



**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  
PUBLIC BOARD MEETING  
MINUTES**

**DATE:** February 17, 2017

**LOCATION:** Department of Consumer Affairs  
1<sup>st</sup> Floor Hearing Room  
1625 N. Market Blvd.  
Sacramento, CA 95834

**BOARD MEMBERS PRESENT:** Amy Gutierrez, PharmD, President  
Deborah Veale, RPh, Vice President  
Victor Law, RPh, Treasurer  
Lavanza Butler, Licensee Member  
Greg Lippe, Public Member  
Valerie Muñoz, Public Member  
Ricardo Sanchez, Public Member  
Allen Schaad, Licensee Member

**BOARD MEMBERS NOT PRESENT:** Ryan Brooks, Public Member  
Stanley Weisser, Licensee Member  
Albert Wong, Licensee Member

**STAFF PRESENT:** Virginia Herold, Executive Officer  
Anne Sodergren, Assistant Executive Officer  
Laura Freedman, DCA Staff Counsel  
Debbie Damoth, Staff Manager

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**Note:** A webcast of this meeting may be found at:

<http://www.pharmacy.ca.gov/about/meetings.shtml>

**Wednesday, February 17, 2017**

**Call to Order**

**9:11 a.m.**

**I. Call to Order, Establishment of Quorum and General Announcements**

President Gutierrez called the meeting to order at 9:11 a.m.

Board members present: Valerie Muñoz, Lavanza Butler, Victor Law, Amy Gutierrez, Deborah Veale, Ricardo Sanchez, Allen Schaad and Gregory Lippe.

## **II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings**

Lauren Berton on behalf of OmniCare, a CVS Health Company, addressed the board regarding the issue of professional practice components of Automated Drug Delivery Systems (ADDS) and requested clarification from the board regarding its statutory authority. Ms. Berton requested the board consider language of implementing statutes, practical implementation of long term care and vendor capabilities. Specifically, Ms. Berton referred to Business and Professions Code section 4105.5 and Health and Safety Code section 1261.6(g). CVS supports the use of ADDS and believes ADDS help long-term pharmacies comply with California Department of Health regulations that require emergency STAT medications to be available within one to four hours depending on the situation, comport with pharmacy best practices, enhance patient care, and prevent diversion of prescription medications.

Charlie Hartig, Senior Legal Counsel with CVS, addressed the board regarding the January 4, 2017, Enforcement and Compounding Committee opining and agreeing that pharmacy technicians and pharmacy employees could replenish the ADDs. Mr. Hartig explained CVS understood that the board meeting on February 17, 2017, was called to discuss the replenishment of ADDS by long-term care facility or health care professionals other than pharmacists and pharmacy employees. CVS requests the board memorializes in writing the committee's recommendation to allow pharmacy employees to restock the machines so long as the pharmacist is aware of the replenishment activity.

Mr. Hartig encouraged the board to consider the statutory change through Business and Professions Code section 4105.5 and Health and Safety Code section 1261.6. Mr. Hartig explained CVS believes that stocking is supported for multiple reasons: 1) The statute supports it; 2) Multiple statutes and regulations allow other health care professionals to handle and administer medication; 3) ADDS are more secure with logs than tackle boxes/emergency kits; and 4) Limiting the replenishment to pharmacy employees does not make the ADDS more secure. Mr. Hartig advised the board that half of the states allow non-pharmacy personnel to restock ADDS, a quarter of the states have not opined on this, and the remaining quarter do not allow restocking of ADDS by non-pharmacy personnel.

## **IV. Discussion and Consideration of the Proposed Regulation to Add Title 16 CCR Section 1746.5, Related to Travel Medications**

President Gutierrez reported that at the June 2015 board meeting, the board approved proposed text to add section 1746.5 of Title 16 CCR, related to Travel Medications. She added that on April 27, 2016, following a 45-day comment period and two 15-day comment periods, the board adopted the regulation language and delegated to the executive officer the authority to make technical or non-substantive changes as may be required by Office of Administrative Law (OAL) or the Department of Consumer Affairs (DCA) to complete the rulemaking file.

President Gutierrez reported that at the January 2017 board meeting, the board approved a modified text to address concerns raised by OAL and initiated a third 15-day comment period. The 15-day comment period began on February 1, 2017, and ended on February 16, 2017.

President Gutierrez explained that at this meeting the board will have the opportunity to discuss the regulation and determine what course of action it wishes to pursue. Among its options:

1. Amend the regulation to address any concerns raised by stakeholders.
2. Adopt the regulation as approved by the Board on January 24, 2017.

Executive Officer Virginia Herold encouraged the board to adopt the regulation as approved by the board on January 24, 2017. Board staff recommended to the board to amend the term to read as follows:

**Add** §1746.5 to Article 5 of Division 17 of Title 16 of the California Code of Regulations as follows:

**§1746.5 Pharmacists Furnishing Travel Medications.**

(a) For purposes of Business and Professions Code section 4052(a){10}{A}(3), prescription medications "not requiring a diagnosis" means a prescription medication that is either:

- (1) For a condition that is both self-diagnosable and recognized as self-treatable by the federal Center for Disease Control and Prevention's (CDC) Health Information for International Travel (commonly called the Yellow Book), or
- (2) A prophylactic.

(b) A pharmacist furnishing prescription medications not requiring a diagnosis that are recommended by the CDC for individuals traveling outside the 50 states and the District of Columbia pursuant to section 4052(a)(10) of the Business and Professions Code shall follow the requirements of this section.

(c) Training: A pharmacist who furnishes travel medications shall keep documentation of the following on site and available for inspection by the Board:

(1) Completion of an immunization ~~certification~~ ~~certificate~~ program that meets the requirements of Business and Professions Code section 4052.8(b)(1),

(~~1~~ ~~2~~) Completion of an ~~approved~~ travel medicine training program, which must consist of at least 10 ~~20~~ hours of training and cover each medication related element of the International Society of Travel Medicine's Body of Knowledge for the Practice of Travel Medicine (2012),

(~~2~~ ~~3~~) Completion of the CDC Yellow Fever Vaccine Course, and

(~~3~~ ~~4~~) Current basic life support certification.

(d) Continuing Education: Pharmacists must complete two hours of ongoing continuing education focused on travel medicine, separate from continuing education in immunizations and vaccines, from an approved provider once every two years.

(e) Prior to furnishing travel medication, a pharmacist shall perform a good faith evaluation of the patient, including evaluation of a patient travel history using destination-specific travel criteria. The travel history must include all the information necessary for a risk assessment during pre-travel consultation, as identified in the CDC Yellow Book. An example of an appropriate and comprehensive travel history is available on the Board's website.

(f) Notifications: The pharmacist shall notify the patient's primary care provider of any drugs and/or devices furnished to the patient within 30 days of the date of **dispense furnishing**, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with written record of the drugs and/or devices furnished and advise the patient to consult a physician of the patient's choice.

(g) Documentation: For each travel medication furnished by a pharmacist, a patient medication record shall be maintained and securely stored in physical or electronic manner such that the information required by title 42, section 300aa-25 of the United States Code and title 16, sections 1707.1 and 1717 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide the patient with a progress note, which fully documents the clinical assessment and travel medication plan. An example of an appropriate and comprehensive progress note is available on the Board's website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4052 **and** **4052.8**, Business and Professions Code.

The board reviewed the comment submitted by Dr. Shirley Poon. The board determined that what Dr. Poon submitted was a question on the process for providing travel medication, not a comment on the regulation itself.

There were no comments from the public.

**Motion:** Adopt the regulation as approved by the board on January 24, 2017.

**M/S:** Lippe/Law

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			

Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser				x
Wong				x

**Motion:** Delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Office of Administrative Law or the Department of Consumer Affairs to complete the rulemaking file.

**M/S:** Lippe/Law

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser				x
Wong				x

There were no comments from the board or from the public.

**V. Discussion and Consideration of the Proposed Regulation to Amend Title 16 CCR Section 1760, Related to Disciplinary Guidelines**

Assistant Executive Officer Anne Sodergren reported as the board was advised during the January 2017 Board Meeting, OAL disapproved the board’s rulemaking. OAL disapproval of the rulemaking was based on the grounds that the board did not meet the clarity and necessity standard in some of the language included in the terms and conditions of the language. OAL’s disapproval also indicated that the board did not follow the required APA procedures. Board staff had the opportunity to discuss the disapproval with the assigned OAL attorney on February 9, 2017, to discuss the language specifically. To date, the board has not received the comments back from the assigned OAL attorney.

Ms. Sodergren continued in addition to the proposed language below, the board also made nonsubstantive changes. For example, the revision date will be updated to reflect the current date.

Ms. Sodergren explained to the board the clarity issues noted by OAL in the disapproval letter. Ms. Sodergren continued the disapproval noted that Term 2 requires a respondent to “report to the board quarterly, on a schedule and in a form or format, as directed by the board or its designee.” Although the term continues on to state that “the report shall be made either in person or in writing as directed” OAL’s disapproval states that the term “in a form or format does not specify what form or format the request is not required to use.

Board staff recommended the following:

## 2. Report to the Board

Respondent shall report to the board quarterly, on a schedule ~~and in a form or format~~, as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation.

Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

Ms. Sodergren reported the disapproval noted that Term 24 establishes the Drug and Alcohol Testing requirement does not meet the clarity standard because the board uses the term “geographic area” but does not define the term. The disapproval further notes that the board specifies the necessary information and documentation must be provided to an alternate testing vendor, but the board does not detail what this necessary information and documentation is.

Board staff recommended to the board to amend the term to read as follows:

~~**22-24. Random Drug Screening Drug and Alcohol Testing** (If PRP provision is required, this term is also to be included to allow for continued fluid monitoring by the Board in cases where a respondent successfully completes the PRP before completion of the probation period; terms is also appropriate for those cases where the evidence demonstrates that the respondent may have a problem with chemical dependency (drugs, alcohol) but where the PRP is not required – (Appropriate for those cases where the evidence demonstrates substance use.)~~

~~Respondent, at his or her [his/her] own expense, shall participate in random testing, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other drug screening program as directed by the board or its designee. Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be determined by the board or its designee. At all times, respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples for the detection of alcohol, narcotics, hypnotics, controlled substances, and dangerous drugs and/or dangerous devices. or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall be considered a violation of probation. Upon~~

request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and shall result in the automatic suspension of practice of pharmacy by respondent. Respondent may not resume the practice of pharmacy until notified by the board in writing. Testing protocols may include biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other testing protocols as directed by the board or its designee. All testing must be pursuant to an observed testing protocol, unless respondent is informed otherwise in writing by the board or its designee. Respondent may be required to participate in testing for the entire probation period and frequency of testing will be determined by the board or its designee.

By no later than thirty (30) days after the effective date of this decision, respondent shall have completed all of the following tasks: enrolled and registered with an approved drug and alcohol testing vendor; provided that vendor with any necessary information and documentation, and any information necessary for payment by respondent; commenced testing protocols, including all required contacts with the testing vendor to determine testing date(s); and begun testing. At all times, respondent shall fully cooperate with the testing vendor, and with the board or its designee, with regard to enrollment, registration, and payment for, and compliance with, testing. Any failure to cooperate timely shall be considered a violation of probation.

Respondent may be required to test on any day, including weekends and holidays. Respondent is required to make daily contact with the testing vendor to determine if a test is required, and if a test is required must submit to testing on the same day.

Prior to any vacation or other period of absence from the ~~geographic area of the~~ where the approved testing vendor ~~provide services~~, respondent shall seek and receive approval from the board or its designee of an alternate testing vendor ~~to ensure testing can occur in the geographic area to be visited or resided in by respondent~~. Upon approval, respondent shall enroll and register with the approved alternate drug testing vendor, provide ~~to~~ that alternate vendor ~~with~~ any ~~necessary~~ information and documentation ~~required by the vendor~~, including any necessary payment by respondent. During the period ~~of absence of the area of visitation or residence in the alternate geographic area~~, respondent shall commence testing protocols with the alternate vendor, including required daily contacts with the testing vendor to determine if testing is required, and required testing. Any failure to timely seek or receive approval from the board or its designee, or to timely enroll and register with, timely commence testing protocols with, or timely undergo testing with, the alternate testing vendor, shall be considered a violation of probation.

Upon detection of an illicit drug, controlled substance or dangerous drug, the board or its designee may require respondent to timely provide documentation from a licensed practitioner authorized to prescribe the detected substance demonstrating that the substance was administered or ingested pursuant to a legitimate prescription issued as a necessary part of treatment. All such documentation shall be provided by respondent within ten (10) days of being requested.

Any of the following shall be considered a violation of probation and shall result in respondent being immediately suspended from practice as a [insert license type] until notified by the board in writing that [he/she] may resume practice: failure to timely complete all of the steps required for enrollment/registration with the drug testing vendor, including making arrangements for payment; failure to timely commence drug testing protocols; failure to contact the drug testing vendor as required to determine testing date(s); failure to test as required; failure to timely supply documentation demonstrating that a detected substance was taken pursuant to a legitimate prescription issued as a necessary part of treatment; and/or detection through testing of alcohol, or of an illicit drug, or of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment. In the event of a suspension ordered after detection through testing of alcohol, an illicit drug, or of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment, the board or its designee shall inform respondent of the suspension and inform [him/her] to immediately leave work, and shall notify respondent's employer(s) and work site monitor(s) of the suspension.<sup>3</sup>

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party-logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices and controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a ~~pharmacist~~ [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation. Failure to comply with any requirement or deadline stated by this term shall be considered a

violation of probation.

Ms. Sodergren explained the disapproval noted that Term 30 (relating to worksite monitor requirements) specifies a respondent “shall complete **any** required consent forms and sign **any** required agreement with the worksite monitor and/or the board to allow the board or its designee to communicate **freely on the subject of respondent’s work performance and sobriety** with the work site monitor.” OAL concluded that this language is inconsistent with the uniform standards, which requires respondent “shall complete **the** required consent forms and sign an agreement...” and noted that the board’s current language also restricts the content of the communication between the board and the worksite monitor.

Ms. Sodergren provided the board with staff recommendation to amend the term to read as follows:

**41.30. Work Site Monitor** (Appropriate for those cases where the evidence demonstrates substance use.)<sup>4</sup>

Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board or its designee, who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the board monthly or on another schedule as directed by the board or its designee. Should the designated work site monitor suspect at any time during the probationary period that respondent has abused alcohol or drugs, he or she shall notify the board immediately.

In the event of suspected abuse, the monitor shall make at least oral notification within one (1) business day of the occurrence, and shall be followed by written notification within two (2) business days of the occurrence. If, for any reason, including change of employment, respondent is no longer able to be monitored by the approved work site monitor, within ten (10) days respondent shall designate a new work site monitor for approval by the board or its designee. Failure to timely identify an acceptable initial or replacement work site monitor, or to ensure monthly reports are submitted to the board by the monitor, shall be considered a violation of probation.

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<sup>4</sup> ~~This probationary term is not new, but is being moved from the previous section “Pharmacy Technician – Standard Terms and Conditions” for purposes of consolidation. The language of this term is also changing from the previous version.~~

Within thirty (30) days of being approved by the board or its designee, the work site monitor shall sign an affirmation that he or she has reviewed the terms and conditions of respondent’s disciplinary order and agrees to monitor respondent. The work site monitor shall at least:

- 1) Have regular face-to-face contact with respondent in the work environment, at least once

per week or with greater frequency if required by the board or its designee;

- 2) Interview other staff in the office regarding respondent's behavior, if applicable; and
- 3) Review respondent's work attendance.

The written reports submitted to the board or its designee by the work site monitor shall include at least the following information: respondent's name and license number; the monitor's name, license number (if applicable) and work site location; the date(s) the monitor had face-to-face contact with respondent; the staff interviewed, if applicable; an attendance report; notes on any changes in respondent's behavior or personal habits; notes on any indicators that may lead to substance abuse; and the work site monitor's signature.

Respondent shall complete ~~any the~~ required consent forms and sign ~~any the~~ required agreement with the work site monitor and/or the board to allow the board or its designee to communicate ~~freely on the subject of respondent's work performance and sobriety~~ with the work site monitor.

**Option (Alternate language that is appropriate for respondents enrolled in PRP or who are given the PRP enrollment term:** It is a condition of respondent's enrollment in the Pharmacists Recovery Program (PRP) that [he/she] is required to have a work site monitor approved by the PRP who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the PRP monthly or on another schedule as directed by the PRP. Should the designated work site monitor suspect at any time during the probationary period that respondent has abused alcohol or drugs, he or she shall notify the PRP immediately. The initial notification shall be made orally within one (1) business day of the occurrence, which shall be followed by written notification within two (2) business days of the occurrence. If, for any reason, including change of employment, respondent is no longer able to be monitored by the approved work site monitor, within ten (10) days of commencing new employment for prior approval by the PRP. Failure to identify an acceptable initial or replacement work site monitor, or to ensure monthly reports are submitted to the PRP by the work site monitor, shall be considered a violation of probation.

Within thirty (30) days of being approved by the PRP, the work site monitor shall sign an affirmation that he or she has reviewed the terms and conditions of respondent's disciplinary order and agrees to monitor respondent. The work site monitor shall at least:

- 1) Have regular face-to-face contact with respondent in the work environment, at least once per week or with greater frequency if required by the board or its designee;
- 2) Interview other staff in the office regarding respondent's behavior, if applicable; and
- 3) Review respondent's work attendance.

The written reports submitted to the PRP by the work site monitor shall include at least the following information: respondent’s name and license number; the monitor’s name, license number (if applicable) and work site location; the date(s) the monitor had face-to-face contact with respondent; the staff interviewed, if applicable; an attendance report; notes on any changes in respondent’s behavior or personal habits; notes on any indicators that may lead to substance abuse; and the work site monitor’s signature.

Respondent shall complete any required consent forms and sign any required agreement with the work site monitor and/or the PRP to allow the PRP to communicate freely on the subject of respondent’s work performance and sobriety with the work site monitor.

President Gutierrez inquired if Ms. Sodergren had concerns from a substantive point of view about the changes. Ms. Sodergren indicated the changes do not impact the policy the board was implementing through the rulemaking file but address the concerns raised by OAL.

Board Member Lippe inquired if another comment period was required. Ms. Sodergren indicated another comment period was required because some of the changes were substantive.

**Motion:** Approve the modified text presented at the board meeting and authorize the 15-day notice. Assuming no negative comments are received, authorize the executive officer to proceed with the rulemaking file.

**M/S:** Veale/Butler

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser				x
Wong				x

**Motion:** In the event the OAL directs as a substantive comment, authorize the executive officer to make substantive edits that are consistent with the policies set forth by the board.

**M/S:** Lippe/Veale

Board Member	Support	Oppose	Abstain	Not Present
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Brooks				x
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser				x
Wong				x

## VI. Automated Drug Delivery Systems (ADDS)

Board President Gutierrez reported Business and Professions Code section 4186, Health and Safety Code section 1261.6 and other statutes set specific requirements for pharmacies operating ADDS devices in licensed health facilities. Among other requirements, ADDS machines must “collect, control and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy and accountability.” Key provisions specify who is responsible for stocking an ADDS with medication and how restocking may be done outside the health facility.

President Gutierrez continued, as many ADDS devices today offer features not addressed in pharmacy law, the board decided to invite vendors to present information about technological features and how the devices are affected by existing statutes. The board is interested in seeking ways to allow pharmacies to provide better quality care and service to patients while maintaining security and protecting the public from diversion of controlled substances and other prescription drugs.

The board received interest from a variety of vendors who submitted questionnaires. All vendors who submitted questionnaires were approved to present to the board. The board was presented with a summary of the vendors’ questionnaires in addition to the vendors’ responses to the questionnaires.

### 1. Presentation(s) Regarding Systems and Features Currently Available

#### a. imgRx MedifriendRX

*Presenter: Kevin Rew, General Counsel and Chief Operating Officer of imgRx*

Mr. Rew provided an overview of imgRx to the board as having 21 pharmacies in California in community clinics to operate as onsite pharmacies and work within the 340(B) for cheaper medicine and pharmacist at point of care. MedifriendRX is an automated prescription dispensing machine capable of bringing pharmacist care into more remote areas. MedifriendRX is able to have the pharmacist control every step of the dispensing process and offer patient consultation.

Mr. Rew explained his purpose is to request to shift some of the responsibility for the

technology away from the community clinic user and to pharmacies that would and can remotely operate the machines.

Mr. Rew provided the machine is stocked with unit of use packaging. The labeling is done within the machine, remotely ordered by the pharmacist who is able to verify the drug; the machine applies the label and the pharmacist reviews the label. The pharmacist checks with the patient to see if a consultation is desired, and the pharmacist releases the drug to the patient.

Mr. Rew explained to the board under the auspices of Business and Professions Code (BPC) section 4186 which requires the presence of a health care worker and each machine is staffed with a pharmacy technician to introduce the machine to the patient, and the technician removes the package from the machine. The prescription is electronically sent to the pharmacy, the pharmacist reviews the prescription, the pharmacist can release the medication remotely and the labeling is done by the pharmacist input at the pharmacy site. Mr. Rew clarified the ADDS is not for unit of use but 30 doses. Patient consultation can be done through an audio/visual end screen on the machine by the pharmacy technician.

Mr. Rew said imgRx's requests the board amend BPC section 4186 or 4119.1 to allow the operation of the ADDS not be under the clinic license but under the pharmacy license. imgRx requests the board shift the responsibility for operation of these types of machines from the clinics and to the pharmacy that operates the machine.

President Gutierrez confirmed a pharmacy is required to report to the board the use of an ADDS.

Mr. Rew clarified in case of medication error, the pharmacy technician is there to review and take the medication back to the pharmacy. The pharmacies are paying the cost of the machines. The machines are restocked by a delivery tote from the wholesaler distributor. The machine is completely locked and i cartridges are placed for each drug within the machine. The invoice is compared with the list of what is produced, and the pharmacist validates it. The restocking is initiated by the pharmacist, but the actual act of restocking is not done by the pharmacist.

Mr. Rew continued imgRX's would like the responsibility of the machine tied to the pharmacy license but not the clinic license. The clinic licensees are concerned that the clinics are not in control of the machines should an error occur. Under BPC section 4186, the pharmacist would have to be an employee of the clinic.

Mr. Rew explained the machines are free standing and secured to the wall. The first iteration is 6 feet tall, 3 feet wide and 25 inches deep. The pharmacist can be at a pharmacy and consult at one or two machines. The counseling is done through audio/visual link with a screen and camera from patient to pharmacist with a telephone. The technician has an iPad with Skype or FaceTime and can also call the patient if more privacy is desired. The pharmacies and clinics are independently owned.

Board Member Veale relayed BPC section 4186 subsection (c) requires stocking by a pharmacist. Mr. Rew clarified the pharmacist checks in real time as the machine is being stocked. If an error is shipped by the wholesaler, there is a holding bin inside the machine.

DAG Room clarified Mr. Rew's request as:

1. Change to 4186(a) - Allow ADDS to be in facilities that are clinics but not board licensed clinics.
2. Change to 4186(c) – Allow for wholesaler or other conveyance to physically restock and watch remotely the restocking by a pharmacist.
3. Change 4186(d) – Remove the requirement that the clinic have responsibility for the machine and have it be exclusively on the pharmacy.
4. Change 4180 – Expand clinics that can be licensed by the board.

Mr. Rew indicated (a) and (d) are least important and the most important is to shift responsibility to the pharmacy license. Mr. Rew supported CVS's public comment to consider others can operate under the supervision of the pharmacist.

DAG Room indicated that DCA Counsel Freedman and he are in unanimous agreement that a statutory change is required and the board cannot authorize by BPC 4119.1(e) to circumvent BPC 4186.

DCA Counsel Freedman provided that the board's ability to authorize studies is very specific and not one that would fit like the UCSD study.

President Gutierrez expressed concerns with the restocking of this type of device as well as why the clinics are concerned as the current structure requires a pharmacist to review with the clinic on a quarterly basis. Mr. Rew explained clinic employees have shared with him that they are concerned with exposing the clinic license to new technology. Mr. Rew shared the goal is to have the pharmacist be responsible for the machine to enhance patient care.

Mr. Rew explained the pharmacists have access to the patient profiles and the clinic's electronic health records. He continued to explain that proprietary technology, bar codes and cameras ensure that the correct medicine is dispensed to the patient. The machine in Napa has not had any errors. The company has a website but does not share the proprietary information about the machine on the website.

The company is a startup company that provides this pharmacy option to clinics. There are currently 21 available in California, 2 available in Virginia, 1 available in Missouri and hopefully a few in available in Oregon soon.

Mr. Rew relayed to the board there have been no problems with Health Resources and Services Administration (HERSA). The clinic sites are registered as a delivery site for the 340B medications and operate within the contract pharmacy framework. One clinic is served per pharmacy in California.

Mr. Rew did not use a PowerPoint presentation.

**b. Cubex**

*Presenters: Anton Visser, President and Chief Executive Officer; and Karen Nishi, Associate of Cubex*

Mr. Visser explained Cubex's key request is for the board to continue to allow pharmacy personnel or a nurse to do the exchange of the medications that come in a secure tamper-evident device called Cubie as per Health and Safety Code section 1261.6. Mr. Visser continued there are three ways to manage medication in long-term health care facilities.

First is the tackle box, which is a manual system and there is no track record of who is going into the tackle box. When the tackle box is opened, all medications are available. There is also a lack of visibility from the pharmacy – who accessed, what did they access and for whom? Second, remote dispensing systems are available but are not included in the presentation today.

Third, and the focus of today's presentation, is the high security medication management system. The goal of this system is to manage first dose and e-kit. It consists of software, cabinet and Cubie pockets, tamper-evident in a variety of different sizes that come from the pharmacy with a microchip to track at the pharmacy and nursing home level. The benefits to the long-term care facility are the increase in patient safety and staff safety. This is done through electronic tracking of the medication through login with BioID (thumbprint). Once in the system, they select the patient and the medication that has been preapproved and appears on the screen. Once accessed, the draw steps forward and the lid is opened and the nurse has access to the medication in the Cubie but no other medication in the system.

Mr. Visser clarified there are multiple doses of the medication in the Cubie, and the Cubie doesn't recognize how much of the medication is taken out. The system allows for additional features such as required countback feature, blind count, witness feature, alerts in the system, and authentication where the pharmacy is called prior to the dispense of the item through a PIN number.

Mr. Visser explained medication can be returned in the case of human error, but the medication is not returned to the same Cubie. There is a specific return bin to prevent cross contamination.

Mr. Visser continued the Cubie system is referred to as a "closed-loop Cubie exchange system." The first step is for the pharmacy technician to log into the system to begin refilling the pocket Cubies and generate a label that goes into the system. The Cubie then goes to step two, where the Cubie is eligible to be inspected by a pharmacist. The pharmacist also logs in through bio-id, and the medication is able to be verified as the medication on the label with an electronic record. Tackle boxes have no means to verify if the medication has been inspected

by a pharmacist. In step three, the Cubie goes into a secure tote that is sealed and transported to the facility. When it reaches the facility, the Cubie is exchanged for a Cubie in the existing cabinet. The user logs in with bio-id and scans the barcode, the cabinet recognizes the medication and the drawer for the medication, and the Cubies are exchanged with an electronic signature. The removed Cubie is tamper-evident. If the Cubies are tampered with in transit, the cabinet will not allow the Cubie to be inserted into the cabinet.

Mr. Visser clarified that the pharmacy would be able to flag patterns of types of medications. President Gutierrez added the pharmacist has access to reports on the back end to identify diversion.

Mr. Visser clarified that each Cubie has a microchip that will prevent the used Cubie from being returned empty to the cabinet. If the Cubie does not arrive at the cabinet, the pharmacy is notified that restocking has not occurred. Mr. Visser explained there is a window that includes the signature of the pharmacist that reviewed the medication.

Mr. Visser continued if the laws change so that a nurse cannot restock or exchange the Cubie, the impact would be that pharmacies would be less likely to use ADDS. First, as there are 48 medications allowed in a tackle box, the amount of medication available would be drastically reduced to the long-term care facilities. Second, it would increase risk to the patient and full access of all the medications for staff members. This results in negative patient care.

Mr. Visser explained there are approximately over 300 facilities using the Cubies in the 1,212 facilities located in the California. Mr. Visser estimated approximately 500 facilities using ADDS for first dose and ekits in California. Mr. Visser clarified this is only for first dose and ekits including controlled substances. The Cubies have been operating for the past 10 years. Mr. Visser explained Cubex has not noticed diversion on controlled substances. Mr. Visser confirmed President Gutierrez's request that these are used for emergency situations at skilled nursing facilities (SNF).

Stan Goldenberg added public comment that in addition to security from Cubex, pharmacies also provide additional measures such as required perpetual inventories. The delivery of the tote in a secure fashion so that it is tamper-evident and pick up of the used totes helps the facilities to secure the medication. Mr. Goldenberg relayed 24-hour patient admissions to long-term care facilities is currently taking place where people are being admitted in pain and need to be treated with medication. The challenge is how to maintain the machine and if someone else is able to return the Cubie to the cabinet. Mr. Goldenberg has not witnessed any diversion. If only pharmacy personnel are able to restock the machines, the unintended consequence might be that more doses are being stocked in the machine than needed.

Mr. Visser confirmed delivery from the pharmacy is directly to the SNFs. Mr. Visser confirmed Cubex's request to the board is for pharmacists and nurses to be allowed to continue to

restock the Cubex machines and not allow pharmacy personnel to be allowed to restock the Cubex machines.

A copy of the Cubex presentation is included with these minutes.

**c. Becton Dickinson (formerly known as CareFusion, Cardinal Health and Pyxis)**

*Presenters: David Swenson, Vice President, Clinical Strategy Medical Affairs, Medication Management Systems; and Rodney Chin, Clinical Consultant*

Mr. Swenson explained to the board Becton Dickinson's (BD) hypothetical scenario. A wholesaler sends an order to the fire station, where the order is scanned into the ADDS perpetual inventory, like a Cubie. Another scenario may be where the medication is secured at a SNF or hospital from the facility to the fire house. Mr. Swenson explained he believed the latter provided more security.

Dr. Chin provided to the board that medications are filled by emergency personnel by going to the hospitals with their manual inventory sheets to pick up the medications. The gap in the law is the pharmacy director is licensed for that particular hospital and does not have jurisdiction but has some liability because the medications are being filled by the hospital pharmacy.

Mr. Swenson continued there is an opportunity for emergency personnel to order through the wholesalers or to leverage current technology used at the SN/LTC facilities. Mr. Swenson confirmed that emergency personnel have a smaller formulary that the wholesaler would be more familiar with than the SN/LTC facilities.

Mr. Swenson continued once the medication arrives at the fire station, the ambulances need to be stocked with the medication and traditionally have used double locked totes. The inventory would be signed out by the responsible person and signed into the inventory for the ambulance using log sheets. Mr. Swenson recommended increasing security by having package-specific log sheets so the log sheet is specific to the package. The completed log sheet would be required for new inventory. Mr. Swenson suggested BD is looking at the possibility of having a miniature cabinet for ambulances. Controlled substances would be subject to the scanning.

Mr. Swenson provided the Pyxis MiniDrawer allows for single and multi-dose modes. Dr. Chin added the lid to the Cubie has increased protection for diversion. BD is partners with Cubex and provides Cubex the hardware while Cubex adds the software. Pyxis is in over 2,700 hospitals nationwide. There are a few installations in firehouses in California now, and uniformity would be appreciated if the board can provide or require it. Dr. Chin added additional security can be added by user privileges being used and defined.

Mr. Swenson continued the Pyxis CII Safe can be used for controlled substances with a closed loop for a large group like LA Fire where the purchases are under the physician's DEA license - typically the medical director of the fire department - and not a pharmacy license.

Mr. Swenson said BD hires "white hat" hackers to see how they are able to hack into the systems. The system also provides for reports that detect average and above average usage. The system provides for a chain of custody.

Ms. Herold said the board is the sponsor of a bill by Senator Hernandez (SB 443) that went into print February 16, 2017.

A copy of the BD presentation is included with these minutes.

The board took a break at 10:57 am and resumed at 11:17 am.

DAG Room addressed inaccurate information in some of the materials and statements made during presentations that the board is taking away the nurses ability to stock ADDS. DAG Room clarified under current law, both in a clinic environment and in a licensed health care facility, the only persons that should be involved in stocking an ADDS is the pharmacist; or in certain circumstances where cards or cartridges are being used, licensed pharmacy personnel may restock under the direct supervision of a pharmacist remotely. Nurses and wholesalers are not authorized under current pharmacy law to restock ADDS. DAG Room continued the statement that the board is changing the law to take away the ability of nurses or wholesalers to restock ADDS is not accurate.

### **III. Comments from Senator Hernandez to the Board of Pharmacy**

Senator Hernandez addressed the Board of Pharmacy. Senator Hernandez thanked the board for its work on SB 493 implementation and promulgating the associated regulations.

Senator Hernandez wanted to discuss with the board how SB 493 came about and the importance of SB 493 and the impact it will have on California and the entire country. When elected to the Assembly in 2006, Senator Hernandez explained he was assigned to a subcommittee on workforce and realized there was a huge workforce shortage even before the Affordable Care Act (ACA) specifically with a distribution problem of providers in California and throughout the country. With the passage of the ACA, there was a huge influx of patients into Medi-Cal and a huge access problem to primary care providers.

Senator Hernandez explained to the board his role as chair of the Senate Health Committee consists of three things: successful implementation of the ACA, access for everyone, and controlling health care costs. An increase of access would require an increase in medical schools to increase the number of physicians graduating, which would take over 10 years to accomplish. Senator Hernandez explained his experience in visiting pharmacy schools and understanding the breadth of experience of pharmacists, thereby making the expansion of the pharmacist profession the most natural approach to providing primary care access for everyone. Based on what a pharmacist does - including

undergraduate degree, doctorate, and residency program - pharmacy is a natural fit to fill the void of primary care in the state.

Senator Hernandez relayed his belief pharmacists are underutilized based on their advanced education, and something needed to be done. Senator Hernandez considers SB 493 one of his key signature pieces of legislation, including changing the smoking age from 18 to 21. Senator Hernandez wanted to speak to the board because pharmacists will now be able to provide primary care and hopefully be reimbursed for the primary care provided one day. Additionally, pharmacy schools are being built in the state revolving around SB 493, and other states are starting to look at implementing similar bill. Senator Hernandez is excited about the national trend that began in California and how pharmacists will play an important part in health care in the country.

Senator Hernandez concluded his address with the board indicating he will be carrying the board's bill SB 443 and opened the floor to questions from the board.

Ms. Herold thanked Senator Hernandez for authoring the bill on behalf of the board.

Mr. Law explained that clinical pharmacy has been part of the Pharm.D. degree but Senator Hernandez was the one who put everything together and the profession owes him thanks.

President Gutierrez shared California has always been a leader and inquired what Senator Hernandez is hearing from other states nationwide. Senator Hernandez said he is hearing other states are looking toward the language. Most pharmacy graduates want to do this type of direct patient health care and will see this spread throughout the country.

President Gutierrez said the board began licensing advanced practice pharmacists (APH). Ms. Herold said approximately seven have been licensed. The first permit was issued to the first pharmacist who qualified, Richard Dang.

Ms. Butler shared with Senator Hernandez that she appreciates what the senator has done for the profession. She recalled attending continuing education in Louisiana where SB 493 was discussed.

Ms. Veale thanked Senator Hernandez for being an advocate for pharmacy in the state legislature.

Ms. Munoz thanked Senator Hernandez for being at the meeting and an advocate for pharmacy and health care in general in California.

Senator Hernandez thanked the board.

## **VI. Automated Drug Delivery Systems (ADDS) - continued**

### **d. AscribeRx**

*Presenters: Reef Gillum, AscribeRx, President; Susan Trujillo, Outside Counsel for AscribeRx, Quarles & Brady, LLP*

Mr. Gillum advised the board the pharmacist is responsible for filling the canisters that are

going out and it is a patient-specific packaging system that has been cleared through the pharmacy process. To understand the technology of their ADDS, it has a chip on the bottom of their canister that controls the canister.

Mr. Gillum explained once the canister is loaded at the pharmacy by the pharmacy staff, the stock bottle is scanned to the chip and produces the error free system. The pharmacy staff identify themselves, the pharmacist and the drug that is going into the canister. A label is printed. The pharmacist reviews the label and contents of the canister prior to affixing the label and tamper-evident seal. The manifest is built from scanning the canister prior to being loaded in the tote and sealed prior to transport to the facility. Upon arrival at the facility, the nurse in other states (pharmacy personnel in CA) removes the canister, scans the canister out of the tote and into the machine. The chip tells the machine what the medicine is and the machine reads the chip. The dispensing happens from electronic files that have been approved and cleared.

Mr. Gillum explained they use a system with firewalls that is HIPAA compliant, and after 10 years of operation, the system has not been hacked. Once the electronic file has updated the DUR and review of allergies, it is sent to the machine and at that point the machine is ready for dispense. Prior to that, it is incapable of being dispensed.

Mr. Gillum continued the machines have the ability to dispense CII because there is a special lock and video surveillance for the ADDS and the room where the ADDS is housed. An email goes to the pharmacist when the CII is accessed. The user has to be an authorized user.

Mr. Gillum explained when the canister is scanned into the machine that is confirmation that the trip from the pharmacy to the machine has been successful. Each canister also maintains a perpetual inventory. If the inventory doesn't match, the policies and procedures for tampering are initiated.

Mr. Gillum explained during the process of filling the canister, the quantity is added to the electronic record, and as every dispense happens the perpetual inventory is decreased. Reorders are done automatically. The PAR value is based on the demand for the medications and there is a safety number. The reorder is completed for a three-day safety order. The return process mirrors the filling process. The frequency of filling depends on the facility, cost of reorder, availability of the medicine and a variety of other reasons. The medication is delivered by the delivery contractors from the pharmacy.

Mr. Gillum provided there is one machine installed in California. The pharmacies maintain an exact copy of the machine in case of emergency or machine failure.

Mr. Gillum explained the canisters are manually counted to reconcile when returned to the pharmacy. The machine is able to identify who is attempting to divert medication by all of the safety features, including video cameras. Additionally, the error rate is lower for their machines versus the push packets because of the accuracy limitation of human exposure.

Mr. Gillum shared on a rare occasion a lot is mixed in the canister. Up to three lots are

allowed using the soonest expiration date of the lots in the canister. If that is the case, all three lot numbers are included. If either the lot number is recalled or the lot number expires, the canister is disabled. Only pharmacist-reviewed canisters can be used. Prescriptions can be cleared through the canister in three minutes using the internet, which is faster than an e-kit in some cases.

Mr. Gillum explained the types of facilities their machines service in other states include assisted living and skilled nursing facilities with the interest broadening. Each site is DEA registered. It also reduces the amount of medication in med carts.

Mr. Gillum explained the canisters are customizable for the facilities and safer than a blister card.

Susan Trujillo of Quarles & Brady introduced herself and Darryl Marr from the Department of Veterans Affairs, which uses nine different but similar machines with the same technology (Talyt) throughout California. Mr. Marr highlighted the tamper-evident seal that reflects VOID if tampered.

Mr. Marr requested DAG Room provide the reference that allows pharmacy personnel - specifically pharmacy technicians - to fill the machines under camera supervision. DAG Room provided section 1261.6(g) describes requirements when done remotely in a secured container.

Ms. Trujillo explained she respectfully disagreed with DAG Room and the facilities are able to stock the canisters. Ms. Trujillo continued if that continues to be the board's interpretation, additional clarity is appreciated.

Mr. Gillum clarified their request is to allow placement of ADDS without board approval in other locations such as a doctor's office large enough to sustain a machine for first dose or take home dispensing.

Mr. Marr is requesting on behalf of CalVet that a pharmacy technician be allowed to load a pharmacist reviewed canister.

Mr. Gillum would like to extend that to nursing as that has been done in other states for 10 years without loss of control.

A copy of the AscribeRx presentation is included with these minutes.

**e. Omnicell, Inc.**

*Presenters: William McGuire, RPH, Pharmacy Consultant, Regulatory Affairs; and Richard Hooper, National Sales Director Vendor Solutions*

Mr. McGuire said the cabinet is all steel. Barcoding goes down to the NDC level to ensure coverage of the Drug Supply Chain Security Act. The safety stock is unique for Omnicell.

When the safety stock arrives at the facility, the safety stock guides the personnel stocking the machine. Biometric finger scans and tall man lettering are available. Patient allergy shows up on the screen. There is real-time interface. First emergent doses are reviewed after the fact. Mr. McGuire clarified the machines are for first doses where the prescription comes after.

Mr. McGuire clarified diversion prevention tactics such as witness restocks, blind counts and unit dose trays. There is a real-time alarm and message sent to whomever the facility wants to receive the message. The NDC must be followed for public protection and Medicare fraud. There is also an external return bin only emptied by pharmacy personnel.

Mr. McGuire explained there is restocking and medicine retrieval with barcodes. There are closed matrices for the controlled substances and everything in California. Lights guide users to the exact bins needed. There are larger sections for larger items such as IV bags.

Mr. McGuire noted the transactions report documents when someone is trying to get into the machine. Discrepancy reports, blind counts and witnesses all help to prevent diversion. Barcoding errors will not allow stocking. Reports include who is taking out what to identify possible diversion (e.g., two standard deviations). Reviewing of reports is critical.

Mr. McGuire requested on behalf of Omnicell assistance and clarification for machines to be included in: PACE (programs for all-inclusive care for the elderly), which is a Medicare based reimbursement that is federally funded; assisted living facilities; standalone free standing emergency facilities; ambulatory settings; infusion centers; and doctors' offices. Omnicell had a large contract with EMS in the state but had to cancel the contract because of lack of a roadmap to allow the machine to be used in the state.

Mr. Hooper said approximately several hundred hospitals and 75 skilled nursing facilities use Omnicell machines in the state of California. Omnicell's customer is the institutional pharmacy providing pharmacy services in facilities. It would be helpful if nurses could restock the machines, as it has limited customers.

A copy of the Omnicell presentation is included with these minutes.

**f. Asteres**

*Presenter: Mark Currie, Vice President*

Mr. Currie reported to the board that Asteres has been presenting to the board since 2009 and is currently working with UCSD on a study that will be reported to the board at the April 2017 Enforcement and Compounding Committee meeting.

Mr. Currie explained Asteres has a filled finished prescription product which means it is completely done by the pharmacist. Asteres provides the pharmacist-approved and -reviewed product to the consumer. Asteres presented a five-minute video about the machine at ScriptCenter Demonstration.

Mr. Currie said Asteres is looking for an extension of CCR section 1713 so they can put the

machine technology farther away from the pharmacy as well as in work site locations (e.g., hospitals) away from the licensed facilities.

Mr. Currie reported Asteres has OSHPD approval for the bolts to secure the 1,300 pound machine, and the machine is fire resistant.

The link for the video provided by Asteres can be found at: <https://vimeo.com/203203050>.

The board took a break for lunch at 12:24 pm.

Board Member Valerie Hernandez left the meeting for the day.

Board Members Lavanza Butler and Victor Law left the meeting, depriving the board of quorum.

The board reconvened from lunch at 1:07 pm

**g. MedAvail**

*Presenters: Seema Siddiqui, Director of Pharmacy and Regulatory Affairs; Earl Key, Jr., Pharmacist Consultant; and Edward Rickert, Quarles & Brady LLP, National Pharmacy Counsel for MedAvail*

MedAvail provided a short video to demonstrate the interfaces with their technologies.

Mr. Rickert clarified MedAvail's ADDS is fully automated and uses barcodes and cameras so that the pharmacist can see the label on the bottle. The ADDS is meant to supplement the pharmacy, not replace it.

MedAvail can use manufacturer's bottles and provide multiple languages if the pharmacy provides a different language.

President Gutierrez commented that the board will want to consider if the ADDS can meet language requirements.

The system will not provide more medication than what the prescriber allows.

**h. Arxium**

*Presenter: Scarlett Eckert, Pharm. D., Pharmacy Consultant, Arxium*

Dr. Eckert informed the board the system is like a vending machine. If the amount is different, the pharmacist would ask the patient if he or she wanted to smaller amount now and the

balance delivered or picked up. Biometric sensors are used, and password options available. Access levels are determined by the administrator.

Dr. Eckert reported there are many types of reports: access, transition, inventory, etc. The narcotics are secure. There is a triple-check barcode system. The scanned prescription, records and interactions are all checked by the pharmacist before the prescription can be released by the machine. There are many types of configurations. There is a label printer that prints what the pharmacy sends, and it can accommodate other languages if the pharmacy sends in a different language. The ADDS are free standing and can be bolted down.

Dr. Eckert explained these ADDS are not for consumers but for clinics and possibly physicians' offices. The bottle has manufacturer information with a bar code, and the label is printed and attached to the bottle. There are three sites in clinics in California – Chula Vista, San Diego and Reseda. There is a two-way video/audio for consulting, or the ADDS could use Skype. The pharmacist is stocking the ADDS.

Dr. Eckert relayed to the board Arxium's desire to have a pharmacist intern or pharmacy technician restock the machine with a tamper-evident seal. Controlled substances can be dispensed. The pharmacies owning the machines are transporting their controlled substances into a location not on their license. The other request is if the monthly inspection could be done by a pharmacy technician and the quarterly review done by a pharmacist.

Dr. Eckert requested clarification on Business and Professions Code section 4186(f) to see if the licensed pharmacist who verified the prescription had to be located in California.

A copy of the Arxium presentation is included with these minutes.

**i. PharMerica Corporation**

*Presenters: Scott Anderson, Implementation Manager; and Deborah Irvinson, Lead Implementation Consultant*

Mr. Anderson clarified for the board that this ADDS is for first-dose emergency dose and first-dose medication. Ms. Irvinson continued the ADDS allows for refill based on PAR level setting, integrated with pharmacy database, and is restocked by a pharmacy. There are approximately 30 ADDS in California with more pending. The machines are registered in advance.

Ms. Irvinson said the machines are more secure than a tackle box and the inventory is better managed. ADDS is prompted for expiring medication. All medications are barcoded. These ADDS are typically in rural facilities.

Ms. Irvinson continued the ADDS prompted for the medication to be dispensed. The top drawer is a unit dose dispenser for controlled substances. It is a closed-door coil system, and the nurse only receives the items. Medications must be barcoded after dispensed. There are unit dose settings that are prepacked. There are also drawers for bulky items.

Ms. Irvinson explained the nurse is only presented with the drawer for the medication that is requested. Mr. Anderson further explained that a nursing facility has access to narcotics where a pharmacist does the restocking with a secured tote.

Ms. Irvinson provided it is a closed-loop system. Controlled substances are on a blind count with no indication of how many should be there. A flag is sent to the pharmacy if there is a discrepancy.

Mr. Anderson explained the access is controlled by PharMerica. Access can be through PIN, user name or biometric.

Ms. Irvinson explained it operates like an e-kit. Mr. Anderson said it weighs about 900 pounds with nothing in it and has mechanisms to email the facility and/or pharmacy.

Ms. Irvinson relayed the request for a pharmacy technician, intern or nursing staff to restock for remote locations.

A copy of the Omnicell presentation is included with these minutes.

## **2. Discussion of Current and Potential Circumstances Under which ADDS are Used and the Impact on Public Safety**

Ms. Sodergren provided an overview of the requests made from the vendors who presented. She clarified the board may want to opine if different requirements are necessary for an e-kit versus a cabinet ADDS system.

Ms. Sodergren continued the first vendor inquired if a clinic could operate an ADDS it owned within a clinic. Currently, the pharmacy needs to own the ADDS. There is also a question if the wholesaler can drop the drug stock off to the ADDS in a secured tote and if the restocking can be done remotely by a pharmacist with a video screen.

President Gutierrez commented that with the automation, the pharmacy walls are being extended outside the pharmacy. It may be worthwhile to look at licensing locations that are allowed to store the ADDS and not in a pharmacy.

Ms. Veale reiterated it was a good item to contemplate for enforcement. Ms. Herold reminded the board that some of the registration of ADDS are required because they are not in an area that is licensed by the board.

Ms. Herold indicated there are more requirements if the ADDS are licensed, not registered. President Gutierrez relayed she thought it was a good idea if the board maintains control for consumer safety and protection.

Ms. Herold indicated the features of the ADDS are patient friendly provided the law is flexible to allow and the ability to regulate it, specifically patient consultation.

President Gutierrez inquired if this licensure would be legislation or regulation change. DCA Counsel Laura Freedman commented she believed it to be legislation. Legislation is required for licensing a location not tied to a pharmacy. DAG Room indicated the board should consider coordination with the Department of Public Health (CDPH) on where ADDS are located.

Ms. Sodergren inquired what environments are appropriate. President Gutierrez is concerned about transit and tamper-proof evidence as there is an area for diversion. Tamper-evident proof may be able to be allowed by a pharmacy technician.

### **3. Discussion and Consideration of Next Steps by the Board**

President Gutierrez referred this item to the Enforcement and Compounding Committee for further discussion for licensing and restocking.

Steve Gray representing Kaiser made a public comment requesting clarification on licensing. When the wholesaler delivers and the pharmacist ensures the medication is put in the right place, CCR 1783 can only deliver to licensed facilities. Additionally, the board should clarify when there is a licensed clinic with CDPH and the board, do the drugs belong to the clinic? Things to keep in mind: Who owns the machines? Who owns the drug stock?

Mr. Lippe suggested legislation to supersede CCR 1783.

Dr. Gray continued in 2014, the law was changed that the licensed clinics can dispense if prescribed by a licensed prescriber, specifically; AB 2346 effective 1/1/13 changed Business and Professions Code section 2725.1. The law needs clarification when the clinics dispense the drugs, do they have to follow labeling laws a pharmacy would need to abide?

Robert Stein, KGI School of Pharmacy, requested the board classify the devices based on site location, function, pharmacist access afterhours, patient consultation quality in the video format and tamper evident requirements.

Charlie Hartig, Senior Legal Counsel with CVS, requested the Enforcement and Compounding Committee consider nurse replenishment in 1261(g) and memorialization of pharmacy personnel for the restocking. Ms. Herold indicated the attorneys previously opined.

Mr. Hartig continued Health and Safety Code section 1250 currently provides the framework of who is able to have an ADDS.

President Gutierrez indicated she wanted to work with the CDPH while clarifying.

Mr. Hartig continued with a reservation on having a nonpharmacy ownership of the machines. To allow licensure of ADDS is potentially problematic and should be considered on a case-by-case basis.

Stan Goldenberg suggested having some vendors discuss the future technology uses during the Enforcement and Compounding Committee meeting. Dr. Goldenberg suggested a frequency of twice a year as technology happens fast.

Ms. Herold announced the March 11<sup>th</sup> joint DEA/UCSD and Board of Pharmacy.

**VII. Closed Session**

The board went into closed session at 2:29 pm.

**XVII. Reconvene Open Session**

The board reconvened in open session at 3:04 pm.

President Gutierrez adjourned the meeting at 3:04 pm.