



**California State Board of Pharmacy**

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**STATE BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
ENFORCEMENT COMMITTEE PUBLIC MEETING  
MINUTES**

**DATE:** January 10, 2014

**LOCATION:** DCA Headquarters  
1625 N Market Blvd – Hearing Room  
Sacramento, CA 95834

**COMMITTEE MEMBERS**

**PRESENT:** Amy Gutierrez, PharmD, Chair  
Rosalyn Hackworth, Public Member  
Gregg Lippe, CPA, Public Member  
Stanley Weisser, RPh

**COMMITTEE MEMBERS**

**NOT PRESENT:** Victor Law, RPh

**OTHER BOARD MEMBERS**

**IN ATTENDANCE:** Allan Schaad, RPh

**STAFF**

**PRESENT:** Virginia Herold, Executive Officer  
Anne Sodergren, Assistant Executive Officer  
Robert Ratcliff, RPh, Supervising Inspector  
Joshua Room, Supervising Deputy Attorney General  
Michael Santiago, DCA Staff Counsel  
Carolyn Klein, Manager II  
Rob Buckner, Criminal Convictions Manager  
Laura Hendricks, Administrative Analyst

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The meeting was called to at 9:36 a.m. Dr. Gutierrez, Chair, welcomed those in attendance. Roll call was taken and a quorum was established.

## I. Enforcement Matters

### a. **Discussion on the Preemption of California’s e-Pedigree Requirements, as Required by California Business and Professions Code Section 4034.1 and Enacted H.R. 3204, the Federal Drug Quality and Security Act**

#### Background

On November 27, 2013, President Obama signed HR 3204, establishing a track and trace system for the US. This legislation contains language that immediately upon enactment preempts any state’s track and trace systems. This exemption is:

#### **“SEC. 585. UNIFORM NATIONAL POLICY**

##### **“(a) PRODUCT TRACING AND OTHER REQUIREMENTS.**

—Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue in effect any requirements for tracing products through the distribution system (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) which are inconsistent with, more stringent than, or in addition to, any requirements applicable under section 503(e) (as amended by such Act) or this subchapter (or regulations issued thereunder), or which are inconsistent with—  
“(1) any waiver, exception, or exemption pursuant to section 581 or 582; or  
(2) any restrictions specified in section 582.

In California’s Business and Professions Code section 4034.1, there are additional provisions that preempt California’s e-pedigree requirements should federal legislation be enacted. The law also requires that the board post action about the inactivation of California’s standards with section 4034.1. Specifically, the law provides that:

#### **4034.1. Enactment of Federal Pedigree Legislation**

- (a)
  - (1) Upon the effective date of federal legislation or adoption of a federal regulation addressing pedigree or serialization measures for dangerous drugs, Sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 shall become inoperative.
  - (2) Within 90 days of the enactment of federal legislation or adoption of a regulation addressing pedigree or serialization measures for dangerous drugs, the board shall publish a notice that Sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 are inoperative.
  - (3) Within 90 days of the enactment of federal legislation or adoption of a regulation that is inconsistent with any provision of California law governing the application of any pedigree or serialization requirement or standard, the board shall adopt emergency regulations necessary to reflect the inoperation of state law.

- (b) (1) If the Food and Drug Administration (FDA) enacts any rule, standard, or takes any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, that provision of California law shall be inoperative.
- (2) Within 90 days of the FDA enacting any rule, standard, or taking any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, the board shall publish a notice that the provision is inoperative.
- (3) Within 90 days of the FDA enacting any rule, standard, or taking any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, the board shall adopt emergency regulations necessary to reflect the inoperation of state law.
- (c) If the board fails to recognize the inoperation within 90 days pursuant to this section, nothing in this section shall preclude a party from filing an action in state or federal court for declaratory or injunctive relief as an alternative to filing a petition with the board.

#### At this meeting

The committee considered recommending specific action to the board regarding California's e-pedigree law:

1. To provide and publish a notice of preemption to the public
2. To seek a legislative repeal of California's provisions via 2014 proposed legislation
3. Stop the adoption of and withdraw pending regulations to implement California's e-pedigree requirements.

#### Proposal 1: Provide and publish a notice of preemption to the public:

The board's staff developed the following notice regarding preemption of California's e-pedigree requirements.

Pursuant to Business and Professions Code section 4034.1, which provides in pertinent part that "[u]pon the effective date of federal legislation . . . addressing pedigree or serialization measures for dangerous drugs, Sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 shall become inoperative," and which requires that within 90 days of the enactment of such legislation the board publish a notice regarding the invalidation of these statutes, the California State Board of Pharmacy is hereby publishing notice that federal legislation meeting the requirements of section 4034.1 has been enacted, and that Business and Professions Code sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 became inoperative as of November 27, 2013.

The board's staff proposed to publish this notice in the California Regulation Notice Registry, as well as include it in a subscriber alert, and post it on the board's website as a notice. It would also be included in a newsletter article to be published in the next *The Script*.

Proposal 2: Seek legislative repeal of California's e-pedigree provisions via 2014 board-sponsored legislation:

To provide for clear understanding to licensees and the public about components in California law, inactive/preempted sections of law should be removed so that California Pharmacy Law contains only sections of law that are in effect. As such staff recommended that the board sponsor legislation to remove the inactive/preempted provisions dealing with e-pedigree in California law.

Proposal 3: Stop the adoption of and withdraw pending regulations to implement California's e-pedigree provisions

There are currently two noticed rulemakings in progress regarding implementation of e-pedigree requirements. The staff recommended that the board withdraw and or stop action on the following two rulemakings:

1. Pedigree Requirements – Unique Identifier; Identification of 50 Percent of Product Serialized for Sale in California; Grandfathering – Adoption of sections 1747 -1747.1

**Status:** Disapproved by the Office of Administrative Law received on October 31, 2013 (the disapproval would have been corrected via addition of documents to the rulemaking file for 15 days)

2. Drop Shipment, add section 1747.2 to Title 16 California Code of Regulations

**Status:** Regulation noticed for 45 days of public comment, hearing held 10/29/13  
**Board adopted:** 10/29/13

Again, the staff recommended that the board withdraw and or stop action on the aforementioned two rulemakings.

Discussion

Dr. Gutierrez provided a background and overview.

Mr. Room gave his opinion and stated that the board is not required to do anything in response to the passage of H.R. 3204 but publish notice within 90 days as required by Business and Professions Code section 4034.1(a)(2). He suggested using the language recommended by board staff. In addition, Mr. Room stated that it would be worthwhile for the board to sponsor legislation to repeal the provisions in the California e-Pedigree law to avoid any confusion in the future. He also stated there are a few provisions in the law that are separate from e-Pedigree that the board needs to preserve/re-instate. Those provisions would be otherwise rendered inoperative without legislation.

Ms. Sodergren gave an update on the status of the board's two rulemakings.

**Committee Recommendation #1:** Publish a public notice of preemption  
M/S: Lippe/Hackworth

Support: 4 Oppose: 0 Abstain: 0

No public comment

**Committee Recommendation #2:** Sponsor legislation to repeal California's e-Pedigree Law

M/S: Lippe/Hackworth

Support: 4 Oppose: 0 Abstain: 0

No public comment

**Committee Recommendation #3:** Withdraw and stop the adoption of pending regulations to implement California's e-pedigree requirements

M/S: Lippe/Hackworth

Support: 4 Oppose: 0 Abstain: 0

No public comment

**b. Discussion on Federal Legislation that Eliminated Licensure of Third Party Logistics Providers as Wholesalers, Pursuant to the Enacted H.R. 3204, the Federal Drug Quality and Security Act**

Background

The federal legislation enacted to eliminate California's e-pedigree requirements also contained provisions to establish national standards for wholesalers and establish specialized regulation of third party logistics providers (3PLs). The new federal law requires the FDA to establish regulation provisions regarding national standards for wholesalers and 3PLs over the next one to two years. If a state does not regulate wholesalers and 3PLs, the national registration will be required.

California has regulated wholesalers for more than 25 years. In recent years, the board has regulated 3PLs as wholesalers, in fact, California law defines 3PLs as a subdivision of wholesalers – specifically:

**4045. Third-Party Logistics Provider or Reverse Third-Party Logistics Provider** "Third-party logistics provider" or "reverse third-party logistic provider" means an entity licensed as a wholesaler that contracts with a dangerous drug manufacturer to provide or coordinate warehousing, distribution, or other similar services on behalf of a manufacturer, but for which there is no change of ownership in the dangerous drugs. For purposes of Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, a third-party logistics provider shall not be responsible for generating or updating pedigree documentation, but shall maintain copies of the pedigree. To be exempt from documentation for pedigrees, a reverse third-party logistic provider may only accept decommissioned drugs from pharmacies or wholesalers.

The federal provisions which took effect November 27, 2013, however, prohibit the regulation of 3PLs as wholesalers (which is exactly what California's current law does).

Specifically: Section 585(b)(2)

“(b) WHOLESALE DISTRIBUTOR AND THIRD -PARTY  
LOGISTICS PROVIDER STANDARDS.—

“(1) IN GENERAL.—Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under section 503(e) (as amended by such Act), in the case of a wholesale distributor, or section 584, in the case of a third-party logistics provider.

“(2) STATE REGULATION OF THIRD-PARTY LOGISTICS PROVIDERS.—No State shall regulate third-party logistics providers as wholesale distributors.

Consequently effective November 27, 2013, neither the state nor federal government is requiring registration of 3PLs until the federal requirements are put in place. Since 3PLs are vital members of the supply chain who store, select and ship prescription drugs, staff suggest that legislation be pursued by this board to restore licensure of 3PLs as a separate category of licensee, but to include them in California Pharmacy law everywhere wholesalers are mentioned.

### Discussion

Dr. Gutierrez provided background information and an overview of the effect of new federal legislation on the state’s ability to regulate third party logistical providers (3PLs).

Ms. Herold stated that the board currently treats wholesalers and 3PLs exactly the same. Mr. Room clarified that 3PLs are separately defined in law, but they are still defined as a class of wholesaler.

Mr. Room stated that the new federal law does not allow states to license 3PLs as wholesalers. Therefore, for the board to maintain regulatory oversight of 3PLs, a new license type for 3PLs has to be created.

No public comment.

**Committee Recommendation:** Pursue legislation to license 3PLs as a separate licensing category, but include them in California Pharmacy Law everywhere wholesalers are mentioned.

M/S: Lippe/Hackworth

Support: 4 Oppose: 0 Abstain: 0

### **c. Update on Implementation of AB1136 (Levine) Chapter 304, Statutes of 2013, regarding Warning Labels on Prescription Container Labels**

#### Background

Existing law requires a pharmacist to inform a patient orally or in writing of the harmful effects of a drug (1.) if the drug poses a substantial risk to the person consuming the drug, when taken in combination with alcohol, or if the drug may impair a person’s ability to drive a motor vehicle, whichever is applicable, and (2.) the drug is determined by the Board of Pharmacy to be a drug or drug type for which the warning shall be given.

Assembly Bill 1136 (Levine), signed by the Governor on September 9, 2013, amended Business and Professions Code section 4074 to require a pharmacist on or after July 1, 2014, to include a written label on a prescription drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel, if in the pharmacist's professional judgment, the drug may impair a person's ability to operate a vehicle or vessel. The required label may be printed on an auxiliary label that is affixed to the prescription container.

The specific classes of drugs which trigger a pharmacist's verbal or written notice to patients where a patient's ability to operate a vehicle may be impaired are found in 16 CCR section 1744. Section 1744 was provided as an attachment.

### Discussion

Dr. Gutierrez provided background information on Assembly Bill 1136 and raised concern that the list in Section 1744 doesn't list every drug that is potentially harmful.

President Weisser opined that it might be better to rely on the judgment of pharmacist rather than an incomplete list when determining what is harmful for a patient.

Ms. Herold stated that current law would have to be amended in order to eliminate the current list because the statute directs the board to develop a list.

Mr. Lippe suggested adding language such as "including, but not limited to" to the list so a pharmacist can use his or her professional judgment.

### Public Comment

Steve Gray, representing himself, spoke in support of the recommendation. He believes that the change will let pharmacists use their own professional judgment and will probably result in more warnings being affixed to the prescription bottles. Mr. Gray also stated he believes the word "vessel" needs further clarification.

**Committee Recommendation:** Direct staff to draft new language which would add "including, but not limited to" to the list of potentially harmful drugs found in 16 CCR Section 1744.

M/S: Lippe/Hackworth

Support: 4    Oppose: 0    Abstain: 0

#### **d. Request for Comments from the D.E.A. on the Possible Scheduling of Tramadol into Federal schedule IV**

### Background

Tramadol was approved for marketing as a non-controlled analgesic in 1995 based on information related to its low potential for abuse and very weak narcotic effect. Recent data, however, indicates that tramadol produces effects, including adverse, analgesic, and other effects, similar to opioids in Scheduled III and IV.

Because of inadequate labeling due to its non-controlled status and lack of established potential abuse, many physicians felt tramadol was safe to prescribe. As a result, it has become one of the most prescribed opioids in the United States and numerous reports have surfaced regarding its misuse, abuse, and diversion.

As a result, on November 4, 2013, the Drug Enforcement Administration (DEA) published a notice of proposed rulemaking (NPR) to place tramadol in Schedule IV of the Controlled Substances Act. If tramadol is placed in schedule IV, entities that handle it, by the effective date of the final rule, will be subject to registration, security, labeling, packaging, inventory, recordkeeping, reporting, prescription, and import and export requirements required for substances placed in Schedule IV. Written comments on the NPR were due earlier this month.

A copy of the comments submitted by Executive Officer Herold and Board President Weisser to the DEA were provided at the meeting.

### Discussion

Dr. Gutierrez provided background.

Ms. Herold stated that the board has seen cases in which Tramadol has been abused like other controlled substances and feels it is appropriate to place Tramadol in Schedule IV.

This item was informational only. No action was taken by the board and no public comments were made.

### **e. Request from Sharp Healthcare for a Waiver of 16 California Code of Regulations Section 1713(d) to Permit Expanded Use of Automated Prescription Dispensing Machines**

#### Background

Several years ago, the board promulgated regulations (16 California Code of Regulation section 1713) to allow for the use of automated delivery devices, which are markedly like vending machines, to permit the furnishing of refill medication in specified circumstances, to include the requirement that the patient must opt in to use the machine and that the medication to be refilled through the machine is appropriate. A copy of the regulation was provided.

In recent years, the board has received several requests to use automated delivery devices in a variety of settings including workplace clinics, hospital lobbies, other areas on a hospital campus, and in employment locations. During each of these discussions, several concerns have been raised about whether the request would comply with current regulations and whether the board had the authority to approve the request without specific regulatory changes. To date the board has not approved any waivers since enactment of the regulation.



At the June 2013 committee meeting, representatives from Asteres and Sharp Healthcare requested a revision to section 1713 to allow three separate pilot studies on the campuses of Sharp, UCSD Health System and USC Hospital to expand the use of automated delivery devices. At the July 2013 board meeting, Mr. Burgess, representing Asteres reminded the board that section 1713(b) already allows the delivery of prescriptions to employees at their worksite. An excerpt of the previous meeting minutes were provided.

Mr. Burgess proposed to revise section 1713(d)(6) to allow for the placement of automated devices in a secure building controlled by a Board licensee at an alternate location readily accessible for Board inspection, but not adjacent to a secure pharmacy area.

### Presentation/Discussion

During this meeting, Phil Burgess and Sara Lake representing Asteres and Kim Allen representing Sharp HealthCare made a brief presentation and offered their formal proposal to request a waiver of the provisions of Section 1713 for purposes of conducting a study with UCSD to determine if use of the technology improves medication adherence in the targeted audience.

Ms. Allen indicated that they previously had intended to place an automated dispensing machine (kiosk) in an unlicensed corporate office. At the previous committee meeting, they were asked to get a license for the facility and return with a more robust study proposal. Because they were informed in the interim that they could not license a corporate office as a pharmacy, they decided to place the kiosk in the lobby area of a licensed hospital for this proposal. The kiosk would be serviced by a retail pharmacy located less than a mile away and the kiosk would include new prescriptions as well as refills.

Ms. Allen reviewed the process by which prescriptions get into the kiosk and to the patients. She said prescriptions first come to the retail pharmacy and are processed and filled by pharmacy staff and verified by a pharmacist. Those who chose to have their prescriptions delivered to the kiosk would have their medications segregated for delivery to the kiosk. Pharmacy staff would take the medications to the kiosk and fill the machine. The kiosk would read the barcodes on the new medications and send an email to the patient that the medication was ready for pick up. To avoid errors, the computer system would alert to any discrepancy between the original prescription and what was placed in the kiosk. The system would generate a report with an audit trail.

For new prescriptions, a pharmacist would consult with the patient prior to the medication being released from the kiosk. Dr. Gutierrez asked if the pharmacist counseling would be in person. Ms. Allen answered that the counseling would be done via telephone on the kiosk. Ms. Allen summarized current regulations which state that medications may be delivered to a patient and that the patient need not be counseled but only advised that counseling with a pharmacist is available. She indicated that their proposal goes a step further because every patient will be counseled when they pick up the medications.

Ms. Allen stated that once the patient is counseled, the pharmacist would make a note in the computer that the patient was counseled and then electronically release the medication to the patient via the kiosk.

Ms. Allen also indicated that the kiosk would monitor medications. If a medication wasn't picked up within a three days, a reminder email would be sent to the patient. If the patient did not pick up the medication after seven days, the medication would drop into a bin, and pharmacy staff would retrieve the medication and return it to the pharmacy for reconciliation.

Ms. Allen indicated that Sharp was working with UC Santa Diego and had created a much more robust study. They are planning to make the kiosk available to Sharp employees and their families.

Dr. Gutierrez asked where the pharmacy was located in the hospital building. Ms. Allen answered that there is an inpatient pharmacy in the hospital but that the kiosk would be supported by an outpatient pharmacy within walking distance.

President Weisser asked for clarification about why the inpatient pharmacy would not be supporting the kiosk. Ms. Allen responded that the kiosk would be best supported by an outpatient pharmacy because it would be much easier for an outpatient pharmacist to answer questions and provide assistance.

Mr. Lippe asked counsel whether the board has the authority to approve the request. Mr. Room stated that the board does have the authority.

Mr. Santiago stated he felt the kiosk might meet the definition of a pharmacy pursuant to state law and might have to be license as such.

President Weisser stated that 16 CCR 1713(d) only allows for the use of a kiosk to deliver previously dispensed medications in an area adjacent to the secure pharmacy area.

Mr. Room clarified that the board has authority to waive the aforementioned requirements pursuant to 16 CCR 1706.5.

Ms. Hackworth asked whether the building which will house the kiosk is open 24 hours. Ms. Allen answered that the building is open 24 hours and is not restricted to only employees.

Mr. Ratcliff asked if the outpatient pharmacy that supports the kiosk is open 24 hours. Ms. Allen replied that the outpatient pharmacy is not open 24 hours, but a pharmacist with remote access to a patient profiles will be available to answer the kiosk phone 24 hours daily.

Ms. Herold commented that the six-month pilot as planned is too short to collect enough usable data. Ms. Link asked for feedback on how they could write their request to meet the board's requirements. Ms. Herold advised providing a progress report to the board after six months, but continuing to collect data on an ongoing basis and provide periodic reports thereafter.

President Weisser asked to be taken through the process when an on-call pharmacist receives a phone call for a consultation. He was concerned that a pharmacist might not be available to answer a call for a consultation after hours. Ms. Allen indicated the on-call pharmacists have experience dealing with phone calls after hours. On the positive side, however, Ms. Allen said the patient at least has the opportunity to pick up a prescription that they wouldn't have if they had to get their prescription from a closed retail pharmacy.

Dr. Gutierrez expressed her concern about the proposal including new prescriptions and not just refills. She said the Sharp employees have access to retail pharmacy networks with 24 hour service and would get consultation when picking up a new prescription. She would be more open to including only refills in the proposal.

Ms. Hackworth asked whether Sharp planned to branch out to their other regional hospitals. Ms. Allen answered that the plan is to eventually put kiosks in their hospitals to meet employee needs. She believes employee patient care will improve due to the convenience of the kiosks. Employees will be more likely to pick up the medications in a timely manner.

Mr. Lippe stated he had no problem with including new prescriptions in the proposal. Because the pilot study is not permanent and because data will be gathered to determine if there are problems, he believes the pilot study is a perfect time to implement the proposal and see if it will work. If there are problems after six months, the board can make a determination at that time.

Mr. Burgess agreed with Mr. Lippe and indicated they will track data and report back to the board with any problems. If the board determines changes are necessary, they will make those changes.

Ms. Herold stated the board strongly supports patient consultation. Recently, the board worked with the District Attorney in three counties to pursue pharmacies that are failing to consult with patients. The board has reached a settlement with at least one major pharmacy chain is having in the process of finalizing other settlements as well.

Ms. Herold also asked for clarification on what will be measured in the study because the documentation seemed to indicate most of the measurements would be made to determine consumer satisfaction. Ms. Allen stated that they would collect data and measure anything the board would like to see.

Dr. Gutierrez indicated she would be more comfortable with the study moving forward with only refills. Mr. Lippe stated that if the concern is new prescriptions, collecting six months of data on only refills isn't going to put the board in a better position to make a decision about whether new prescriptions should be included. He believed both refills as well as new prescriptions should be included in the pilot study. He suggested that Asteres/Sharp report to the board once a month instead of once after the six month study had concluded.

Committee members asked many other clarifying questions regarding the process.

### Public Comment

Scott Guess, retail pharmacist, suggested that the study include formal outcomes and have the patients enroll into the study. He also stated that he doesn't have the option of not counseling a patient regarding a new prescription and didn't understand how the consultation would work with the kiosk.

Steve Gray, Chair, California Society of Health-System Pharmacists, spoke in strong support.

Ed Rickert, on behalf of MedAvail, spoke in support.

Brian Warren, California Pharmacists Association, acknowledged technological improvements in pharmacy practice, but raised his concern about safety and the lack of face to face consultation.

Mr. Lippe clarified something he had heard earlier. He stated that when the prescription is called in, the consultation by a pharmacist during normal business hours.

Ms. Allen verified Mr. Lippe's understanding and added that an email notification will not be sent to the patient and the medication will not be available for pick up until the initial consultation is completed.

**Committee Recommendation:** Approve the waiver provided that no medication for a new prescription is released from the kiosk without a consultation taking place at the licensed pharmacy prior to the close of business hours

M/S: Lippe/Hackworth

Support: 3 Oppose: 1 (Weisser) Abstain: 0

**f. Request from MedAvail for a Waiver of 16 California Code of Regulations Section 1713(d) to Permit Expanded Use of Automated Prescription Dispensing Machines**

Background

Related to the prior agenda item, board staff also received a request from MedAvail to provide a presentation to the committee on its technology for automated dispensing.

There has been no formal waiver request for the committee to discuss during this meeting. The presentation is for informational purposes only.

Presentation

During the meeting, the committee watched a short video and heard a brief presentation that included the existing use of the technology and possible its use in California. Presenting were Loreto Grimaldi, COO and General Counsel at MedAvail; Ed Rickert, a pharmacist/attorney consulting with MedAvail; and Sunny Lalli, a pharmacist consulting with MedAvail.

Information provided included:

The kiosk is linked to a pharmacy licensed by the state in which the pharmacy is located. The pharmacy would own and operate the kiosk and be responsible for its use.

The kiosk is pre-loaded with room temperature medications that are found to be used/needed most often. At a kiosk, a patient may submit a prescription, consult with a pharmacist, pay for the medication, and have it dispensed. Licensed pharmacists staff a call center 24 hours daily.

If a patient needs a medication that is not pre-loaded or is out-of-stock, the patient is directed to another nearby pharmacy or kiosk.

**Dr. Gutierrez recessed for lunch at 12:03 p.m.**

**The meeting reconvened at 12:23 p.m.**

**g. Request from Sharp Healthcare and Scripps Health San Diego for a Waiver of California Business and Professions Code Section 4118 Pertaining to Licensure as a Centralized Hospital Packaging Pharmacy, Sections 4128 et seq.**

Background

In 2012 the California Society of Health System Pharmacists and the California Hospital Association sponsored legislation to establish a centralized hospital packaging license which would allow a hospital chain under common ownership to consolidate packaging operations into a single location in a specialized pharmacy to prepare single dose medications that are bar coded. The specific provisions were contained in AB 377 (Solorio, Chapter 687, Statutes of 2012). Included in the provisions of this measure was the requirement that the unit dose medications filled by the centralized hospital packaging license be barcoded to be readable at the inpatient's bedside and specifies the information that must be retrievable when the barcode is read.

The board supported this measure and actively advocated for its passage because of the significant positive impact the use of barcoding would have on the reduction of medication errors that occur in hospitals. Specifically, the board's letter to the governor included the following:

“...Bar coding is important for patient safety. Before a medication is administered to a patient, by scanning the bar code on a medication, a patient's chart and a patient's wristband – the right medication, in the right dose will be ensured at the patient's bedside. This provides an important step forward to improve patient safety and decrease the rate of medication errors and potential adverse drug events...”

Recently board staff was advised that Scripps Health San Diego has limitations in its software that prohibit full compliance with the barcode requirements specified in Section 4128.4. Scripps Health system is requesting that the board interpret the meaning of those provisions more broadly to allow additional time following licensure to fully comply with the requirements.

In preparing for this meeting, board staff conferred with counsel on the applicability of such a waiver given the specificity of the language in B&PC 4118. This request is being brought to the committee for consideration and to provide direction to staff on the waiver request as well as interpretation and application of B&PC 4118.

Presentation/Discussion

Representing Scripps Health San Diego were Bob Miller, Ken Scott, Eric Kastango, and Amy Benner. Mr. Miller stated that Scripps became aware that the provision in the new law which speaks to the retrieval of patient information at the patient's bed side was being interpreted by the board differently than what they had expected. Their expectation was that if they put a barcode on all their doses which included their lot number, then based on the lot number, they would be able to retrieve the patient information at the bedside. Their barcoding system, however, doesn't actually

pull up that information and show it to the nurse. The purpose of the presentation, therefore, was to ask the board to adopt a broader interpretation of the provisions of the new law and make their case as to why their system is in compliance, or ask the board for a waiver until the can come in to compliance.

Ken Scott explained that all the required patient information is actually retrievable from the label.

Mr. Room provided information regarding Business and Professions Code section 4128.4 which states that upon reading the barcode, the six data elements shall be immediately retrievable. In his opinion, one of the conditions of licensure is that the licensee have the ability to perform that technological service.

Mr. Room presented three different options with which the board could deal with this situation. First, pursuant to Business and Professions Code section 4118, the board has the ability to waive a requirement for licensure. Second, the board could exercise enforcement discretion and allow a specified period to come into compliance. This option would have to be applied to all licensees. Lastly, the board could return to the legislature and to clarify which data elements, if any, have to be retrievable at the bedside.

Dr. Gutierrez stated the data elements need to be retrievable in case of a recall. She asked for an explanation of Scripps' process if a medication is recalled. Ms. Benner stated that the batch record is an electronic record and they capture all data elements including the lot number, expiration date, and all components of the compound. The recalled medication could be traced back to a patient by conducting a search.

Ms. Herold stated that the board wants barcoding at the patient's bedside to ensure the right medication gets in the right patient with right strength and the right dose.

Mr. Room stated that although the data elements are readable (on the label), he thinks the intent of the law was to link the data elements on the barcode to a database where the elements would be present and retrievable.

Mr. Santiago stated that it was arguable whether the board could grant a waiver pursuant to Business and Professions Code section 4118 because the language is a waiver for a requirement of licensure. Ms. Herold clarified that Scripps had not been issued a license based on their inability to meet the law's requirements.

Mr. Santiago also stated that the board could not use its enforcement discretion across the board because that would constitute an underground regulation. Mr. Room agreed and further explained his earlier statement.

### Public Comment

Steve Gray, representing the California Society of Health-System Pharmacists (CSHP), stated that CSHP was the sponsor of the bill and he was personally involved in developing the language. He stated that the board's interpretation of the law is incorrect and that the intent was not to have the

data readable at the bedside. He didn't believe that a waiver was necessary, but he offered to work with the CHA to create some clarifying language.

Perry Flowers, representing Kaiser Permanente, spoke in support of Scripps and Sharp.

**Committee Recommendation:** Approve waiver for Scripps and Sharp - As long as the required data elements are otherwise retrievable, waive the requirement that the data elements be retrievable at the patient's bedside by way of a barcode

M/S: Weisser/Hackworth

Support: 4    Oppose: 0    Abstain: 0

#### **h. Request from K. Scott Guess, PharmD, RPh, to Present his Proposal for Safe, Effective Dispensing of Controlled Substances**

##### Background

Dr. K. Scott Guess requested the opportunity to appear before the Enforcement Committee to discuss his proposal for safe, effective dispensing of controlled substances.

##### Presentation

Dr. Guess indicated pharmacies cannot get an adequate supply of controlled substances and patients are being affected negatively. Wholesalers are reducing or eliminating supplies due to pressure from the DEA who say they're just enforcing the controlled substances act. There is increased pressure on everyone in the supply chain to reduce the number of controlled substance prescriptions due to an increase in prescription drug-related deaths.

Dr. Guess proposed creating a "Controlled Substances Advanced Practice Pharmacy" registration which could be regulated at the federal or state level. This new registration would allow pharmacies that meet the requirements to safely, consistently, and effectively dispense controlled substances to patient in need of pain management.

This item was informational only. No action was taken by the board and no public comments were made.

## **II. Compounding Matters**

### **a. Update on Implementation of New California Sterile Compounding Laws: Senate Bill 294 (Emmerson) and Assembly Bill 1045 (Quirk-Silva) – (Note: Currently Pending Proposed Regulation Changes to 16 CCR Sections 1735 et seq. and 1751 et seq. Will Not be Discussed at This Meeting)**

##### Background

Last year the board sponsored legislation following two large-scale public health emergencies in which contaminated products compounded by two out-of-state pharmacies were shipped nationwide. Senator Emmerson authored SB 294 for the board.

Senate Bill 294 (Chapter 565, Statutes of 2013) strengthens the board's ability to regulate and monitor pharmacies that compound sterile drug products. This law prohibits a pharmacy from compounding or dispensing to patients in this state, sterile drug products for injection, administration into the eye, or inhalation, unless the pharmacy has obtained a sterile compounding pharmacy license. Such licensure must follow a board-performed inspection. The law also eliminates accreditation by designated agencies as an alternative to board licensure.

Assembly Member Quirk-Silva authored AB 1045 (Chapter 302, Statutes of 2013) that amends existing California law to revoke a nonresident pharmacy's license by operation of law if its pharmacy license is suspended or revoked in the pharmacy's home state. It also requires resident and nonresident pharmacies that issue a recall notice regarding a sterile compounded drug to contact the recipient pharmacy, prescriber or patient of the recalled drug and the board within 12 hours of the recall notice.

Since enactment board staff has been taken steps to implement the provisions of both measures including both education of our licensees revisions to application and renewal forms and advocating for the necessary staff and training resources. Board staff estimates that about 612 sterile compounding pharmacies will require inspection prior to July 1, 2014 when enactment of these provisions takes effect so as to not create a drug shortage. In addition staff estimates another 150 site will require inspection before the end of the calendar year. Inspections will be conducted on a random, unannounced basis and.

An attachment was provided that include the current proposed sterile compounding application. The law requires every location where sterile compounding is preformed to be licensed as a sterile compounding pharmacy. In the case of a hospital, the board may need to issue several sterile compounding licenses if a centralized model is not used. In such cases, it is the staff's intent to only require a single hospital license and link each separate sterile compounding location to the main hospital's pharmacy license.

### Discussion

Dr. Gutierrez provided background information.

Ms. Herold indicated the board is initiating inspections ahead of the July 1, 2014 license requirement. She stated the new compounding pharmacy licenses will be tied to the normal hospital pharmacy license. The application is being modified but the current online application is acceptable for now.

Ms. Herold also stated that the board is going to be communicating to all interested parties via subscriber email list in the next few months as we move closer to the Jul1, 2014 deadline.

Dr. Gutierrez asked whether a sterile compounding request has to be submitted for each location. Ms. Herold indicated that each location needs to submit a request. Mr. Room and Mr. Ratcliff verified that statement.

### Public Comment



Jeffrey Nehira asked for guidance in the licensure of a compounding pharmacy.

Steve Gray, representing California Society of Health-System Pharmacists, verified that if an application was made now, an inspection would be based on current regulations. Secondly, he verified that each separate area in which compounding takes place, needs a separate license. He pointed out that there is no definition of a satellite pharmacy in law or regulation.

In response, Mr. Room explained, for example, that if a hospital has four locations with varied conditions, the board can't state that the hospital meets the requirements in the regulations if the requirements are not being met in all locations. There is no way to capture all the conditions and issues that might be taking place at different locations under one sterile compounding license.

A question was also raised regarding whether records would need to be kept in the main pharmacy or at each satellite pharmacy. Mr. Room stated that for immediate use it would be best to keep records in the satellite pharmacy, but for long term storage it is perfectly acceptable to keep he records in the main hospital pharmacy.

This item was informational only. No action was taken by the board.

**b. Discussion Regarding Extension of Board Approval of Accreditation Agencies for Sterile Injectable Compounding Pharmacies Until July 1, 2014**

Background

Business and Professions Code Sections 4127 – 4127.8 provides for the regulation of pharmacies that compound sterile injectable drug products in a pharmacy. Pharmacy law currently creates an exemption from the licensure requirements for a pharmacy that is accredited by a private accreditation agency approved by the board (B&PC 4127.1 (d) and 4127.2 (c).) This exemption will be repealed July 1, 2014 when the provisions of SB 294 take effect.

There are currently five accreditation agencies approved by the board. As a matter of process, the board approved such entities for a specified period to allow for periodic review. Approval of four entities will expire in February 2014 unless the board grants an extension. Below is a list of the entities whose approval is set to expire.

1. Accreditation Commission for Health Care, Inc (ACHC) – 66 sites accredited
2. Community Health Accreditation Program (CHAP) – 51 sites accredited
3. Pharmacy Compounding Accreditation Board (PCAB) – 24 sites accredited
4. American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) – 5 sites accredited

Pharmacies that are currently performing sterile injectable compounding and sought accreditation in lieu of licensure will need to secure licensure with the board in advance of July 1, 2014.

However, because the board's current approval of the above accreditations agencies expires in February the board needs to consider an extension in the approval term to June 30, 2014. The 5<sup>th</sup> accreditation agency's approval will expire June 30, 2014.

### At this meeting

The committee will need to determine if a limited extension is appropriate for each of the above agencies to allow pharmacies to continue to perform sterile injectable compounding until the provisions of SB 294 take effect. In the interim, board staff will be contacting all of the accredited pharmacies and encouraging early submission of applications for licensure with the board.

No public comment.

**Committee Recommendation:** Approve extensions of accreditation agencies

M/S: Lippe/Weisser

Support: 4    Oppose: 0    Abstain: 0

### **c. Discussion on Compounding Provisions Enacted by H.R. 3204, the Federal Drug Quality and Security Act**

#### Background

Included as part of the federal Drug Quality and Security Act (HR 3204) are provisions that establish provisions for federal regulation and oversight of large scale drug compounding by “outsourcing facilities.” The federal law sets forth voluntary requirements for licensure and enforcement.

### At this meeting

During the meeting counsel will provide a high level overview of the sterile compounding requirements of this new law for informational purposes only. It is important to note that California’s law is more restrictive than the federal law in several areas.

California will continue to require any pharmacy that is compounding sterile products for California residents or practitioners to possess licensure with our board and comply with CA requirements.

An attachment was provided with the relevant compounding sections of HR3204.

### Discussion

Mr. Room provided an over view of the provisions of the new law. He also stated that until the FDA says otherwise, he believes California should continue to enforce the licensing requirements against both in-state and out-of-state facilities that dispense compounded medications to California patients.

### Public Comment

William Blair, Ron McGuff, and Damon Jones of McGuff Compounding Pharmacy, asked whether the board could provide any direction regarding the California allowance for prescriber office use and the apparent federal disallowance of compounding for prescriber office use.

Mr. Room stated that the board had not addressed the question and that it would be up to the FDA to decide whether they will to enforce in a way that is contrary to California state law. California state law permits prescriber office use.

Mr. Blair then stated that it was his understanding that California will have to enter into a memorandum of understanding (MOU) with the federal government to regulate interstate distribution. The MOU is supposed to define an inordinate amount of compounding and make sure that California will follow up on complaints. In his view, California already defines an inordinate amount of compounding and he hoped the board would use that as a basis for discussions when entering into an agreement. He also hoped that the MOU would not restrict interstate compounding. He felt that limiting interstate compounding to a percentage would hurt California pharmacies as well as patients.

Mr. Room stated that previous attempts to define an amount which would establish a line between compounding and manufacturing were unsuccessful. He indicated that the FDA has not yet initiated talks to enter in to an MOU.

Ms. Herold indicated that the FDA has always taken the position that pharmacy compounding begins pursuant to a prescription. Although California law has allowed it for over 25 years, the FDA doesn't recognize compounding for prescriber office use at all. Any compounding pharmacy could be declared a manufacturer by the FDA at any time. Without a prescription in hand, compounding pharmacies are running a risk of someone somewhere declaring them a manufacturer.

Ms. Herold stated that the FDA issued a letter on January 9, 2014, that they intend to only see patient-specific compounding.

A suggestion was made that when the board begins talks to enter into the MOU that the board consider using the language in 16 CCR 1735.2 which concentrates on control over safety in quality without restricting interstate trade.

Rich Kruzynski, President of Pharmedium Services, stated Pharmedium had registered as a 503(b) and indicated that they will be under much more scrutiny from the FDA than they would be from any state regulator. He believes registration is a better way to getting oversight for a large-scale sterile compounding operation.

George Suarez, retail pharmacist, asked whether 503(b) just pertains to sterile products. Mr. Room answered that it applies to all pharmacy compounding – sterile and non-sterile.

Tony Park, on behalf of the California Pharmacists Association, asked if the board has considered some sort of reporting mechanism to facilitate the reporting of out-of-state compounding pharmacies who continue to engage in illegal activities.

#### **d. Recalls of Compounded Drugs Throughout the United States**

An attachment was provided which detailed the circumstances of three recalls.

### **III. Future Meeting Dates**

The Enforcement Committee will meet on the following dates in 2014:

March 27, 2014

June 26, 2014

September 30, 2014

December 17, 2014

IV. Closing Comments

No additional public comment.

V. Public Comment on Items Not on the Agenda/Agenda Items For Future Meetings

*Note: The committee may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code Sections 11125, 11125.7(a)]*

ADJOURN

2:09 p.m.