State of California | Department of Consumer Affairs

Memorandum

To: Board Members | Date: October 25, 2005

From: Jan E. Perez
Legislation and Regulation Coordinator

Subject: Prescription Drop Boxes and Automated Self-Use Delivery Devices For Refill Prescriptions: Amendment to repeal 16 CCR § 1717(e) and to add 16 CCR 16, §1713

At this meeting 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 §1717(e) and to add 16 CCR §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 is in Attachment A.

The board received eight written comments by the close of the comment period on October 10, 2005. 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 §1713, dated October 19, 2005. (Attachment B)

Additional testimony will be taken during the hearing at the board meeting. Upon conclusion of the regulation hearing, the board will discuss the proposed regulation and determine what action you wish to take. Some of the options are:

(1) Adopt the regulation as originally noticed. (Attachment A)
(2) Adopt the regulation as originally noticed with some modifications.
(3) Consider the revised draft. (Attachment B)
(4) Consider the revised draft with additional modifications.

Any changes to the original regulation will require at least a 15-day notice. One thing to keep in mind when discussing whether or not to revise the regulation is, that the board used the language in the regulation to approve the waivers for the use of automated delivery devices. While the board has received comments on the regulation, there has been no demonstrated need, based on the actual use of the machines, to change the regulation.

Attachment C is the comments from the CPhA and our recommendations regarding comments. Attachment D is the comments from Bill Marcus and our recommendations regarding comments. Attachment E is copies of the other comment letters received along with a chart that summarizes the comments.

Attachment A

TITLE 16. Board of Pharmacy

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on October 10, 2005.

The board will hold a public hearing starting at 1:30pm on October 25, 2005 at the Crown Plaza Hotel, located at 1177 Airport Boulevard, Burlingame, CA 94010, telephone (650) 342-9200. At the hearing any person may present statements or arguments orally or in writing relevant to the proposed action described in the Informative Digest. The board requests, but does not require that persons who make oral comments at the hearing also submit a written copy of their testimony at the hearing.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by Sections 4005 of the Business and Professions Code, and to implement, interpret or make specific Sections 4005, 4052, 4116 and 4117 of said Code, the Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Section 4005 of the Business and Professions Code grants the Board of Pharmacy authority to adopt regulations relating to the practice of pharmacy.

Section 4052 of the Business and Professions Code describes the range of activities in which a pharmacist may engage.

Section 4116 of the Business and Professions Code limits the access of controlled substances to pharmacists and pharmacy interns.

Section 4117 of the Business and Professions Code describes who may enter into an area where narcotics are stored.

This proposed regulation will permit the use of prescription drop-off boxes and an automated, self-services delivery devices. The regulation authorizes a patient to deposit a prescription in a secure container that is at the same address as the licensed premises. The pharmacy is responsible for the security and confidentiality of the prescriptions deposited into the container.

The regulation will also allow a patient to access his or her filled prescriptions from a self-services automated delivery device under the following specified conditions:

- The automated delivery device is used for refill prescriptions only.
- It is the patient's choice to use the automated delivery device.
- The automated delivery device is located adjacent to the licensed pharmacy premises.
- The device is secure from access and removal by unauthorized individuals.
- The pharmacy provides the means for the patient to obtain a consultation with a pharmacist if requested by the patient.
- The pharmacy is responsible for the prescriptions stored in the automated delivery device.
- A pharmacist is not to use the automated delivery device to dispense refilled prescriptions if the pharmacist determines the patient requires counseling pursuant to Title 16 of the California Code of Regulations section 1707.2(a)(2).

The use of self-services automated delivery devices has raised concerns among some pharmacists who see the machines being used to replace pharmacists and to reduce the patient pharmacist consultations.

The board addressed these concerns at public meetings and believes that the use of self-services automated delivery devices will provide consumers with greater access to picking up their refill prescriptions, by allowing access both during regular pharmacy hours and when a pharmacy is closed.

The proposed regulation requires that 1) a pharmacy provides patients using automated delivery devices with a means for consultation with a pharmacist if the patient requires a consultation or has questions, and 2) the pharmacy is not to use the device for prescriptions if a pharmacist determines that a patient requires counseling for a prescription. These safeguards will protect the safety of the patients who choose to use the automated delivery devices. Patents do not generally receive consultations on refill medications.

1. Add Section 1713

Establishes requirements for the placement and use of secure prescription drop boxes and

secure automated delivery devices. This section also contains some provisions currently contained in section 1717(e), which is otherwise being repealed.

2. Amend Section 1717(b)

Amendments to this section are technical in nature and will correct an erroneous code reference.

3. Repeal Section 1717(e)

This provision is being repealed and certain of its contents dealing with the delivery of medication to patients at specific locations has been incorporated into section 1713.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: The proposed regulation does not mandate the use of drop-off boxes or automated delivery devices; it permits the use of the devices for pharmacies that choose to use the technology.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None.

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None.

Business Impact: The proposed regulation does not mandate the use of drop-off boxes or automated delivery devices; it permits the use of the devices for pharmacies that choose to use the technology. For pharmacies that choose to use a drop-off box or an automated delivery device, there will be initial short-term costs to purchase the equipment, install the equipment, and comply with the board's regulations. These costs may be offset by increases in pharmacy sales from customers who like the convenience of the machines. However, there may be no benefit to the pharmacy to use the devices if the patients do not "opt-in" to use them.

Impact on Jobs/New Businesses: The use of automated delivery devices has raised concerns among some individuals who see the machines being used to replace pharmacists. The board believes that the use of the machines will not lead to a reduction in pharmacy staff, but rather will free up time clerks spend cashiering sales of refill medications in pharmacies.

The impact from the use of drop-off boxes is anticipated to be neutral.

Cost Impact on Representative Private Person or Business: The Board of Pharmacy does not mandate the use of this technology. It is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS

The proposed regulation does not mandate the use of automated delivery devices; it permits the use of the devices for pharmacies that choose to use the technology. Consequently, there will be no effect on small business.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposal described in this Notice.

Any interested person may present written statements relevant to the above determinations to the Board of Pharmacy at the above-mentioned address or during the hearing.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained at the hearing or prior to the hearing upon request from the Board of Pharmacy at 400 R Street, Suite 4070, Sacramento, California 95814, or from the Board of Pharmacy website (www.pharmacy.ca.gov).

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

CONTACT PERSON

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Jan E. Perez
Address:	400 R Street, Suite 4070 Sacramento, CA 95814
Telephone No.:	(916) 445-5014 x 4016
Fax No.:	(916) 327-6308
E-Mail Address:	jan_perez@dca.ca.gov

The backup contact person is:

Name:	Virginia Herold
Address:	400 R Street, Suite 4070 Sacramento, CA 95814
Telephone No.:	(916) 445-5014 x4005
Fax No.:	(916) 327-6308
E-Mail Address:	virginia_herold@dca.ca.gov

Website Access: Materials regarding this proposal can be found at www.pharmacy.ca.gov.

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Prescription Drop Boxes and Automated Delivery Devices

Sections Affected: Add 1713 and Amend 1717

Specific Purpose of the Proposed Changes:

Section 1713 (Add)

Establishes requirements for the placement and use of secure prescription drop-off boxes and secure automated delivery devices. This also relocates some provisions currently contained in section 1717(e), which is otherwise being repealed.

Section 1717(b) (Amended)

Amendments to this section are technical in nature and will correct an erroneous code reference.

Section 1717(e) (Repeal)

This provision is being repealed and certain of its contents dealing with the delivery of medication for later pickup by patients at specific locations has been incorporated into section 1713.

Factual Basis

This proposed regulation will permit the use of prescription drop-off boxes and a self-services automated delivery devices. The regulation authorizes a patient to deposit a prescription in a secure container that is at the same address as the licensed premises. The pharmacy is responsible for the security and confidentiality of the prescriptions deposited into the container.

The regulation will also allow a patient to access his or her filled prescriptions from a self-services automated delivery device under the following specified conditions:

- The automated delivery device is used for refill prescriptions only.
- It is the patient's choice to use the automated delivery device.
- The automated delivery device is located adjacent to the licensed pharmacy premises.

- The device is secure from access and removal by unauthorized individuals.
- The pharmacy provides the means for the patient to obtain a consultation with a pharmacist if requested by the patient.
- The pharmacy is responsible for the prescriptions stored in the automated delivery device.
- A pharmacist is not to use the automated delivery device to dispense refilled prescriptions if the pharmacist determines the patient requires counseling pursuant to Title 16 of the California Code of Regulations section 1707.2(a)(2).

In October 2005 the board approved a waiver of section 1717(e) to allow Longs Drug Stores to use prescription drop boxes and secure self-services automated delivery devices, statewide.

In an initial evaluation of the delivery devices conducted by Longs at the one store in which such a device was installed between December 2004 and March 2005, Longs found 600 patients voluntarily enrolled to use the devices and the machines dispensed approximately 1,000 refill prescriptions. Board staff inspected the store using the automated delivery device and found the store was operating the devise within Pharmacy Law and Regulations. The board has subsequently approved a waiver of 1717(e) for Safeway Inc., the University of California San Diego Medical Center, Walgreen's, and White Cross Drug Store of San Diego.

The board notes that use of self-services automated delivery devices has raised concerns among some individuals who see the machines being used to replace pharmacists and to reduce pharmacist consultations to patient.

The board has also discussed these concerns at public meetings and addressed them in the proposed regulation which states that 1) a pharmacy is required to provide patients using automated delivery devices a means for consultation with a pharmacist if the patient requires a consolation or has questions, and 2) the pharmacy is not to use the device for prescriptions if a pharmacist determines that a patient requires counseling for a prescription. These safeguards should protect the safety of the patients who choose to use the automated delivery devices. Patents do not generally receive consultations on refill medications.

The board also believes that the use of self-services automated delivery devices will provide consumers with greater access to picking up their refill prescriptions, by allowing access both during regular pharmacy hours and when a pharmacy is closed but the rest of the store is open. The regulation establishes requirements that mean for patients to contact a pharmacist is provided as a requirement to use the delivery machine.

Underlying Data

None.

Business Impact

The proposed regulation does not mandate the use of drop-off boxes or automated delivery devices; it permits the use of the devices for pharmacies that choose to use the technology. For pharmacies that choose to use a drop-off boxe or an automated delivery device, there will be initial short-term costs to purchase the equipment, install the equipment, and complying with the board's regulations.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment. There are at least two manufacturers of the delivery devices operating delivery machines in California currently under a waiver from the board.

Consideration of Alternatives

The board has not identified any equally effective alternatives that would lessen the impact on small business.

Board of Pharmacy
Specific Language

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.
(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 a device to dispense refilled prescriptions provided:
(1) The patient chooses to use the device.
(2) The device is located adjacent to the licensed pharmacy premises.
(2) The device has a means to identify the patient and only release that patient's prescriptions.
(3) The device is secure from access and removal by unauthorized individuals.
(4) The pharmacy provides a means for the patient to obtain a consultation with a pharmacist if requested by the patient.
(5) The pharmacy is responsible for the prescriptions stored in the device.
(6) The pharmacy does not use the device to dispense refilled prescriptions if a pharmacist determines that the patient requires counseling as set forth in section 1707.2(a)(2).

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.

Attachment B

Board of Pharmacy

Revised Language - October 19, 2005

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 and signed a written consent form 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 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 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 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:

(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.

Attachment C

Comments from John Cronin, CPhA – Staff Response

1. Create a new section 1713.5 for the use of the automated delivery devices and require each pharmacy to notify the board of each device and its location prior to its use.

   Recommendation: Not necessary to create a new section and notify the board of each device and its location.

2. Require the board to issue a waiver based on a pharmacy services plan that details how the automated delivery devices will be used, the impact such use will have on pharmacist-patient contact, and how the intended use of the device will contribute to a high standard of patient safety, consistent with good patient care.

   Recommendation: The purpose of the proposed regulation is to eliminate the waiver process for the use of automated delivery devices. The board does not require a "pharmacy services plan" for any pharmacy operation. The purpose of the Pharmacy Law is to assure patient safety with good patient care.

3. A description of how the pharmacy will determine appropriate patients use the device. (1713.5(b)(1))

   Recommendation: Accept – placed in new version 1713(d)(2) and (e)(2).

4. Require a pharmacist check the prescription prior to being placed in the device. (1713.5(b)(2))

   Recommendation: Not necessary – current law requires a pharmacist to check all prescriptions. Also covered by new version 1713(d)(2) and (e)(2).

5. A description of the means available for the patient using the device to obtain a consultation with a pharmacist upon request. (1713.5(b)(3))

   Recommendation: Accept – placed in new version 1713(d)(5) and (e)(3).

6. A notice is provided to patients when expected medications are not available in the device. 1713.5(b)(4)

   Recommendation: Accept with modification – placed in new version 1713(e)(5).

7. A description of pharmacy personnel that will be involved in (a) the preparation of and (b) the loading of, prescriptions that are placed into the device. (1713.5(b)(5))

   Recommendation: Accept with modification – new version 1713(e)(4).

8. Locate automated delivery devices adjacent to the licensed pharmacy area (1713.5(b)(6)).

   Recommendation: Current language. The new version 1713(d)(6) requires the device to be located adjacent to the licensed pharmacy counter. The language was modified from the noticed version to make it clearer about the placement of the device unless the board wants make this section broader.

9. Require a pharmacy to be responsible for the prescriptions stored in the device and the generation and maintenance of records of drugs placed in and removed from the device. (1713.5(b)(7))

   Recommendation: Accept with modification – new version 1713(d)(8) and (e)(1) – This section specifies the security requirements for the device and the pharmacy's responsibility. Specifying the need for record keeping on all prescriptions in placed in the device is not necessary because a pharmacy is already required by law to keep records of all prescriptions.

10. Proof of security measures adequate to prevent loss, theft, or misdelivery of any drugs maintained in the device. (1713.5(c)(1))

    Recommendation: Accept – new version 1713(d)(7) and (e)(1).

11. Procedures for determining which prescriptions are appropriate to be placed in the device and for which patients, including whether consultation is appropriate. (1713.5(c)(2))

    Recommendation: Accept – new version 1713 (d)(2) and (e)(2).

12. Procedures to ensure the patient are aware of the availability of consultation. (1713.5(c)(3))

    Recommendation: Accept – new version 1713(d)(5) and (e)(3).

13. Allow a waiver and a pharmacy services plan to be applied to multiple locations owned by the same person or entity. (1713.5(d))

Recommendation: The purpose of the proposed regulation is to eliminate the waiver process for the use of automated delivery devices. The board does not require a "pharmacy services plan" for any pharmacy operation. The purpose of the Pharmacy Law is to assure patient safety with good patient care.

14. The board shall act to approve or disapprove a pharmacy services plan submitted pursuant to this section within 60 days of receipt. Failure by the board to take action within 60 days shall be deemed to be approval of the pharmacy services plan and the waiver. (1713.5(e))

    Recommendation: The purpose of the proposed regulation is to eliminate the waiver process for the use of automated delivery devices. The board does not require a "pharmacy services plan" for any pharmacy operation. The purpose of the Pharmacy Law is to assure patient safety with good patient care.

15. The pharmacy shall update or affirm the pharmacy services plan at least annually as part of the permit renewal process or within 30 days of any change in plan that substantially affects the high standard of patient safety, consistent with good patient care that is required to grant the waiver. (1713.5(f))

    Recommendation: The purpose of the proposed regulation is to eliminate the waiver process for the use of automated delivery devices. The board does not require a "pharmacy services plan" for any pharmacy operation. The purpose of the Pharmacy Law is to assure patient safety with good patient care.

16. The pharmacist-in-charge and permit holder shall be jointly responsible for compliance with this section. (1713.5(f))

    Recommendation: Not necessary because the pharmacist-in-charge is responsible for compliance with this section as specified in B&P Code §4113(b) regarding the pharmacist-in-charge.

17. Records of compliance with this section shall be maintained for a period of three (3) years from making and may be maintained in electronic form provided that they are open to inspection, and printing of a hardcopy, at all times during business hours. (1713.5(g))

    Recommendation: Accept with modification – new version 1713(f).

18. Failure of the pharmacy to ensure use or performance of the device consistent with the pharmacy services plan and other provisions of this section shall be grounds for rescission of the waiver and disciplinary action. (1713.5(h))

    Recommendation: Not necessary because the board has authority to take disciplinary action for any violation of the regulation.

18. The board may refuse to allow a pharmacy to use a device (or more than one device) for good cause. (1713.5(i))

    Recommendation: Not necessary because the board has authority to take disciplinary action for any violation of Pharmacy Law, including CCR 1713.

October 7, 2005

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

Re: Comments on Proposed Regulation Change to Title 16, Sections 1717 and 1713

Dear Ms. Perez:

Enclosed please find comments from the California Pharmacists Association on the above referenced regulation. CPhA has proposed alternative language as part of those comments. CPhA will be represented at the hearing on this regulation on October 25, 2005 and will provide testify in support of our comments and alternative proposed language.

Sincerely,

John Cronin, Pharm.D., J.D.
Senior Vice President and
General Counsel

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Comments on Proposed Regulation
Sections 1713 and 1717 of Title 16
Prescription Drop Boxes and Automated Delivery Devices
Submitted by
The California Pharmacists Association
October 7, 2005

Introduction

The Board is proposing to amend Section 1717 and add Section 1713. The Amendment to 1717 essentially removes certain provisions regarding receipt and delivery of prescriptions, which are then addressed in the proposed new section 1713. This proposal is the next step in the Board's consideration of the use of automated delivery devices in retail pharmacies. These machines are intended to be used both when the pharmacy is open and when the pharmacy is closed. In recent months, the Board has considered waiver requests from several pharmacies to install these devices to provide patients with access to refilled prescriptions without interaction with pharmacy personnel. In sharply divided votes, the Board has granted waiver requests for the use of these devices to Longs Drugs, the UCSD Medical Center, Safeway, Walgreens and the White Cross Drug Store of San Diego.

History

In 2004, the Board's Enforcement Committee was asked by Longs Drugs for a waiver under section 1717(e) to allow the installation of a ScriptCenter device in its store in Del Mar, California. The ScriptCenter is developed by Asteres, Inc., which is also located in Del Mar and whose founder is Linda Pinney, who happens to be a patron of the Longs Pharmacy involved in this initial request. Longs also requested a waiver to allow the use of a secure drop-box for prescriptions and refills. At the same meeting, the Board unveiled proposed regulation language to allow the use of these devices without having to go through the waiver process.

The California Pharmacists Association (CPhA) was present at this meeting and we raised several concerns about this technology and its use that we felt needed to be addressed. In particular, we expressed concern about the decreased interaction between the consumer and the pharmacist. We noted that the Board has spent considerable effort and resources over the last 10 years to promote interaction between consumers and pharmacists. In fact, the Board's logo is an image of two people engaged in conversation and advises consumers to "Be Aware, Take Care – Talk to your Pharmacist!" These efforts have won the Board national recognition in the form of multiple awards from the National Association of Boards of Pharmacy. Others at the meeting also raised concerns, included one pharmacist who opined that the unregulated use of these devices would be the antithesis of everything for which the Board currently stood.

The Board committee's response was that the Board also wanted to encourage the use of new and more efficient technology that could improve the drug delivery process while protecting public safety. With that in mind, the committee referred the regulation language and Long's request for waiver to the full Board for consideration.

When considered by the Full Board, Longs had clarified its waiver request to ensure that it extended to the entire Longs chain and that request was approved by the Board. The Board chose to defer the regulation language until the future, pending collection of information about the use and utilization of the ScriptCenter in the Del Mar Longs. At subsequent Board meetings, Safeway, UCSD Medical Center and Walgreens all sought, and were granted, waivers to install the ScriptCenter Device and White Cross Drug Store in San Diego was granted a waiver to install a competing device, made by ddn Corp.. Throughout this entire process, CPhA continued to raise its concerns about the way the Board would oversee the way these devices were being used. Despite our concerns, the Board decided to move forward with the same regulation language that had been proposed in 2004.

Shortly after the first request by Longs Drugs, Asteres, Inc. invited CPhA to visit its facilities and learn more about the Asteres ScriptCenter. This visit led to a very productive exchange between CPhA and Asteres about these devices. Later, CPhA met with pharmacy management from the UCSD Medical Center about their waiver request, which ultimately included performance of a study about the use of the ScriptCenter and consumer interaction with the device. (The study has not yet been done) CPhA has had additional contact with Asteres and UCSD about the regulation and the use of drug delivery devices such as the ScriptCenter.

In general, our improved understanding of the Asteres ScriptCenter and its competitor from ddn Corp. have led CPhA to recognize that our concerns are not with the technology itself, but with the way the technology could be used. We believe that our initial concerns about patient-pharmacist interaction continue to be valid; however, we recognize that this technology has a place in the delivery of medications to patients, particularly in the current economic environment for healthcare. We believe that our ongoing concerns justify a moderate level of regulation of the use of these devices by the Board - a level that is higher than that proposed by the Board.

Comments on the Board's Proposed Language
Amendments to Section 1717

CPhA has no objections to the proposed amendments to section 1717. We agree that the issues being addressed here should be pulled from section 1717 and incorporated into separate new regulation sections.

New Section 1713

CPhA does not object to the Board's proposed language for sections 1713(a) thru (c), including the new subsection (c), which deals with secure containers for depositing prescriptions. CPhA believes the Board's proposed regulation language in 1713(d) does not strike an appropriate degree of regulation for drug delivery devices. We proposed that the Board's language for section 1713(d) be amended and that a new section 1713.5 be added to deal specifically with these drug delivery devices.

Proposed Alternative Regulation Language

(a) New section 1713(d)

CPhA's proposal takes the Board's proposed new section 1713 and incorporates into it a new subsection (d) to retain the waiver system and reference the simplified waiver process for drug delivery devices described in our proposed new section 1713.5. The language proposed by the Board to deal with these devices (contained in the Board's proposed 1713(d)) is incorporated as part of our section 1713.5.

CPhA believes this is necessary to balance the interests of administrative simplicity and protection of the public interest. The Board's proposed language clearly favors a system that reduces the administrative burden on the Board and its staff. CPhA believes this goes too far and risks compromising the public safety in the use of these devices. In reaching this conclusion, we reference many of the media reports about these devices and note that Business and Professions Code Section 4118 establishes the standard for waiver of licensure requirements as: " . . . a high standard of patient safety, consistent with good patient care . . . ." CPhA believes that the same standard should apply to use of drug delivery devices and that the appropriate means to achieve this is through a waiver process.

(b) New Section 1713.5

At the same time that we propose some form of waiver process as necessary, we recognize that the current system, which requires full board action, is overly burdensome and unnecessary. What we propose is a simplified waiver process that will make utilization of these devices easier to authorize while maintaining regulatory oversight that does not endanger public safety nor compromise good patient care. At the same time, we believe the burden imposed by our proposal is both *reasonable* in its scope and *reasonably attainable* in its execution.

Our proposal introduces the concept of a "Pharmacy Services Plan," which is a written document, submitted by the pharmacy and approved by the Board, and which details how the device will be used, the impact such use will have on pharmacist-patient contact and how the use of the device will contribute to a high standard of patient safety consistent with good patient care. [1713.5(a)] The proposal lists components that must be addressed in the pharmacy service plan, but does not establish criteria for approval or disapproval by the Board. [Proposed 1713.5(b)]

It is our intent that the pharmacy services plan will provide some clear indicators of how the device will be used which will establish parameters for evaluation by the Board in its oversight role. Two "requirements" that are incorporated into the proposal at this point are that the device must be located "adjacent" to the licensed pharmacy area and that the pharmacy is responsible for the prescriptions stored in the device and the generation and maintenance of records regarding drugs placed in and removed from the device. These requirements should not be controversial as they are either included in the Board's proposed language or are a restatement of existing law.

Our proposal includes requirements for any pharmacy that employs a drug delivery device [1713.5(c)]. These provisions should not be controversial as they are restatements or minor elaborations of provisions in the Board's proposed language.

Section 1713.5 (d) thru (i) are based on discussions among a small group of stakeholders who met to discuss a possible consensus proposal for regulation of these devices. Although complete consensus was not reached, these sections reflect areas that all involved felt should be addressed in the regulation.

- 1713.5(d) Addresses the applicability of a pharmacy services plan to multiple sites under common ownership. This provision was felt to be reasonable and necessary to avoid excessive cost for applicants and the Board.
- 1713.5(e) requires the Board to take action on a submitted pharmacy services plan within 60 days or have the plan deemed approved. This provision is necessary to avoid unreasonable delays in plan approval that may occur due to factors beyond the control of the pharmacy submitting the plan.
- 1713(f) requires the pharmacy to update or affirm the pharmacy services plan at least annually or within 30 days of any change that substantially affects the standard of patient safety that is required for approval of a waiver. This provision is necessary to inform the Board of any issues that may result in an inspection of the pharmacy regarding the drug delivery device or that would initiate review of the waiver.
- 1713(g) thru (i) are provisions that were felt to be necessary to ensure adequate Board oversight of the waiver process and the ongoing use of the devices.

The advent of these devices may well drive a major reassessment of the role for pharmacists in the health care system. The need for devices like the Asteres ScriptCenter reflects a greater focus by society in general on reducing the costs associated with the provision of prescription medications. However, there is a real risk that this focus may reduce the impact of pharmacists on the selection and appropriate use of these medicines. The Board members should be well

aware of the research data in the medical literature that supports the value of pharmacists in controlling not only drug costs, but also overall medical costs. These savings are realized not only through prudent efforts to control the cost of drug delivery to consumers, but also through appropriate utilization of prescribed medications.

It is often said that the most expensive medicine is the one that is never taken. Likewise, health care costs escalate when drugs are taken inappropriately. Many pharmacists currently play a key role in monitoring the appropriate use of prescription drugs. While few in the profession would argue that pharmacists cannot do a better job in this area, the reality is that the "job" is currently linked to the drug dispensing and delivery process. In considering any effort to deliver drugs more efficiently, the Board needs to consider what impact such change will have on the ability of pharmacists to provide their other skills and professional expertise to consumers.

These drug delivery devices bring to the consumer some added value over the existing system of drug delivery. The questions are, of what value and at what cost? The Board, in its Initial Statement of Reasons. states: "The board notes that use of self-services automated delivery devices has raised concerns among some individuals who see the machines being used to replace pharmacists and to reduce pharmacist consultation to patient." [sic] This is an overly broad generalization of the comments made by CPhA and others on this issue. The risk is not to jobs and consultations; it is to the opportunities for pharmacist-patient contact – what pharmacists see, hear and intuit that leads to a discussion with the patient about their medication use. Every pharmacist can give examples of this type of interaction – and the value of the resulting exchange between pharmacist and patient. The Board – consistent with its vision, mission and strategic plan - needs to ensure that use of any type of new technology does not compromise the opportunity for this type of interaction.

Without proper regulation, the use of these devices will be driven by the predominant factor in the healthcare marketplace today – cost. The impact could well be to break irrevocably the link between the pharmacist and the patient – the drug delivery process. The loss of that connection carries with it a potentially greater loss – the reduced possibility that, within the current healthcare system, pharmacists will eventually provide a much greater benefit to the overall health of the public. That benefit will come not only in the form of cost savings but also in the form of reduced medication side effects and better outcomes – exactly the "high standard of patient safety, consistent with good patient care" that should drive the Board's decision here.

CPhA's view is that the Board is well advised to move cautiously and should itself "Be Aware, Take Care" to ensure that consumers will continue to be able to "Talk to your Pharmacist." CPhA's proposed alternative provides a realistic alternative to the language proposed by the Board – which was drafted prior to having any

experience with the use of these devices. It is clear that some modification of the Board's language is in order. We believe our alternative addresses the needs and concerns of all who have an interest in this issue.

Conclusion

CPhA recognizes the benefit of new technologies to pharmacy practice. However, the Board should not embrace these new technologies without considering all the impacts that may result. CPhA has proposed alternative language that provides a needed balance as this technology develops. It allows the advancement of technology without jeopardizing the pharmacist-patient relationship. We urge you to adopt our alternative and incorporate a simplified waiver process for pharmacies who want to use drug delivery devices.

Respectfully Submitted,

John Cronin, Pharm.D., J.D.
Senior Vice President and General Counsel

Alternate Language to that proposed by the Board for use drop off boxes and automated drug delivery devices
(changes to Board language in bold italics)

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.

(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) *The Board may in its sole discretion waive the application of the regulation for good cause shown or pursuant to section 1713.5.*

Add a new section 1713.5

1713.5. Waiver Process for use of Devices to deliver refilled prescriptions; pharmacy services plan required.

A waiver to allow a pharmacy to use a device to deliver refilled prescriptions shall be granted provided the pharmacy complies with the following:

(a) the pharmacy submits and the board approves a pharmacy services plan regarding the location and operation of the device. For the purposes of this section, "pharmacy services plan" means a written plan that details how the device will be used, the impact such use will have on pharmacist-patient contact, and how the intended use of the device will contribute to a high standard of patient safety, consistent with good patient care.

(b) The pharmacy services plan required by this section shall provide, at a minimum:

1. *a description of how the pharmacy will determine appropriate patients to use the device;*
2. *that a pharmacist check the prescription prior to being placed in the device;*
3. *a description of the means available for the patient using the device to obtain a consultation with a pharmacist upon request;*
4. *a copy of the notice provided to patients when expected medications are not available in the device;*
5. *a description of pharmacy personnel that will be involved in (a) the preparation of and (b) the loading of, prescriptions that are placed into the device;*
6. *that the device is located adjacent to the licensed pharmacy area;*

7. *that the pharmacy is responsible for the prescriptions stored in the device and the generation and maintenance of records of drugs placed in and removed from the device;*

(c) *Any pharmacy that employs such a device shall have and maintain:*

1. *Proof of security measures adequate to prevent loss, theft, or misdelivery of any drugs maintained in the device;*
2. *Procedures for determining which prescriptions are appropriate to be placed in the device and for which patients, including whether consultation is appropriate;*
3. *Procedures to ensure the patient is aware of the availability of consultation;*
4. *A form, to be signed by the patient, consenting to the use of the device;*

(d) *The pharmacy services plan required by this section may be applied to multiple locations owned by the same person or entity. Waivers granted pursuant to this section may extend to all locations covered by an approved pharmacy services plan.*

(e) *The board shall act to approve or disapprove a pharmacy services plan submitted pursuant to this section within 60 days of receipt. Failure by the board to take action within 60 days shall be deemed to be approval of the pharmacy services plan and the waiver.*

(f) *The pharmacy shall update or affirm the pharmacy services plan at least annually as part of the permit renewal process or within 30 days of any change in plan that substantially affects the high standard of patient safety, consistent with good patient care that is required to grant the waiver.*

(g) *The pharmacist-in-charge and permit holder shall be jointly responsible for compliance with this section. Records of compliance with this section shall be maintained for a period of three (3) years from making and may be maintained in electronic form provided that they are open to inspection, and printing of a hardcopy, at all times during business hours.*

(h) *Failure of the pharmacy to ensure use or performance of the device consistent with the pharmacy services plan and other provisions of this section shall be grounds for rescission of the waiver and disciplinary action.*

(i) *the board may refuse to allow a pharmacy to use a device (or more than one device) for good cause.*

Attachment D

Comments from Bill Marcus – Staff Response

1. Create a new section 1713.5 for the use of the automated delivery devices and require each pharmacy to notify the board of each device and its location prior to its use.

   Recommendation: Not necessary to create a new section and notify the board of each device and its location.

2. Require proof of security measures adequate to prevent loss, theft, or misdelivery of any drugs maintained in the device and to prevent unauthorized access to the device or its removal (1713.5(a)(1)).

   Recommendation: Accept – placed in new version 1713(d)(7) and (e)(1).

3. Proof of measures to ensure a pharmacist review each prescription before it is placed in the device (1713.5(a)(2)).

   Recommendation: Not necessary – current law requires a pharmacist to check all prescriptions. Also covered by new version 1713(d)(2) and (e)(2).

4. Procedures for determining which prescriptions are appropriate to be placed in the device and for which patients, including whether consultation is appropriate (1713.5(a)(3)).

   Recommendation: Accept – placed in new version 1713(d)(2) and (e)(2).

5. Procedures to ensure the patient is aware of the availability of consultation (1735(a)(4)).

   Recommendation: Accept –placed in new version 1713(d)(5) and (e)(3).

6. A form, form signed by the patient, consenting to the use of the device (1713.5(a)(5)).

   Recommendation: Accept – placed in new version 1713(d)(1).

7. Each device shall be located within the pharmacy premises or within or adjacent to the building in which the pharmacy is located. (1713.5(b)).

   Recommendation: Not accept – new version 1713(d)(6) requires the device to be located adjacent to the licensed pharmacy counter. The language was modified from the noticed version to make it clearer about the placement of the device unless the board wants make this section broader.

8. The pharmacy shall remain responsible for each prescription until it is delivered to the patient or the patient's authorized agent.

   Recommendation: Accept with modification – new version 1713(d)(8) and (e)(1) – These sections specify the security requirements for the device and the pharmacy's responsibility.

9. The pharmacy shall review compliance with the requirements of subdivision (a) at least annually and whenever a mistake or misdelivery warrants review. (1713.5(c))

   Recommendation: Accept – new version 1713(d)(9) and (e)

10. The pharmacy shall notify the board within (10) days of the removal or moving of any existing device. (1713.5(d))

    Recommendation: Not necessary

11. The pharmacist-in-charge and permit holder shall be jointly responsible for compliance with this section. (1713.5(e))

    Recommendation: Not necessary because the pharmacist-in-charge is responsible for compliance with this section as specified in B&P Code §4113(b) regarding the pharmacist-in-charge.

12. Records of compliance with this section shall be maintained for a period of three (3) years from making and may be maintained in electronic form provided that they are open to inspection, printing of a hardcopy, at all times during business hours. (1713.5(e)).

    Recommendation: Accept with modification – new version 1713(f)

Office of Bill Marcus

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October 10, 2005

Patricia F. Harris
Executive Officer
Calif. State Bd. of Pharmacy
400 R Street, Suite 4070
Sacramento CA 95814

Re: Proposed Regulation re Delivery and Pick-up of Prescriptions and Filled Prescriptions

Dear Ms. Harris:

I wanted to submit my comments regarding the board's proposed regulation, section 1713. I have no concerns or issues about the portion relating to the dropping off of prescriptions, but I have some concerns about the provision that would authorize the pick-up kiosks the board has, to date, been authorizing by waiver.

First, I am very concerned that the board has still not fully addressed, as first raised by John Cronin at a committee meeting in 2005, the preliminary, and urgent, issue of the role pharmacists should play in the prescription dispensing process. I believe that pick-up kiosks, at least for certain refill prescriptions, is probably unstoppable now that they are here; however, even for refills, it is imperative that the pharmacist engage in a substantive review of each order, including in light of the required review of patient profiles, and always provide, or at least offer, consultation where it is, in the pharmacist's professional opinion, warranted.

Not only will kiosks make it easier for a pharmacist to make a less reasoned decision before allowing a refill prescription to be placed in the kiosk, it will dissuade patients who might otherwise have time to ask questions from doing so. Nor do I believe that simply providing patients of a written notice that they may contact a pharmacist is a sufficient substitute.

I believe that beyond the scope of this immediate proposal the board should conduct an informational hearing, and preferably several around the state, in 2006 to hear the views of the profession and others on the future of pharmacy and pharmacists, particularly the provision of cognitive, clinical and consultative services (both to consumers and to other professionals) in the future. I ask that the board set such hearings, to be held in conjunction with its regularly scheduled 2006 meetings, which are conveniently scheduled for each of the major population areas of the state—S.F., Sacramento, L.A. and S.D.

But reservations aside, as I said above, these kiosks won't go away and need to be regulated. How, of course, is the question.

I have attached my approach, which combines the board's approach—that is, to allow any pharmacy who meets certain requirements to have kiosks, rather than requiring them to apply to the board for a waiver—with elements of a proposal I understand is being made by CPhA and others—which would break the rules for kiosks into a separate section, 1713.5.

I don't believe a waiver approach is practical, including because many, if not most, pharmacies, will, with a relatively short period of time, make use of such kiosks. I believe it would impose an unnecessary burden on the board and its staff. Rather, I think treating kiosks as quality assurance and self-assessment are makes more sense: require the pharmacy to meet and document certain requirements.

With orders of correction, citations, discipline, etc., including for any violation of any board regulation, the board should be able to monitor and punish any pharmacy that abuses the authority to have kiosks.

Much of my language is taken from the board's proposal, but I have made some substantive changes:

1. In 1713(d), I have dropped the board's (d), mostly into a new 1713.5, and I've substituted a new (d), allowing the board to waive the provisions of 1713
2. 1713(a) allows pick-up kiosks without a waiver. It only allows their use for refills that do not require direct contact or consultation with a pharmacist. It allows for the possibility of more than one kiosk for a pharmacy, and it requires the board be notified a pharmacy intends to use a kiosk and where it will be located prior to its use (so that the board may readily inspect the kiosk, rather than searching for its location)
3. In (a)1, I incorporated, but broadened, what are the board's 1713(d)(3) and (4). While the board's language deals with misdelivery and removal of the device and unauthorized access in general, I believe the language should also address security against such as loss
4. (a)(2 is to ensure a pharmacist actually reviews the completed order before it is placed in the device. The board's proposal has no such language, and I think it is essential, or it is an invitation to use the devices indiscriminately.
5. (a)3 and 4 are intended both to ensure the pharmacy has procedures for the use of kiosks and for ensuring reasoned selection of the refills that don't require consultation, as well as notice to patients of the availability of consultation. I think this is stronger than the board's (d)(4) and (6)
6. (a)5 is because I think there should be a signed consent, both to ensure the patient understands that to which he or she is agreeing and, frankly, for the pharmacy's own protection. It is a minimal, one-time requirement. I think this is better than the board's (a)(1).
7. (b) is broader than the board's (d)(2) and, I think, more practical. The board's proposal only provides for a kiosk adjacent to the licensed pharmacy. Technically, that would not permit a kiosk in the pharmacy, but outside the "pharmacy" premises, and it wouldn't allow one that is in or adjacent to the building in which the pharmacy is located, but which is not adjacent to the pharmacy itself. If the device is sufficiently secure and if the board is going to authorize such devices, as it has already been doing, I believe the language I've proposed is more real world. The portion of (b) regarding the pharmacy's continuing responsibility until the prescription is picked up is, I think, a little clearer than the board's version ((d)(5)).

8. My (c) is intended to make sure the pharmacy conducts a review of the device and its use at least annually and more often as needed.
9. My (d) is to ensure that a pharmacy cannot simply move or remove a kiosk without notifying the board.
10. Finally (e) is to make clear the dual responsibility of the PIC and the owner and to require the records described in 1713.5 be kept for three years and accessible to the board (since not all the records described in this section are necessarily records of acquisition and disposition, they would not be subject to the three year requirement in Section 4080.

I hope to be at the board meeting this month and would be happy to address both my concerns and suggestions further at that time.

Sincerely,

Bill Marcus
Encl.: draft proposal for 1713 and 1714.5

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.

(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) The Board may in its sole discretion waive the application of this regulation for good cause shown.

1713.5. Use of devices for delivery of refilled prescriptions.

(a) Notwithstanding section 1713, a pharmacy may, without a waiver, employ a device through which prescription refills that do not require direct contact or consultation with a pharmacist may be picked up by patients. Any pharmacy that employs one or more such devices shall notify the board of each such device and its location prior to its installation and use. Any pharmacy that employs such a device shall have and maintain:

1. Proof of security measures adequate to prevent loss, theft, or misdelivery of any drugs maintained in the device and to prevent unauthorized access to the device or its removal;
2. Proof of measures to ensure a pharmacist reviews each prescription before it is placed in the device;
3. Procedures for determining which prescriptions are appropriate to be placed in the device and for which patients, including whether consultation is appropriate;
4. Procedures to ensure the patient is aware of the availability of consultation;
5. A form, to be signed by the patient, consenting to the use of the device;

(b) Each such device shall be located within the pharmacy premises or within or adjacent to the building in which the pharmacy is located. The pharmacy shall remain responsible for each prescription until it is delivered to the patient or the patient's authorized representative.

(c) The pharmacy shall review compliance with the requirements of subdivision (a) at least annually and whenever a mistake or misdelivery warrants review.

(d) The pharmacy shall notify the board within ten (10) days of the removal or moving of any existing device.

(e) The pharmacist-in-charge and permit holder shall be jointly responsible for compliance with this section. Records of compliance with this section shall be

maintained for a period of three (3) years from making and may be maintained in electronic form provided that they are open to inspection, and printing of a hardcopy, at all times during business hours.

Attachment E

State of California | Department of Consumer Affairs

Memorandum

To: Board Members | Date: October 25, 2005

From: Jan E. Perez
Legislation and Regulation Coordinator

Subject: Prescription Drop Boxes and Automated Self-Use Delivery Devices For Refill Prescriptions: Comments received by the board by October 10, 2005.

The board received eight written comments by the close of the comment period on October 10, 2005. Bill Marcus and John Cronin provided substantial comments. Additionally, Safeway and the National Association of Chain Drug Stores provided comments regarding 1) the location of automated delivery devices within the licensed address of a pharmacy; and 2) clarification that a device could be used when a pharmacy is closed. Staff has proposed revised language (Attachment B in this packet) that would require an automated delivery device to be located adjacent to a licensed pharmacy counter. Staff believes that a provision expressly stating the times in which an automated delivery device can be used is unnecessary.

Copies of the comment letters received are attached.

Name	Representing	Support /Oppose	Concerns
Ron Bingaman, RPh	Safeway	Support	Allow unit to be located anywhere on in the licensed address of the pharmacy. Clarify that unit can be used when a pharmacy is closed.
Kevin Nicholson, RPh, J.D. Mary Staples, Gov. Affairs	National Assoc. of Chain Drug Stores	Support	Change "adjacent to" "within view." Add that machines can be used with or without a pharmacist present.
Daniel F. Luce	Wallgreens	Support	None.
James Kramme, RPh	Self	Oppose	Reduced patient interaction with pharmacists.
Bret Miller, Pharm. D.	Self	Oppose	Reduced patient interaction with pharmacists.
Robert Reed, RPh, Pharm. D.	Self	Oppose	Reduced patient interaction with pharmacists.

SAFEWAY

BOARD OF PHARMACY
2005 OCT 12 PM 2:18

October 7, 2005

California State Board Of Pharmacy
400 R Street, Suite 4070
Sacramento, California 95814
Attn: Jan E. Perez

Re: Proposed Pharmacy Regulation:

On behalf of Safeway Inc., I am writing to the Board of Pharmacy in support of the proposed adoption of regulations authorizing prescription drop-off boxes and automated, self-service delivery devices.

These options would allow more convenient access by patients to needed pharmacy services while ensuring patient safety and access to pharmacist consultation. In many cases, people are now working extended hours - often with both spouses working to meet the family's financials needs. Safeway supports the Board's efforts to reach out to patients by authorizing additional options for greater access and flexibility to prescription services.

I would like to offer two suggestions regarding the content of the proposed regulation that addresses the automated, self-service prescription delivery unit:

1). The location of the delivery unit in proposed language is defined as "adjacent." I would suggest the descriptive of location be clarified. A unit that is required to be located next to the pharmacy itself may cause additional congestion at the pharmacy. It could also discourage a patient from approaching a pharmacist for consultation and/or questions. In a congested area, the confidentially of any medical information discussed could also be compromised.

Clarifying language added that allows the unit to be located anywhere in the licensed address of the pharmacy (four walls of the building) would be useful.

2). In the supporting documents regarding the proposed regulation, it is clearly stated the self-service delivery unit can be used while the pharmacy is open or closed. I would suggest the Board consider adding this reference to the adopted regulation for clarity.

Sincerely,

Ron Bingaman

Ron Bingaman, R.Ph.
Corporate Pharmacy Director: Administration and Compliance

CC. File

Safeway Inc.
5918 Stoneridge Mall Road
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NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

October 10, 2005

Ms. Patricia Harris
California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

RE: Proposed Regulation Section 1713, Receipt and Delivery of Prescriptions

Dear Ms. Harris:

On behalf of our 31 member companies operating approximately 3,122 chain pharmacies in the State of California, the National Association of Chain Drug Stores (NACDS) appreciates the opportunity to submit comments for the Board of Pharmacy's ("Board") consideration on the amended proposed Title 16, Section 1713 regulation on receipt and delivery of prescriptions. The Board has advised that comments must be sent by October 10, 2005.

Under proposed new Section 1713, the Board aims to allow a patient to deposit a prescription in a secure container for retrieval by pharmacy personnel, and to allow a pharmacy to use an automated device to dispense refilled prescriptions so long as certain, specific conditions are met.

We applaud the Board's proposal. Prescription volume continues to grow; however, the number of licensed pharmacists is not keeping pace with the growing demand for pharmacy services. Pharmacies and pharmacists are seeking ways to meet this increasing demand, including using technology solutions. The volume of prescriptions filled by community pharmacies has risen dramatically over recent years from 2.78 billion in 1998 to more than 3.2 billion per year in 2004. Prescription volume is expected to continue to increase significantly with the new Medicare drug benefit law, along with an aging population and the expected increased use of prescription drugs in this population. Between 2004 and 2010 the supply of all community pharmacists is expected to increase only 7.8% vs. an estimated 27% increase in number of prescriptions dispensed, going from 3.27 billion in 2003 to over 4.1 billion in 2010.[1] We believe that the Board's proposed rule will greatly assist pharmacies and pharmacists in meeting the demand for pharmacy services.

We believe the Board's proposed rule will benefit patients, as well. In our busy and hectic society, consumers appreciate streamlined services that make the best use of their time. Under the Board's proposed rule, patients will be able to drop off prescriptions at the pharmacy when it is convenient for them, even when the pharmacy is closed.

[1] Source: NACDS Economics Department

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Moreover, they will be able to drop off prescriptions without having to wait in line when the pharmacy is open.

Prescription refills do not usually require patient counseling. Patients picking up prescription refills will be able to do so without waiting in line behind patients being counseled. They will be able to pick up prescription refills even when the pharmacy is closed. Of course, counseling would be provided via telephone upon request.

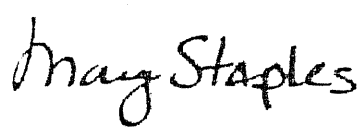
Again, we applaud the Board's proposal. However, we would like to suggest two modifications to improve the Board's proposed language. First, under proposed Rule section 1713(d)(2), the device to dispense refilled prescriptions must be "adjacent to the licensed pharmacy premises." We believe that this requirement would lead to congestion in the pharmacy area and would negate many benefits that such device could provide.

From a practical perspective, if the dispensing devices are stationed too close to the pharmacy area, the area in front of the pharmacy becomes very congested with patients waiting to drop off prescription orders, pick up filled prescriptions, speak with a pharmacist, and use the devices. Furthermore, the heaviest utilization of the devices is during peak times, thereby compounding the congestion problem. In fact, this problem was brought up at the first Board hearing on this topic by a Board member, who suggested the devices not be located too close to the pharmacy area. To resolve this problem, we suggest substituting "'within view of' for 'adjacent to' the licensed pharmacy premises."

Second, proposed Rule 1713 does not mention that patients may use the dispensing devices to pick up refilled prescriptions when a pharmacist is not present. We ask that the Board clarify this point in the Rule. We suggest the following additional underlined language for proposed Rule section 1713(d): "A pharmacy may use a device to dispense refilled prescriptions, with or without a pharmacist present within the licensed premises, provided:".

For the benefit of both consumers and pharmacists, we urge the Board to adopt Rule 1713 with our suggestions for modifications. Thank you for your consideration of these comments.

Sincerely,



Kevin N. Nicholson, R.Ph, J.D.
Director, Pharmacy Regulatory Affairs

Mary Staples
Regional Director, State Government Affairs

Walgreens

October 10, 2005

Patricia Harris, Executive Officer
California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

RE: Adoption of Section 1713 of Division 17 of Title 16 of the California Code of Regulations

Dear Ms. Harris,

On behalf of Walgreens, I would like to commend the Board for the proposal to adopt changes to Division 17 of Title 16 of the California Code of Regulations to permit the use of prescription drop-off boxes and automated, self-service delivery devices. As you know, Walgreens was recently granted a waiver to install such devices in their stores. We see tremendous value in having the regulation changed.

Our customers, like the pharmacy customers throughout the state, are increasingly time constrained. Having a device which enables them to safely and accurately pick up and pay for a refill prescription not requiring consultation allows them to avoid lines at the pharmacy counter – a time-saver in today's busy world. Additionally, providing the ability for customers to pick up prescriptions after hours provides them with a great convenience. Customers can shop at a time that is convenient for them, not the time dictated by the pharmacy hours. We believe that pharmacy self-service technology has had tangible benefits for consumers, and adoption of the changes will benefit the public.

At the same time, we believe that new technology must be introduced in ways that are consistent with existing standards of pharmacy practice. We feel confident that the proposed language for Section 1713 of Division 17 of Title 16 of the California Code of Regulations will ensure continued public safety. The language maintains the pharmacist's vital role in the dispensing process, and supports the requirement to provide patient counseling.

Walgreens is excited to be one of the first retailers to install such a device. We look forward to being an example of how the profession of pharmacy can adopt new technology while adhering to existing professional standards.

Sincerely,

Daniel F. Luce
Manager, Pharmacy Affairs
(847) 914-2354

10-10-05

Dear Calif. State Board of Pharmacy,

As a pharmacist, I feel that Kiosks are bad medicine. Due to no counseling etc they are not in the best interest of the publics health. It's time for the board to really consider what is in the best interest to the patient and not fall into "what is best for chain drug stores."

James Kamme RPh

Pharmacy Board Members,

As a Pharmacist in charge with 21 years of working the case experience I'm quite surprised by the Boards proposed change to add Section 1713 Receipt and Delivery of Prescriptions. I don't foresee any problems with the drop off portion of the addition you proposed and in fact it's a needed change. I believe that your proposed addition to allow for automated delivery devices on the other hand will lead to long term changes in access to pharmacists. In your statement of reason your analysis of the impact of these machines I believe is flawed. Has the Board considered that centrally filled prescriptions are going to be the majority of the prescription placed in these units? The Pharmacist in Charge I assume will have liability for these prescriptions and yet a Pharmacist at the pick up site will not have been involved anywhere in the process of filling or dispensing the prescription. In light of this, how can the Board claim that it won't have an impact on either the patient health or on the Pharmacy staff level? Interactions with the Pharmacist will be lessened by these delivery devices. What about OTC and Rx drug interactions that are often discovered when picking up prescriptions? During routine pick up of Prescriptions I'm interacting with my Patients, checking there health and in general making them feel comfortable interacting with me. When we take away this we are creating an impersonal event that weakens Pharmacist care. I believe that employers will use the central fill – automated delivery devices to cut staff that will further put stress on the pharmacist remaining. Please reconsider your proposed addition of Sec. 1713 as I believe it will have a negative impact on the general public health and safety which the Board of Pharmacy is mandated to protect.

Bret Miller, Pharm.D.

Robert A. Reed, Rph, PharmD

1570 W. Branch St.

Arroyo Grande, Calif. 93420

October 10, 2005

California State Board of Pharmacy

400 R. Street Suite 4070

Sacramento, Calif. 95814

Pharmacy Board Members:

I have been a licensed practicing pharmacist in California since 1977 and in light of my experience would like to express my concerns regarding your proposed addition of Sec. 1713 to the current pharmacy law. Over the years, I have seen our profession pulled and tugged in many different directions. In my opinion this proposed change will take our profession in a drastically new and detrimental heading. I see it warping our effectiveness and usefulness in providing quality health care. Patient contact and accessibility is pharmacies most distinguishing aspect. We are available to all by simply allowing the patient to approach us with questions without a prior appointment and to help themselves to our knowledge and professional advice. This is how we are perceived and what the public expects from us and it is I believe, in large part why our profession has been held in such high esteem for so long by the public. I ask you to consider what is the driving force behind this new legislation. Who stands to gain? It is certainly not the public. The service they receive will lack our personal attention and contact and it will increase patient medication errors and dosing errors. Pharmacy will certainly not benefit. Employers will replace pharmacists with there new mechanized dispensers. Following the money trail leads me to believe that the push for this change is being led by those who will profit by it, namely the corporations which maintain pharmacies in there department stores such as Longs, Rite-aid, K-mart, CVS, Walgreen's, Costco and the like. To be blunt, I firmly believe that this legislation is being pushed through by corporate greed, with no thought of its effects on the quality of patient care or the future of the practice of our profession. If I were a betting man, regarding the adoption of Sec 1713, I would place my wager on the side with the power and the money, and that is unfortunate. It is my hope you will take these concerns to heart before you lead the parade over a cliff.

Respectfully,

Robert A. Reed, Rph, PharmD