



California State Board of Pharmacy

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

LEGISLATION AND REGULATION COMMITTEE REPORT

Regulation Report and Action Items

1. Pending Regulations

Board Approved – Pending Administrative Approval

NO ACTION

On October 25, 2005 the board approved CCR 1727.1 to exclude the posting of pharmacist intern addresses on the Internet. This proposed regulation is currently undergoing administration review. It is anticipated that this regulation will be effective in late spring 2006.

Board Approved - Awaiting Notice

NO ACTION

Repeal CCR 1717.2, Notice of Electronic Prescription Files. The purpose for repealing the regulation is to remove a barrier that prevents pharmacists, in certain situations, from having full knowledge of all the prescription drugs that a patient is taking. Removing this barrier will result in better patient care while protecting patient medical record privacy. Staff is in the process of drafting the Initial Statement of Reasons and Notice documents so action can be taken at the April 2006 board meeting.

Amend CCR 1760, Disciplinary Guidelines. This rulemaking would allow the board to use the 2006 revision of the Disciplinary Guidelines when deciding appropriate discipline action to take for violations of Pharmacy Law. Staff anticipates it will complete its final internal review of the guidelines by the end of January 2006. At that time the Guidelines will be ready for public notice and the formal start of the rulemaking process. The matter will be brought before the board at the board's April 2006 meeting.

Add CCR 1784, Self-Assessment of a Wholesaler by the Designated Representative-In-Charge. Staff has completed its internal review of the assessment form. It will be publicly noticed and brought to the board for action at the board's April 2006 meeting.

Attached is a copy of the specific language for each proposed regulation awaiting notice.

2. Proposed Regulations -Committee Recommendations

FOR ACTION

Action Item 1: The committee recommends noticing revised language incorporating comments from the October 2005 public hearing to repeal 16 CCR section 1717(e) and to add 16 CCR section 1713 Prescription Drop Boxes and Automated Self-Use Delivery Device for Refill Prescriptions.

Discussion: At the Legislation and Regulation Committee (committee) on January 26, 2006 staff presented the committee with a revised version of 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 procedures in place to ensure the delivery of prescriptions to patients in the event that a device is disabled or malfunctions.

The committee approved moving a revised regulation to the board so the board may decide if it would like to start the rulemaking process anew with revised language.

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 by the board through January 20, 2006, are in Attachment 1.

Action Item 2: Request from the California Society 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 (Aanestad, 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.

At the committee meeting on January 26, 2006 this item was discussed. The committee, on a vote of three to one, voted to move the proposal to the board. Mr. Jones, the committee chair, asked CSHP and the California Pharmacists Association (CPhA) to work out their differences and bring an amended proposal to the board meeting on February 1, 2006.

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, a letter from CPhA, and testimony submitted by CSHP at the January 26, 2006 committee meeting are in Attachment 2.

Action Item 3: The committee recommends noticing a repeal 16 CCR Section 1786 - An Outdated Provision Related To Exemtees.

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.

Repeal Section 1786 of the California Code of Regulations, to read:

~~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.~~

Action Item 4: Abandonment of Application Files

The committee recommends noticing a proposed revision to CCR 1706.2 that would add veterinary food-animal drug retailer, hypodermic needle and syringes, and designated representatives to the regulation. [Note: Approved by the committee on October 25, 2005.]

Discussion: In 1997, the board established the provisions of 1706.2 to define when an application for a pharmacy, manufacturer, supplier, clinic, medical device retailer, or warehouse of a medical device retailer, had been abandoned. In 2005, the board updated this regulation to add non-resident pharmacy, sterile injectable compounding pharmacy to the regulation and to delete the terms, manufacturer, supplier, medical device retailer, and warehouse of a medical device retailer. This proposed regulation change would update the regulation to add veterinary food-animal drug retailer, hypodermic needle and syringes, or designated representatives to the regulation.

Revise Section 1706.2 of the California Code of Regulations, to read:

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.

Action Item 5: Contested Citations

The committee recommends noticing a proposed revision to CCR 1775.4 that would allow a person or entity to reschedule an informal office conference only one time when contesting a citation. [Note: Approved by the committee on October 25, 2005.]

Discussion: 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.

Revise Section 1775.4 of the California Code of Regulations, to read:

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 calendar 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.

Proposed Regulations - Section 100 Changes

Discussion: Section 100 changes are technical corrections made to existing regulations to make the regulation consistent with new laws or correct obvious or nonsubstantive errors. Section 100 is a streamline rulemaking process.

Action Item 6: Designation of Pharmacist in Charge

The committee recommends noticing a proposed revision to CCR 1709.1 that would replace the term “exemptee-in-charge” with “designated representative-in-

charge”. The term “designated representative-in-charge” was added to pharmacy law in 2005 by Senate Bill 1307 (Chapter 857, statutes of 2004) and became effective on January 1, 2006. [Note: Approved by the committee on October 25, 2005.]

Revise Section 1709.1 of the California Code of Regulations, to read:

- 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.

Action Item 7: Minimum Standards for Wholesalers

The committee recommends noticing a proposed revision to CCR 1780 that would update the USP standards, to require the 2005 USP Revision. [Note: Approved by the committee on October 25, 2005.]

Revise Section 1780 of the California Code of Regulations, to read:

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.

Action Item 8: Minimum Standards for Veterinary Food-Animal Drug Retailers

The committee recommends noticing a proposed revision to CCR 1780.1 and 1781 that would replace the term “exemptee” with “designated representative.”

The term “designated representative” was added to pharmacy law in 2005 by Senate Bill 1307 (Chapter 857, statutes of 2004) and became effective on January 1, 2006.

Revise Section 1780.1 and 1781 of the California Code of Regulations, to read:

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.

Board Approved - Awaiting Notice

Repeal CCR 1717.2, Notice of Electronic Prescription Files

Amend CCR 1760, Disciplinary Guidelines

**Add CCR 1784, Self-Assessment of a Wholesaler by the
Designated Representative-In-Charge**

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Board of Pharmacy
Specific Language for Repeal of Section 1717.2

Repeal Section 1717.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~§1717.2. Notice of Electronic Prescription Files.~~

~~(a) Any pharmacy which establishes an electronic file for prescription records, which is shared with or accessible to other pharmacies, shall post in a place conspicuous to and readily readable by prescription drug consumers a notice in substantially the following form:~~

~~NOTICE TO CONSUMERS:~~

~~This pharmacy maintains its prescription information in an electronic file which is shared by or accessible to the following pharmacies:~~

~~By offering this service, your prescriptions may also be refilled at the above locations. If for any reason you do not want your prescriptions to be maintained in this way, please notify the pharmacist in charge.~~

~~(b) Whenever a consumer objects to his or her prescription records being made accessible to other pharmacies through use of electronic prescription files, it is the duty of the pharmacy to assure that the consumer's records are not shared with or made accessible to another pharmacy, except as provided in Section 1764. The pharmacist to whom the consumer communicated the objection shall ask the consumer to sign a form which reads substantially as follows:~~

~~I hereby notify (name of pharmacy) that my prescription drug records may not be made accessible to other pharmacies through a common or shared electronic file.~~

(date) _____ (signature of patient)

_____ (acknowledgment of pharmacist)

~~The pharmacist shall date and co-sign the form, and shall deliver a copy thereof to the patient. The original shall be maintained by the pharmacy for three years from the date of the last filling or refilling of any prescription in the name of the consumer.~~

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

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Board of Pharmacy
Specific Language to Amend Section 1760

Amend Section 1760 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1760. Disciplinary Guidelines.

In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.) the board shall consider the disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. 1/~~2004~~ 2006), which are hereby incorporated by reference.

Deviation from these guidelines and orders, including the standard terms of probation, is appropriate where the board, in its sole discretion, determines that the facts of the particular case warrant such a deviation--the presence of mitigating factors; the age of the case; evidentiary problems.

Authority cited: Section 4005, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 4300 and 4301, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

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Board of Pharmacy
Specific Language to Add Section 1784

Add Section 1784 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1784. Self-Assessment of a Wholesaler by the Designated Representative-in-Charge.

(a) The designated representative-in-charge of each wholesaler as defined under section 4022.5 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new wholesaler permit has been issued, or

(2) There is a change in the designated representative-in-charge, and he or she becomes the new designated representative-in-charge of a wholesaler.

(c) The components of this assessment shall be on Form M- (created 1/06) entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self- Assessment which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4201, and 4160 Business and Professions Code.

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Attachment 1

**Repeal 16 CCR section 1717(e) and to add 16 CCR
section 1713 Prescription Drop Boxes and Automated
Self-Use Delivery Device for Refill Prescriptions**

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

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

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

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

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

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription, 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 medications to patients in the event the device is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.

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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California State Board of Pharmacy

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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. Cronin's 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 therapeutic 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

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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:

Unknown bag

- 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.

Bag stuck on hooks

- 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



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Telephone: (925) 979-3931
Fax: (925) 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 in providing the professional oversight of the program. While the

Letter to Patricia Harris
January 16, 2006
Page 2

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

To,

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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