

## **Board of Pharmacy**

### **Final Statement of Reasons**

**Subject Matter of Proposed Regulation:** Prescription Drop Boxes and Automated Self-Use Delivery Devices for Refill Prescriptions.

**Title 16 Sections Affected:** 1713 and 1717(e)

**Hearing Date:** April 26, 2006

#### **Updated Information**

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the board's position regarding the use of prescription drop boxes and automated self-use delivery devices for refill prescriptions.

The board notes that comments received on this rulemaking pertain to sections 1713 and 1717(e), the sections referring to the "automated delivery devices" or "kiosks." No comments were received regarding the drop boxes for patients to use outside to leave a written prescription that will be filled by the pharmacy for later pick up by the patients (Section 1713(c)). As such, the discussion below is related to the rulemaking involving automated delivery devices only.

#### **Summary of Comments Received During the 45-Day Comment Period:**

The board received 2 letters in support of the proposed regulation change during the 45-day comment period. These letters are in section I of this rulemaking file.

The board received written comments requesting clarification on these proposed regulatory changes.

1. In a letter dated March 3, 2006, Steven Gray, Pharm.D., J.D. representing Kaiser Permanente, offers comments regarding the proposed regulation.

These comments were forwarded to the Office of the Attorney General for research and response. A copy of the response is attached to Dr. Gray's letter section J of this rulemaking directly after Mr. Gray's letter. The board agreed with several comments made by Dr. Gray and modified the language. This modified language was released for an completed an additional 15-day comment period beginning May 2, 2006.

2. In a letter dated April 10, 2006, John Cronin, Pharm.D., J.D. representing the California Pharmacists Association (CPhA) also expressed some concern about the proposed regulation. Dr. Cronin first states his

understanding of the intent of the proposed regulation and provides a brief history about the board's previous actions specific to the proposed changes. Dr. Cronin notes that the CPhA also provided comments regarding a similar proposal sought by the board in October 2005, and requested that comments made by the CPhA for that rulemaking also be included in this current rulemaking file.

Both the CPhA's previous and current comments are included in this rulemaking file.

Dr. Cronin states that the CPhA recognizes the need to promote the use of new technologies and agrees with the board that some form of regulation is needed to address the administrative burden associated with the waiver process the board has used to deal with requests to use these devices. He continues to state that the question for the CPhA is whether this regulation language reaches the proper balance of the risks and benefits to consumers and the provision of health care associated with the use of this technology.

The board believes that the risks to patients from the technology authorized by these changes are minimal. Testimony from those using the automated delivery machines (via authorization of a board-issued waiver) indicates that the use of these delivery devices actually reduces by 6 percent prescription errors that arise from a patient receiving a prescription labeled and filled for a different patient. This is a demonstrated benefit to California consumers.

Dr. Cronin states that the proposed regulation goes a long way toward addressing the issues that the CPhA has raised throughout this rulemaking process. The CPhA believes that the board and the manufacturers of these devices have made a serious and good faith effort to deal with the concerns of the CPhA. He continues to state however that the CPhA has concerns about the impact of the use and potential misuse of these devices and its effect on the proper delivery of health care and the role pharmacists will play in the future.

The board may take administrative action against any licensee for violations of pharmacy law including these regulations. If significant misuses occur in the future, the board, as with all aspects of regulating pharmacy, would take appropriate steps to remedy the problem.

Dr. Cronin indicates that the CPhA has no objections to the proposed amendments to section 1717 and agrees that the issues being addressed should be pulled from section 1717 and incorporated into separate new regulation sections. In addition, Dr. Cronin states that the CPhA also does not object to the proposed modified language for sections 1713 (a) thru

(c), including new subsection (c), which deals with secure containers for depositing prescriptions.

Dr. Cronin states that the CPhA continues to have concerns that the proposed language for sections 1713 (d) and 1713 (e) does not strike the appropriate regulatory balance. The CPhA believes that the board should require pharmacies to provide more specific statements of how these devices will further a higher standard of patient safety, promote good patient care and advance pharmacist-patient communication.

The board disagrees that this is necessary. It is not the board's intent to over regulate the pharmacy profession. Consumers may choose to use this technology as a safe and convenient alternative to dropping off or picking up prescriptions. Consumers are not required to use these devices. Additionally, testimony provided to the board details the high success rate of using the automated delivery devices and demonstrates their use actually reduces the likelihood of certain prescription errors.

The board agrees that communication between a pharmacist and consumer is a vital component of the health care relationship. Given this, the use of these automated delivery devices is limited in scope; specifically, the device can only be used on previously dispensed prescriptions when patient consultation is not required by law. The patient must elect to use the delivery device. In addition, as a precautionary measure, the board has empowered the pharmacist to prohibit the use of the delivery device when, in his or her professional judgment, use would compromise a consumer's health outcome. Also, a consumer can request and obtain an immediate telephone or in-person consultation with a pharmacist when obtaining medication from an automated delivery device.

Dr. Cronin states that the driving force for this regulation appears to be the board's desire for a system to allow use of these devices without the current administrative burden on the board and its staff to issue waivers. The CPhA's approach is for a system that requires some review of the request before approval. The CPhA believes that additional discussion will not produce any consensus as to acceptable language; however the CPhA would be happy to participate should the board desire to explore this issue.

The driving force for the board is always consumer protection and advancing patient care in California. The use of these delivery devices decreases the number of prescriptions errors that occur from the wrong prescription being dispensed to a patient from the "will call" shelf in a pharmacy (e.g., a prescription labeled for T. Smith is dispensed to another patient, Tom Smith). In addition, because these devices allow prescription drugs available after the pharmacy is closed, consumers can continue

their drug regimen uninterrupted because they have access to their medications even when the pharmacy is closed.

Dr. Cronin states that if the concerns of the CPhA are eventually realized, it will be much more difficult for the board to rectify the situation than it is to correct the problems now. He continues that the board's reluctance to give serious consideration to the CPhA's proposals is a source of frustration for them, particularly in light of the board's published vision statement, mission statement and strategic plan.

The board does not believe that the proposed language is in conflict with the board's vision or mission statement contained within the strategic plan. Moreover, declining to include all recommendations made by Dr. Cronin is not indicative that the board did not seriously consider each proposal. The CPhA did not further define their concerns in these comments.

Dr. Cronin included a technical change to the wording in section 1713(d)(5) to "The pharmacy provides a means for each patient to request and obtain an immediate consultation with a pharmacist, either in person or via telephone."

At the April 2006 board meeting, during the regulation hearing, the board amended this section, and released the language for a 15-day comment period in May.

In conclusion Dr. Cronin states that the CPhA recognizes the benefit of new technologies to pharmacy practice and agrees that automated drug delivery devices can provide safe, convenient and cost-effective access to prescription refills. Dr. Cronin continues that the board's regulation should promote not only administrative efficiency but also advance public health and consumer safety and states that in the view of the CPhA, this language falls short of that goal.

The board believes that the proposed regulation advances public health and consumer safety. Automated delivery machines are successfully operating in California and in other states.

Dr. Cronin attached comments submitted in response to a previous version of the proposed regulations section 1713 and 1717 - - Prescription Drop Boxes and Automated Delivery Devices, submitted by the CPhA, dated October 7, 2005.

These previous comments provided by CPhA as well as the board's staff response is included in Background Information in this rulemaking file.

3. In a letter dated April 10, 2006, Shane Guzman provides comments opposing the proposed regulations on behalf of the United Food and Commercial Workers (UFCW). Specifically Mr. Guzman states that the UFCW is very concerned about the potential impact on patient safety and creation of liability for pharmacists. Mr. Guzman continues to state that the proposed regulations seem to be driven by economics rather than patient health.

The board disagrees with this statement. The proposed regulation is designed to assist consumers with receiving medications via a delivery device that is accessible while the pharmacy is open as well as after the pharmacy is closed. This will ensure continuity in a drug regimen that could otherwise be interrupted if the patient has to wait until the following day to receive a prescription. The use of these delivery machines and prescription drop boxes are for patient convenience. Moreover, there are several safeguards in place to ensure that a patient's safety is not compromised, (e.g., immediate consultation with a pharmacist for patients with questions or an issue, a pharmacist's judgment in whether a medication will be dispensed this way).

Mr. Guzman states that the UFCW is concerned that unlimited use of automated delivery systems will result in less interaction between the patient and pharmacist and while reducing lines at pharmacies is a noteworthy goal, that benefit hardly outweighs the potential negative outcomes when patients have difficulty consulting with a pharmacist. Mr. Guzman continues to state that providing the patient with a telephone number hardly ensures that there will be somebody else on the other end.

The board disagrees with Mr. Guzman's statements. First, the automated delivery system can only be used under specific conditions, the proposed language does not allow for unlimited use. Additionally, the consumer must elect to use the system, not the pharmacist. The board also disagrees with the statement that consumers will have difficulty consulting with a pharmacist. Any prescription that requires consultation cannot be delivered or dispensed with the automated delivery device. In addition, the proposed regulation requires that a pharmacist be immediately available for either an in-person or telephone consultation upon request of the patient even when the pharmacy is closed. Accordingly, if the pharmacy is open, the consumer can speak with the pharmacist after obtaining the prescription from the delivery device. If the pharmacy is closed, the pharmacy must make a pharmacist available immediately upon required for either an in-person or telephone consultation.

Mr. Guzman states that the proposed regulation is much too vague and fails to provide enough guidance in several key areas. He continues that the regulation should specify at a minimum what information should be

provided in the patients' written consent and that the regulation should specify what a pharmacy should communicate to patients concerning use of the machines and procedures when the devices malfunction.

It is not the board's intent to over-regulate the profession that takes the place of professional judgment. The board outlines what the pharmacy must do prior to use and on an annual basis thereafter, but does not get into the specific language that a patient's consent form must include. Rather this is left to the discretion of pharmacy personnel as devices may function differently and policies differ from pharmacy to pharmacy. The proposed regulation is very clear that immediate patient consultation must be made available should the patient request it. The proposed regulation also requires the pharmacy to orientate a consumer about the use of the delivery device and must also make a prescription available in the event of a machine malfunction.

Mr. Guzman states that the UFCW is concerned about the potential licensure liability for pharmacists who have these devices where they practice and that the devices will be placed in retail pharmacies not by the choice of the pharmacists but by the chain drug store management. Mr. Guzman continues that management will choose where to place the device and which device to use; yet if the device malfunctions, it will be the pharmacist's license that will be on the line.

The proposed regulation defines where and under what circumstances a delivery device can be used. Specifically, section 1713 (d)(6) details where the device must be located. Any malfunction of the device must be reviewed as part of the pharmacy's quality assurance program; it will not automatically result in discipline against the pharmacist as asserted above.

Last, Mr. Guzman suggests two changes to the proposed regulation to address the licensure issue. First he suggests that the board make it clear that the pharmacist has complete discretion over what medications are dispensed through these devices and two, that to ensure this discretion, the pharmacist should be protected from discipline or discharge from his or her employer for exercising their good faith professional judgment.

The board does not believe these suggested changes are necessary. Specifically, section 1713(d)(4) provides the latitude for a pharmacist not to use the device to deliver a previously dispensed prescription medication if the pharmacist determines that the patient requires counseling. In addition pharmacists have the discretion to determine that a patient using the device meets the inclusion criteria for use of the device as established by the pharmacy, section 1713(d)(2).

Mr. Guzman states that the pharmacist should be expressly immune from licensure sanctions if an automated delivery device malfunctions or an error results from the patient's use of the machine.

The board disagrees with this conclusion. The board pursues administrative or disciplinary action against a pharmacist when there is a suspected violation of pharmacy. Section 1713 (d)(9) states that any incident involving the device where a complaint, delivery error or omission has occurred must be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

On April 13, 2006 the board received written comments from Gary R. Solomon, RPh. Mr. Solomon also opposes to the proposed regulation but states that if the majority of the board is determined to approve the regulation, then he proposes modifications. Mr. Solomon states that there are too many areas that are vague as written and need to be more defined and specific. Mr. Solomon continues that every licensed pharmacy applying to use these devices must also provide a concise policy and procedure with each application and that the regulation shall include the following language and each applicant's policy and procedure shall specifically address this criteria. Mr. Solomon recommends that 1713(d)(2) read "Upon application, the criteria for patient use shall be specifically spelled out in policy and procedure for operation and/or use of the device established/drawn up by the pharmacy which is submitted and approved by the BOP prior to operation of the machine and patient use."

The board disagrees with the suggested language. The board is uncertain what application Mr. Solomon is referring to, as no application is required pursuant to the proposed regulation. The language in its current form, states that the pharmacist responsible for compliance with pharmacy law is responsible for determining if a patient using the device satisfies the criteria for use. Additionally, it is not the board's intent to over regulate the pharmacy profession, nor does the board have the appropriate resources to individually review and approve each set of criteria established by licensees. However, should the board determine either as part of an investigation or routine inspection that the licensed premises fails to have appropriate criteria in place, it can hold the responsible person(s) accountable for the violation of this section.

Mr. Solomon's next recommendation is, "The policy for carrying out this procedure shall be included in the policy and procedure manual and submitted to the Board of Pharmacy with the application for review to insure that all laws and regulations are met prior to any approval."

Again the board is unclear about the “application” referenced in Mr. Solomon’s suggestion. As stated above the board does not have sufficient resources to review each individual premises policies and procedures, however if as part of an investigation or routine inspection, the board discovers a violation of pharmacy law, identified licensees will be held accountable for such violation(s).

Mr. Solomon next recommends the addition of the following wording, “Methodology and procedure for making this determination shall be outlined in the P&P and will insure that every refill order is reviewed by the pharmacist on duty before the orders can be installed in the device.”

Current pharmacy law already requires that a pharmacist review each prescription, refill or new, as part of the filling and dispensing process. The use of the automated delivery device does not change or alter this requirement.

Mr. Solomon also offers the following language to use instead of the term “adjacent to the pharmacy.” “The device shall be located no further than 15 to 25 feet from the pharmacist’s filling station or pharmacists counseling station. The device shall be operational only during prescription services hours and only when a pharmacist is on duty.”

After must discussion at board meetings, the board determined that the language in its current form sufficiently addresses the acceptable location of the device. In addition the proposed language also speaks to the security of the device. Although Mr. Solomon did not include the rationale behind this recommendation, one can assume that the reason for the second sentence in his recommendation is to ensure that a consumer has access to a pharmacist for patient counseling. As included in the language of the proposed regulation, “immediate consultation with a pharmacist shall be available at the request of the patient. “

Mr. Solomon recommends that the policy and procedure manual spell out minimum requirements for securing the device to insure that installation meets current laws and regulations. This will include who has internal access to the device and where the keys or lock combination for access are secured. “If the device is serviced by a central fill or other remote delivery service to the pharmacy is the driver approved for access to the device or delivering to the pharmacy and leaving the refill orders in a secure lock box.”

The board does not believe that the above modifications are necessary. The proposed regulation does not alter who has access to the licensed pharmacy area, nor does it alter requirements for security of a licensed premises. The delivery device is considered part of the licensed area and

as such the security measures that apply to the licensed area, appropriate personnel etc. also apply to the delivery device.

Mr. Solomon states that the board needs to redefine existing laws and regulations. He states that the pharmacists on duty should bear responsibility at the store level if the supplies come from that store and the refill orders are filled with those supplies. He continues that if prescription orders come from the outside facility, such as from a central fill facility, there should be shared responsibility if the policy and procedure manual requires review of all orders being placed in the device prior to dispensing. He suggests that if at the store level the pharmacist staff is excluded from this process, then the filling entity and pharmacy ownership shall bear all responsibility.

Mr. Solomon's recommendation goes far above the intent of the proposed regulation. It is not the board's intent to redefine all pharmacy operations. Rather the proposed regulation is merely to allow the use of a prescription drop box and automated delivery device. The proposed regulation does not alter the accountability of licensees to adhere to existing pharmacy law, nor does it alter those requirements. It is only adding the option of a delivery device to be included in the licensed premises should the pharmacy choose to employ such a device and a consumer subsequently elects to use the device.

Mr. Solomon also recommends that any incident be committed to writing within 48 hours of the incident and that a report be made to the Board of Pharmacy within 72 hours if the incident caused hospitalization of the patient or requires an extreme level of medical intervention.

The board does not agree with the proposed recommendation. It is unclear what possible scenario Mr. Solomon is attempting to address with this recommendation. Section 1713(d)(9) requires that any incident involving the device be reviewed as part of the pharmacy's quality assurance program as mandated in Business and Professions Code section 4125. It does not seem reasonable to hold a pharmacy electing to use this delivery device to a higher standard than other licensed entities not using the device as would be required by the notification to the Board of Pharmacy provision. Any error, either caused by the device or not, should be treated in the same manner. During investigations and routine inspections it is board policy to review the quality assurance program.

Mr. Solomon's final statement includes that Section 1713(e)(7) needs the role of the central fill facility included in this part of the operational policy.

The board disagrees. The role of the central fill pharmacy is not changed with the use of this device in a pharmacy. Section 1707.4 details the

requirements for both the central fill pharmacy as well as the pharmacy where the consumer obtains the medication.

4. On April 17, 2006 the board received comments and questions from Fred S. Mayer, R.Ph., M.P.H., President, Pharmacists Planning Service, Inc (PPSI). In his letter Mr. Mayer asks several questions.

Specifically Mr. Mayer asks if there will be Kiosk refills for C3s, C4s and C5s.

The proposed regulation would allow medications classified in schedules III, IV and V to be dispensed via the automated delivery machine.

Mr. Mayer also asks if medications with Black Box warnings can be placed in kiosks?

Yes. The automated delivery devices can be used on all previously dispensed prescription medications as defined in the proposed regulation. However if federal law requires that additional information be provided with a prescription, the pharmacy will need to comply with those requirements as well. Moreover, a pharmacist's professional judgment is required to determine whether any drug, controlled substance or drug with a black box warning will be placed in the delivery device.

Mr. Mayer asks if there will be discretion of pharmacists and if so, how, when, where and what means.

The proposed regulation details when a pharmacist can refuse to use the automated delivery device. Moreover, a pharmacist's professional judgment is required to determine whether any drug, controlled substance or drug with a black box warning will be placed in the delivery device.

Mr. Mayer asks if there will be a list of drugs that cannot be put into kiosks, such as insulin, restricted drugs, FDA special warning drugs such as Accutane, etc.

No. The automated delivery devices can be used on all previously dispensed prescription medications as defined in the proposed regulation. However a pharmacist's professional judgment is required to determine whether any drug, controlled substance or drug with a black box warning will be placed in the delivery device.

Mr. Mayer asks if there will be a questionnaire or survey to patients and pharmacists who do not wish to have kiosk prescriptions on their watch. If so, how will it be done. Mr. Mayer also requests a copy of the

questionnaire/survey or information sheet that is between management and the practicing pharmacist.

No. A consumer must elect to use the delivery device, but is not required to use it. In addition, pharmacies are not required to purchase and use these delivery devices. Rather, the proposed regulation will allow the use of such devices, should the pharmacy decide to do. The board is not developing a questionnaire or survey for employers to use so to determine whether a pharmacy should install a delivery device. Should a licensed premises determine that a survey is necessary, the development of the survey will be the pharmacy's responsibility.

Mr. Mayer asks how will consultation issues work for those patients who want further consultation and who will be there to response to the telephone inquiries. Mr. Mayer also asks if someone will be available after hours, Sundays, holidays, etc.

The proposed regulation specifies that a patient who used a delivery machine must have immediate access to a pharmacist either in person or via the phone. It is a business decision for the licensed premises to determine the best manner in which to ensure this occurs. Any violation could result in administrative or disciplinary action by the board.

Mr. Mayer concludes his letter by indicating that he will be faxing the board a copy of a March 14<sup>th</sup> letter from Senator Jackie Speier regarding Senate Concurrent Resolution (SCR 49) on prescription drug errors. Mr. Mayer suggested that the board needs to be represented in the interest of public health safety and harm on this medication error panel.

These comments are outside the scope of the proposed regulation. The board fully supports the efforts of the SCR 49 task force to reduce prescription errors.

### **Summary of Comments Received During the Public Hearing April 26, 2006.**

1. The following individuals provided testimony in support of the proposed regulation.
  - Bob Hansen representing Asteres
  - Richard Mazzoni representing Albertsons
  - Bill Holmes representing ddn Corporation
  - Steve Gray representing Kaiser Permanente
  
2. **Fred Mayer, representing Pharmacists Planning Services, Inc. (PPSI)**

Fred Mayer, representing Pharmacists Planning Services, Inc. (PPSI), acknowledged that the amendments to the proposed regulations help to clarify consumer issues. Mr. Mayer stated that PPSI still had concerns and referred to the information and 18 exhibits PPSI submitted for the October 25, 2005, board meeting and requested that these items be included in the rulemaking file to be forwarded to the Office of Administrative Law.

Mr. Mayer referred to Section 201.57 of the Code of Federal Regulations, requiring pharmacists to distribute medication guides with prescriptions to patients. He referred to a study published by Public Citizen that revealed that only one out of 20 pharmacies surveyed gave out medicine guides and the remainder did not. He introduced this study as exhibit 19.

This testimony is outside of the proposed regulation. No changes to the requirements of Section 201.57 of the Code of Federal Regulations are being made through this proposed regulation.

Mr. Mayer expressed concern that pharmacists are not counseling patients enough now and that by using these automated delivery units, consultation will decrease even further. He added that it isn't clear what the definition of "up to the pharmacist's discretion" is and stated the proposed regulation is ambiguous.

The proposed regulation does not eliminate the patient counseling requirements detailed in pharmacy law. The use of the automated delivery devices is limited to only those prescriptions that do not require patient counseling as defined in pharmacy. However, if a patient requests consultation, section 1713(d)(5) requires that a pharmacy provide an immediate consultation with a pharmacist upon request of any patient who uses an automated delivery device.

Mr. Mayer introduced as exhibit 20, an article published in the September 26, 2005, titled "Duane Reade on Fast Track with DR Express." The article states that Duane Reade, a regional chain with 250 stores in New York and New Jersey has immediate video conferencing with pharmacy staff on all of their 212 kiosks.

As stated above, the regulation requires an immediate consultation with a pharmacist upon the request of a patient. The proposed regulation does not mandate that this consultation be available via video conferencing.

Mr. Mayer also expressed concern about how patients would contact their pharmacist as they use the system. He added that another concern is for non-English speaking patients and he asked how the board would deal with this issue.

The board recognizes that language differences present a possible barrier to patient consultation. The proposed regulation however does not remove the patient consultation requirement. The only prescriptions that may be delivered via the automated delivery device are those that do not require patient consultation as required by pharmacy law. The proposed regulation does not change the requirements for patient consultation. The proposed regulation does not change how pharmacists communicate with non-English speaking patients. Access to a pharmacist via the telephone is not difference for a non-English speaking patient than face to face communication.

Mr. Mayer introduced as exhibit 21 a report titled “Probe Finds Food and Drug Needs More Muscle” that shows that two thirds of the new drug studies conducted have no post market surveillance. He added that this is wrong. He stated that more consultation is needed, not less.

The proposed regulation does not change the requirements under which a patient consultation is required. However, a pharmacist may determine that a particular patient should not be using an automated delivery machine to obtain refill medication. Instead the patient should talk with the pharmacist. Such a patient would not be able to obtain his or her medications from an automated delivery device.

Mr. Mayer referred to SCR 49 and a prescription error study by Senator Jackie Speier and he asked the board to delay any action on the proposed regulation until the results of the study are revealed. He added that using kiosks would not reduce errors. He asked that the board delay action until the results of this study are revealed.

The board does not intend to delay moving forward with this regulation. Testimony provided indicates that the use of the automated delivery devices does not cause prescription errors. To the contrary, it eliminates those prescription errors that result from the wrong medication being dispensed to a patient when he or she picks up medication (e.g., due to a mix up in names, similar or identical names, etc).

Mr. Mayer stated that if automated delivery machines are approved, PPSI requests that all kiosks have video conferencing abilities for delivery of all medications, especially those with black box warnings.

The proposed regulation does not require the use of video conferencing, although interest pharmacies and vendors could use such technology.

Mr. Mayer introduced as exhibit 21, a “Medication Guide for Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).” He added that that 16,000 deaths

occur based on a Stanford University study. He added that after seven years of petitioning the federal Food and Drug Administration, Black Box warnings on non-steroidal drugs and medication guides will be distributed to everyone. He added that these drugs should not be used in kiosks.

The board is not altering or in any way influencing any federal requirements with respect to black box warnings. These comments are outside of the scope of this regulation.

Mr. Mayer restated that if kiosks are approved, PPSI requests that all kiosks have similar video conferencing such as the Duane Reade's DR Express available.

The proposed regulation does not require the use of video conferencing, although interest pharmacies and vendors could use such technology.

Mr. Mayer expressed concern that Controlled Substance II-III prescriptions could be available in kiosks. He added that there is nationally an epidemic of overuse of Vicodin. He asked how the pharmacist would counsel patients on Controlled Substances III – V prescriptions.

The regulation as currently constituted, would permit these machines to be used to deliver controlled substances. Permitting use of these machines will have no contributing affect on the overuse of Vicodin

Mr. Mayer's additional exhibits included the following:

- A. A copy of the testimony provided at the regulation hearing.
- B. Letter from Senator Jackie Speier regarding Senate Concurrent Resolution (SCR) 49.
- C. A copy of the testimony provided by Mr. Mayer at the October 25, 2005, regulation hearing.
- D. A copy of a letter from Harry dated September 27, 2005 as well as a portion of an e-mail from Roget Klotz.
- E. A copy of a letter from James Kramme, RPh.
- F. A copy of a letter from Bret Miller, Pharm.D.
- G. A copy of a letter from Robert A. Reed, RPh, Pharm.D.
- H. A copy of an article entitled "Worst Pills, Best Pills, A Consumer's Guide to Avoiding Drug-Induced Death or Illness"
- I. A copy of an e-mail from Larry S. Sasich, Pharm.D. MPH that includes the words "Black box Warnings."
- J. A copy of an article entitled "Useful Drug Information: 20 Years and Still Waiting" as published in Drug Topics, July 7, 2003.
- K. A document entitled, "Statistics on Consumers' Mixing Prescription Medicines with Over-the-Counter Drugs and Herbals." The source is not referenced.

- L. A copy of an article from the Wall Street Journal entitled, “Generic Fares Well in Big Psychiatry Study.”
- M. A copy of an article entitled “5 Widely Used Drugs Called Unsafe.”
- N. A copy of an article entitled, “Pharmacists Can Be Liable for Drug Risks.”
- O. A copy of a report for the Medication Error Analysis Proposal funded by the National Association of Boards of Pharmacy Foundation.
- P. An article entitled “FDA Strengthens Controls, Issues Consumer Alert on Importing Certain Prescription Drugs” as published in FDA News.
- Q. A copy of a letter from Steven K Galson, M.D., M.P.H, the Acting Director for the Center for Drug Evaluation and Research dated July 26, 2005.
- R. A copy of an article entitled, “Day Surgery Patients Found At Risk for Medication Errors” as published in Pharmacy Practice News in September 225.
- S. A copy of an article entitled, “Generic Drugs Sampled Freely in Aetna Test” as published in the Wall Street Journal.
- T. A copy of an agenda for the Campaign for Patient Safety.
- U. A copy of a letter from Mr. Mayer to the board dated September 20, 2005, detailing concerns to be presented at the board’s Licensing Committee.
- V. A copy of an article entitled, “ATMs Not the Answer for Drugs.”
- W. A copy of an article entitled, “Will ATMs Replace Us?” as published in Drug Topics
- X. A copy of an agenda for the Dietary Supplement Safety Committee (DSSC) Meeting.
- Y. A copy of the board’s “Notice to Consumers” poster distributed to all pharmacies, and required by California Code of Regulations section 1707.2 to be posted in all pharmacies.

Exhibit A – Testimony provided at the Regulation Hearing.

The board responded to these items.

Exhibit B – Letter from Senator Jackie Speier.

This letter discusses Senate Concurrent Resolution (SCR 49) which creates a 17-member panel charged with producing a report with recommendations on ways to reduce the incidence of medication errors.

The board fully supports the efforts behind SCR 49. The board does not believe that the use of automated delivery devices will increase medication errors. To the contrary, testimony provided during the regulation hearing indicates that the

use of such devices will decrease the number of certain types of medication errors.

Exhibit C – A copy of testimony provided by Mr. Mayer at the October 25, 2005, regulation hearing.

Mr. Mayer's testimony from this previous hearing included the introduction of several exhibits being discussed below. In addition Mr. Mayer asks how a pharmacist can provide consultation when a prescription is dispensed from a kiosk.

The proposed regulation does not remove the patient consultation requirement. The only prescriptions that may be delivered via the automated delivery device are those that do not require patient consultation as required by pharmacy law. However, a pharmacist may determine that a particular patient should not be using an automated delivery machine to obtain refill medication. Instead the patient should talk with the pharmacist. Such a patient would not be able to obtain his or her medications from an automated delivery device. Additionally, should a patient request a consultation with a pharmacist with a prescription delivered by the automated delivery device, the patient must be provided with an immediate consultation either via the phone or in person as required by this regulation.

Exhibit D – Copy of an e-mail from Harry and a portion of an e-mail from Robert Klotz.

The e-mail from Harry poses two questions. First, what does the term "when the pharmacy is closed mean?" and second, "how does a patient have access to a pharmacist when the pharmacy is closed?"

The term "when the pharmacy is closed", means that the licensed pharmacy area is closed, but the non-pharmacy business is still open. As required in the regulation, the automated delivery device must be adjacent to the pharmacy; it cannot be contained outside of the licensed area as suggested by Harry. Also, as required by the regulation, should a patient request a consultation with a pharmacist with a prescription delivered by the automated delivery device, the patient must be provided with an immediate consultation either via the phone or in person. It is up to the pharmacy to determine how to comply with this requirement.

The partial e-mail from Roger Klotz provides information about his business as a consultant and that he continues to see patients with problems and diseases induced by drugs.

The board recognizes the importance of a thorough drug utilization review to prevent adverse drug events. That is why the use of automated delivery devices is limited to only previously dispensed medications.

Additional comments are made by Mr. Klotz. They are outside of the scope of this regulation.

Exhibit E – A letter from James Kramer, RPh.

Mr. Kramer states that he feels that kiosks are bad medicine due to no counseling etc and are not in the best interest of the public's health. He continues to state that it is time for the board to consider what is in the best interest of the patient, not the chain drug stores.

The board disagrees with Mr. Kramer's comments. The use of kiosks, or automated delivery devices is limited in scope to prevent the use of such a device on a prescription medication that requires patient consultation or when a pharmacist feels that it is not in the best interest of the patient to do so. The board is not pursuing this regulation because it is in the best interest on chain drug stores. The proposed regulation is designed to assist consumers with receiving medications via a delivery device that is accessible during after the pharmacy is closed to ensure continuity in a drug regimen that could otherwise be interrupted if the patient has to wait until the following day to receive a prescription. The use of these delivery machines and prescription drop boxes are for patient convenience.

Exhibit F – A letter from Bret Miller, Pharm.D.

Dr. Miller's letter states that the use of automated delivery devices will lead to long term changes in access to pharmacists. He questions whether the board considered that centrally filled prescriptions are going to be the majority of the prescriptions placed in these units.

The proposed regulation is designed to assist consumers with receiving medications via a delivery device that is accessible during and after the pharmacy is closed to ensure continuity in a drug regimen that could otherwise be interrupted if the patient has to wait until the following day to receive a prescription. The use of these delivery machines and prescription drop boxes are for patient convenience. As required by the regulation, any patient using the delivery device may request an immediate consultation with a pharmacist upon receipt of the prescription. In addition, the role of the central fill pharmacy is not altered by the use of the automated delivery device.

Dr. Miller also questions how the board can claim that the use of the delivery device will not have an impact on either the patient health or on the pharmacy staff level.

The use of the delivery device can improve a patient's health by ensuring the continuity of a drug regimen by making prescriptions available after the pharmacy is closed. The board does not anticipate any impact on the pharmacy staff levels.

Dr. Miller states that interactions with the pharmacist will be lessened by these delivery devices and asks about drug interactions that are often discovered by him when a patient picks up a prescription.

In general a consumer obtains a prescription from a walk-in area from a pharmacy clerk, not a pharmacist. However, any prescription that requires consultation cannot be delivered or dispensed with the automated delivery device. In addition, the proposed regulation requires that a pharmacist be immediately available for either an in-person or telephone consultation upon request of the patient.

Dr. Miller states that use of the automated delivery devices will cut staff that will further put stress on the pharmacist remaining.

The board disagrees with this statement. The board does not anticipate any reduction in staffing levels at a pharmacy electing to use this device.

Exhibit G – Letter from Robert A. Reed, RPh, Pharm.D.

Dr. Reed states that the proposed changes will take the pharmacy profession in a drastically new and detrimental heading and that he sees the proposal as warping the effectiveness and usefulness in providing quality health care.

The board disagrees with this statement. The proposed regulation is designed to assist consumers with receiving medications via a delivery device that is accessible during and after the pharmacy is closed to ensure continuity in a drug regimen that could otherwise be interrupted if the patient has to wait until the following day to receive a prescription. Moreover, there are several safeguards in place to ensure that a patient's safety is not compromised, (e.g., immediate consultation with a pharmacist for patients with questions or an issue, a pharmacist's judgment in whether a medication will be dispensed this way).

Dr. Reed states that pharmacists are available to all by simply allowing the patient to approach them with questions without a prior appointment and to use a pharmacist's knowledge and advice and continues on that the patient will not gain from this proposal.

The board recognizes the integral role a pharmacist's plays in a patient's health care. The use of these automated delivery devices is limited in scope; specifically, the device can only be used on previously dispensed prescriptions

when patient consultation is not required by law. The patient must elect to use the delivery device. In addition, as a precautionary measure, the board has empowered the pharmacist to prohibit the use of the delivery device when, in his or her professional judgment, use would compromise a consumer's health outcome. Also, a consumer can request and obtain an immediate telephone or in-person consultation with a pharmacist when obtaining medication from an automated delivery device. If the pharmacy is closed at the time that the prescription is delivered to the patient via this device, the patient will still have access to a pharmacist - - currently a patient only has access to a pharmacist while the pharmacy is open. Additionally, the proposed regulation is designed to assist consumers with receiving medications via a delivery device that is accessible after the pharmacy is closed to ensure continuity in a drug regimen that could otherwise be interrupted if the patient has to wait until the following day to receive a prescription. The use of these delivery machines and prescription drop boxes are for patient convenience.

Dr. Miller states that he firmly believes that the proposed regulation is being pushed through by corporate greed, with no thought of its effects on the quality of patient care of the future practice of the pharmacy profession.

The driving force for the board is always consumer protection and advancing patient care in California. Testimony provided including testimony by a board inspector based a review of the waiver granted to Longs, indicated that the use of these delivery devices decreases the number of prescriptions errors that occur from the wrong prescription being dispensed to a patient from the "will call" shelf in a pharmacy (e.g., a prescription labeled for T. Smith is dispensed to another patient, Tom Smith). In addition, because these devices allow prescription drugs available after the pharmacy is closed, consumers can continue their drug regimen uninterrupted because they have access to their medications even when the pharmacy is closed.

Exhibit H – Copy of a subscription entitled "Worst Pills, Best Pills, A Consumer's Guide to Avoiding Drug-Induced Death or Illness."

The board is uncertain why Mr. Mayer included this as part of comments in opposition to this proposed regulation. The articles discuss adverse drug reactions and drug-induced diseases. No arguments are included or related to the use of automated delivery devices. These articles are outside the scope of the regulation.

Exhibit I – Copy of an e-mail from Larry D. Sasich, Pharm.D., MPH

The board is uncertain why Mr. Mayer included this as part of comments in opposition to this proposed regulation. These comments are outside the scope of the regulation as the proposed regulation is not altering or modifying any reporting requirements.

Exhibit J – A copy of an article entitled, “Useful Drug Information: 20 Years and Still Waiting.”

This article discusses several items outside the scope of this regulation. However, the article does reinforce the importance of interaction with a pharmacist.

The board recognizes the integral role a pharmacist’s plays in a patient’s health care. The use of these automated delivery devices is limited in scope; specifically, the device can only be used on previously dispensed prescriptions when patient consultation is not required by law. The patient must elect to use the delivery device. In addition, as a precautionary measure, the board has empowered the pharmacist to prohibit the use of the delivery device when, in his or her professional judgment, use would compromise a consumer’s health outcome. Also, a consumer can request and obtain an immediate telephone or in-person consultation with a pharmacist when obtaining medication from an automated delivery device. If the pharmacy is closed at the time that the prescription is delivered to the patient via this device, the patient will still have access to a pharmacist - - currently a patient only has access to a pharmacist while the pharmacy is open.

Exhibit K – Statistics on Consumers’ Mixing Prescription Medicines with Over-the-Counter Drugs and Herbals.

There are several relevant comments included in this fact sheet. First, kiosks will take away all refills and place them in an ATM machine without a pharmacist’s supervision and consultation.

No source was cited for this statistics, as such the board can neither refute or support this information.

The fact sheet cites that over 20 million refills prescriptions for Vioxx were dispensed and questions if a Kiosk was used how would the pharmacist have ever known if the patient was experiencing side effects to report to the FDA.

The board has empowered the pharmacist to prohibit the use of the delivery device when, in his or her professional judgment, use would compromise a consumer’s health outcome.

The fact sheet states that patients want to be able to consult with a pharmacist on their prescription medicines.

The board recognizes the integral role a pharmacist’s plays in a patient’s health care. The use of these automated delivery devices is limited in scope; specifically, the device can only be used on previously dispensed prescriptions

when patient consultation is not required by law. The patient must elect to use the delivery device.

The fact sheet poses several rhetorical questions including how a patient can ask the kiosk a question, why bother to waste tax payer's money with producing a "Notice to Consumers" sign, why train pharmacists to receive a pharmacy license for patients to get medicines from a kiosk, and does any care that 107,000 deaths occur each year.

Obviously a patient cannot pose a question to a kiosk which is why the proposed regulation requires an immediate consultation with a pharmacist upon the request by a consumer. The "Notice to Consumer" sign is not a waste of taxpayer money and continues to be relevant. As required in the proposed regulation, the kiosk can only be used for previously dispensed medications. Pharmacist's play an integral role in a patient's healthcare and will continue to do so.

Exhibit L – Article entitled, "Generic Fares Well in Big Psychiatry Study."

The article is not relevant to the proposed rulemaking.

Exhibit M – Article entitled, "5 Widely Used Drugs Called Unsafe."

This article is not relevant to the proposed regulation.

Exhibit N – Article entitled, "Pharmacists Can Be Liable for Drug Risks."

This article is not relevant to the proposed regulation.

Exhibit O – Copy of a report entitled, "Medication Errors from Citation/Fine Date Reports 1999-November 2003.

This report summarizes the number of citations issued by Medication Error Category.

None of the categories listed attribute medication errors to the use of automated delivery devices. However, testimony provided at the regulation hearing indicate that 12 errors reported or 6.2% of those reported would have been eliminated had a automated delivery device been used. Use of these devices eliminates the possibility of a patient receiving someone else's prescription.

Exhibit P – Article entitled, "FDA Strengthens Controls, Issues Consumer Alerts on Importing Certain Prescription Drug."

This article details drugs added to the Import Alert and is outside the scope of the proposed regulation.

Exhibit Q – Letter from Steven K. Galson, M.D., M.P.H.

This letter confirms that a request from PPSI to require a MedGuide for distribution with all prescription non-steroidal anti-inflammatory drugs was granted. This letter is outside the scope of the proposed regulation.

Exhibit R – Article entitled, “Day Surgery Patients Found At Risk for Medication Errors.”

The portion of the article provided discusses the error rates of prescriptions written for surgical patients upon discharge. This article is outside the scope of the proposed regulation.

Exhibit S – Article entitled, “Generic Drugs Sample Freely in Aetna Test.”

This article is about the use of MedVantix machines installed in doctor’s offices. These machines are used to dispense generic drugs at the physician’s office. The proposed regulation is to allow the use of automated delivery devices in pharmacies that elect to do so in California. This article is outside the scope of the proposed regulation.

Exhibit T – Copy of Agenda for Campaign for Patient Safety (CPS).

The board is unclear why this agenda was provided. There is nothing listed on the agenda within the scope of this proposed regulation.

Exhibit U – Copy of letter from Mr. Mayer to the board dated September 20, 2005 wherein PPSI raises issues of concerns.

The first issue raised by Mr. Mayer surrounds the findings of the Medication Error Analysis Study from the Cite and Fine Committee. Mr. Mayer suggests that the Licensing Committee institute e-scripts for all healthcare providers, have the ICD-9 codes listed on all prescriptions and increase the amount of consultation by pharmacists which would take care of the problems.

The board is also concerned about the number of prescription errors. However, the first two suggestions are outside the scope of the proposed regulation. The board recognizes the integral role a pharmacist’s plays in a patient’s health care. The use of these automated delivery devices is limited in scope; specifically, the device can only be used on previously dispensed prescriptions when patient consultation is not required by law. The patient must elect to use the delivery device. In addition, as a precautionary measure, the board has empowered the pharmacist to prohibit the use of the delivery device when, in his or her professional judgment, use would compromise a consumer’s health outcome. Also, a consumer can request and obtain an immediate telephone or in-person

consultation with a pharmacist when obtaining medication from an automated delivery device. If the pharmacy is closed at the time that the prescription is delivered to the patient via this device, the patient will still have access to a pharmacist - - currently a patient only has access to a pharmacist while the pharmacy is open.

The second item Mr. Mayer requests that the Licensing Committee direct the board to look into violation of use by pharmacies in compliance with Medication Guides.

This request is outside the scope of this proposed regulation.

The third request from PPSI is to ask all Pharmacy Benefit Managers and mail order firms etc, to be in compliance with Medicare Modernization Act 2003 which requires that pharmacists should be performing one-on-one patient consultation and drug utilization review.

The board agrees with this request. In fact both the one-on-one patient consultation and drug utilization review are already requirements in pharmacy law. The proposed regulation only affects previously dispensed medications which do not require a drug utilization review or patient consultation by a pharmacist unless requested by the patient.

Exhibit V – Copy of article entitled, “ATMs Not the Answer for Drugs.”

This article appears to be an editorial by Whallen Fong discussing the use of automated prescription vending machines. Mr. Fong states that the use of these machines may help customers who don't want to wait in line, but will have to wait in line anyway if they want to speak with a pharmacist.

The proposed regulation is designed to assist consumers with receiving medications via a delivery device that is accessible during and after the pharmacy is closed to ensure continuity in a drug regimen that could otherwise be interrupted if the patient has to wait until the following day to receive a prescription. A consumer can request and obtain an immediate telephone or in-person consultation with a pharmacist when obtaining medication from an automated delivery device. If the pharmacy is closed at the time that the prescription is delivered to the patient via this device, the patient will still have access to a pharmacist - - currently a patient only has access to a pharmacist while the pharmacy is open. A patient may end up waiting in two lines if the pharmacy is open when they pick up their prescription from the automated delivery device. However, the patient made the decision to use the device.

Mr. Fong continues to state that there is still a need for someone to fill these machines and to verify that the medication put into the bag is correct and that he

does not see this as a way to decrease the amount of staffing in a pharmacy but rather a way to create a new line for customers.

A consumer must elect to use the delivery device, but is not required to use it. In addition, pharmacies are not required to purchase and use these delivery devices. Rather, the proposed regulation will allow the use of such devices, should the pharmacy decide to do.

Exhibit W – Article entitled, “Will ATMs Replace You?”

A significant portion of this article speaks in favor of the use of automated delivery devices. However some concerns are addressed in article as raised by Fred Mayer, PPSI. Specifically Mr. Mayer asks how a machine can be as safe as picking up a refill from a human being, talking to that person, who can check that you received the correct medication and warn you about anything you need to know.

Testimony provided at the hearing as well as information provided in this article indicate that an automated delivery device reduces the risk of a patient receiving someone else’s medications. A consumer can request and obtain an immediate telephone or in-person consultation with a pharmacist when obtaining medication from an automated delivery device. If the pharmacy is closed at the time that the prescription is delivered to the patient via this device, the patient will still have access to a pharmacist - - currently a patient only has access to a pharmacist while the pharmacy is open.

The article continues to quote additional concerns raised by Mr. Mayer, including that seniors could be robbed of their medications depending of there the machines are located and that he is worried that refills are just the beginning and that in time these devices will be used to fill first-time orders. He also believes that these devices are meant to store and dispense certain medications and can pose serious health risks to women who are or are not about to become pregnant.

The board is unclear the proposed regulation would increase the risk that seniors could be harmed while still in the pharmacy. Consumers elect to use the machines; there is not requirement in this proposal to require use of the delivery device. The proposed regulation is only for previously dispensed medication. There is no discussion about using the delivery device for anything other than previously dispensed medications as defined in the proposed regulation. Lastly, the pharmacist has ultimate discretion to determine if a prescription can be placed in the delivery device. It would be contrary to good pharmacist care to place an item in the delivery device that could cause a patient harm.

The article then quotes John Rector, general counsel for the National Community Pharmacists Association. Mr. Rector states that there should be more patient-

pharmacist interaction, not less and that these vending machines put more distance between them, without any apparent remedy in place if there is a mistake.

The board disagrees with Mr. Rector's statement. The automated delivery system can only be used under specific conditions, the proposed language does not allow for unlimited use. Additionally, the consumer must elect to use the system, not the pharmacist. Any prescription that requires consultation cannot be delivered or dispensed with the automated delivery device. In addition, the proposed regulation requires that a pharmacist be immediately available for either an in-person or telephone consultation upon request of the patient.

Since use of these devices began, there has not been one instance reported to the board of a patient receiving the wrong prescription. In addition Section 1713(d)(9) requires that any incident involving the device be reviewed as part of the pharmacy's quality assurance program as mandated in Business and Professions Code section 4125.

Mr. Mayer is then quoted in the article stating that every time a person picks up a drug, he or she should have the opportunity to talk face-to-face with their pharmacist.

The board agrees with this statement. First it is important to note that a consumer elects to use this machine, not the pharmacist or pharmacy. In addition, any patient receiving a prescription via the delivery device can request an immediate consultation although it may not be face-to-face if the pharmacy is closed. However, currently if a patient picks up a prescription while the pharmacy is open and later has a question for the pharmacist after the pharmacy is closed, the patient cannot receive any consultation at all.

Exhibit X – A copy of an agenda for the Dietary Supplement Safety Committee (DSSC) Meeting.

The board is unclear why this agenda was provided. There is nothing listed on the agenda within the scope of this proposed regulation.

Exhibit Y – A copy of the Notice to Consumers poster developed and distributed by the Board of Pharmacy.

The board is unclear why this was provided.

### **3. John Cronin, representing the California Pharmacists Association**

Dr. Cronin referred to written comments submitted on behalf of the California Pharmacists Association (CPhA). Dr. Cronin stated that the

CPhA believes that these devices are basically safe and represent a useful tool for consumers but the CPhA does not believe that the board's regulation ensures that the use of these machines will further a high standard of patient safety, promote good patient care and advance pharmacist-patient communication.

The purpose of the pharmacy law is to assure patient safety with good patient care. The board believes that the proposed regulation will promote patient care by allowing consumers access to prescription medications even when a pharmacy is closed, ensuring continuity of medication therapy.

Dr. Cronin referred to section 1713(d) of the California Code of Regulations where the language states that a pharmacy may use an automated delivery device to deliver previously dispensed prescription medications, provided a number of specified items.

Dr. Cronin stated that "previously dispensed" indicates that the patient has had this drug before. In reading the comments, this was the intent of adding the language. He referred to CCR section 1713(g) where it states "because they have been previously dispensed to the patient by the pharmacy in the same dosage or strength with the same written directions." Dr. Cronin stated that this seems to imply that the prescription was filled at that pharmacy before. He added that the board's intent must be consistent between the two sections. Either the patient had the prescription before from another pharmacy, or, there is a requirement that the prescription must be filled in the pharmacy where the devices are located.

Section 1713(g) defines a "previously dispensed prescription medication" as a prescription medication that does not require mandatory consultation under section 1707.2(b)(1), because the medication has been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same directions." Given this definition, the prescription must have been filled in the pharmacy where the device is located to qualify for use.

Dr. Cronin stated that the language should allow retail pharmacies to compete with mail order pharmacies. Mail order pharmacies never fill an original prescription; they dispense medication that has been filled before by other pharmacies. Mail order pharmacies are unable to perform face-to-face consultation and consequently do not want new prescriptions. He asked if this is the board's intent; that this refers to a previously dispensed medication that would qualify for inclusion in these devices.

The board's definition of "previously-dispensed prescription medications" is clear in Section 1713(g). According to this section the meaning of a "previously-dispensed prescription medication" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1) because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions. The board is not considering expanding the definition. Additionally, at the conclusion of the regulation hearing, Deputy Attorney General Mr. Room referred to Dr. Cronin's comment about the use of the phrase "previously dispensed." Mr. Room stated that the language is from section 1707.2 of the California Code of Regulations and the intent was to use these machines synonymously in situations where consultation is not automatically required.

4. **Liberty Sanchez, representing the Law Offices of Barry Broad, on behalf of the United Food and Commercial Workers Union (UFCW) in Opposition of the Proposed Regulations.**

Ms. Sanchez referred to written comments dated April 10, 2006, submitted to the board by the UFCW.

Ms. Sanchez stated that the UFCW requests the board to conduct a more thorough study of the issue prior to promulgating the regulations. The UFCW believes that as drafted, the regulations have a lot of statements and a lot of ambiguity. The UFCW has concern that the underlying purpose of adopting the regulations is more of a consumer convenience than of consumer protection and safety.

The board disagrees. The purpose of the Pharmacy Law is to assure patient safety with good patient care. The board believes that the proposed regulation will promote patient care by allowing consumers access to prescription medications even when a pharmacy is closed, ensuring continuity of medication therapy in these situations where 1) the patient requests to use an automated delivery device and 2) the reviewing pharmacist does not believe that the patient should discuss the refill with the pharmacist. And requirements of this regulation mandate that a patient using an automated delivery machine must be provided with a means to immediate consultation with a pharmacist if the patient has a question. This guaranteed expedited access could result in a patient using the machine to have faster access to a refill medication and speaking with a pharmacist than a patient who elects not to use the automated device and must otherwise wait in line in the pharmacy to get the medicine and speak with a pharmacist.

Ms. Sanchez stated that the UFCW is concerned that the required consent form that the patient must complete isn't clear enough for patients to make what an informed decision about giving consent.

Section 1713(d)(1) requires that 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. A consumer elects to use this device, it is not a requirement. It is reasonable to assume that only consumers that feel comfortable with the use of the device will elect to do so. Consumers can still receive their previously-dispensed prescription medications in the traditional fashion or can ask questions about the form if they don't understand. No form can answer all question.

Ms. Sanchez stated that the regulation provides that "providing a means to speak to a pharmacist or make a call on a 1-800 number" when a patient makes such a request is not sufficient. She added that a "means" could be interpreted to mean, "we have the phone, we have the 1-800 number," but no one is actually there to answer the 1-800 number.

While the board did not feel this language was ambiguous, the board altered the language at the board meeting to further clarify section 1713(d)(5) to remove any ambiguity. This change resulted in a subsequent 15-day notice in May 2006 to alter section 1713(d)(5) to read "the pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of the patient."

Ms. Sanchez stated that the UFCW is concerned that there are different types of kiosk devices and some might be better than others. This aspect hasn't been thoroughly investigated. The UFCW does not believe that the proposed regulations provide an appropriate method for patients who encounter a broken machine to understand what to do to secure their medication in an alternative manner.

Section 1713(d)(9) requires that any incident involving the device shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125. Additionally, section 1713(e)(6) requires that the pharmacy is required to ensure the delivery of medications to patients in the event the device is disabled or malfunctions. Any failure on the part of the pharmacy to comply with these requirements would constitute a violation of pharmacy law.

Ms. Sanchez stated that UFCW is very concerned about the lack of discretion afforded pharmacists in determining whether or not these machines can be placed in their pharmacies and if so, what types of prescriptions can be dispensed from the machines, particularly in light of the fact that the pharmacist would still be liable if errors are made if the

machine breaks down, or if the machine erroneously dispenses the wrong drug, etc.

Section 1713(d)(4) provides the latitude for a pharmacist not use the device to deliver a previously-dispensed prescription medication if the pharmacist determines that the patient requires counseling. In addition pharmacists have the discretion to determine that a patient using the device meets the inclusion criteria for use of the device as established by the pharmacy (Section 1713(d)(2)).

Ms. Sanchez stated the UFCW is requesting that the liability issues be addressed and amended into the regulations. She added that it needs to be clear that pharmacists have complete discretion over what prescription drugs are dispensed through the devices and in order to ensure that discretion; the pharmacist should be protected from any discipline or discharge from his or her employer when the pharmacist is exercising his good faith professional judgment. She stated that the UFCW is suggesting that the pharmacist be expressly immune from licensure sanctions if an automated delivery device malfunctions or an error results from the patient's use of the machine.

The board disagrees with this conclusion. It is not the board's intent to unfairly pursue administrative or disciplinary action against a pharmacist, unless he or she is found in violation of pharmacy. Section 1713 (d)(9) states that 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.

The board believes that whereas there has been no problem with mechanical failure of these devices currently in use, the pharmacy still must be responsible for the accuracy of the dispensing process. Providing such a waiver as proposed by Ms. Sanchez could have the unwanted effect of careless placing and refilling of prescription medications into the automated delivery device resulting in the patient getting the incorrect medication and yet no one in the pharmacy would be held accountable for it. This is absolutely not in a patient's interest.

Ms. Sanchez stated that the UFCW is opposed to the proposed regulations and urges the board to study the issue further before adopting the regulations.

The board is not going to delay the implementation of the proposed regulation. However several modifications were made as a result of the regulation hearing resulting in an additional 15 day notice.

The board inquired if there were other areas of vagueness in the proposed regulation not previously addressed by Ms. Sanchez. Ms. Sanchez responded that the only vagueness issues addressed were the lack of clarity in the written consent form, what the form should look like and the type of communication needed between the pharmacy and the patient to convey how the machine works, what the patient needs to do and what recourse the patient has if the machine malfunctions, etc. She added that the issues she raised were the 1-800 number, the phrase in the proposed regulations “provide a means to immediately reach the pharmacist or a pharmacist via the 1-800 number.” She added that “provide a means” is insufficient and should be clarified so patients have the ability for actual immediate contact, not just a means for immediate contact. Additionally, the UFCW is very concerned about the liability concerns and the lack of clarity there.

The 15-day proposed regulation addresses the items Ms. Sanchez stated were vague. Specifically, section 1713(d)(1) requires that each patient choosing to use this device must sign a consent form demonstrating his or her informed consent to do so. As a consumer elects to use this device, only consumers comfortable with receiving previously dispensed prescription medication in this manner will elect to do so. Section 1713(e)(5) requires that consumers must be oriented on the use of the automated deliver device as well as when expected prescription medications is not available. Patients seeking the medication from the delivery devices will have options for problems if the devices don’t work or if the patient has questions he or she wants to discuss with a pharmacist. The patient can also alter his or her decision to use the device, or even to obtain the medication from another pharmacy in the future (if he or she requests to have the prescription transferred to another pharmacy).

Ms. Sanchez stated that another issue Mr. Gusman raised in his letter was a discretion issue in relation to the pharmacy and the pharmacist regarding the ability to determine if kiosks should be placed in the pharmacy and what exactly can be dispensed in them.

The proposed regulation specifies the conditions under which the device can be used. It states that the pharmacy is responsible for the prescription medications stored in the device. A pharmacist will not allow the use of the device to delivery previously dispensed prescription medications if he or she determines that the patient requires counseling.

### **Summary of Comments Received after 15-Day Notice.**

The board received two comments in response to the additional 15-Day Notice.

1. On May 2, 2006, the board received an e-mail from Fred S. Mayer, R.Ph., M.P.H., President, PPSI. He requested that that the board include a continuing education program entitled, "The Pharmacist's Legal Duty to Counsel Patients" printed in the Drug Topics magazine on April 17, 2006 issue to be submitted as official testimony in the record for this rulemaking.

This article reinforces the importance of patient consultation. This article is outside of the scope of 15-Day notice. The proposed automated delivery devices cannot be used to dispense any prescription medication that requires patient consultation or on any prescription the pharmacist determines requires patient consultation. In addition, immediate consultation by a pharmacist must be provided upon the request of the patient. The board agrees with Mr. Mayer on the importance of patient consultation and has throughout this rulemaking continued to require patient consultation in those situations where it is required or when the patient has questions.

2. On May 11, 2006, the board received a letter from Liberty Sanchez on behalf of the United Food and Commercial Workers Union, Western States Council.

The letter submitted by Ms. Sanchez is identical to that submitted by Shane A. Guzman dated April 10, 2006. These comments are not relevant to the 15-Day Notice and have been addressed previously in this document.

**Local Mandate:**

None

**Business Impact:**

This regulation will not have a significant adverse economic impact on businesses, which must opt to use the devices - - there is no mandate that they use the devices. This determination was based on the absence of testimony indicating adverse economic impact regarding these rulemaking proposals at the informational hearing held by the board, during the initial 45-day comment period, the hearing held on April 26, 2006, and following the 15-day notice. Pharmacies that opt to use the devices must comply with the requirements of the regulation.

**Specific Technologies or Equipment:**

This regulation does not mandate the use of specific technologies or equipment, but does allow pharmacies to use automated delivery devices for previously

dispensed medications and “drop boxes” for submission of prescriptions to the pharmacy.

**Consideration of Alternatives:**

Yes, the board considered continuing to grant waivers to allow for the use of the automated delivery devices. After consideration the board determined that pursuing this regulation would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to the affected persons than the proposed regulation.