cassettes filled by other pharmacy technicians in the inpatient environment. In response to strong opposition from some professional organizations and community pharmacists, who were concerned that the exemption could be expanded outside of the inpatient pharmacy environment and jeopardize pharmacist jobs, the board voted not to grant this petition. However, the board did express a desire to receive additional evidence to further evaluate allowing pharmacy technicians to perform this function. Thus, Cedars-Sinai Medical Center (CSMC) and Long Beach Memorial Medical Center (LBMMC) petitioned the board to grant a waiver of the California Code of Regulations to conduct an "experimental program" under the direction of the University of California, San Francisco, School of Pharmacy. The purpose of the program was to compare the accuracy of unit dose medication cassettes checked by pharmacists with those checked by trained, registered pharmacy technicians in the inpatient setting. In May 1998, the waiver was granted for the experimental program known as "Evaluating the Use of Board Registered Pharmacy Technicians in a Unit-Dose Drug Distribution System." The waiver was initially granted through November 1, 2000, and was extended to December 2002 on the basis of data generated from this study, which was presented to the board in January 2001.

CSMC is a 900-bed, acute tertiary care hospital in Los Angeles, California, and LBMMC is a 540-bed, acute tertiary care hospital in Long Beach, California. The unit dose drug distribution system used by CSMC and LBMMC is diagrammed in Figure 1. It should be emphasized that the process of filling and checking unit dose medication cassettes is preceded by the review and verification of all medication orders by a pharmacist. The pharmacist evaluates the appropriateness of the medication, dose, dosage form, route of administration, and frequency in the order and screens for drug allergies, drug–drug interactions, and contraindications. A pharmacist is also responsible for dispensing any initial medication doses needed before the regularly scheduled unit dose cart distribution.

Pharmacy technicians do not evaluate the accuracy and appropriateness of medication orders. Pharmacy technicians perform manipulative and nondiscretionary functions only under the supervision of pharmacists. When filling a medication cassette with unit dose medications, a technician reads a list of medications (a "fill list") previously verified by a pharmacist, removes the unit dose medication from stock, and places it in a patient's cassette or medication drawer. Next, a "checker" verifies the filled cassette against the fill list to minimize the possibility of errors before the medications are sent to the nursing areas. In California, only a pharmacist can check these unit dose cassettes, which necessitated the waiver from the board of pharmacy to allow technicians to perform this function in this program. It should be noted that nurses also check the medication when removing it from a patient's cassette and confirm it with the medication administration record (also reviewed and approved by a pharmacist) before administering the medication to the patient, in accordance with Joint Commission on Accreditation of Healthcare Organizations and California Department of Health Services requirements. Thus, a medication is triple-checked before it is administered to a patient.

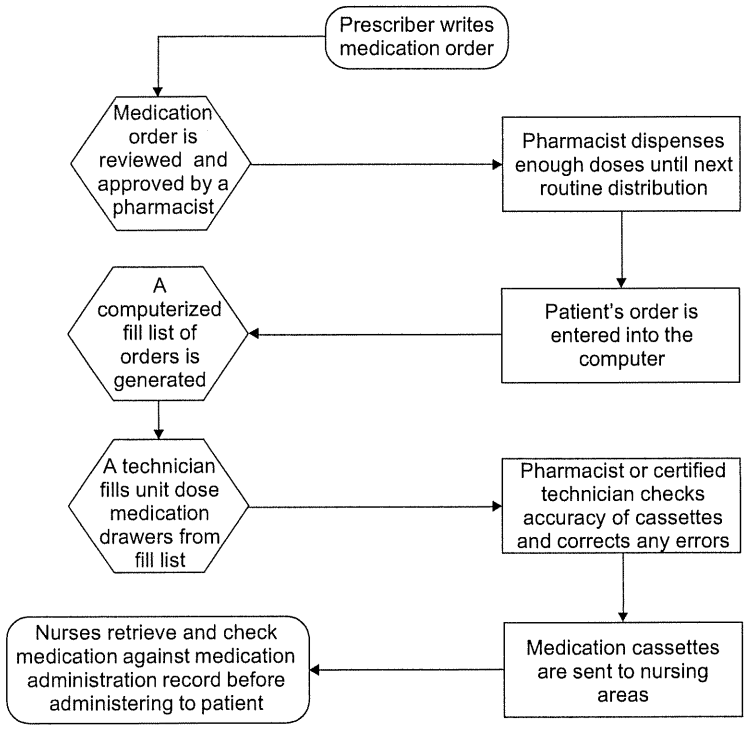
This article describes the experimental program and the accuracy of trained technicians checking unit dose medication cassettes compared with that of pharmacists.

Methods

This study was conducted concurrently at both CSMC and LBMMC and consisted of the following three phases, which were modeled from previous studies[7-13]:

- Phase I: Assessing the baseline accuracy rate of pharmacists checking unit dose medication cassettes,
- Phase II: Developing a technician training program for checking unit dose cassettes and certifying technicians who successfully completed the training program, and

Figure 1. Diagram of the inpatient unit dose drug distribution system used at both Cedars-Sinai Medical Center and Long Beach Memorial Medical Center in normal practice and during the study.



- Phase III: Evaluating the accuracy of certified technicians checking unit dose medication cassettes by conducting quality assurance audits.

Phase I began in June 1998 with the goal of auditing a minimum of 12,500 doses at each institution. Staff pharmacists checked all unit dose cassettes filled by technicians as was the pharmacists' normal routine during the day shift. They were aware that audits were being conducted. Study participants were selected on the basis of their normal work schedules, and no attempt was made to alter assignments. In addition to any spontaneous errors made by technicians filling the cassettes, artificial errors were randomly introduced by pharmacist "auditors" assigned to oversee the study process. Artificial errors were introduced at a rate of at least one error per 500 doses (0.2%) to coincide with a 99.8% minimum accuracy rate.[7] The pharmacist checkers documented and corrected any errors they detected. Subsequently, the pharmacist auditor would audit and verify the accuracy of the pharmacist checker in detecting and correcting artificial and spontaneous filling errors for all doses dispensed during the audit period. Spontaneous and artificial errors overlooked by the pharmacist checkers were documented on an audit form and corrected by the pharmacist auditors before the medication cassettes were distributed to the nursing stations. There were a total of three pharmacists at CSMC and five at LBMMC who were responsible for introducing artificial errors and auditing the pharmacists. In all three phases of the study, an error was defined as a wrong drug, dose, quantity, or dosage form; expired medication; inaccurate concentration; wrong patient's medication cassette; or missing drug.

During Phase II of the program, the pharmacy services departments at CSMC and LBMMC collaborated on a training syllabus, qualifying examination, and data collection forms. Technicians and pharmacy interns (employed and functioning as technicians) were eligible to be included in the study if they were registered with the California State Board of Pharmacy and had at least six months of experience filling unit dose medication cassettes. They were then given didactic and practical training, in accordance with the approach used by the Minnesota Society of Hospital Pharmacists in a pilot project in which technicians were trained to check unit dose cassettes filled by other technicians.[7] The didactic component consisted of lectures on the unit dose process, proper packaging and repackaging techniques, medication safety, and basic pharmaceutical calculations. The didactic training concluded with an examination. Technicians were required to achieve a minimum passing score of 80% on the examination. The practical training included observing a pharmacist checking unit dose cassettes and actual hands-on experience. After successful completion of the didactic and practical training, the technicians were audited for accuracy in checking unit dose cassettes for at least 3500 consecutive doses. Artificial errors, as described for Phase I of the program, were also introduced in this process. The audits were conducted by the same pharmacist auditors as in Phase I. To become a certified technician checker in this program, an overall accuracy rate of at least 99.8% was required. This phase of the study began in June 1998 and was continued as new technicians were trained and included in the program.

Phase III began in April 1999. In this phase, certified technician checkers were responsible for checking unit dose medication cassettes as a daily activity while under the supervision of a pharmacist. Monthly quality assurance audits of at least 500 doses were conducted for each certified technician checker, using

the same procedure of introducing random artificial errors as previously described. Accuracy was to be maintained at 99.8% or higher. If a certified technician checker failed a monthly audit, the audit was to be repeated within 30 days. If the technician failed the second audit, the technician would be removed from the checking position until he or she was retrained and recertified. If a certified technician checker did not perform this function for more than three months, an audit would be conducted when the technician restarted checking medication cassettes. If a technician had not checked cassettes for more than six months, recertification was required.

In January 2000, the board approved the following requested amendment to the program: "In Phase III of the study, a monthly audit will be conducted for 3 months, and if the accuracy rate meets or exceeds the minimum target of 99.8% for three consecutive audits, future audits will be conducted quarterly thereafter for that technician. Technicians failing a quarterly audit will have to pass three consecutive monthly audits before resuming quarterly audits." The amendment had been requested by CSMC and LBMMC, since no certified technician had failed a monthly audit.

Error rates were calculated as the number of errors discovered by the auditors divided by the total number of unit doses audited. The accuracy rate was defined as one minus the error rate, which was then converted to a percentage. The 95% confidence intervals for these rates and p values for comparing the pharmacist and technician checkers were computed using SAS, version 6.12 (SAS Institute, Cary, NC). An additional analysis was conducted to ensure that wide variation in accuracy rates among individual technicians did not exist, since this could result in a favorable mean accuracy rate and mask the performance of one or more technicians who performed below the established goal of 99.8%. Mixed-effects logistic regression models with a random-checker effect were used to confirm the results.

Results

Twenty-nine pharmacists (15 at CSMC, 14 at LBMMC) participated in Phase I of the study to supply baseline data of the checking accuracy of pharmacists. A total of 41 technicians (24 at CSMC, 16 at LBMMC, and 1 working at both), three of whom were interns, participated in Phase II of the study. All 41 technicians successfully completed the didactic training, 39 successfully completed the audits and became certified checkers for Phase III, and 2 technicians (including 1 of the interns) did not complete the certification audits because they were reassigned or had resigned.

Table 1 lists the combined-institution accuracy rates of pharmacist and technician checkers in Phase I and II, respectively. For technicians, both the observed average accuracy rate and its lower confidence limit exceeded the minimum requirement of 99.8% for a certified checker. The difference in accuracy rates between pharmacists and technicians was significant ($p < 0.0001$). Interestingly, the mean accuracy rates for technicians were identical at the two institutions ($p = 1.0$). The two pharmacy interns had accuracy rates of 99.89% and 99.97%. One technician had an accuracy rate of 99.75%, which was just below the target rate, and subsequently met the minimum requirement and became certified after the next audit.

In Phase III, all certified technicians at both institutions maintained a minimum accuracy of 99.8% during their monthly and quarterly audits. Phase III began in April 1999; through December 2001, no certified technician checker had failed any quality assurance audits. However, some technicians were removed from the list of certified checkers during the study period because of work reassignments or other non-study-related issues. The board of pharmacy was continually updated on the names of certified technician checkers in the semiannual reports submitted.

Discussion

The proposition of allowing trained technicians to check unit dose medication cassettes filled by other technicians has been hotly debated in California in the past decade (appendix). This study's results appear to support the ability of well-trained technicians to accurately check unit dose medications.

Several studies have been published evaluating the accuracy of pharmacy technicians in checking other technicians in a unit dose medication fill system.[7-13] Our results corroborate the findings from these studies; in fact, we observed a higher accuracy rate for technicians than for pharmacists ($p < 0.0001$). The boards of pharmacy in Kansas, Minnesota, and Washington currently allow technicians to check unit dose medication cassettes filled by other technicians. In addition, the American Society of Health-System Pharmacists and the

Table 1.
Accuracy of Pharmacists and Technicians in Checking Unit Dose Medication Cassettes

Checker	No. Participants	No. Doses Checked	Mean Accuracy Rate(%)[a]	95% Confidence Interval (%)
Pharmacists	29	35,829	99.52	99.44–99.58
Technicians[b]	39	161,740	99.89	99.87–99.90

[a]The difference in accuracy rates between pharmacists and technicians is significant ($p < 0.0001$), using mixed-effects logistic regression models.
[b]Includes two pharmacy interns who were employed and functioning as technicians.

California Society of Health-System Pharmacists (professional policy 9801, October 1998) support the role of the technician in checking unit dose medication cassettes.

The expansion of the technician's role has been shown to increase pharmacists' productivity.[14] We estimated that pharmacists at each institution spent approximately one hour per day per pharmacist checking unit dose medication cassettes before the program was implemented. In this experimental program, the pharmacists were able to use this additional time to expand clinical services and respond to drug therapy-related requests from physicians, such as dosing recommendations. The training and auditing of technicians for checking medication cassettes are centralized and carried out by the technician supervisor, who is under the direction of a pharmacist manager. By centralizing this responsibility, decentralized pharmacists gain additional time for direct patient care activities. Also, pharmacists at both institutions have reported an increase in job satisfaction after implementing the experimental program.

When evaluating the study results, some limitations should be acknowledged. The pharmacist checkers selected to determine the baseline accuracy rate of checking unit dose medication cassettes were those who happened to be staffing the inpatient areas on the dates that the audits were performed. Neither the pharmacist checkers nor the dates of the audits were randomized. The pharmacists and the technicians were cognizant of the study, although they did not necessarily know when audits were to be conducted. Artificial errors introduced were not randomized using a random numbers table but were based on the judgment of the pharmacist auditors who attempted to introduce a variety of different errors. The auditors at each institution introduced errors independently. In addition, the severity of errors was not defined in the study; therefore, this information was not included in the results.

The results of this study were presented to the California State Board of Pharmacy, which is now reconsidering allowing technicians to check unit dose cassettes filled by other technicians in the inpatient setting, under the same conditions of this study. The waiver for this study expires in December 2002. Until state regulations are changed or the expiration date is reached, both institutions will continue to gather data from the quarterly audits.

Conclusion

In this study, we concluded that pharmacy technicians who had been trained and certified in a closely supervised program that incorporates quality assurance mechanisms could safely and accurately check unit dose medication cassettes filled by other technicians.

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Appendix—History of California state regulations allowing technicians to check unit dose medication cassettes filled by other technicians

Year	State Regulation
Before 1993	Acute care hospitals in California were permitted to allow technicians to check the accuracy of technician-filled inpatient unit dose medication cassettes, under chart order exemption in the pharmacy regulations.
1993	The use of inpatient pharmacy technicians to check technicians filling unit dose cassettes was deemed unacceptable by the California State Board of Pharmacy, as evidenced by the following correspondence provided to the California Association of Hospital and Health Systems: "Please note the law does not authorize a technician to check another technician. While a technician may check another technician, the final check must always be done by a pharmacist."

Continued on next page

Appendix—History of California state regulations allowing technicians to check unit dose medication cassettes filled by other technicians *(continued)*

Year	State Regulation
1994	The Hospital Pharmacy Committee of the California State Board of Pharmacy proposed draft language to add a section to the California Code of Regulation (CCR1717) to allow pharmacy technicians to check the work of other pharmacy technicians in connection with filling unit dose medication cassettes for patients whose orders had been previously reviewed by a pharmacist.
1995	This draft language was presented in May at a board of pharmacy informational hearing.
1996	In June, as a result of failure to reach agreement over the proposed language, the board developed a technician committee. This committee was charged to evaluate the entire pharmacy technician program including changes necessary to improve the program, discuss and plan for future changes and roles of technicians, and pursue any statute or regulatory changes necessary to accommodate these practices. The committee, in an October report to the board, recommended several potential changes including asking the board to consider allowing technicians to check the work of other technicians for unit dose medication cassette filling under a waiver system that included specific provisions (e.g., functions). In response to this report, the board of pharmacy voted to move forward with regulatory action to allow technicians to check the accuracy of technicians' work in a unit dose medication cassette fill system. During this time, the board of pharmacy began to enforce the California Code of Regulations relating to the use of technicians for checking of unit dose medication cassettes and required facilities to discontinue the practice.
1997	In May, responding to requests from multiple health systems and the California Society of Health-System Pharmacists, the board of pharmacy gave notice of its intent to amend regulations to allow technician checking of technician-filled unit dose medication cassettes. All interested parties were provided an opportunity to provide oral testimony at the proposal hearing in July. At that time, the board of pharmacy did not approve moving forward with the amended regulations. In response to the many delays in reaching consensus to change current regulations, representatives from LBMMC and CSMC developed the proposal in collaboration with the University of California, San Francisco, School of Pharmacy to perform a study in order to provide the board with objective data.
1998	On May 27, the board granted the requested waiver of the California Code of Regulations to conduct the "experimental program." The waiver was initially granted until November 1, 2000. However, the waiver was subsequently extended until February 1, 2001.
2001	In January, having reviewed the results of this study, the board extended the waiver until December 2002.

Evaluation of the Impact of Pharmacists in the Prevention of Medication Errors Associated with Prescribing and Administration of Medications in the Hospital Setting

Summary of Results

June 21st 2004 - May 22nd 2005

A Collaborative Study Between
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
SCHOOL OF PHARMACY
and the
Pharmacy Services Department of
CEDARS-SINAI MEDICAL CENTER

Background

- Study to determine the impact of pharmacists on prevention of medication errors during the equivalent time spent on checking medication cassettes
- 2 year study (waiver) allows technicians to check technicians filled medication cassettes
- The number and types of medication errors prevented at the prescribing step (order written by the physician) and at the administration step (medication administered by the nurse) of the medication use process will be reported

Study Objectives

- Determine top 10 drugs involved in potential prescribing and administration errors
- Determine type and frequency of medication ***errors intercepted*** at the prescribing and administration steps
- Compare ***intercepted errors*** with USP MedMARX data on errors
- Evaluate factors contributing to prescribing and medication administration errors
- Evaluate potential harm that could have resulted if error was not intercepted

Medication Related Encounters

June 21st 2004 - May 22nd 2005 (48 weeks)

Total Medication Related Encounters: **28,969 (603/week)**

- Potential Errors Intercepted (prevented): **1296**

Medication Prescribing :	885 (68%)
Medication Administration:	411 (32%)

- Other Medication Related Encounters :

Pharmacist dosing per MD request:	25,342
STAT orders:	360
Rounds:	58
Code Blue:	29
Drug Information:	1661

Medication Prescribing
Potential Errors Intercepted
June 21st 2004 - May 22nd 2005 (48 weeks)

- Potential prescribing errors prevented by the pharmacist: 885
- Orders requiring clarification: 534 (type of error not specified)
- Types of medication ***errors intercepted which prevented****:

Wrong Dose	48.9 %	Medication Contraindicated	3.1 %
Allergy Contraindication	21.7 %	Drug Interaction	2.3 %
Necessary medications not ordered	11.7 %	Wrong Frequency/Rate	2.0 %
Duplication in therapy	5.7 %	Wrong Drug	0.6 %
Wrong Route	4.0 %		

* In those situations where error type was specified

Additionally, there were 57 incomplete orders requiring clarification.

Examples of Medication Prescribing Errors Prevented

Problem Identified	Pharmacist Recommendation	Outcome Avoided
Ganciclovir: 5mg/kg iv q12h pt s/p kidney transplant & renal insufficiency	Pharmacist recommended 2.5mg/kg/day for CMV induction	*Avoided adverse drug reaction (ADR) from overdose*
Oxaliplatin (chemotherapy) dosage in patient with renal insufficiency	Pharmacist recommended dosage adjustment	*Avoided ADR due to excessive dose of chemotherapy*
Celebrex ordered in patient with sulfa allergy	Pharmacist recommended alternative	*Avoided morbidity associated with an allergic reaction*
Ceftazidime ordered as 1 gm q8h for meningitis in young patient	Pharmacist recommended 2 gm q8h to achieve adequate effect	*Avoided sub-optimal treatment, possible mortality/morbidity*
Lovenox 40 mg daily ordered in patient with chronic renal failure	Pharmacist recommended change to Heparin	*Avoided increased risk of bleeding in patient already receiving blood transfusions*

Medication Administration
Potential Errors Intercepted
June 21st 2004 - May 22nd 2005 (48 weeks)

Potential medication administration errors prevented by a pharmacist: 411 encounters

Types of medication ***errors intercepted which prevented:***

Omission of Dose	41.2 %	Wrong Rate	5.5 %
Transcription Error	13.9 %	Wrong Drug	4.8 %
Wrong Dose	8.1 %	Drug to be given to patient was not ordered	3.8 %
Wrong Patient	6.0 %	Wrong Route	3.1 %
Extra Dose	7.9 %		
Delay in Dose	5.7 %		

Examples of Medication Administration Errors Prevented

Problem Identified	Pharmacist Recommendation	Outcome Avoided
Pt. scheduled for chemotherapy in AM.	Pharmacist identified that chemo was not given	*Avoided omission of chemotherapy*
Pt was about to receive Tobramycin at a 12 hr interval; order was for q24h	Pharmacist notified nurse that dose was to be given every 24 hr	*Avoided potential renal (kidney) toxicity*
PCA pump was programmed incorrectly	Pharmacist notified nurse	*Avoided potential adverse events associated with excessive narcotic dose*
Pt receiving Potassium Chloride 60meq infusion; order was for 20meq	Pharmacist notified nurse to change infusion	*Avoided potential hyperkalemia and cardiac arrest*
Nurse transcribed Kayexalate when Kaopectate ordered	Pharmacist notified nurse about transcription error	*Avoided potential hypokalemia and cardiac toxicity*

Results compared to USP MedMARX Data

Leading types of errors include:

	USP MedMarx Data 2003[1]	Research Study
Omission error	24 %	22.7 %
Improper dose/quantity	23 %	26.4 %
Unauthorized drug	10 %	2.1 %
Extra dose	5 %	4.2 %
Wrong patient	5 %	3.3 %
Wrong route	2 %	3.4 %

1. http://www.magnetmail.net/actions/email_web_version.cfm?recipient_id=9223078&message_id=63691&user_id=USP

TOP 10 Medications/Classes

June 21st 2004 - May 22nd 2005 (48 weeks)

Top 10 medications/classes involved in potential prescribing and administration errors

Medication Prescribing

- Chemotherapy
- Electrolytes
- Enoxaparin (Lovenox)
- Vancomycin
- Warfarin
- Levofloxacin
- Neupogen
- Fluconazole
- Cefepime
- TPN

Medication Administration

- Vancomycin
- Heparin
- Chemotherapy
- Electrolytes
- TPN
- Erythropoietin
- Warfarin
- Fluconazole
- Insulin
- Levofloxacin

Preliminary Evaluation of Potential Patient Outcomes

Pharmacist prevented medications errors associated with potential harm: 422

No Harm	340
Temporary Harm	387
Permanent Harm	11
Increase in Length of Stay	23
Death	1
Type of harm unspecified	534

Factors Contributing to Prescribing Errors

- Incomplete patient information
- Drug allergies overlooked
- Wrong drug name, dosage form or abbreviation
- Incorrect dosage calculations
- Incorrect dosage frequency
- Laboratory results not checked prior to ordering medications
- Concomitant therapy (e.g. supportive drugs for chemotherapy) necessary to prevent adverse reactions not ordered

Factors Contributing to Administration Errors

- Two patient identifiers not used
- Illegible orders
- Drug name confusion
- Incorrect pump programming
- Patients transferred and orders not transcribed accurately
- Environmental factors- distractions, interruptions and significant workload
- Staffing issues- such as shift changes and floating staff

Summary of Study Results to Date

Results of the 48 week study demonstrates the impact of pharmacists on prescribing and administration errors:

- 1296 errors intercepted by the pharmacist
- 27450 medication related encounters including dosing of medications per MD request, participation in codes, rounds and drug information questions
- Preliminary evaluation of outcomes: 422 pharmacist encounters prevented potential harm of which:
  - 387 prevented temporary harm
  - 11 prevented permanent harm
  - 23 prevented an increase in length of stay
  - 1 prevented death

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Regulation Proposals for 2006

Attachment 2

PROPOSED REPEAL
TITLE 16 CCR SECTION 1786

~~**1786. Exemptions.**~~

~~(a) If a person, on the basis of whose qualifications a certificate of exemption has been granted under Business and Professions Code Section 4054, leaves the employ of a supplier, said supplier shall immediately return the certificate of exemption to the board.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4051, 4053 and 4054, Business and Professions Code.~~

Regulation Proposals for 2006

Attachment 3

Board of Pharmacy

Revised Language – January 26, 2006

Adopt Section 1713 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1713. Receipt and Delivery of Prescriptions.

(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 refilled prescriptions 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 ~~for delivery of prescriptions using the device~~.
(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 prescriptions 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 ~~dispense~~ deliver refill prescriptions 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 a means for each patient to obtain an immediate via telephone or in-person consultation with a pharmacist if requested by the patient.
(6) The device is located adjacent to the licensed pharmacy counter.
(7) The device is secure from access and removal by unauthorized individuals.
(8) The pharmacy is responsible for the prescriptions stored in the device.
(9) Any prescription, or delivery errors or omissions, or complaints from patients, arising from use of the device, are 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, 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 filling procedures for the automated delivery device.
(5) Orienting participating patients on use of the automated delivery device, notifying patients when expected prescriptions 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 prescriptions 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.

Note: Authority cited: Sections 4005 Business and Professions Code. Reference: Sections 4005, 4052, 4116 and 4117 Business and Professions Code.

Amend Section 1717 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1717. ~~Pharmaceutical~~ Pharmacy Practice.

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.
Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:
(1) a patient med pak is reused only for the same patient;
(2) no more than a one-month supply is dispensed at one time; and
(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."
(b) In addition to the requirements of Business and Professions Code Section 4040 ~~4036, Business and Professions Code~~, the following information shall be maintained for each prescription on file and shall be readily retrievable:
(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist ~~preceptor~~ before they are dispensed.
(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and
(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.
(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing.
Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.
(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.
(e) ~~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.~~
~~However, 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. The Board may in its sole discretion waive this application of the regulation for good cause shown.~~

~~(f)~~ A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, 1306.26.

Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of Section 1716. Information maintained by each pharmacy shall at least include:

(1) Identification of pharmacist(s) transferring information;
(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;
(3) Original date and last dispensing date;
(4) Number of refills and date originally authorized;
(5) Number of refills remaining but not dispensed;
(6) Number of refills transferred.

~~(g)~~ (f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Note: Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

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

EXCERPT

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES

DATE: **October 25 and 26, 2005**

LOCATION: **Crowne Plaza San Francisco Airport**
San Diego Mission Valley
1177 Airport Blvd.
Burlingame, CA 94010

BOARD MEMBERS PRESENT:

Stanley Goldenberg, President
William Powers, Vice President
Marian Balay
Richard Benson
Ruth Conroy
David Fong
Clarence Hiura
John Jones
Kenneth Schell
Andrea Zinder

STAFF PRESENT:

Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judith Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Dennis Ming, Supervising Inspector
Joshua Room, Deputy Attorney General
LaVonne Powell, Department of Consumer Affairs Legal Counsel
Jan Perez, Legislative Coordinator

REGULATION HEARING

- **Prescription Drop Boxes and Automated Self-Use Delivery Devices for Refill Prescriptions – Proposed Amendment to Repeal 16 California Code of Regulations Section 1717(e) and add 16 California Code of Regulations Section 1713**

President Goldenberg read the following:

This hearing is to consider adopting requirements for prescription drop boxes and automated self-use delivery devices for refill prescriptions; proposed amendment to repeal 16 CCR § 1717(e) and to add 16 CCR 16, §1713, as outlined in the public notice.

At this time, the hearing will be opened to take oral testimony and/or documentary evidence by any person interested in these regulations for the record which is now being made by tape recorder. All oral testimony and documentary evidence will be considered by the Board pursuant to the requirements of the Administrative Procedure Act before the Board formally adopts the proposed amendment to these regulations or recommends changes which may evolve as a result of this hearing.

If any interested person desires to provide oral testimony there is a sign-up sheet in the back of the room. It will be appreciated if the person commenting comes forward and give his or her name and address, and if he or she represents an organization, the name of such organization, so that we will have a clear record of all those who appear.

Please keep in mind the following when making comments:

A. This is a public forum to receive comments on the proposed regulations. It is not intended to be a forum for debate or defense of the regulations.

B. Written testimony may be summarized but should not be read. The board will give equal consideration to written and oral testimony.

C. If you have a question about a proposed regulation, please re-phrase your question as a comment. For example, instead of asking what a particular subdivision means, you should state that the language is unclear, and explain why you find it to be unclear.

After all interested parties have been heard, the issue will stand submitted.

President Goldenberg asked if there were any questions concerning the nature of the proceedings or the procedure to be followed.

President Goldenberg stated that the board is conducting a regulation hearing to establish requirements for prescription drop boxes and automated self-use delivery devices for refill prescriptions; proposed amendment to repeal 16 CCR Section 1717(e) and to add 16 CCR Section 1713. The 45-day notice for the regulation hearing was published on August 16, 2005. A copy of the Notice, Initial Statement of Reasons, and proposed language was provided to the board as well as the public.

President Goldenberg stated that the board received eight written comments by the close of the comment period on October 10, 2005. He stated that Bill Marcus and the California Pharmacist Association (CPhA provided substantial comments). Upon review of the comments received, staff revised the proposed language to incorporate some of the recommended changes and drafted a new version of Section 1713, dated October 19, 2005.

The following comments were made:

- **Bill Marcus**

Mr. Marcus referred to the comments he submitted in a letter dated October 10, 2005. He was pleased that staff revised the regulation language [October 19th revisions] based on written comments received prior to the hearing. He referred to a disagreement between he and John Cronin regarding Mr. Cronins' suggestion for a waiver process and stated that he did not feel that a waiver process is necessary.

Mr. Marcus stated that he has concerns about the use of kiosks because of the importance the board places on pharmacist contact for patients. Mr. Marcus believes there is a demonstrated need to adopt the regulation with changes recommended by he and Mr. Cronin.

- **Frederick Mayer, representing PPSI**

Mr. Mayer presented written comments from six pharmacists to the board.

Mr. Mayer referred to the board's Notice to Consumer where it states: "Talk to your Pharmacist" and he added that this doesn't fit in when you stock a kiosk with drugs. Mr. Mayer stated that these devices are distinct from the role of the pharmacist

Mr. Mayer referred to page 16 of his written comments submitted at the hearing, where Aetna plans to add a list of drugs to kiosks in doctor's offices and asked if the pharmacist does not have to counsel anymore or look at the screen. He asked if the doctors have to counsel and look at the screen.

Mr. Mayer's main concerns were:

1. The location of the machines.
2. Hours of use of the machines.
3. Lack of consultation with a pharmacist.
4. The types of drugs placed in the machines.

Mr. Mayer thanked the board for the opportunity to testify.

Mr. Mayer asked that board members Dave Fong, Ken Schell and Ruth Conroy recuse themselves from voting because he felt that this would be a conflict of interest because of the companies they work for.

- **David Schieser**

Mr. Schieser stated his concern was about the loss of patient consultation. He added that when he began practicing as a pharmacist, pharmacists were not allowed to talk to patients about their drugs because this was the doctor's job. He added that now that pharmacists have the training and education, everything has changed, and he felt that this was the wrong direction to take.

- **Jim Gross, representing the California Pharmacists Association**

Mr. Gross referred to the waiver process and the difference of opinion between Mr. Marcus and the CPhA.

Mr. Gross stated that the CPhA believes that it is appropriate and necessary for the entities that install and use these devices to have an established process to present to the board on how they will be used and monitored. He added that without this process, the waiver process would become automatic.

Mr. Gross referred to Mr. Mayer's comments about the problem of allowing these devices to be distinct from the role of the pharmacist. He added that he knows that the board does not want that to occur and values the cognitive role of the pharmacy, the oversight of the dispensing prescriptions. He added that the numerous changes made to the noticed language are reflected in the October 19th language. However, if the process is not to be reviewed by the board anyway, there is legitimate concern of falling victim to these devices. He encouraged the board to consider this requirement. He added that more pro-active steps should be required.

Mr. Gross referred to the October 19th revised language, section 1713 (d)(9), where it states: "Any prescription or delivery errors or omissions arising from use of the device are reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125", and he added that the CPhA feels that this fails to address a likely occurrence from the consumer about whether the device is working correctly. And it does not provide for consent.

In response to Mr. Gross' comments, Mr. Room referred to the October 19th revised language, section 1713 (d)(1) where it states "Each patient using the device has chosen and signed a written consent form for delivery of prescriptions using the device."

Mr. Room referred to changes made from the noticed version to the October 19th revised language to section 1713 (e)(5), where it states "Orienting participating patients on use of the automated delivery device and ensuring that patient use of the device does not interfere with delivery of prescription medications."

Mr. Gross added that the CPhA does not believe the October 19th revised language adequately addresses the problem of notifying patients when a prescription is not available and will not be dispensed in the device when it had been dispensed previously. He felt section 1713 (e)(5) was too general. He added that it is important that entities have ongoing communication with patients about any change to the system such as how prescriptions are dispensed or when a particular drugs cannot be used in the unit.

- **Rod Bingaman, representing Safeway**

Mr. Bingaman commended the board on taking positive action to embrace new tools and robotics. He added that the board has taken a positive approach to this.

Mr. Bingaman referred to two suggestions he submitted in his letter dated October 7, 2005. He asked for more clarification on the word "adjacent." He clarified that the unit is basically for refill prescriptions only.

Mr. Bingaman asked that the board to consider this as an evolving tool to technology. He added that we need this type of technology for busy families.

Mr. Jones asked Mr. Bingaman if he wanted the board to specify how close the unit must be to the pharmacy.

Mr. Bingaman referred to the revised language that states "adjacent to the pharmacy counter." He added that this would require the unit to be next to the pharmacy area and cause pharmacy congestion. He suggested that the board include general language in a header of section 1713, authorizing the use of the unit when the pharmacy is closed and when a pharmacist is not present. He added that there are provisions for a 1-800 number or contact that provides consumers with the ability to contact a pharmacist by telephone.

Mr. Bingaman suggested that a pharmacy could use mail delivery for prescriptions if a machine failed to work or shut down due to system failure.

- **Raymond Smith, representing the UCSD Medical Center**

Mr. Smith stated that he supports the original noticed language and has general support for the modified language. He referred to section 1713 (d)(5) where it states "The pharmacy provides a means for each patient to obtain an immediate consultation with a pharmacist if requested by the patient." He added that consultation could be provided by telephone, and not necessarily provided in person. He asked for clarity.

Mr. Smith referred to section 1713 (d)(6) where it states: "The device is located adjacent to the licensed pharmacy counter." He added that a hospital pharmacy or clinic pharmacy might not have a traditional pharmacy counter but instead have an opening in the wall in a lobby. He added that this could cause difficulty in interpretation.

Mr. Smith stated that he prefers that the language state that the device be located within the licensed clinic facility or health care facility and not necessarily within sight of the pharmacy counter or pharmacy opening itself. He added that he would support either proposal as written.

- **Shane Gusman, Counsel on behalf of the United Food and Commercial Workers, representing pharmacists and pharmacy personnel in the retail setting**

Mr. Gusman stated that this proposal seems to be going in the opposite direction of freeing up the pharmacist so the pharmacist can provide patient consultation. He suggested that a study be conducted because there isn't enough information on these devices.

Mr. Gusman referred to the regulation and stated that it should be clear on patient consent forms and what to expect, such as when the machine breaks down. Also, the pharmacist is responsible if the machine breaks down and this is problematic.

Mr. Gusman referred to the proposal to delete section 1717 (e) and he stated that he did not feel that deleting the entire paragraph is necessary. He suggested instead to only delete the statement "unless as required under section 1713" and leave in the rest of the language.

Dr. Fong referred to mail order pharmacy where patients have access to a pharmacist and have options for patients if the machine breaks down.

- **Bob Hansen, representing Asteres**

  Mr. Hansen stated that prescription receipts printed by the machine have a 1-800 number on them that a patient can call if they would like a consultation with a pharmacist after the patient has left the pharmacy. Additionally, a 1-800 number could be posted so if the machine fails to deliver a prescription, a patient could call the number and have their prescription delivered to them.

  Mr. Hansen stated that many of the issues have already been addressed during previous meetings. He agreed that the pharmacist should be available for consultation and that patients need to know the type of drugs that will be dispensed from the machine.

  Mr. Hansen stated that for after hours use, these machines must be running correctly or people won't use them or purchase them.

- **William Holmes, President of ddn Corp.**

  Mr. Holmes represents another vendor for this type of technology. He the machine were installed in Utah three years ago and no errors have been reported in using the machines.

- **Cookie Quandt, representing Longs Drugs**

  Dr. Quandt stated that last October the discussion of automated delivery system was first discussed. She stated that errors occur more frequently in the pharmacy so this system is even more reliable. No instances have occurred where the machine delivered the wrong prescription to the wrong patient. Sometimes clerks deliver the wrong prescription to the wrong patient.

  Dr. Quandt added that this is not a dispensing unit and she feels that there is some misconception. It does not dispense drugs into a vial for a patient. A pharmacist must first check a prescription even if it is filled by a technician, prior to going into the unit. Each and every prescription is checked. Also, a drug utilization review is conducted on the medication, check for theraputic duplication.

  Ms. Quandt stated that the automated delivery system does not replace the pharmacist. The patient still comes into the pharmacy and the pharmacist is still available for the patient. For after hour prescriptions when patients have questions, a 1-800 number is provided. She added that the number of calls placed to pharmacists using the 1-800 number has only been 10 calls. She added that they have moved very slowly in implementing the units at Longs.

  Dr. Quandt referred to concerns about the consent forms and added that before patients sign up they are made aware of medications that would not be filled by the dispensing unit and it is the pharmacist's discretion whether to dispense from the unit.

  If a consumer chooses to discontinue using the unit, it is very easy for them to opt by telling the pharmacy staff and there is no pressure placed on the patient. She added that the unit provides greater HIPPA protection.

President Goldenberg closed the proceedings of the regulation hearing and thanked the audience for their testimony.

Chairperson Jones stated that staff published a 45-day notice on August 16, 2005, to establish requirements for the placement and use of secure prescription drop-off boxes and secure automated delivery devices. The notice period ended on October 10, 2005. He added that if the board adopts this regulation, the rulemaking package will be submitted for administrative review in November 2005; the regulation should be in place by early 2006. If the board makes modifications, a 15-day comment period will be required.

MOTION: That the board adopt an amendment to repeal CCR § 1717(e) and to add 16 CCR 16 § 1713 – Prescription Drop Boxes and Automated Self-Use Delivery Device for Refill Prescriptions

M/S/C: CONROY/FONG

Mr. Hiura requested clarification of the meaning of adjacent to the pharmacy.

Staff Counsel LaVonne Powell stated that the pharmacy must have control of the area where the unit is placed and the area must be secure.

Chairperson Jones stated that if the patient receives their medication from the unit, and then feels that they need to speak to the pharmacist, the pharmacy should be in view of the unit.

Mr. Room recommended that the unit be no more than 10 feet from the pharmacy.

Mr. Fong stated that it is important to have proper controls, security and specific criteria for these units and he feels that these units compliment what is already offered by the pharmacy. He added that he supports having the unit in close proximity, if not adjacent to the licensed area.

Mr. Hiura expressed concern regarding the 24-hour telephone access and asked if this ties in directly with the pharmacy.

Mr. Powers stated that he continues to have concerns and although he supports new technology, it must be beneficial to consumers, rather than just a cost-saving money for corporation. He suggested that each pharmacy have a pharmacy plan and that a study be conducted. He cautioned the board not to move to quickly.

Mr. Fong stated that the regulation should address the areas of concern and options for patients if the machine does not work as well as telephone access.

Ms. Zinder recommended amendments to the language that pharmacist would not be disciplined for using their discretion and that the unit could only be used after the patient received consultation regarding the prescription.

MOTION: That the board table the motion to adopt the proposed amendment to repeal 16 CCR § 1717 (e) and to add 16 CCR 16, § 1713 – Prescription Drop Boxes and Automated Self-Use Delivery Device for Refill Prescription

M/S/C: POWERS/SCHELL

SUPPORT: 4 OPPOSE: 5

MOTION: That the board adopt the proposed amendment to repeal 16 CCR § 1717 (e) and to add 16 CCR 16 § 1713 – Prescription Drop Boxes and Automated Self-Use Delivery Device for Refill Prescription

Mr. Schell stated that he continues to have concerns regarding the proposed regulations.

SUPPORT: 3 OPPOSE: 5 ABSTAIN: 1

January 12, 2006

Patricia Harris
Executive Officer
California State Board of Pharmacy
1625 North Market Boulevard, Suite N219
Sacramento, CA 95834

Ms. Harris:

Asteres Inc. appreciates the on-going interest the Board has had in ScriptCenter®, a prescription refill delivery kiosk. We have made efforts to ensure the Board is knowledgeable about the system, including having the Board visit our office for a demonstration back in July of 2004. Additionally, Asteres has solicited guidance from the Board to ensure our practices are consistent with your expectations.

Asteres has gained much experience since the initial installation in December, 2004, and believe the technology has performed well in the marketplace. Several State Boards have approved the use of ScriptCenter in their states; see attached document for details. The time is right for the Board to support the proposed regulation change that would allow usage of automated delivery devices without requiring each retailer to obtain a waiver. To that end, Asteres will share with the Board a summary of our experiences with ScriptCenter thus far.

- As of the end of 2005, there were seven ScriptCenters installed (Six in California and one in Virginia)
- Almost 5000 people have signed up to use ScriptCenter.
- Nearly 19,000 individual prescriptions have been delivered by ScriptCenter.
- Uptime during the first month of usage showed that ScriptCenter was up almost 99% of the time during store hours.

System performance has been very good, but there have been issues on occasion, most commonly:

<u>Unknown bag</u>

- Description: ScriptCenter cannot read the bar code on the ScriptCenter bag, usually due to a bar code scanner failure.
- ScriptCenter Action: The bag is moved to a specific tray, and ScriptCenter goes out of service.

<u>Bag stuck on hooks</u>

- Description: A bag is stuck on the hooks and is not moved to its intended location. This is usually due to a bar code scanner failure, though sometimes it is a general hardware failure.

- ScriptCenter Action: The bag is left on the hooks, and ScriptCenter goes out of service.

Failure moving bag:

- Description: ScriptCenter occasionally fails when moving bags within the machine.
- ScriptCenter Action: ScriptCenter automatically goes out of service and remains out of service until the bag in question is removed by the pharmacy staff.

In each of the cases above, the pharmacy staff must remove the bag before the system can go back in service. Asteres treats every system issue very seriously, and continues to improve the reliability of ScriptCenter.

Asteres is very interested in consumer reaction to ScriptCenter. Over 80 customers have completed a survey about ScriptCenter, with the results being very positive. For all three of the following questions, the average response was somewhere between the two highest measures:

- How satisfied are you with ScriptCenter?
- How likely is it that you will use ScriptCenter after hours (when the pharmacy is closed)?
- Would you recommend ScriptCenter to others?

Customers have included comments on their surveys as well:

"This is the best thing Longs could have done. I hope other pharmacies follow. Thank you!"

"New prescriptions, please."

"I have now used the ScriptCenter twice and have found it to be a quick, no-nonsense alternative to standing in line for refill prescriptions."

ScriptCenter technology has been positively received by both consumers and retailers alike. While the system has occasional failures, in none of the almost 18,000 transactions has ScriptCenter delivered a wrong prescription to a consumer. Asteres urges the Board to approve the regulation change to prevent barriers to using this beneficial new system.

Sincerely,
Bob Hansen, PharmD.
Vice President Pharmacy Services
Asteres Inc.

State Board of Pharmacy Approvals and Conditions
Granted to Asteres Inc. as of December 31, 2005
Provided to the Board by Bob Hansen, PharmD, Asteres Inc.

CALIFORNIA: currently granting waivers to allow refill prescriptions not requiring consultation. The waiver also allows for prescription pick-up even if the pharmacy is closed providing the patient can receive a consultation on his or her medications when the pharmacy is closed.

HAWAII: currently may be used for new or refill, non-scheduled drug prescriptions that do not require the offer of consultation (OBRA 90 patients). The machine can only be used when the pharmacy is open.

VIRGINIA: has granted a one store pilot to use ScriptCenter for refills only. The pilot allows for prescription pick-up if the pharmacy is closed provided a patient can receive a consultation on his or her medications when the pharmacy is closed.

NEW YORK: may be used for refill prescriptions of non-scheduled drugs, but only when the pharmacy is open.

OHIO: pending a final inspection ScriptCenter can be used under the following conditions: (1) it is to be accessible only when the pharmacy department is open for business. (2) Access to the machine by both staff and patients must be in compliance with
The board's definition of positive identification (4729-5-01(N)OAC). (3) Controlled substances may be included in the medications in the machine. (4) The system may be used for both new and refill prescriptions. (5) The system must be physically attached to the Pharmacy Department with access only from inside the business. (6) The system must comply with all of the Board's record keeping requirements. (7) The offer to counsel must occur after the patient selects the products to be obtained.

MARYLAND: Ahold had requested to be able to use ScriptCenter for all prescriptions and to be able to deliver prescriptions only when the pharmacy was open. The Board's response was "As long as a pharmacist is present, the ScriptCenter device appears to be in compliance with the Maryland Pharmacy Act".

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Longs Drugs

General Offices: 141 North Civic Drive, P.O. Box 5222, Walnut Creek, California 94596, (925) 937-1170

Telephone: (925) 979-3931
Fax: (926) 210-6222
E-mail: mcantrell@longs.com

SENT VIA FAX AND U.S. MAIL

January 16, 2006

Patricia Harris
Executive Director
California State Board of Pharmacy
1625 North Market Blvd., Suite N 219
Sacramento, CA 95834

Dear Ms. Harris:

The first ScriptCenter® was put into service at Longs Drug Store #247 Del Mar, California in December 2004. Subsequently, three additional units have been deployed in California—one in the north and two in the south. To date, approximately 4,000 patients are registered users & almost 19,000 prescription refills have been delivered to patients via the ScriptCenter®. The experience of our pharmacists has been that these units enjoy superior up-time and deliver prescriptions in an extremely reliable manner. The manufacturer, Asteres, has also provided our pharmacists and pharmacy staff with excellent user training and instructive materials.

Interestingly, the most popular time for patient utilization of the ScriptCenter® is between the hours of 4:00 and 7:00 pm. The units see only minimal use (approximately 5% of the total transactions) when the pharmacies are closed, but the remainder of the store is open. Even though a limited number of transactions occur after the pharmacy is closed, patients who use a ScriptCenter® still have access to a pharmacist at a nearby Longs 24-hour pharmacy, in the event they have a question about the prescription they are picking up or the unit is temporarily out of service. To date, I am aware of only one such instance where the ScriptCenter® unit was out of service after the pharmacy was closed. When the unit was brought back up, all planned processes performed as expected.

Longs Drug Stores realizes there can be instances when placement of a registered user's refill prescription in the ScriptCenter® might be inappropriate. We therefore rely entirely on the professional judgment of our pharmacists to decide whether a particular prescription should be placed in the ScriptCenter® or not.

These units offer our patients an alternate, yet convenient, prescription delivery system. Since the unit may not be practical for everyone, patients are not required to use the units and may opt-in or opt-out at any time. In addition, patients who use the ScriptCenter® during normal pharmacy hours still have the opportunity to speak with a pharmacist, face-to-face. We also have found that patients who use the ScriptCenter® are much more likely to pick up a filled prescription, as compared to the pharmacy's general patient population. Thus, we believe the unit may increase a patient's compliance with their drug regimen, thereby improving the patient's clinical outcome. Many patients have provided written comments about the ScriptCenter®, its ease of use, etc. and a sample of the Emails Longs has received, is also included.

In summary, the ScriptCenter® provides a safe, easy, convenient and accurate method for patients to receive their prescription refills. Patients are free to opt-in or opt-out of the program at any time, as they choose. Pharmacists are instrumental is providing the professional oversight of the program. While the

ScriptCenter® still allows patients face-to-face access to a pharmacist during regular pharmacy hours, it also allows late night access to a Longs pharmacist when the pharmacy is closed. Finally, patients who use the ScriptCenter® appear to be more compliant in picking up their filled prescriptions. Thus, the unit may actually lead to improving a patient's clinical outcome.

Sincerely,

LONGS DRUG STORES CALIFORNIA, INC.

Michael Cantrell
Vice President Professional Services

MLC/me

Enclosures

cc: Cooky Quandt

July 20, 2005

Letter of Support for ScriptCenter provided by Longs Drugs

California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

Dear Sirs and Madams:

I had the pleasure of attending your board meeting today, July 20, 2005, and found it an interesting afternoon. The care and diligence that each item received was reassuring to me as a consumer of the pharmaceutical industry. I was hoping to address the board regarding my experience with the ScriptCenter at the Del Mar Long's, but the opportunity did not arise before I had to leave. I would like to share a few comments with you here.

I am a semi-retired, private investor; previously, I was lead international portfolio manager at Nicholas Applegate and worked very long hours, including weekends. The major consumer advantages of a ScriptCenter are quite obvious: convenience and time savings. Now you may be wondering why I would be such a proponent when I have more free time, but A-type personalities don't change very easily. The one thing we can't stand is wasting time and waiting in line is a killer for us.

Not only is Scriptcenter great for consumers, but the retailers experience advantages as well. I now have all my prescriptions filled at the Del Mar Longs. With ScriptCenter in place, I have no concerns about stopping in when I only have a few minutes because I know that is all it will take. Generally though, I spend time strolling around the store just in case there is something I might need. Needless to say, I spend more money than I was intending.

I must confess, I have not always been a loyal Del Mar Longs' customer. When I first moved to Del Mar, I thought Longs was convenient because the store was close to my home. However, I soon became very frustrated with the business hours and the 4 to 5 people generally in line ahead of me. I began getting my prescriptions filled at a grocery store in La Jolla that was physically convenient, but the major advantage was it was open 24 hours a day. In addition, the staff was exceptionally helpful and friendly. I did this for four years.

When ScriptCenter became available, I began getting my prescriptions filled back at Longs due to the greater convenience and access. I have not had any problems with ScriptCenter in terms of pharmacy errors or its operation. I find it quite straight forward and easy to use. I am an individual who takes an active responsibility for my health and would wait for a pharmacist if I had a question or concern.

Lastly, it is a great feeling to walk in when there is the usual line waiting for assistance from the pharmacy staff and I essentially get to go to the head of the line without waiting. My only concern is, with greater consumer adoption, someday I may be waiting in line again.

Respectfully submitted,

Loretta Morris
418 Seventh Street
Del Mar, CA 92014

Letter of Support for ScriptCenter provided by Longs Drugs

Jo,

What I tell my family and friends is that the ScriptCenter is a great way to order your refill and reduce your overall interaction time with the pharmacy. For me that's a great bonus. Also, the ScriptCenter allows me to pickup my prescription anytime (again ... no pharmacy dependency). This is an important factor for me with the busy schedule that I keep.

From a security perspective I feel that the system takes precautions to make sure I am who I say I am. I'm not asked to continually provide personal information e.g., insurance, ssn, etc. therefore, the logon/use of the system in a public area doesn't expose me to unnecessary security risks.

All of my prescriptions are paid for by my insurance so I haven't had the opportunity to use the billing interface.

Net-Net ... I love it ... No unnecessary waiting in lines or talking to the pharmacist assistant. It's a great convenience. I encourage everyone I know to sign up if they have the opportunity.

Evelyn Schuck

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Regulation Proposals for 2006

Attachment 4

Regulation Proposals Approved by the Committee on October 25, 2005

ITEM 1: Abandonment of Application Files

For years, the board has had a regulation that establishes provisions defining when an applicant has abandoned an application. However, applications for veterinary food-animal drug retailer, hypodermic needle and syringes, or designated representatives are not included. This proposal would make consistent the board's provisions for when an application has been abandoned.

CCR 1706.2. (a) An applicant for a license to conduct a pharmacy, non-resident pharmacy, sterile injectable compounding pharmacy~~,~~ wholesaler, out-of-state distributor, ~~or~~ clinic, veterinary food-animal drug retailer, or to sell hypodermic needle and syringes who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his, her or its file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements in effect at the time of reapplication.

(b) An applicant for a pharmacy technician license or a designated representative license who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.

(c) An applicant who fails to pay the fee for licensure as a pharmacist required by subdivision (f) of section 1749 of this Division within 12 months after being notified by the board of his or her eligibility be deemed to have abandoned the application and must file a new application and be in compliance with the requirements in effect at the time of reapplication.

(d) An applicant to take the pharmacist licensure examinations who fails to take the examinations within 12 months of being deemed eligible, shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements in effect at the time of reapplication.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4029, 4037, 4043, 4110, 4112, 4115, 4120~~,~~ 4127.1, 4160, 4161, 4180, 4190, 4200, 4201, 4202, 4203, 4204, and 4205, Business and Professions Code.

ITEM 2: Contested Citations

In 2003, the board revised its system for issuing citations to make its procedures more consistent with the procedures used by other boards within the Department of Consumer Affairs. During the revision process, a provision in CCR 1775(a) that allows a person or entity to only reschedule an informal office conference one time was left out of the revised regulations. This proposal would restore the provision to CCR 1775.4.

CCR 1775.4. (a) Any person or entity served with a citation may contest the citation by appealing to the board in writing within 30 days of the issuance of the citation. Appeals shall be conducted pursuant to the adjudication provisions of the Administrative Procedure Act. (Government Code Section 11500 et seq.)

(b) In addition to requesting a hearing, as provided for in subdivision (a), the person or entity cited may, within 14 calendar days after service of a citation, submit a written request for an informal office conference. The person or entity cited may contest any or all aspects of the citation. The informal office conference will be conducted by the executive officer or his/her designee within 30 calendars days of receiving the request. Persons or entities may reschedule an informal office conference once.
(c) The executive officer or his/her designee shall hold an informal office conference upon request as provided for in subdivision (b) with the person or entity cited and their legal counsel or authorized representative if they desire representation at the informal office conference. At the conclusion of the informal office conference, the executive officer or his/her designee may affirm, modify or dismiss the citation, including any administrative fine levied or order of abatement issued. The executive officer or his/her designee shall state in writing the reasons for their action and serve or send by certified mail, a copy of their findings and decision to the person or entity cited within 14 calendar days from the date of the informal office conference. This decision shall be deemed to be a final order with regard to the citation issued, including the administrative fine levied and/or an order of abatement.
(d) The person or entity cited does not waive their request for a hearing to contest a citation by requesting an informal office conference after which the citation is affirmed by the executive officer or his/her designee. If the citation is dismissed after the informal office conference, the request for a hearing on the matter of the citation shall be deemed to be withdrawn. If the citation, including any administrative fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. If a hearing is requested for the subsequent citation, it shall be requested within 30 days of the issuance of the subsequent citation.

Authority cited: Sections 125.9, 148 and 4005, Business and Professions Code.
Reference: Sections 125.9 and 148, Business and Professions Code.

Section 100 Changes

Section 100 changes are technical corrections made to existing regulations to make the regulation consistent with new laws or correct obvious errors (and nonsubstantive errors). This is a streamlined rulemaking process.

ITEM 3: Designation of Pharmacist in Charge

Replaces the term "exemptee-in-charge" with "designated representative-in-charge," a term added to the statutes in 2004.

CCR 1709.1. (a) The pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.
(b) The pharmacy owner shall vest the pharmacist-in-charge with adequate authority to assure compliance with the laws governing the operation of a pharmacy.
(c) No pharmacist shall be the pharmacist-in-charge of more than two pharmacies. If a pharmacist serves as pharmacist-in-charge at two pharmacies, those pharmacies shall not be separated by a driving distance of more than 50 miles.
(d) No pharmacist shall be the pharmacist-in-charge of a pharmacy while concurrently serving as the ~~exemptee-in-charge~~ designated representative-in-charge for a wholesaler or a veterinary food-animal drug retailer.
(e) Notwithstanding subdivision (a), a pharmacy may designate any pharmacist who is an employee, officer or administrator of the pharmacy or the entity which owns the

pharmacy and who is actively involved in the management of the pharmacy on a daily basis as the pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity which owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with documentation of the involvement of a pharmacist-in-charge designated pursuant to this subdivision with the pharmacy and efforts to obtain and designate a permanent pharmacist-in-charge.
(f) A pharmacist may refuse to act as a pharmacist-in-charge at a second pharmacy if the pharmacist determines, in the exercise of his or her professional judgment, that assuming responsibility for a second pharmacy would interfere with the effective performance of the pharmacist' s responsibilities under the Pharmacy Law. A pharmacist who refuses to become pharmacist-in-charge at a second pharmacy shall notify the pharmacy owner in writing of his or her determination, specifying the circumstances of concern that have led to that determination.
(g) A person employing a pharmacist may not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4113, 4305, and 4330, Business and Professions Code.

ITEM 4: Minimum Standards for Wholesalers.
Updates the USP standards to require the 2005 USP Revision.
CCR 1780. The following minimum standards shall apply to all wholesale establishments for which permits have been issued by the Board:

(a) A wholesaler shall store dangerous drugs in a secured and lockable area.
(b) All wholesaler premises, fixtures and equipment therein shall be maintained in a clean and orderly condition. Wholesale premises shall be well ventilated, free from rodents and insects, and adequately lighted. Plumbing shall be in good repair. Temperature and humidity monitoring shall be conducted to assure compliance with the United States Pharmacopeia Standards (~~1990, 22nd~~ 2005, 28th Revision).
(c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.
    (1) All facilities shall be equipped with an alarm system to detect entry after hours.
    (2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
    (3) The outside perimeter of the wholesaler premises shall be well-lighted.
(d) All materials must be examined upon receipt or before shipment.
    (1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
    (2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.
(e) The following procedures must be followed for handling returned, damaged and outdated prescription drugs.

(1) Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be placed in a quarantine area and physically separated from other drugs until they are destroyed or returned to their supplier.
(2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be placed in a quarantine area and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.
(3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug shall be destroyed or returned to the supplier unless testing or other investigation proves that the drug meets appropriate United States Pharmacopeia Standards (~~1990, 22nd~~ 2005, 28th Revision).

(f) Policies and procedures must be written and made available upon request by the board.
(1) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for maintaining records to document proper storage.
(2) The records required by paragraph (1) shall be in accordance with Title 21, Code of Federal Regulations, Section 205.50(g). These records shall be maintained for three years after disposition of the drugs.
(3) Wholesale drug distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of wholesale drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.
(4) Each wholesaler shall provide adequate training and experience to assure compliance with licensing requirements by all personnel.

(g) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, 4051, 4053, 4054, 4059, 4120, 4160, 4161 and 4304, Business and Professions Code.

ITEM 5: Minimum Standards for Veterinary Food-Animal Drug Retailers.
Replaces the term "exemptee" with "designated representative," a term added to the statutes in 2004.

CCR 1780.1. In addition to the minimum standards required of wholesalers by section 1780, the following standards shall apply to veterinary food-animal drug retailers.
a. Drugs dispensed by a veterinary food-animal drug retailer pursuant to a veterinarian's prescription to a veterinarian's client are for use on food-producing animals.
b. Repackaged within the meaning of Business and Professions Code section 4041 means that a veterinary food-animal drug retailer may break down case lots of dangerous drugs as described in 4022(a), legend drugs or extra label use drugs, so long as the seals on the individual containers are not broken. Veterinary food-animal drug retailers shall not open a container and count out or measure out any quantity of a dangerous, legend or extra label use drug.

e. When a vet retailer ~~exemptee~~ designated representative dispenses a prescription for controlled substances, the labels of the containers shall be countersigned by the prescribing veterinarian before being provided to the client.
f. Whenever a vet retailer ~~exemptee~~ designated representative dispenses to the same client for use on the same production class of food-animals, dangerous drugs, legend drugs or extra label use drugs prescribed by multiple veterinarians, the vet retailer ~~exemptee~~ designated representative shall contact the prescribing veterinarians for authorization before dispensing any drugs.
g. Refilling A Veterinarian's Prescription

(1) A veterinary food-animal drug retailer may refill a prescription only if the initial prescription is issued indicating that a specific number of refills are authorized. If no refills are indicated on the initial prescription, no refills may be dispensed. Instead, a new prescription is needed from the veterinarian.

(2) A veterinary food-animal drug retailer may not refill a veterinarian's prescription order six months after the issuance date of the initial order. Records of any refills shall be retained by the veterinary food-animal drug retailer for three years.

h. Labels affixed to a veterinary food-animal drug dispensed pursuant to Business and Professions Code section 4041 shall contain the:

(1) Active ingredients or the generic names(s) of the drug
(2) Manufacturer of the drug
(3) Strength of the drug dispensed
(4) Quantity of the drug dispensed
(5) Name of the client
(6) Species of food-producing animals for which the drug is prescribed
(7) Condition for which the drug is prescribed
(8) Directions for use
(9) Withdrawal time
(10) Cautionary statements, if any
(11) Name of the veterinarian prescriber
(12) Date dispensed
(13) Name and address of the veterinary food-animal drug retailer
(14) Prescription number or another means of identifying the prescription, and 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, etc.)
(15) Manufacturer's expiration date

i. A record of shipment or an expanded invoice shall be included in the client's shipment, and shall include the names of the drugs, quantity shipped, manufacturer's name and lot number, date of shipment and the name of the pharmacist or vet retailer ~~exemptee~~ designated representative who is responsible for the distribution. Copies of the records shall be distributed to the prescribing veterinarian and retained by the veterinary food-animal drug retailer for three years.
j. If a retailer is unable at any one time to fill the full quantity of drugs prescribed, the retailer may partially ship a portion so long as the full quantity is shipped within 30 days. When partially filling a veterinarian's prescription, a pharmacist or vet retailer ~~exemptee~~ designated representative must note on the written prescription for each date the drugs are shipped: the quantity shipped, the date shipped, and number of containers shipped, and if multiple containers are dispensed at one time, each container must be sequentially numbered (e.g., 1 of 6 containers), If a retailer is unable to dispense the full quantity prescribed within 30 days, a new veterinarian's prescription is required to dispense the remainder of the drugs originally prescribed.

k. Upon delivery of the drugs, the supplier or his or her agent shall obtain the signature of the client or the client's agent on the invoice with notations of any discrepancies, corrections or damage.

l. If a person, on the basis of whose qualifications a certificate of exemption has been granted under Business and Professions Code Section 4053 (the vet retailer ~~exemptee~~ designated representative), leaves the employ of a veterinary food-animal drug retailer, the retailer shall immediately return the certificate of exemption to the board.

m. Training of Vet Retailer ~~Exemptee~~ Designated Representative:

(1) A course of training that meets the requirements of section 4053(b)(4) shall include at least 240 hours of theoretical and practical instruction, provided that at least 40 hours are theoretical instruction stressing:

(A) Knowledge and understanding of the importance and obligations relative to drug use on food-animals and residue hazards to consumers.

(B) Knowledge and understanding of state and federal law regarding dispensing of drugs, including those prescribed by a veterinarian.

(C) Knowledge and understanding of prescription terminology, abbreviations, dosages and format, particularly for drugs prescribed by a veterinarian.

(D) Understanding of cautionary statements and withdrawal times.

(E) Knowledge and understanding of information contained in package inserts.

(2) As an alternative to the training program specified in paragraph (1), other training programs that satisfy the training requirements of 4053 include fulfillment of one of the following:

(A) Possessing a registration as a registered veterinary technician with the California Veterinary Medical Board.

(B) Being eligible to take the State Board of Pharmacy's pharmacist licensure exam or the Veterinary Medical Board's veterinarian licensure examination.

(C) Having worked at least 1,500 hours within the last three years at a veterinary food-animal drug retailer's premises working under the direct supervision of a vet retailer ~~exemptee~~ designated representative. The specific knowledge, skills and abilities listed in sections 1780.1(m)(1)(A-E) shall be learned as part of the 1500 hours of work experience. A vet retailer ~~exemptee~~ designated representative who vouches for the qualifying experience earned by an applicant for registration must do so under penalty of perjury.

Authority cited: Sections 4005 and 4197, Business and Professions Code. Reference: Sections 4040, 4041, 4053, 4059, 4063, 4070, 4081, 4196, 4197, 4198 and 4199, Business and Professions Code.

1781. Exemption Certificate.

A registered pharmacist, or ~~an~~ ~~exemptee~~ designated representative certified in accordance with Section 4053 or 4054 of the Business and Professions Code shall be present and in control of a manufacturer's or wholesaler's licensed premises during the conduct of business.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4053 or 4054, Business and Professions Code.