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
DRAFT

DATE: February 17, 2017

LOCATION: Department of Consumer Affairs
1st 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

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 thatrequire 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 a 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.[3]

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

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.~~<u>30.</u> Work Site Monitor** (Appropriate for those cases where the evidence <u>demonstrates</u> substance use.)[4]
>
> <u>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.</u>
>
> <u>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.</u>

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			

Board Member	Support	Oppose	Abstain	Not Present
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
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 Guitierrez 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 CIISafe 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 CIIs 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 (Talyst) 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 Omincell 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-pproved 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 that 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 throughPIN, 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 11th 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.

CUBEX
Automated First Dose and Emergency Kit Overview

February 17, 2017

Agenda

- Three Different Types of Dispensing

- "Closed Loop" Process
  Positively impacts:
    - Patient & Staff safety
    - Security
    - Accuracy and Accountability
    - Inventory controls
    - Regulatory Compliance

Board Request

Continue to allow pharmacy personnel or nurse to exchange sealed tamper evident medication pockets with used medication pockets as per CA PracAct 1261.6 paragraph 7(A)(g)(3)

The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the pockets, cards, or drawers are properly placed into the automated drug delivery system.

Types of Medication Management

High Security Medication Management
First Dose & E-Kit ONLY

High Security Medication Management
First Dose & E-Kit ONLY

High Security Medication Management

- **Increased Patient and Staff Safety**
- **Authorized user access only (BIO ID Required)**
- **Single medication access**
- **Witness and Authentication on narcotics**

"Closed-Loop Cubie Exchange"

5. Empty Cubie is returned to pharmacy

1. Pharmacy programs and stocks the Cubie

4. Exchange of the empty Cubie for the new Cubie verified by bar code scanning

myQLink™

2. Pharmacist verifies contents against the label

3. Sealed Cubie is released to secure tamper evident container for transport

CUBEX®
MAXIMIZING EFFICIENCY
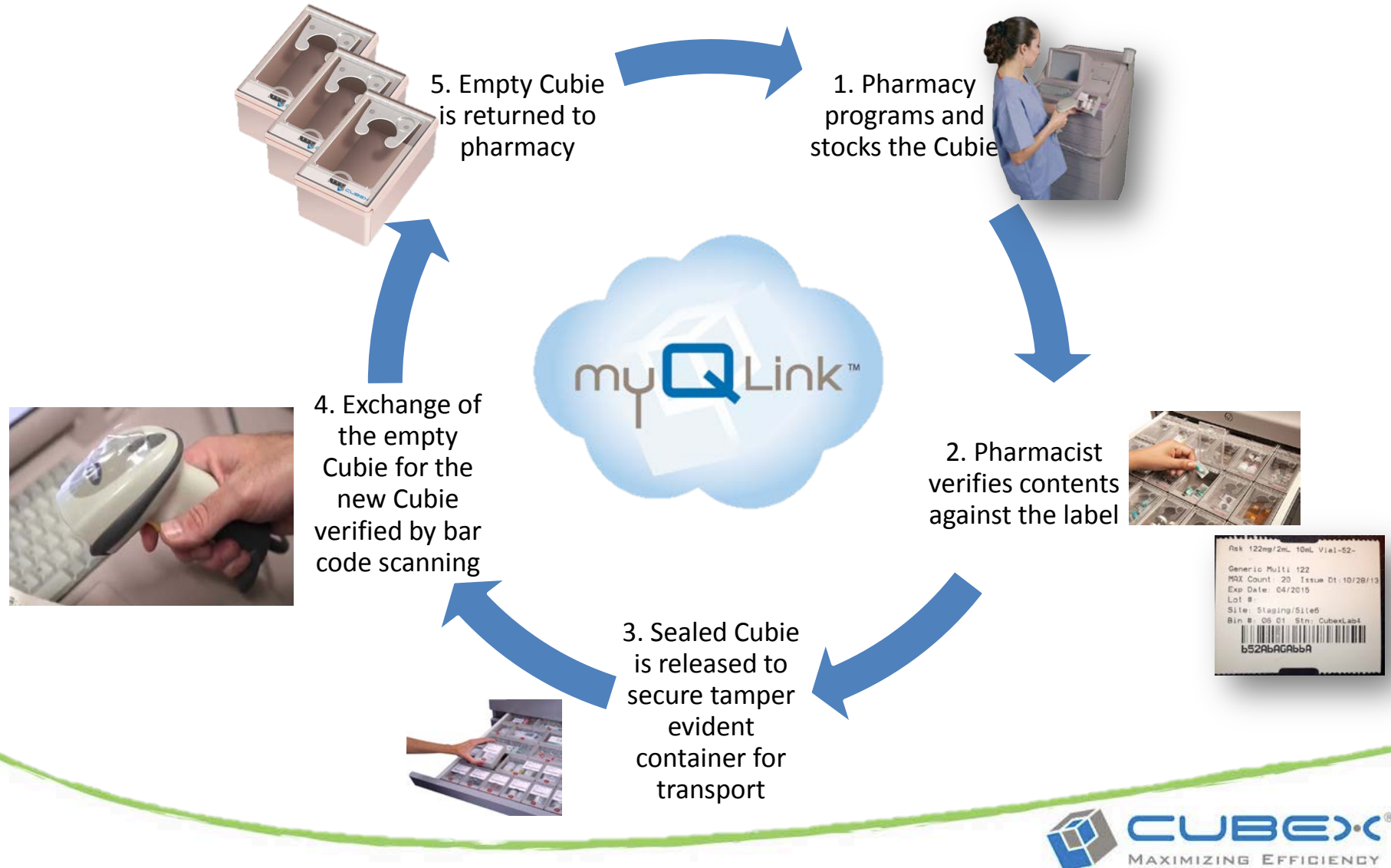
"Closed-Loop Cubie Exchange" Process

Step 1: Cubie Stocked

- Pharmacy technicians uses bio-id to log into the Cubex Cubie Replenishment Station to view what medications need replenishing at the facility
- Pharmacy technician selects the facility and which medication is being stocked in the Cubie
- Pharmacy technician verifies all the information on the stocking screen matching the medication being placed in the Cubie (name of medication, NDC, lot number, expiration date, facility, location in drawer, and bin assignment)
- Upon verification the Pharmacy technician prints the label and inserts the label into the Cubie
- The Cubie is now programmed and has a verification label for Pharmacist to confirm contents and sign-off on Cubie

CUBEX®
MAXIMIZING EFFICIENCY
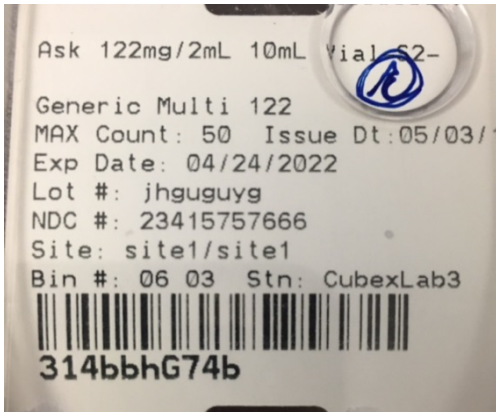
Step 2: Pharmacist Review & Verification

- Pharmacist uses bio-id to log into the Cubie Replenishment Station to begin the process of verifying the medication in each Cubie
- Pharmacist selects the Cubie to be verified.
- The appropriate drawer with the stocked Cubies is opened. Subsequently the Cubie lid is opened.
- Pharmacist verifies the information on the medication matches the information on the label (medication name, NDC, lot number, and expiration date)
- Upon verification the Pharmacist closes the lid on the Cubie, and initials the upper right side of Cubie label.
- Pharmacist releases Cubie from the CR Station and places the programmed and verified Cubie into a secure tote for delivery to the facility

"Closed-Loop Cubie Exchange" Process

Step 3: Cubie shipment prepared
The programmed, tamper evident Cubie is released from the Cubie Replenishment Station and placed in a secure tote for transport to the facility

"Closed-Loop Cubie Exchange" Process

Step 4: Cubie Exchange

- Personnel uses bio-id finger print reader to access the Cubex
- Scans the barcode on the programmed Cubie
- The correct drawer opens
- The empty Cubie is released
- The new Cubie is placed into the correct location
- Transaction is complete

CUBEX®
MAXIMIZING EFFICIENCY

"Closed-Loop Cubie Exchange" Process

Step 5:
- Released Cubies are placed in a secure tote

- Tote returned to Pharmacy

Board Request

Continue to allow pharmacy personnel or nurse to exchange sealed tamper evident medication pockets with used medication pockets as per CA PracAct 1261.6 paragraph 7(A)(g)(3)

The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the pockets, cards, or drawers are properly placed into the automated drug delivery system.

Questions ?

ADDS Questionnaire:

Becton Dickinson Response to California Board of Pharmacy

Dave Swenson, RPh
VP, Medical Affairs
BD/CareFusion

February 17th 2017

Agenda

- Providing Consumer Protection
  - Process overview – "Chain of Custody"
  - System access security
  - Secure storage / replenishment – modular options
  - Customization / configurability
  - Surveillance reporting

- Areas of Pharmacy Law Impeding ADDS Use
  - Federal CS Act – HR 304
  - California State Board regulations

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Process Overview CS Management
Goal; Secure, Documented Chain of Custody

1. Wholesaler order

2. Scanned into ADDS perpetual Inventory

3. Secure access Replenishment

4. Field sign-out and administration

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CS Management Options
User Access

Biometric Positive Identification

- Regulatory compliance

- Enhanced access

  - Time saver for nursing

  - Security

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CS Management Options
Single Dose Access

Modular Drawer Types:

Pyxis MiniDrawer

- Single dose or Multi dose modes

- Different size trays/pockets

- Highly customizable hardware options

1st dose taken

2nd dose taken

3rd dose taken

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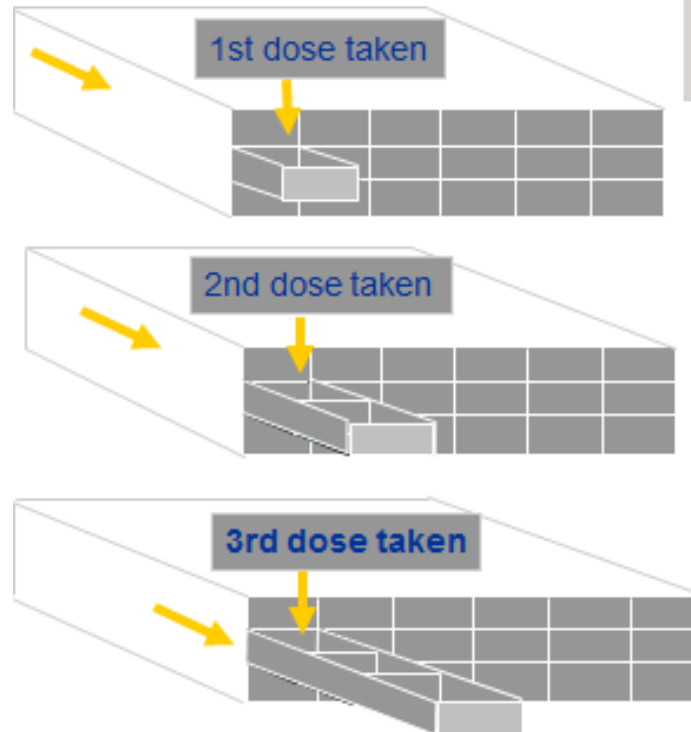
CS Management Options
Single Item Access

Modular Drawer Types:

Pyxis CUBIE® pockets

- Limit access to single, larger medications by user

- Enhanced security supports diversion prevention

- Tamper evident, secure transport

- Multiple sizes

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CS Management Options
Customization / Configurability

Formulary

- Pharmacy and Facility Formulary
- Limited security/override groups
- Options:
    - Blind Count
    - Witness Required
    - Waste While Removing
    - Undocumented Waste

Users

- Active Directory integration
- User privilege templates
- User roles

Devices

- Use of Return bins
- Routine Inventory
- Timeouts
    - Menu
    - Open Drawer
- Discharge Delay

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Secure storage and record keeping
Perpetual Inventory

Pyxis CIISafe® system

- Controlled Substance management for pharmacy

- Automatic Pyxis Re-stock

- Pyxis vs. C^{II}Safe Compare

- Proactive Diversion Search

- Receiving Medications

- Migration Summary (DEA)

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System Surveillance Options

Diversion Detection

- Detect anomalous user activity
- Waste activities and discharge patient activities
- High removals and medication access

Auditing

- Manage discrepancy resolution metrics
- Floating staff , tx, all products in a single report
- Reconcile CS movement from the vault to the ADC

Compliance

- Override management
- Inventory CS medications
- Cancelled transactions
- Modified or temp users

Provide decision support data and insights to effect change

Leverage data from the single hospital or across the health system

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Areas of Rx Law Impeding use

- Federal – HR 304
    - EMS / remote facility ordering and storage
    - Passed House, Senate next
    - Appears to be low enforcement priority

- California State Board regulations
    - ADDS regulations in place:
        - Hospitals, SNF, "Medical Facilities"
    - EMS staging facilities not considered a "Medical Facility"

- Areas of impedance:
    - Ordering/ storage of CS at EMS staging areas –
    - Pharmacist oversight of medication process

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Appendix

Back-up – not for presentation

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System Surveillance Options

Diversion Watch List

User Name	Aggregate User Percentile	Cancelled Transaction (%) (CS Only)		Amount of CS Discrepancy Involvement		Users with CS Doses Dispensed > 2 SD (HouseWide)		Users with CS Doses Dispensed > 2 SD (Station)		Doses Dispensed (CS Only)	
		Percentile	Percentage	Percentile	Amount of CS Discrepancy Involvement	Percentile	Average SD Score	Percentile	Average SD Score	Percentile	No. of Doses
BALLARD, TARIK / Ballard.Ta	100	57	4.9 %	86	4	100	6.9	1	<	96	150
BARBER, ELLA / Barber.Ell	100	9	1.4 %	1	N/A	93	7.3	94	3.5	100	623
FLOWERS, IVY / Flowers.Iv	100	15	1.7 %	1	N/A	100	5.4	94	3	94	138
GRIMES, SLADE / Grimes.Sla	100	30	2.5 %	1	N/A	100	5.3	99	4.2	91	105
LOGAN, PASCALE / Logan.Pasc	100	3	0.9 %	66	2	100	6.3	99	4.1	96	154
LOTT, XENOS / Lott.Xenos	100	5	1.0 %	1	N/A	100	5.6	94	3.1	94	134
BARRETT, COLETTE / Barrett.Co	99	1	0 %	86	4	1	N/A	94	3.8	86	85

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System Surveillance Options

Reports	Frequency
Compare CS Vault removes to ADC refills and loads	Every shift or at least daily
Review CS override removals	Daily
Check modifications in user access	Daily
Review CS discrepancy report (all)	Daily
Review compliance with CS inventory counts	Weekly
Evaluate cancelled transactions	Daily
Review remove reports for high activity	Monthly
Review waste activities for completeness and look for user/witness pairs	Monthly

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System Surveillance Options

Barber, Ella

◉ Table View   ◯ Chart View

Doses Dispensed from Pyxis® MedStation® system

Station Name ▲ ▼	Station Type ▲ ▼	# of Vends ▲ ▼	# of Doses Dispensed ▲ ▼	
MS4000-013	Med Station - Profile	57	601	Trend
MS4000-014	Med Station - Profile	10	14	Trend
MS4000-015	Med Station - Profile	5	8	Trend

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System Surveillance Options

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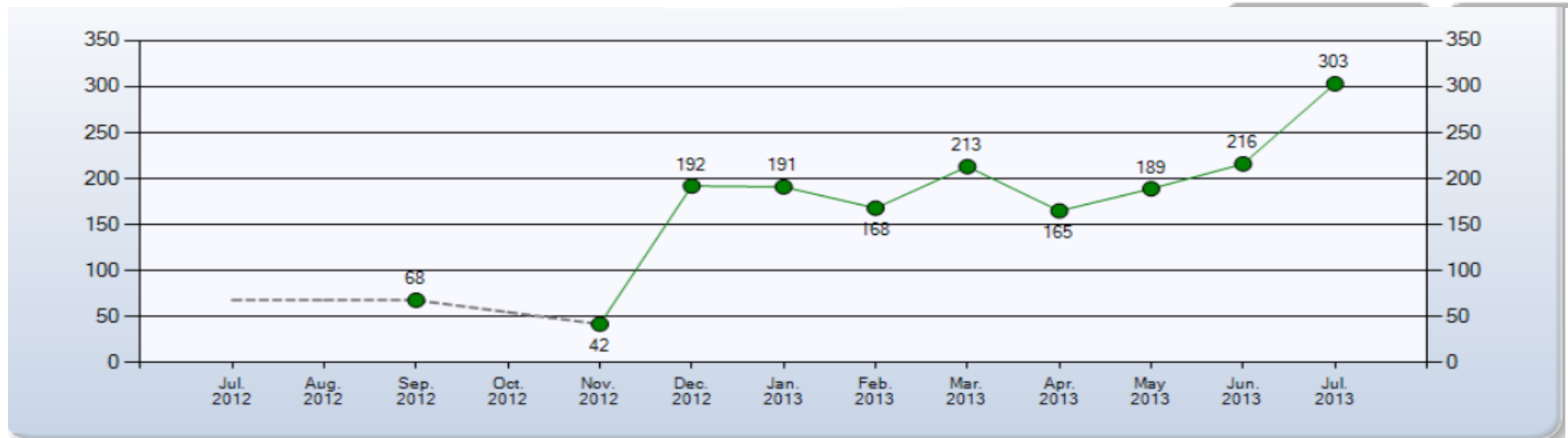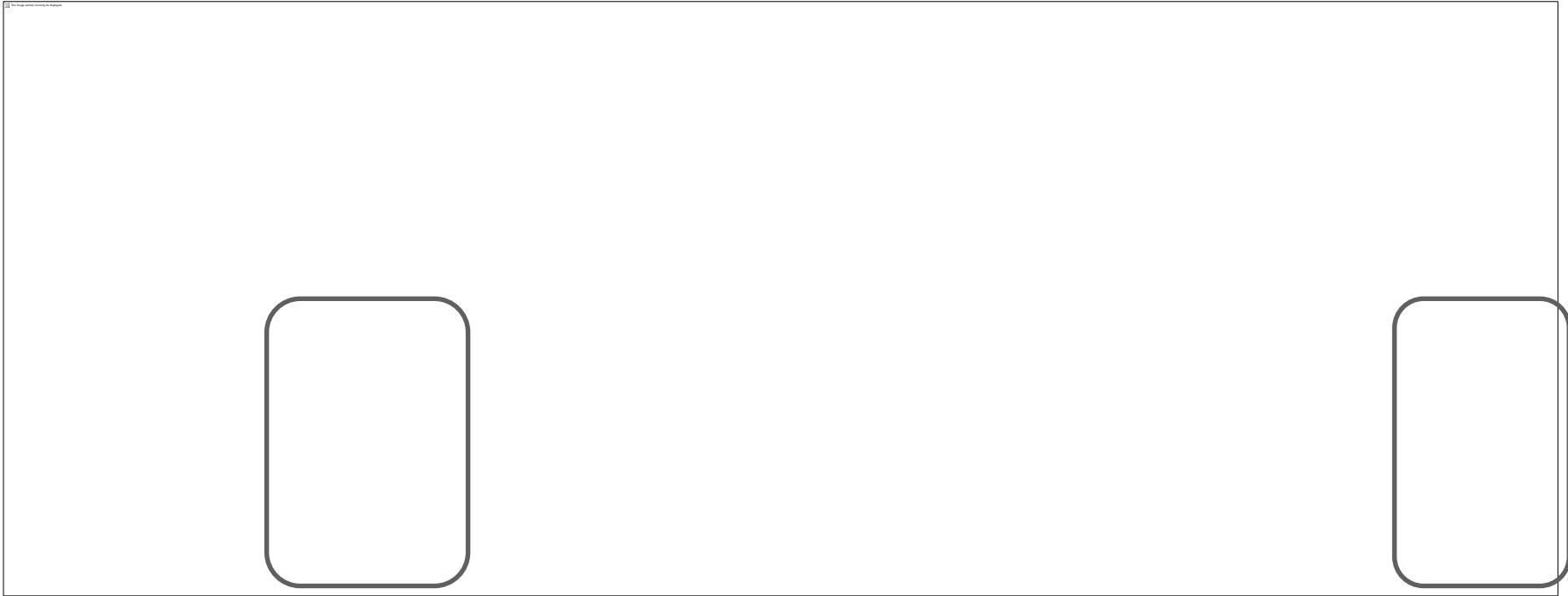
System Surveillance Options

ASHLEY, RIGEL / ASHLEY.RIG User Type: IV START TEAM - RN										
MS4000-014	MORPID21 1	MORPHINE 2 MG 1 ML SYRINGE	SYRINGE	PTN190919	190919	PA1-00190919	Vend	5.0	2.0	01/17/2013 11:27:17
ASHLEY, RIGEL / ASHLEY.RIG User Type: RN										
MS4000-027	ROXIOT5100	OXYCODONE HCL 5 MG TABLET	TABLET	PTN415810	415810	PA1-00321844	Vend	4.0	1.0	09/01/2013 19:00:25
AYERS, MADALINE / AYERS.MADA User Type: RN										
MS4000-084	OXY20.	oxyCODONE SA* 20 MG SA.TAB	SA.TAB	PTN242842	242842	PA1-00242842	Vend	8.0	5.0	04/12/2013 13:43:56
AYERS, MADALINE / AYERS.MADA User Type: RN										
MS4000-003	ROXIOT5100	OXYCODONE HCL 5 MG TABLET	TABLET	PTN239353	239353	PA1-00239353	Vend	4.0	1.0	04/07/2013 20:08:03

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System Surveillance Options

Waste Station	Type of Waste	Waste Amount	Waste User ID	Waste User Name	Waste User Type	Witness User ID	Witness User Name	Witness User Type	Waste Transaction Date/Time	Duration to Waste	Dispense User = Witness User
Stn24	WASTE	(AMT WASTED: 0.1 MG)	DNE8904	Dawson, Eleanor	RN	Scott.Broc	Scott, Brock	CHARGE NURSE	09/06/2013 22:17:23	02:27:26	N
Stn56	WASTE	(AMT WASTED: 2 MG)	CNK5415	Herrera, Perry	CRNA	Mclaughlin	Mclaughlin, Marshall	CRNA	09/06/2013 17:27:21	02:55:13	N
Stn13	WASTE	(AMT WASTED: 1 MG)	BIL9027	Donaldson, Orli	RN	Hines.Lynn	Hines, Lynn	RN-RAPID RESPONSE	09/06/2013 16:05:43	01:00:50	N
Stn8	WASTE	(AMT WASTED: 790 MG)	FFA9440	Morgan, Hop	RN	Mendoza.Ha	Mendoza, Hakeem	IV START TEAM - RN	09/06/2013 15:24:06	08:33:26	N
Stn43	WASTE	(AMT WASTED: 50 MCG)	VZJ9153	Waller, Eric	RN	Aguilar.El	Aguilar, Elijah	RN	09/06/2013 15:15:31	04:53:47	N
Stn112	WASTE	(AMT WASTED: 100 MCG)	YNH4011	Randall, Martina	RAD TECH	Carney.Upt	Carney, Upton	CHARGE NURSE	09/06/2013 14:50:12	01:11:20	N

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Training Options

Customer Learning Portal

- Mobile app

- On line e-courses

- User role training customized by health system

Continued Education

- Instructor led training

- Monthly on line user group meeting

- Bi-monthly training webcasts with clinical consultant

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Consultation Services

Best Practice

- Clinical documentation on Customer Portal

- Practice Assessments
  - Closed loop controlled substances system
  - Controlled substances storage and inventory
  - User security
  - Discrepancy management
  - Temporary patient management
  - Report utilization

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Questions?

crystal.woodward@carefusion.com

LTC Market Change Impacting Pharmacy Services

The primary dispensing modality has not changed in over 30 years!

- Focus on Short-Term Rehabilitation Residents

- Increased Acuity

- Increased Regulations

- High Nurse/Resident ratio (Baby Boomers)

- Increased Weekend and Evening Admits

- Complexity of Medications on the Market (e.g. Ca Channel Blockers)

Process Overview

Order Entry

OnSiteRx® Enabled Pharmacy
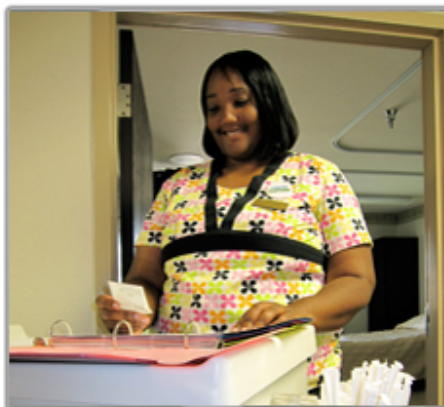
Safe & Efficient Administration

Unit Dose Packets

Canister pathway

Drug Canister Details

- The Automatic Canister Recognition System (ACRS chip) uses an installed chip to establish a unique identifier for each canister.
- Allows for canisters to be placed in any open location in the ADDS machine without having to document its location.
- Software identifies the location of each canister electronically and notifies the ADDS machine from where to dispense a particular medication.
- ACRS chip improves safety by eliminating possibility of canister fill and placement errors.

Canister

Canister Recognition Chip
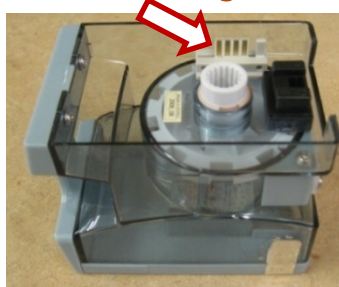
Tamper Evident Seal

Each canister is built to specifications.

Canister Fill Station

Canisters Ready for Shipment

1. Filling Canisters

Filling Procedure

- ➢ Place canister on the chip writer.
- ➢ Scan the NDC barcode on the medication bottle
- ➢ Enter the fill details
  - Qty, Lot #, Exp
- ➢ Print and scan the medication fill label.
  - This verifies the information on the label & canister chip match.

Note: The canister is not coded (will not dispense) until all information verified by system

2. Verifying Canister Contents

Pharmacist Procedure

➢ Verifies the contents of the canister matches the label.

➢ Adheres label & tamper-evident seal.

➢ Initials & dates canister label.

Note: Physical Inspection

Canister Label Details

- ✓ Unique Canister ID
- ✓ Verifying Pharmacist Initials & Date Signed
- ✓ Medication Name & Strength
- ✓ NDC
- ✓ Schedule
- ✓ Color
- ✓ Shape
- ✓ Marking
- ✓ Mfr
- ✓ Lot #
- ✓ Fill Date
- ✓ Exp Date
- ✓ Pharmacist
- ✓ Technician
- ✓ Pill Qty

3. Canister Delivery

➢ Canisters are assigned to a facility by scanning. Creating a shipping manifest.

➢ These canisters are then tracked by the system as "en route".

➢ Canisters and the shipping manifest are transported by delivery personnel in a sealed tote.

4. Canister Reception Process

Licensed Healthcare Professional Procedure

➢ Signs the canister shipping manifest

➢ Receives sealed canisters by scanning the medication fill label while logged into the OnSiteRx® Kiosk. (Tracked as delivered)

➢ Place canister into the secure OnSiteRx® Packager or in a secure storage unit adjacent to the Packager until needed.

Medication Packet

- 5 Sigma Accuracy: 23 Times Safer Than Bingo Cards
- Clearly labeled and well-organized
- Capable of printing 19 lines (drug name, bar code, efficacy, patient name, dosage)

- System setup can be tailored to customer requirements
- Font, text size, and number of letters are adjustable
- Line length and position of the text are also adjustable

Patient Name
Unit/Room/Bed, Patient ID
HOA
Number of Pills, Strength, Medication Name
Marking, Shape, Color, Type
RX Number, Lot Number, Manufacturer
Dispensed Date, Use By Date
Packet Number, Physician Name
Facility Name
Pharmacy Location

KLOCKMAN ROBERT
04SAW3/N201/B   040100050021
TAKE CONTENTS AT 9:00A 03/31
1X 500mg DEPAKOTE EC
NS - OVAL PINK TABLET
RX# 04573773   LOT# 63752AA2   ABBOT
2X 100mg GABAPENTIN
93/38 - OBLONG GRAY CAP
RX# 4922192   LOT# 226045   TEVA
1X 20mg OMEPRAZOLE
APO020 - OBLONG PINK-BROWN CAP
RX# 0501039393 LOT# HZ2525   APOTEX
1X 25mg SEROQUEL
ROUND PEACH TABLET
RX# 04838393   LOT# PT0008   ASTRA ZENECA

DISPENSED: 03/30/2007 USE BY: 08/14/2007
Packet: 033015321451184200 SWANSON, ROBERT
Shady Acres Retirement Home
By: ProvideRx 2000 Green Oaks Dr. Grapevine TX 76051

Medication description and HOA

Reverse clear side of Packet

Blister Cards vs. Unit Dose

Accessing 4 separate blister cards and punching out meds vs. tearing open one packet with the same 4 meds.

MAR   OnSiteRx™ Packet

Drug Waste using Blister Cards

> 95% eliminated with Multi-dose dispense

Prescription pathways

▸ Order Processing to Medication Administration

Prescription Review & Approval

- ➢ Pharmacy receives electronic, or faxed order.
- ➢ Pharmacy process order into PhIS.
  - ◦ DUR & Formulary Check
- ➢ Orders are sent electronically to the facility's OnSiteRx® Kiosk.
  - ◦ Order is available within minutes after the pharmacy processes it.

Retrieving Resident Specific Prescriptions

- The OnSiteRx® Kiosk receives resident specific prescription information via an encrypted communication service.
- The licensed healthcare professional request via the OnSiteRx® Kiosk, to retrieve the resident specific order from the OnSiteRx Packager.
- The licensed healthcare professional confirms that the following information is listed on the packet prior to administering the drug: correct resident-patient name, medication, strength, unit, and quantity as directed by the medication administration record.

OnSiteRx® System Software

▸ Overview

OnSiteRx® Software System

Three (3) main components
- OnSiteRx ® Pharmacy System (OPS)
- OnSiteRx® Dispensing System (ODS)
- Reporting Center

![AscribeRx]

OnSiteRx ® Pharmacy System (OPS)
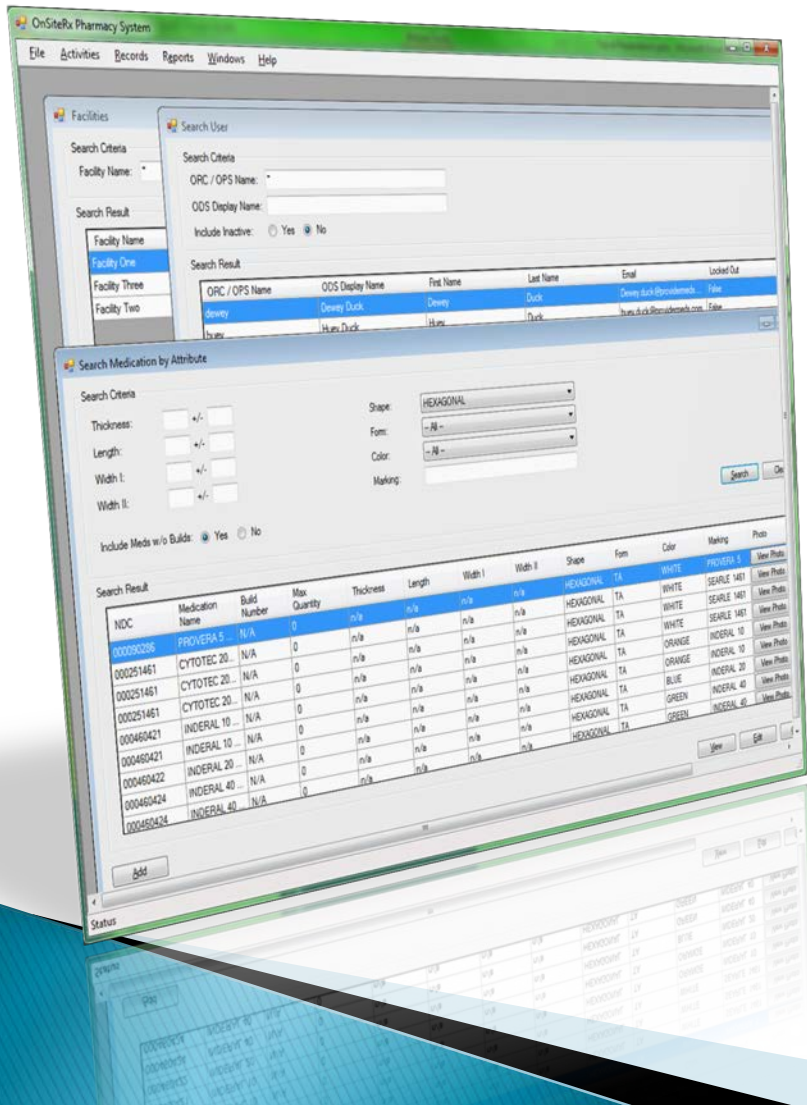
Allows pharmacy and support staff to:
- Encode & initialize canister chips
- Manage canister & build information
- Perform formulary management
- Perform user administration
- Perform ODS administration
- Adjust pharmacy preferences

OnSiteRx® Dispensing System

Functionality
- First and stat dose
- On-demand PRN dispensing
- Leave of absence dispensing
- Re-dispense
- Automatic medication reordering
- On-demand routine medications
- Configurable dispensing by:
  - Resident
  - Hall
  - Nursing Station
  - Med Cart

Reporting Center

Reports include but not limited to

- Review Database Records
- Canister Aging
- Canister Replacement
- Controlled Substances Report
- Current Inventory
- Dispenses
- ODS Access Log
- Prescription Information
- Resident Information
- User Information

Hardware

▸ Canisters, OnSiteRx®
Packager & Security

General Canister Info

Canister Label

Canister Recognition Chip
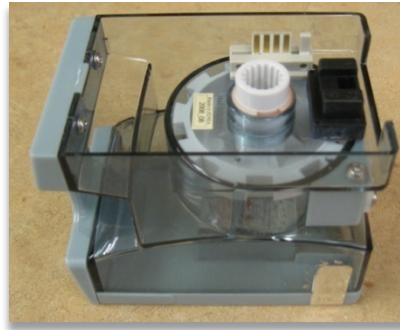
Tamper Evident Seal

Each canister is built to specifications.

Canister Fill Station

Canisters Ready for Shipment

Canister Management

The OnSiteRx® Pharmacy System keeps detailed information regarding each canister.

- ➢ Each canister is assigned a build number and unique canister id upon initialization by our Canister Production team. This information allows us to determine
  - ◦ What medications will fit in the canister and prevent loading of unapproved medications
  - ◦ Where the canister is currently located
  - ◦ What medications it has dispensed in the past
  - ◦ Total pill count dispensed.

OnSiteRx® Packager

There are slots for 240 canisters which medication orders are dropped into packets, sealed and printed.

OnSiteRx® Packager Testing & Routine Maintenance

> Each OnSiteRx System is put through a 262 Point Quality Assurance Test & Inspection.

> No daily maintenance is required by facility or pharmacy staff.

> Regular QA inspections are scheduled by AscribeRx certified technicians

System Security
ALink Now Enhancement

▸ Full electronic tracking of all activities

▸ Live and archived video monitoring

▸ Electronic and manual locking of medication canisters

▸ Separated locked location for Controls

▸ Email alerts for all access to Controlled canisters

▸ Advanced activity reporting

System benefits

▸ Safety, Time, Cost Savings

ADDS Safety Benefits

- Reduced on-hand inventory of medications nurses need to manage
  - Reduction of destruction
  - Less medications in med cart (including controls)
  - Less opportunity for diversion
- Full video and electronic tracking
  - Higher accountability
- Packets can be opened at the bedside aiding in medication verification ("5-Rights")
- Less reliance on ekit due to 1st dose from ADDS available (after RPh review) within mins

Nursing Benefits

- First and stat doses available approximately 15 min after sending to Rx.
- Med Pass time significantly reduced.
- Shift change narcotic count time virtually eliminated.
- Blister pack reordering virtually eliminated.
- Med cart size reduction in size and weight.
- Entering medication administration information on MAR becomes much more accurate as packet matches MAR.

Resident Benefits

- ✓ First and stat dose availability in minutes, not hours.
- ✓ Leave of absence orders organized by day and time of administration.
- ✓ Nurses have more time to spend with residents.

Facility Benefits

✓ Reduction in Med-A and Med-D oral solids waste.

✓ Consulting pharmacist time to witness medication destruction reduced.

✓ Significant reduction of nurse administration time managing orders/reorders/missing doses/receiving cards

✓ Ability to electronically track to the dose level

✓ Centralize storage of medications (e.g. PRNs)

✓ Medication accountability and diversion detection.

✓ Resident plan changes updated immediately.

Doctor, NP and PA Benefits

✓ Dramatic reduction in call backs from nurses regarding pharmacy announcing order "not on formulary".

✓ Incentivized to use CPOE, prescribing professional can view resident diagnosis and all drugs currently being taken while considering order changes or initiation.

OnSiteRx® System Statistics

▸ Overview

OnSiteRx Remote Dispensing Stats

➢ Of the last 4.12Millon meds packaged:
  ➢ 0.02% system error rate
  ➢ 0.008% canister jams
  ➢ 88% average improvement in time to 1st dose.
  ➢ 82.5% average reduction of med waste/returns of oral solids.
  ➢ 27% average reduction of on site medications for oral solids.

Dispensing Process Accuracy

▸ Traditional Dispensing Modalities: 8% Error Rate
▸ OnSiteRx unit: 0.018% Error Rate (n=4.1M)

Monthly average for 10 facilities	
Medication Dispensed	145249
Dispense Sessions	4546
Technical Support Calls	46
Technician Dispatched	1
Successful Dispense	99.997%

Equivalent of approximately 4,800 Blister Cards

Omnicell Automated Drug Delivery Systems (ADDS)

Safety Stock® software

2/17/2017

California Board of Pharmacy

Omnicell®

Agenda Topics requested to be discussed California

1. Advise and describe to the California Bd of Pharmacy specifically how Omnicell provides consumer protection

2. What areas of pharmacy law impedes the use of ADDs

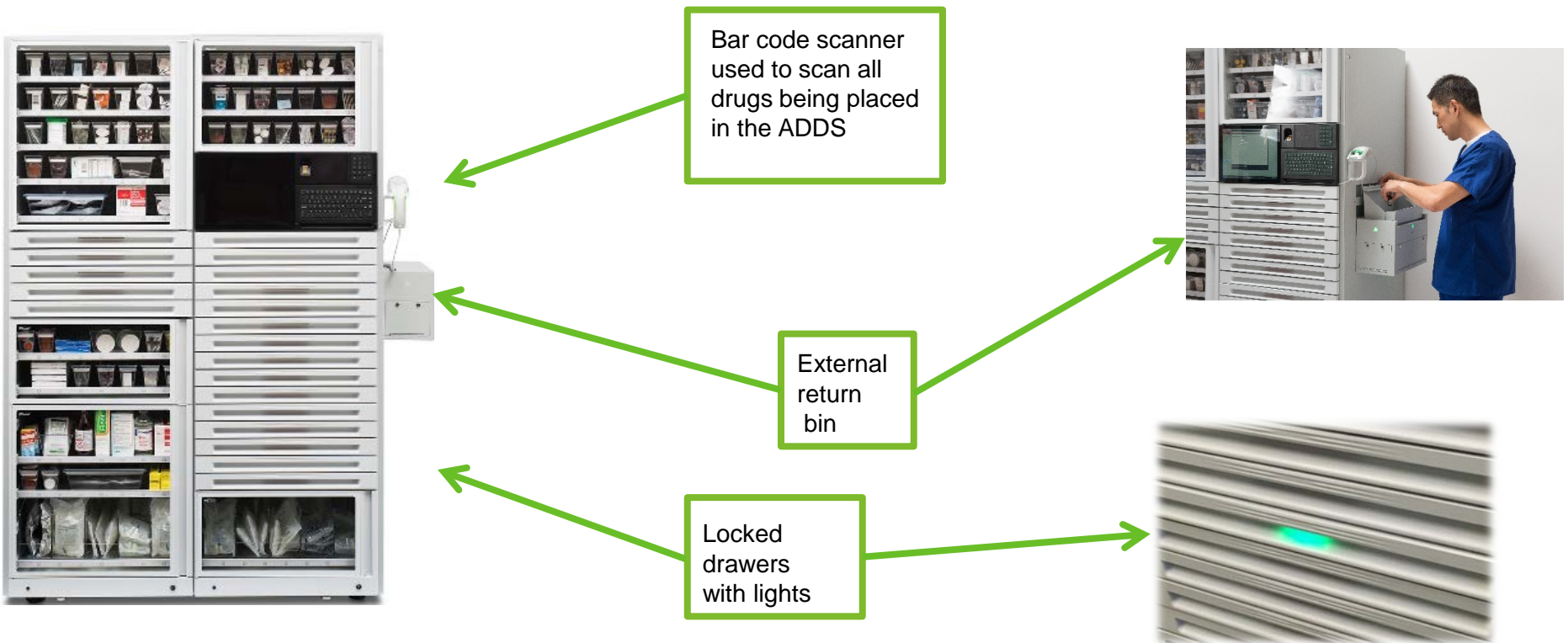3. California Board of Pharmacy primary focus –consumer protection and impediments with the current laws

Omnicell®

1. Advise and describe to the California Bd of Pharmacy specifically how Omnicell provides consumer protection

1. Omnicell Automated Drugs Delivery Systems
2. Restocking with barcoding
3. Safety Stock® software
4. Finger scan/Magnetic card reader
5. Tall man lettering (ISMP recommendation)
6. Patient allergies show up our cabinets
7. Real-time interface with the pharmacy management system
8. Alarm system notifying of unsuccessful attempt into drawer/bin
9. NDC accountability for DSCSA and Medicare Part D billing
10. JW modifiers for drug waste for Medicare Part B patients
11. External return bin
12. Extensive reporting
13. ISMP guidance for ADDs

Automated Drug Dispensing Systems-(ADDS)

- This barcode will tie the medication and the exact location in the LTCF cabinets (ADDS) and eventually to the patient. The pharmacist ensures all repackaged medication is secured, locked in proper keyed closed container for delivery to the remote cabinet.

Bar code scanner used to scan all drugs being placed in the ADDS

External return bin

Locked drawers with lights

Omnicell®

Omnicell XT Series
Automated Dispensing Cabinets

One-Cell

Two-Cell

Three-Cell

Half-Height Cell

Quarter-Height Cell

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Restocking with barcoding

- Bar code technology is the first layer for security and accuracy. This technology in ADDS directs the registrant to the correct location during restock . The software also helps direct the nurse to the correct drug while administering medication to patients.

Scan item bar code location

…and then scan bin

- The registrant barcodes the drug and confirms the restocking by scanning the bin location. Nursing will also use this when withdrawing medication for administration.

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Safety Stock® software

SafetyStock provides an additional layer of safety, using bar code scanning and **light-lid technology** to ensure that medication items are restocked correctly and that the correct medication is issued from the cabinet.

Both the Drawer and the Bin light up to help ensure the registrant to the proper drug

SafetyStock bar code confirmation includes three primary elements:

1. Labeling and scanning confirmation of the correct drug in the correct bin using **light lid technology**

2. Labeling and scanning for restock and return confirmation of the correct drug in the correct bin by using light-lid technology

3. Labeling and scanning for bin location confirmation for the correct drug by using light-lid technology

5. Drawer and bin configuration

All drawers and bins for CII-V controlled substances will be in a "HIGH" security drawer using various bin locking lid drawer.

These drawers and bins are made out of steel and cannot open unless the correct drug is barcoded and Safety Stock is used to guide the operator to the correct bin. **IF the user attempts to open another bin, an alarm goes off, and an email notifies both the DON and PIC immediately**.

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Extensive reporting

a. Overall Report Guide

• Financial

• Operational

• Pharmacy

b. Example of Pharmacy Reports

• Null transaction reports

• Pharmacy discrepancy reports

• Dispensing error reports

• Safety Stock reports

• Medication override reports

• Waste transaction reports

• Return item reports

• Dispensing practice reports

• Restock reports

**Omnicell**®

ISMP Guidance for ADDs

Core Processes established by ISMP[1]

✓ #1 Provide Ideal Environmental Conditions for the Use of ADCs

✓ #2 Ensure ADC System Security

✓ #3 Use Pharmacy-Profiled ADCs

✓ #4 Identify Information that Should Appear on the ADC Screen

✓ #5 Select and Maintain Proper ADC Inventory

✓ #6 Select Appropriate ADC Configuration

✓ #7 Define Safe ADC Restocking Processes

✓ #8 Develop Procedures to Ensure the Accurate Withdrawal of Medications from the ADC

✓ #9 Establish Criteria for ADC System Overrides

✓ #10 Standardize Processes for Transporting Medications from the ADC to the Patient's Bedside

✓ #11 Eliminate the Process for Returning Medications Directly to Their Original ADC Location

✓ #12 Provide Staff Education and Competency Validation

1· Institute for Safe Medication Practices (ISMP) Guidance on the Interdisciplinary Safe Use of Automated Dispensing Cabinets 2008

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2. What areas of pharmacy law impedes the use of ADDs

1. Lack of clarity in the following settings with regards to:

- Nurse restock for SNF?
- PACE and ALF (assisted Living Facilities
- EMS/Fire Departments
- Free Standing Emergency Departments
- Ambulatory settings

Omnicell®
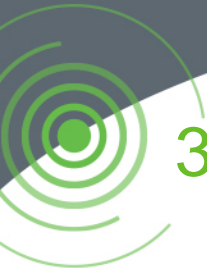
3. Primary focus –consumer protection and impediments with the current laws

- Nurse restock for SNF-need to clarify current regulation

- PACE and ALF-no clear road map for keeping medications in ADDs

- EMS/Fire Departments-no statute allowing the use of ADDs in this setting yet it would make sense to have complete accountability for handling controlled substances
- Free Standing Emergency Departments-some not tied to a hospital system
- Ambulatory settings

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THANK YOU

Questions??

XT Omnicell Video

MedAvail MedCenter ®

Feb 17 2017

Agenda

- Introductions
- MedAvail MedCenter® Demonstration (Dispense)
- Security and Safety Features
- Discussion

MedAvail™

Product Introduction

- The MedAvail MedCenter® is a patient-facing *pharmacist-*controlled and administered remote dispensing solution for Rx and OTC medication.

- The MedAvail MedCenter® provides private, confidential, real-time professional advice and counselling via a robust audio and video link.

- Safety and accuracy are ensured as the system empowers the pharmacist to inspect each item at several stages during dispense (i.e. inventory retrieval, labelling, dispense to patient)

- The pharmacist must review and approve every Rx before any medication is dispensed to a patient, and all transaction records are retained, just as occurs in any other pharmacy setting.

Pharmacy Management System

- All dispenses must be processed in the same manner as community pharmacy, through the use of the pharmacy's management system

- Added safety and security advantages of a Pharmacy Management System (PMS):
  - Maintains all patient information at the pharmacy
  - Connects with DEA approved e-Rx tools – prescribing is not to the machine rather the pharmacy
  - Connection with CURES
  - Adjudication and built-in safety checks are maintained
  - RPh is given the same tools as community pharmacy to detect attempts at diversion

- No patient information is persisted in the MedCenter – it is stored in the PMS. The same as any other community pharmacy

MedAvail

MedCenter: Exterior At a Glance

2-Way Video

2-way video (w/audio) is presented on the upper screen and with the integrated camera

Roles Based Access

Security Scanner and ID code only grants access to components that the user is authorized to access.

Secure Inventory Loading

Stocking is performed using the secure load door. Access can only be granted to approved individuals.

Benefit Cards & ID

Versatile card scanner for ID verification and benefits card

Prescription Scanning

Duplex scanner with multi-size and multi-page document handling (system also handles e-scripts)

Audio

Hi-fidelity hands free stereo audio system tuned and optimized for privacy. **Handset option for additional privacy.**

Touch Screen

Touchscreen user interface can be software branded and customized

Dispense Bay

Secure dispense bay delivers medication and required printouts at completion of transaction

Payment

Payment support with card reader and PIN pad for credit, debit and loyalty cards

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MedAvail

Medication Security and Access Control

• The MedCenter is equipped with alerts and monitoring that are supervised 24/7 by a remote call center.

• Stocking, maintenance, and service functions can only be performed by authorized personnel.

• Access control consists of an electronic swipe card and individually assigned access codes.

• Medication is kept in a 10 gauge high strength steel vault with sensors and alarms on all points of access.

• The unit weighs in excess of 1400 lbs and is bolted to the ground in all deployments

![MedAvail logo - BRINGING PHARMACY TO THE CUSTOMER.]

Security Features and Access

Secure Vault

Medication is protected in a secure vault made of high strength steel. A steel wall protects areas behind the patient interface

Security Access

Access is granted via a security card scanner and unique pin. Access is restricted to areas that personnel are authorized for. I.e. RPh/Tech can access loading door, maintenance tech can access printer paper.

Loading Door

The loading bay door can only be accessed by authorized personnel. No vault access to medication is granted with the loading door open.

Medication Stocking

Stocking of the MedCenter is done by opening the loading door and placing medication items into trays of the appropriate size. When the door is closed the MedCenter will individually place items into inventory.

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MedAvail

MedCenter Dispensing Process Summary

MedCenter Dispensing Process – How Does it Work?

1 **Patient provides proof of ID**

2 **Patient submits or requests their prescription**
- Paper prescription inserted into scanner, OR
- Technician pulls up e-Rx/refill

3 **Pharmacists and Technicians communicate with Patient**
- Live 2 way Audio and Video connection
- Pharmacists provide medication counseling and verify prescriptions before dispensing.

4 **Accuracy and Accountability**
- Pharmacy Management System utilized for prescription processing/adjudication
- Bar code identification of product by unit
- *Fully tracked and auditable (all order entry, drug selection and verifications are recorded and these records maintained)*
- *Pharmacist (RPh) performs final visual verification of Rx package/ label before dispense.*

MedAvail

Prescription Interpretation and Data Entry

- The MedCenter accepts both eRx and paper prescriptions. ERx prescriptions are transmitted to the pharmacy that operates the dispenser, and are received through a pharmacy management system (PMS)

- The MedAvail MedCenter® requires a pharmacy management system to operate (the same that is required for any retail pharmacy)

- When a paper prescription is inserted, the Pharmacist (RPh)/Technician sees a high resolution scan and can zoom for enhanced viewing.

- A RPh is ultimately responsible for all prescriptions dispensed.

- The same standard for RPh accountability and technician entry of information exists in Hospital, Retail and Mail Order practice today

10
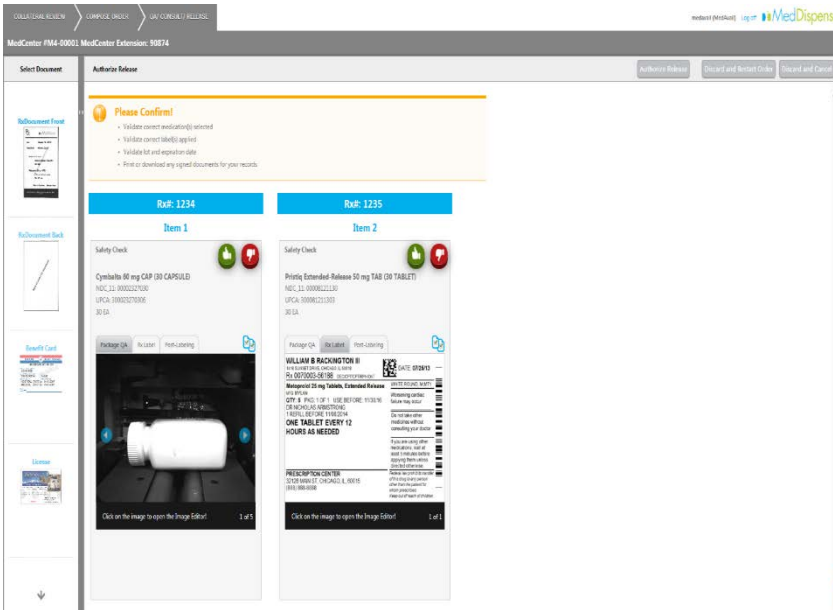
Drug Selection and Labeling

- Prescriptions are processed and a Rx number is generated.

- Medication is selected via robotics using barcode technology and then labeled.

- No items are dispensed until the RPh does a final visual product check and provides approval.

- The same standard of prescription processing and medication selection exists in Retail and Hospital practice today.

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Patient Counseling

- The RPh counsels the patient via a 2 way audio/visual communication.

- The RPh can counsel on all new or refill Rx items or require a consult with the patient.

- All required patient education and documentation is printed and dispensed along with the medication.

- Patient privacy is protected with privacy panels and an optional handset.

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Final Verification
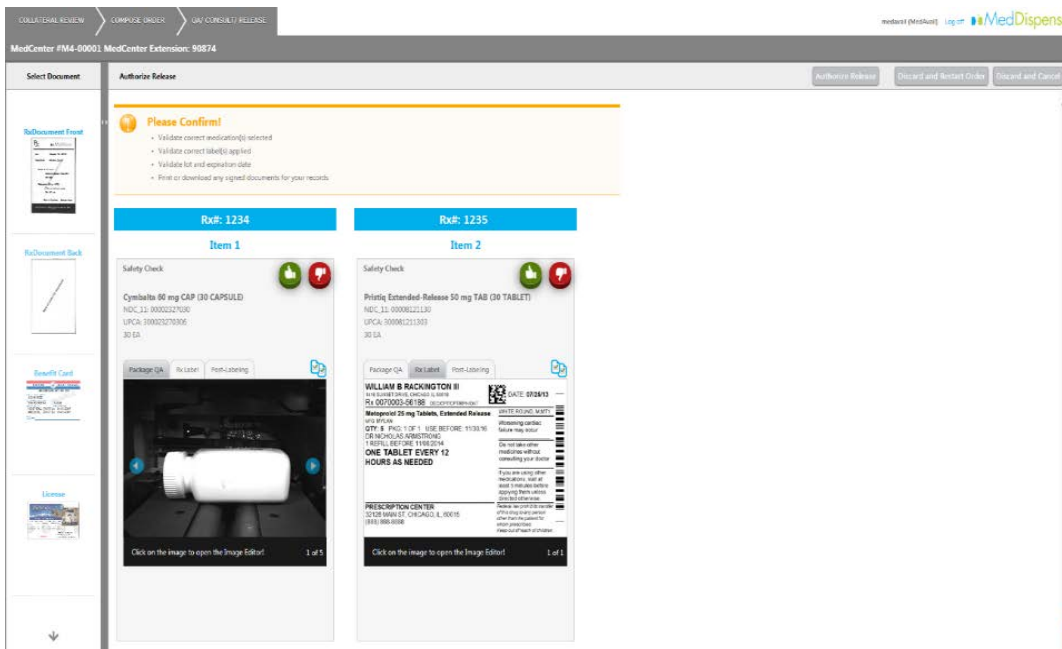
- MedCenter allows the RPh/Technician to process a patient's Rx while viewing the patient's Rx history.

- The RPh can use built in interaction checks in the PMS and through adjudication.

- The RPh verifies the medication and releases it to the patient.

- Expiration date and lot number are encoded in the barcode on the product and therefore can be removed from the system in case of any concerns.

System Security

1261.6 f (4) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

✓ **User access and level of access is controlled by system administrator**

Access Controls

> **Biometric sensor –finger print ID**
> **Password option**
> **Inventory access limited by access level of user**

1261.6 f (5) The automated drug delivery system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.

✓ **All access is recorded, drugs added, drugs removed**
  – **date**
  – **product name and NDC**
  – **quantity removed or added**
  – **remaining balance**
  – **user ID**

✓ **Narcotics Secure**
✓ **Only one container dispenses and is accessible to end user**
✓ **Triple check barcode scanning**

Telepharmacy Solutions

ADM-0100-17-E

Consumer Protection

✓ **Each product/drug vial label has barcode ID containing:**
  - Product NDC
  - Quantity in container
  - Unique identifying number for each container

✓ **Triple check barcode scanning**

✓ **Pharmacist verification required to release product**
  1261.6 f (2) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

✓ **System provides for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video.**

✓ **Verified product label prints from product provider's information system. The product provider's system would need to be configured in compliance with labeling requirements CA BPC Section 4076**.

Inventory Report

- Inventory Report contains:
  - Date
  - Product name
  - Quantity dispensed in container
  - Product NDC
  - RCD ID – section of cabinet
  - Coil Number
  - Remaining quantity on hand
  - PIC level
  - Cost and Price

INVENTORY REPORT   2/16/2017

RCD ID	COL HEL	BRAND NAME	GENERIC NAME	DISP QTY	NDC	ON HAND	PIC LEVEL	MAX LEVEL	DRUG COST	DRUG PRICE
1	02	ACYCLOVIR 800 MG TAB	ACYCLOVIR 800 MG TAB	10.000	68084010901	9	5	30	0	0
1	03	AMLODIPINE 5 MG TAB	AMLODIPINE 5 MG TAB	10.000	51079045120	5	5	30	0	0
1	04	AMOXICILLIN 500 MG CAP	AMOXICILLIN 500 MG CAP	30.000	54348055030	2	3	5	0	0
1	05	AMOX TR-K CLV 500MG/125MG TAB	AMOX TR-K CLV 500MG/125MG TAB	20.000	65862050220	3	3	5	0	0

ADM-0100-17-E

User Access Report

- User Access Report records every time the system is accessed recording:
  - User name
  - Date and time logged into system
  - Date time logged out of system

USER ACCESS REPORT   2/16/2017

USER NAME	IN	OUT
R	2/16/2017 12:30:45	
C	2/16/2017 12:19:00	2/16/2017 12:19:34
Fa	2/16/2017 11:49:38	2/16/2017 12:10:01
Tr	2/16/2017 11:45:22	2/16/2017 11:46:32

ADM-0100-17-E

Transaction Report

Transaction Report:
- Rx number
- Dispensed date and time
- Quantity
- Product name
- Prescriber
- Patient last name, first name
- Logged in user
- Pharmacist ID

TRANSACTION REPORT   2/17/2017

FROM: 02/17/2017 TO: 02/17/2017

RxNumber	DispenseDate/Time	Qty	Brand Name	Prescriber	Lastname	Firstname	LoggedUser	RPH_ID

ADM-0100-17-E

Impediments

- 1261.6 (g) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopoeia, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

- (1) The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

- (2) The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.

4186 (c) The stocking of an automated drug delivery system shall be performed by a pharmacist.

Request additional language:

Include stocking for vials of tablets or capsules, bulk items (creams, inhalers) with tamper-evident seal be included for refilling by a pharmacist, pharmacist intern/resident or pharmacy technician

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Impediments, cont.

- 1261.6 (h) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

- 4186 (d) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the clinic. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

Request additional allowance:

- *Physical inspection may be performed by pharmacist, pharmacist intern/resident or pharmacy technician under the direct supervision of a pharmacist.*

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Impediments, cont.

- 4186 (f) The pharmacist operating the automated drug delivery system shall be located in California.

  - Overseeing operation of ADD: refilling, checking, monitoring.

  - *Request clarification:*

    Order verification requirement:

    Pharmacist is California licensed

    No physical location requirement.

ADM-0100-17-E

Rx*Now*

PharMerica's On-Site Electronic Emergency Medication Cabinet

What is Rx*Now*?

More than just an e-kit!

- Immediate on-site medication availability
- Active item management
- Timely replacement of dispensed meds
- Integrated with pharmacy resident database

PharMerica

Benefits of Rx*Now* System

- More secure than a tackle box e-kit

- Actively managed "medication inventory" keeps the right drugs on-site

- Medication Availability
  - Medications: 350+ items on-site
  - Immediate Access: no wait time for delivery
  - Reduced F-tag risk

- Right drug – barcode verification

- Comprehensive tracking of users and usage

- Reduce STAT deliveries

- Reduce controlled substance diversion

- Easy to install and use

PharMerica

Rx*Now* Security and Storage

- Increased security vs. standard emergency kits
    - Requires User ID/Password and Biometric fingerprint scan
    - Uses secure technology to only provide access to one drawer at a time, based on order
    - Barcode scan/verification for removal of each item

- Separate compartment for controlled substances
    - True unit dose dispense module restricts access and delivers one medication at a time
    - Physical access to meds in compartment is limited to PharMerica staff eliminating the need for shift counts of controlled substances

- Access is limited based on employee role
    - Floor Nurses
    - DON/Administrator

Secured access to controlled substances

Unit dose dispense module

Biometric fingerprint scan

PharMerica
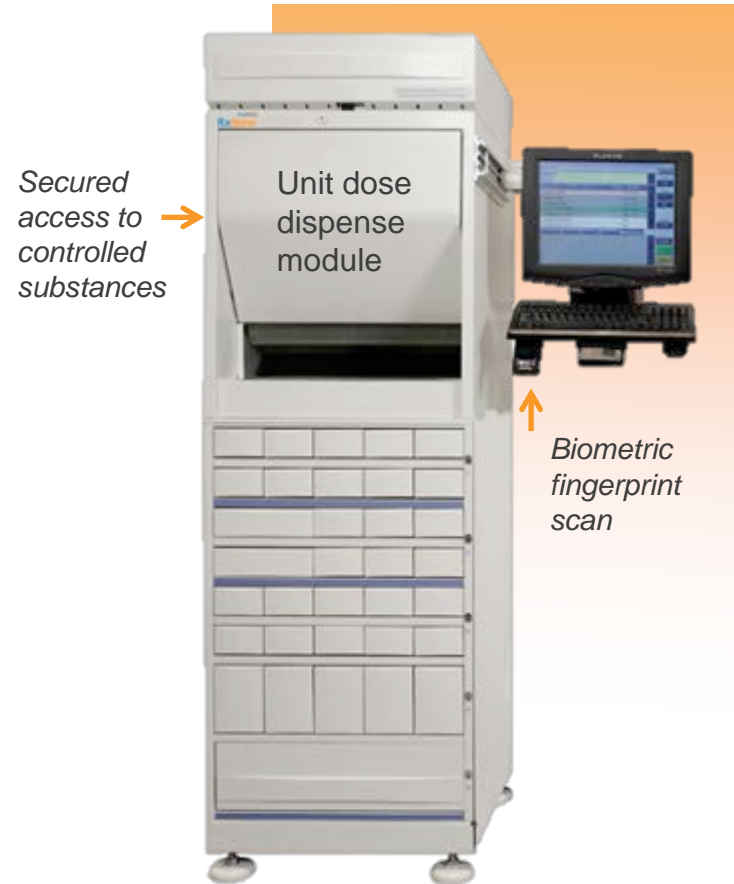
Standard Rx*Now* Configuration

Dimensions:

22.8" W X 27.6" D X 72"H

- Allow a 2' W X 5' D footprint for drawer opening
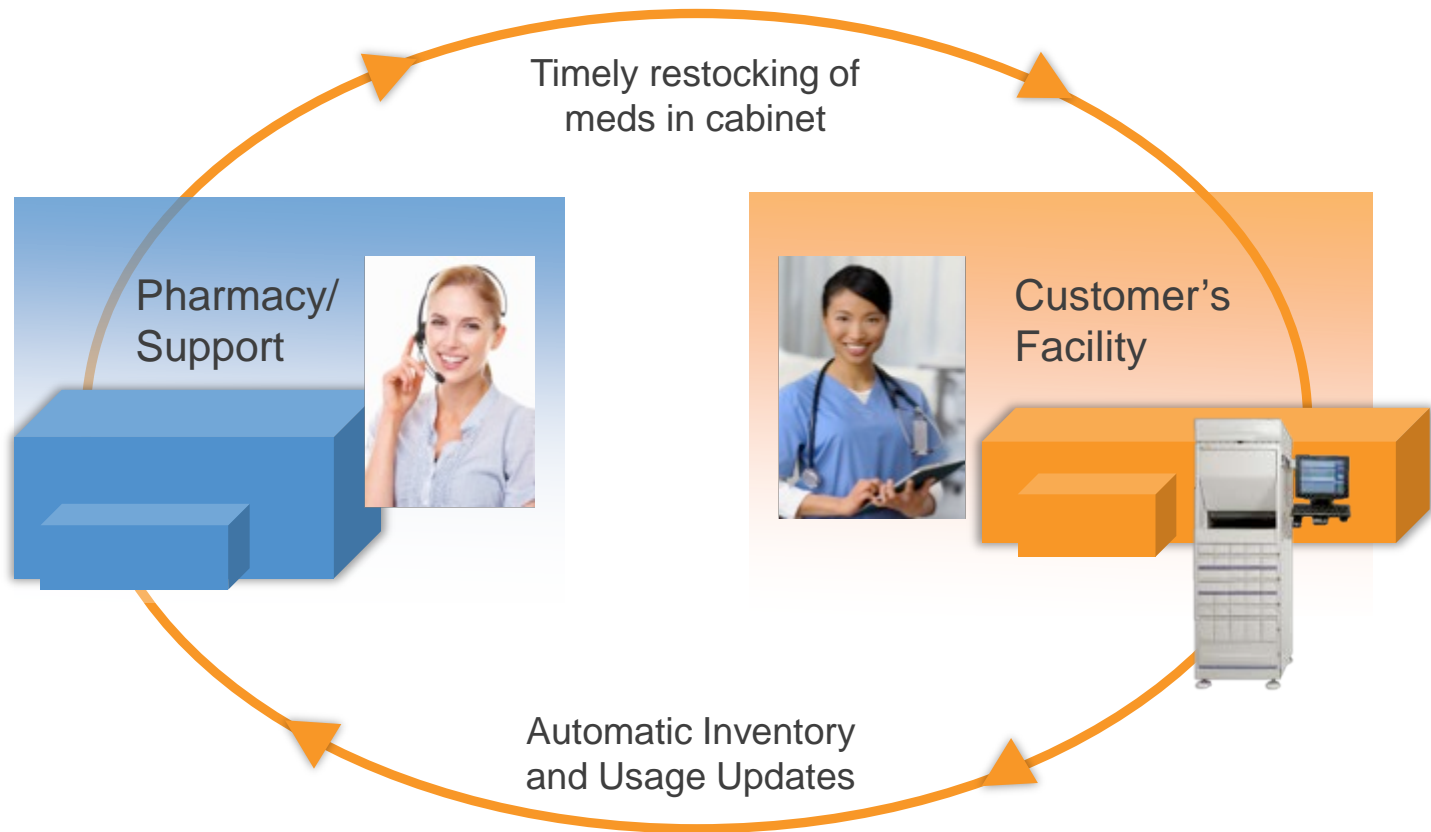- Monitor/keyboard extends 19.6" either side

Unit Dose Module

- Controlled Medications
- Up to 35 different medications
- Over 1,000 single-doses

Drawer Module

- 36 small multi-item access drawers
- 5 medium multi-item access drawers
- 1 Return/Receive drawer

Unit Dose Module

46"H

72"H

How Rx*Now* works with the pharmacy

Timely restocking of meds in cabinet

Pharmacy/Support

Customer's Facility

Automatic Inventory and Usage Updates

Impediments in Pharmacy Law

The Drawer Module

Drawer Position Numbering

- Drawers are labeled with a two digit number as shown below
- The position of a medication inside the drawer is defined by a letter
- The combination of the 2-digit drawer number and the position letter creates a 3-digit unique locator for each drug
- For example, 1-2 C is the third position in the drawer 1-2.
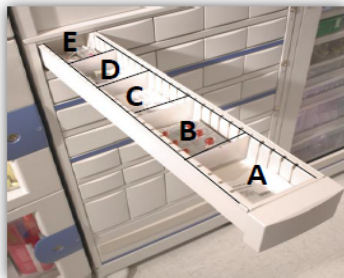
1-1	1-2	1-3	1-4	1-5
1-6	1-7	1-8	1-9	1-10
Return		2-2	2-3	2-4
Retrieve		2-6	2-7	2-8
3-1	3-2	3-3	3-4	3-5
3-6	3-7	3-8	3-9	3-10
4-1	4-2	4-3	4-4	4-5
4-6	4-7	4-8	4-9	4-10
5-1	5-2	5-3	5-4	5-5

Drawer Configuration

- The drawer module has 36 small drawers and 5 medium drawers
- The return drawer is a one-way drawer that drops returned drugs into the retrieve drawer
- Retrieve drawer receives the items dropped down from the return drawer and has limited access
- Drawers are primarily for non-controlled substances
- Drawers can be used for controlled substances that can not fit in UDM, such as patches.
- If a control is placed in a drawer it should be the only item in the drawer and a blind count required
- Open drawer configuration is used to provide maximum flexibility to change stock over time

The Unit Dose Module

Unit Dose Module (UDM)

- Used for controlled substances
- May contain high dollar meds to reduce diversion
- 5 rows
- 7 coils in each row
- 35 total coils
- Each coil can hold 30 medication
- 1,050 total capacity

- **Recommend Change**
  - Current restocking methodology creates redundancy
    - Medications are reviewed by a pharmacist at the time of preparation
    - Medications are verified by a pharmacist at the time of restock
    - Electronic count is reconciled by a pharmacist after a restock