



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

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

DATE: April 18, 2017

LOCATION: Department of Consumer Affairs
First Floor Hearing Room
1625 North Market Blvd.
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT: Amy Gutierrez, PharmD, Licensee Member, Chair
Allen Schaad, Licensee Member, Vice Chair
Greg Lippe, Public Member
Stan Weisser, Licensee Member
Valerie Muñoz, Public Member
Ricardo Sanchez, Public Member

STAFF MEMBERS PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Julia Ansel, Chief of Enforcement
Thomas Lenox, Chief of Enforcement
Laura Freedman, DCA Staff Counsel
Christine Acosta, PharmD, Supervising Inspector
Peg Panella-Spangler, PharmD, Supervising Inspector
Anne Hunt, PharmD, Supervising Inspector
Veronica Wogec, Staff Services Manager II
Laura Hendricks, Executive Assistant

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

Chairperson Gutierrez called the meeting to order at 9:00 a.m. Roll call was taken and the following members were present: Amy Gutierrez, Greg Lippe, Stan Weiser, Allen Schaad and Ricardo Sanchez.

I. Public Comment on Items not on the Agenda/ Agenda Items for Future Meetings

Marie Cottman, Pharm D, compounding pharmacist and business owner, speaking on behalf of herself. Dr. Cottman recommended a change in the agenda regarding the order of the agenda with respect to Section IV, Compounding Matters. She suggested that discussing item h., Discussion and Consideration of the Food and Drug Administration Rule "Guidance for Industry Compounding Animal Drugs from Bulk Drug Substances" and Proposed Lists first would be relevant to understanding the discussion in item e., Presentation by Road Runner Pharmacy Regarding Compounding for Veterinary Prescriber Office Use. She commented that it is important to recognize that the California laws prohibiting non-patient specific

compounding are in direct conflict with the federal guidance and that having a good understanding of the FDA guidance prior to discussing the California regulations would be prudent.

The committee agreed to change the order of the agenda.

Corbin Bennett, Kaiser Permanente, proposed a future meeting to clarify compounding regulations CCR section 1735 et seq. and section 1751 et. seq. in alignment USP < 797> and USP <800>.

Chairperson Gutierrez requested something in writing from Mr. Bennett. He agreed to submit something to the committee. The committee agreed to add this item to the next Enforcement and Compounding Committee Meeting agenda.

III. Enforcement Matters

a. University of California, San Diego's Pilot Program to Permit Patients to Access Medications From an Automated Drug Delivery System Not Immediately Adjacent to the Pharmacy

Background

At the April 2015 board meeting, the board approved an 18-month pilot study under the auspices of the University of California, San Diego (UCSD) School of Pharmacy involving use of an automated drug delivery system (ADDS) for prescription medication from which staff of Sharp Hospital in San Diego and their families who opted in could pick up their outpatient medications. Consultation would be provided via telephone before medication could be dispensed to a patient for first-time fills.

Since that time the committee has received quarterly updates on the study, including usage of the system. At this meeting, the committee heard the final report of the study.

Discussion and Comment

Dr. Jan Hirsch and Kim Allen presented the final results of the study. Survey results were discussed. A copy of the PowerPoint presentation was provided in the meeting materials. Dr. Hirsch reminded the committee that the study's purpose was in relation to CCR section 1713. A waiver for the study was granted for CCR section 1713(b) (4) and (6). The study design was quasi-experimental with a non-randomized control group. The study time line was 10 months. The study focused on return-to-stock rate (RTS), time taken to pick-up medication and patient satisfaction with the ADDS. Dr. Hirsch reviewed extensive data results and answered various questions from the committee regarding the kiosk study.

Dr. Hirsch reported there were 368 users, totaling 8% of campus users. (Current campus employees total 4,820.) The main study variable was RTS. The study compared regular pharmacy counter RTS to the ADDS RTS.

Conclusions from the study:

- The majority of employees surveyed agreed
 - More likely to pick up medications if they had easier access
 - Would benefit from being able to pick up medication while at work
- ADDS usage

- Fairly evenly divided among new, refills and OTC medication
- The majority of new and refill medications were picked up from the kiosk during regular pharmacy hours
- Kiosk dispensing occurred every hour of the day
- Kiosk usage
 - Dispensing was fairly divided among new, refill and OTC medications
 - The majority new and refill medications were picked up during pharmacy hours
 - However, kiosk used every hour of the day
- The majority of kiosk users agreed
 - Their questions were answered regarding prescriptions obtained at the ADDS
 - Questions could be answered by calling the pharmacist
- Kiosk versus regular pharmacy counter
 - No significant difference in mean RTS
 - Mean time to pick up was about one day greater at kiosk
 - Percentage consultations with *no more questions* greater at kiosk
 - No appreciable difference in pharmacists' assessment of their ability to counsel

Next steps: There is a board meeting scheduled for May 3-4, 2017, where the board will discuss the study. The ADDS kiosk is continuing to operate according and Dr. Hirsch reported they plan to pursue publication of the study's results.

The committee discussed the results of the study and directed some questions to Dr. Hirsch and Ms. Allen.

Mr. Weisser commented the study involved a small sample size. Dr. Hirsch agreed it was a small sample.

Discussion included recognition that consultation at the ADDS was one minute shorter than at the pharmacy counter.

Mr. Lippe asked how Sharps made sure everyone on campus knew about of the availability of the ADDS. Ms. Allen commented that was challenging, and that Sharp Memorial Hospital is not a closed system like Kaiser. With respect to patient participation, she noted that there are various entities and barriers to getting individuals to use the pharmacy. One of the barriers is that many individuals don't know they can use the pharmacy within the Sharp system if they have another health care provider.

Mr. Weisser asked if the quality of consultation was similar to that taught in pharmacy schools. Dr. Hirsch was unsure about quality of consultation. She commented that the pharmacists in the study believed they could develop therapeutic relationships with the patients. Dr. Hirsch believes the level and quality of consultation from the pharmacy counter versus the ADDS from the patient's perspective was similar. She could not answer whether the consultation provided was that of the level provided by the students in pharmacy school. Dr. Hirsch believes the level of consultation at Sharp is good. Ms. Allen said they make time for the patient to be consulted. The pharmacists who worked through the ADDS are available 24/7 for consultation. Ms. Allen believes the level of their consultation meets and exceeds what is expected.

Ms. Muñoz commented she is concerned about the sample size in terms of the amount of information the committee has in order to make a decision on this study. She finds it difficult to support the study

completely based on the small sample size. Mr. Lippe commented the board knew the sample size going into the study.

Mr. Weisser stated he was not comfortable recommending the study to the board for approval. He was also concerned about whether the patient does or does not have a relationship with the pharmacist.

Mr. Lippe commented that this service is better than mail order.

Dr. Hirsch commented in the end the people who used the ADDS did find value in it.

Motion

Bring the study to the full board for consideration with recommendations of modifying CCR section 1713 to allow for use of ADDS similar to the one presented in this pilot program. Direct board staff to propose draft regulation language to address concerns regarding counseling and other changes to CCR section 1713.

M/S: Allen Schaad/ Greg Lippe

Support: 2 Oppose: 4 Abstain:

Motion

Bring the study to the full board for an open discussion regarding possible modifications to CCR section 1713.

M/S: Valerie Muñoz/ Stan Weisser

Support: 6 Oppose: 0 Abstain:

b. Discussion and Consideration of CURES 2.0 Prescription Drug Monitoring Program

Background

The California Department of Justice (DOJ), which operates CURES, converted to the exclusive support of CURES 2.0 at the beginning of March. The new CURES 2.0 system contains features that were not available to pharmacists in the prior system. At the January Enforcement Committee meeting, the Department of Justice provided an overview of the new system and highlighted the new features that can be accessed by pharmacists. For example, enrollment in CURES is now a much simpler online registration process.

Executive Officer Herold is one of three DCA staff who sits on the six-member change control board for CURES.

At the January 2017 board meeting, the board identified multiple items for future change with respect to the CURES program and for staff to pursue statutory changes. These changes are:

1. Include the days' supply of medication in the patient activity report (PAR).
2. Permit prescribers to view the prescriptions where they are identified as the prescriber in CURES.
3. Reduce the period for reporting dispensing data to CURES to 48 hours.

4. Add Schedule V prescriptions for reporting to the CURES system.

Discussion

Chairperson Gutierrez and Executive Officer Herold stated that they had met with DOJ regarding the modifications to CURES requested by the board. Executive Officer Herold reported several bills currently pending in the Legislature are related to CURES.

The first change regarding inclusion of the days' supply of medication in the PAR has been implemented.

Dr. Gutierrez stated that the California Medical Association is in support of permitting prescribers to view the prescriptions where they are identified as the prescriber.

Executive Officer Herold stated that reducing the period to report dispensing data to 48 hours and adding Schedule V prescriptions for reporting to the CURES system may not move forward this year. Both of these recommended statutory changes may need to wait until next year to move forward.

The committee did not take action on this item.

c. Presentation by Stericycle of a New Device for Destruction of Controlled Substances in Pharmacies

Background

Recently board staff viewed a demonstration provided by Stericycle. Stericycle was invited to present this system to the committee for use in pharmacies for the destruction of controlled substances.

Discussion

Bill Avery, vice president of sales; Cara Samada, director of regulatory affairs; Selin Hoboy, vice president of Regulatory Affairs; and Jack McGurk, retired state health employee and consultant, were present on behalf of Stericycle. Stericycle provides medical waste services to the health care industry in general. A short presentation was provided during this committee meeting. The representatives introduced a container for wasting narcotics in acute care facilities. The collection container has a carbon-based solution that creates a chemical reaction causing the carbon material to solidify the disposed/ wasted drugs into a non-retrievable mixture and rendering them unusable. Then the solution moves to destruction via pick up of the unit. This is a safe alternative from a diversion and environmental perspective. For example, fentanyl patches can be deposited into this container. The container goes on the wall at a hospital where Stericycle will install and uninstall. Stericycle manages the process from start to destruction. The contents are incinerated upon destruction. Stericycle uses a regulated medical waste incinerator in Ohio. Stericycle is ready to go to market in California with this product.

The committee did not take action on this item.

d. Discussion and Consideration of the Use of Automated Drug Delivery Systems (ADDS) – Follow up from the February 2017 Board Meeting

- 1. Options and Features Currently Available**
- 2. Refilling of ADDS in Skilled Nursing Facilities**

3. Next Steps by the Committee or Board

Background

The board convened a special board meeting in February to focus on new automation technology that has been introduced to provide medications to patients. The board's goal is to seek 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 directed the Enforcement and Compounding Committee to continue to explore this topic and bring recommendations for action to a future board meeting.

Business and Professions Code (BPC) [section 4186](#), Health and Safety Code (HSC) [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.

Because many ADDS devices today offer features not addressed in pharmacy law, the board invited vendors to present information about technological features and how the devices are affected by existing statutes to the February board meeting. This year there are at least two bills in the California Legislature to authorize the use of expanded ADDS devices to provide medications in new ways. One of these bills is sponsored by the board (SB 443, Hernandez) to allow county fire departments to establish ADDS in fire stations to replenish ambulances and emergency vehicles.

In skilled nursing facilities, ADDS are sometimes installed to permit furnishing of emergency medications or to start initial doses of medications to patients receiving care in the facilities. California law directs that drug stock maintained in the ADDS are stock of the pharmacy and that the pharmacy is responsible for restocking the device. However, board staff has been advised that some skilled nursing facilities (SNFs) are using nursing staff or perhaps other employees to refill the ADDS.

The California Department of Public Health and board inspectors note that the refilling an ADDS is similar to restocking emergency kits in SNFs, in that medication is removed from a kit and the kit is returned to the pharmacy for inventory, restocking and recordkeeping functions.

Discussion

Chairperson Gutierrez developed a grid from presentations at the February board meeting to facilitate the committee's discussion. The grid was framed around three categories: Options and Features Currently Available, Refilling of ADDS in Skilled Nursing Facilities, and Next Steps by the Committee or Board. The proposed grids are attached to these minutes as Attachment 1 and provide an overview of two types of medication dispensing technologies.

Supervising Deputy Attorney General Room provided an overview of the use of ADDS in various settings, including SNFs. Mr. Room said that one must start with the language of BPC 4119.1, which is the statute authorizing placement by a pharmacy of an ADDS in a licensed health facility. Mr. Room pointed out that this statute makes clear that the pharmacy must own and operate the ADDS, and the drugs

contained within it are part of the pharmacy inventory. The statute also requires that operation of the ADDS be under the supervision of a licensed pharmacist (supervision may be done remotely). Finally, BPC 4119.1 requires that operation of the ADDS be compliant with H&S 1261.6

Mr. Room noted that HSC 1261.6, in turn, first sets up a default presumption that ADDS machines will only be stocked by and/or under the supervision of a pharmacist. It was on the strength of this general requirement that the Board and CDPH previously opined that even on-site refilling of ADDS machines with removable cards, pockets, and the like could only be done by pharmacy staff. This conclusion was reinforced by the language of HSC 1261.6(g), requiring that stocking “shall be performed by a pharmacist.” However, further review of the exception written into HSC 1261.6(g)(1)-(3) has led both Mr. Room and DCA legal counsel Laura Freedman to reach a different conclusion. Mr. Room stated that those provisions provide for a narrow and specific allowance for ADDS machines that use “removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopoeia” to have the stocking done outside of the (licensed) facility and delivered to the facility, so long as (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, and (3) the facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the automated drug delivery system. In other words, facility staff may perform the limited function of removing the pre-stocked pockets, cards, drawers, or unit of use or single dose containers from the secure tamper-evident container into which they are placed by the pharmacy for transport, and placing them into the ADDS machine.

This is all subject to a further limitation: HSC 1261.6(c) mandates that access to ADDS machines “shall be limited to facility and contract personnel authorized by law to administer drugs.” In other words, only physicians, nurses, and other licensees authorized by law to administer drugs may access the machine, including for purposes of restocking. In addition, because the pharmacy retains ownership of the ADDS and the drugs it contains, and remains responsible for its secure operation, use of facility staff for this purpose must be approved by the pharmacy. HSC 1261.6(f)(3) specifically requires that the pharmacy control and track access to the ADDS machine, and HSC 1261.6(g)(3) requires that the facility and the pharmacy have jointly developed policies and procedures for this access.

Executive Officer Herold requested that Mr. Room write a newsletter article regarding the interpretation of BPC section 4119 And HSC section 1261.6 section (c) and (g) for *The Script*.

Public Comment

Karen Nishi, a pharmacist for Cubex Systems, commented that their system is an ADDS similar to a Pyxis or Omnicell, but what is different about their system is that they have a cube containing medication with a lid and a bar coded label. Each cube is labeled and bar coded with a chip on the bottom of the cube at the pharmacy by the pharmacist. The “Cubbie” is then put in a sealed tote and zip tied.

The committee had a general discuss regarding various types of ADDS and how it will proceed with the use of ADDS to provide patients with medications in different settings.

Art Whitney, Pacific West Pharmacies, asked for guidance from the board. He is confused about which staff can do what now. His technology is a canister that plugs into a machine at a facility. He asked if a

nurse could put the canister in the machine. Laura Freedman commented under some circumstances, it might be permissible under HSC 1261.6 section (c) and (g). Chairperson Gutierrez suggested Mr. Whitney consult an attorney. Mr. Whitney said he is not an attorney and if he presents these issues to an attorney, the attorney will not know the answer either. He said the state should certify whether you can use the machine or not. Industry still does not have clarification, and it puts all owners of ADDS all at risk. Mr. Room said he will provide guidance in the newsletter. Executive Officer Herold said she is uncertain that board can certify machines to be used in California.

Daniel Ham with Pharmerica asked if an ADDS must be registered at a skilled nursing facility for emergency use. Executive Officer Herold replied yes under BPC section 4105.5. Mr. Room added that if the ADDS machine functions for emergency use, then it must still meet the ADDS requirements under HSC section 1261.6. ADDS can be used for general pharmacy services or emergency pharmacy services but must still meet California pharmacy laws' minimum requirements.

Bill McGuire with Omnicell recommended the board review other state laws and regulations. He suggested the board review the registration process of other states, possibly Missouri and New Jersey. He also suggested that the board review mail order and registrations policies.

Paige Tally with the California Council for the Advancement of Pharmacy asked when Mr. Room would have the article ready in the newsletter with clarification on ADDS. It would also be helpful for stakeholders to be able to submit some questions for ADDS like the compounding FAQs which were drafted. Executive Officer Herold committed to developing the newsletter article first.

Recommendation

Provide the board with clarification of automation of category 1 from Chairperson Gutierrez's grid and discuss what the board wants to do with category 2. A newsletter article will be written by Mr. Room to clarify restocking on ADDS in SNFs.

e. Discussion and Consideration of a Proposed Regulation to Add Title 16 California Code of Regulations Section 1715.65 Related to Inventory Reconciliation of Controlled Substances

Background

For over one year, the board has been discussing proposed regulation requirements to ensure pharmacies more closely monitor and periodically count controlled substances as a means to reduce drug losses and to identify any losses sooner. The regulation in its current form requires the counting of all Schedule II controlled substances every 90 days.

At the January 2017 board meeting, the board asked the committee to review the regulation's text to determine if the board can improve its clarity. The board also asked the committee to consider whether the board should initiate a new rulemaking to amend CCR section 1715.6 to replace the requirement to report "any" controlled substances drug loss to the board with reporting "a significant" loss.

The reconciliation regulation would:

- Require pharmacies, including inpatient pharmacies, and clinics licensed by the board under BPC sections 4180 and 4190, to count every quarter all Schedule II drugs in the licensee's possession. This will also include medications in ADDS machines owned by a pharmacy.
- Require that the reconciliation be signed by the PIC or, in the case of a clinic, the professional director. All records must be kept for three years and be readily retrievable.
- Reaffirm the reporting of losses as required by other sections of CA and federal law.
- Require that a new PIC perform an inventory reconciliation of all Schedule II controlled substances within 30 days of becoming PIC, and encourage the outgoing PIC to perform a similar reconciliation before leaving his or her PIC position.

Discussion

The board discussed the proposed modified text and made several modifications as indicated below in double strikeout or underscored and highlighted text. These included specifically that the quarterly audit of Schedule II drugs should rely on the federal schedule (not California's) so that hydrocodone products would be closely monitored.

The committee discussed the definition of "significant loss" under CCR section 1715.6, Reporting of Drug Loss. Assistant Executive Officer Anne Sodergren said the wording of this regulation is existing law and suggested moving forward with the proposed modifications to CCR section 1715.65 and moving forward separately in analyzing the definition of "significant loss".

Public Comment

Mark Johnson with CVS Health commented that perpetual inventory doesn't seem to satisfy the language of this rule. The current rule requires reconciliation at least every 90 days. He will put comments in writing for the next Enforcement Committee meeting.

Steve Gray, PharmD, speaking on behalf of himself, commented that CCR section 1715.65(c)(4) mentions all records used to compile each Inventory Reconciliation Report shall be maintained in the pharmacy for at least three years, but it doesn't comment on how long the report shall be maintained.

Where the regulation mentions Schedule II, controlled substances, Dr. Gray suggested the board provide clarification under section CCR section 1715.65(c). He asked if the regulation is referring to California law or federal law regarding Schedule II controlled substances.

With respect to the word "reconciliation," Dr. Gray asked what we are reconciling against. With respect to CCR section 1715.65(c)(2), the word "acquisitions" is not a clear term to pharmacists. He asked if you require reconciliation against acquisitions, accounts payables documents or just against packing list documentation. Dr. Gray asked for clarification he term "acquisition."

Gregory Tertes with ACS Pharmacist Consultants commented surgery center/ clinics are not included in the law. Executive Officer Herold commented she believes these entities were intentionally left out of the regulation. Executive Assistant Officer Sodergren commented that with respect to surgery centers, this regulation does not change the role of consultant pharmacist. She said a pharmacy consultant's role does not change responsibility for ensuring that the surgery center is operating within the confines of pharmacy law.

Motion

Approve CCR section 1715.65, Inventory Reconciliation Report of Controlled Substances, as modified by the committee.

M/S Stan Weisser/ Greg Lippe

Support: 6

Oppose: 0

Abstain:

1715.65. Inventory Reconciliation Report of Controlled Substances

- (a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances.
- (b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconciliation reports taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports required by this section.
- (c) A pharmacy or clinic shall compile an ~~Inventory Reconciliation Report~~ inventory reconciliation report of all federal Schedule II controlled substances at least every three months. This compilation shall require:
 - (1) A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section;
 - (2) A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last ~~Inventory Reconciliation Report~~ inventory reconciliation report;
 - (3) A comparison of (1) and (2) to determine if there are any variances; and
 - (4) All records used to compile each Inventory Reconciliation Report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form; ~~and~~ (5) Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.
- (d) ~~A pharmacy or clinic shall report in writing identified losses and known possible causes, shall be identified in writing and reported to the board and, when appropriate, to the Drug Enforcement Administration within 30 days unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days. If the pharmacy or clinic is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and actions security improvements necessary to prevent additional losses of controlled substances.~~
- (e) ~~Likely Possible causes of overages shall be identified in writing and incorporated into the Inventory Reconciliation Report.~~
- ~~(f)~~ The Inventory Reconciliation Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or professional director, (if a clinic) and be readily retrievable in the pharmacy or clinic for three years. A countersignature is not required if the pharmacist-in-charge or professional director personally completed the inventory reconciliation report.
- ~~(g)~~ A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report within 30 days of becoming pharmacist-in-charge as identified in subdivision (c) within 30

days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge also should complete an inventory reconciliation report as required in subdivision (c).

(hg) For inpatient hospital pharmacies, a separate quarterly Inventory Reconciliation Report inventory reconciliation report shall be required for federal Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location.

(ih) The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that:

(1) All controlled substances added to an automated drug delivery system are accounted for;

(2) Access to automated drug delivery systems is limited to authorized facility personnel;

(3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and

(4) Confirmed losses of controlled substances are reported to the board; and

~~5) A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses and improve security of controlled substance access to prevent losses.~~

f. Discussion and Consideration of March 11, 2017, Training Provided by the Board and DEA on CURES and Prescription Drug Abuse, and Possible Future Training Sessions

Background

On March 11, 2017, the board, the Drug Enforcement Administration and UCSD provided a day-long conference on prescription drug abuse, corresponding responsibility and preventing drug losses from a pharmacy. There were nearly 200 attendees who earned six hours of continuing education credit for attending this training, and another 132 individuals who earned one additional hour of continuing education to secure the training needed to provide naloxone under California protocol. A copy of the agenda was provided.

Discussion

Ms. Herold and the board's new chief of enforcement, Thomas Lenox, attended the conference.

Ms. Herold commented that Mr. Lenox, Supervising Inspector Tony Ngondara and DAG Desiree Kellogg presented at the conference for seven hours of continued education credit. Evaluations of the training were positive. Staff will schedule additional training sessions in other areas of California in the next fiscal year.

g. Report Submitted to the Assembly Budget Committee Regarding the Board's Prescription Drug Abuse Team

Background

During the Legislature's 2016-17 state budget negotiations, the board was asked to provide a report on the initial results of the formation of a specific team of investigators to proactively identify and initiate investigations involving prescription drugs. This report was due in April 2017. A copy of this report was provided.

The report asked for information on five items:

1. Narrative description of the preceding year's activities related to combatting prescription drug abuse.
2. Funding and expenses information including the budgeted, allocated and expended money.
3. Number of positions and responsibilities.
4. Number of cases and disposition of cases referred to the Office of the Attorney General (AG) as a result of a case opened from a coroner report.
5. Number of hours spent combating prescription drug abuse, including separately identifying the total number of hours spent reviewing coroners reports and submitting public records requests to obtain the reports.

Discussion

Assistant Executive Officer Anne Sodergren reported on the conclusions of the report. She stated that the board identified some methods that yielded data to proceed against violations and other data that was not so useful. For example, initiating investigations based on suspicious wholesaler records is a good indication of possible violations. Of the 30 cases initiated as the source, 10 were referred for formal discipline to the AG's office. She commented that the staff once thought that initially coroner's information was going to be a good source of productive investigations, but this has not been the case. Board staff will continue to do analysis and refocus some efforts away from coroner's information.

IV. Compounding Matters

a. Discussion and Consideration of Statistics Regarding Outcomes of Board of Pharmacy Compounding Inspections

Discussion

Supervising Inspector Christine Acosta provided a presentation describing the number and type of violations identified involving compounding during Board of Pharmacy inspections since the beginning of July 2016.

Dr. Acosta outlined compounding corrections versus violations. Since July 1, 2017, 50 percent of the compounding locations inspected by the board have been given corrections, and 5 percent have received violation notices.

Some of the top corrections and violations include:

- 129 (36%) issued for noncompliance with facility and equipment standards - CCR section 1751.4
 - 56 (16%) issued for not cleaning compliantly or not cleaning on the required schedule - CCR section 1751.4(d)
- 93 (26%) issued for noncompliance with records of compounding limitations and requirements - CCR section 1735.2
 - 57 (16%) issued for noncompliance with master formula requirements - CCR section 1735.2 (d) & (e)
 - 18 issued for noncompliance with BUD assignments –CCR section 1735.2 (i)
- 67 (19%) issued for noncompliance with sterile compounding quality assurance and process validation – CCR section 1751.7

- 29 issued for noncompliance with process validation – CCR section 1751.7 (b)
- 13 issued for noncompliance with a written quality assurance plan – CCR section 1751.7(a)
- 56 (16%) issued for noncompliance with records of compounded products – CCR section 1735.3
 - 39 (11%) issued for noncompliance with master formula and compounding log – CCR section 1735.3(a)

b. Discussion and Consideration of Waiver Requests for Compounding Construction Compliance Delays Pursuant to Title 16 California Code of Regulations, Sections 1735 et. seq. and 1751 et. seq.

Background

Title 16 of the California Code of Regulations (CCR) section 1735.6 (f) states that where compliance with California’s compounding regulations requires physical construction or alteration to a facility or physical environment, the board may grant a waiver for a period of time to permit the required physical changes. There is a related provision in CCR section 1751.4 dealing with sterile compounding.

Dr. Acosta provided the following information for the committee’s review:

1. Update

- Status of waiver requests received as of 3/30/17:
 - Total processed: 509
 - Pharmacies processed without a sterile compounding license (LSC): 98 (98/509=19%)
 - Inpatient hospital pharmacies processed: 213 (213/509= 41.85%)
 - Community pharmacies with LSC permits processed: 242 (242/509= 47.54%)
- Outcomes:
 - Denied: 47 (47/509= 9.24%)
 - Withdrawn: 45 (42/509=8.84%)
 - Approved: 289 (289/509= 56.77%)
 - In process: 128 (128/509= 25%)
- Overview Perspective:
 - Waivers received
 - Inpatient hospitals: 213/480 = 44.3% HSPs applied for a waiver
 - Community sterile compounders: 242/6586= 3.67% PHYs applied for a waiver
 - Nonresident pharmacies: 15/ 513= 2.92% of NRPs applied for a waiver
- Pending review:
 - Unprocessed emails with waiver attachments: 92

2. Process for Review of Requests

Background

Toward the end of 2016, the board established a waiver process. Application for any waiver must be made in writing, identify the provisions requiring physical construction or alteration, and provide a timeline for any such changes. The board is able to grant the waiver for a specified period when, in its discretion, good cause is demonstrated for the waiver.

At the October 2016 board meeting, the board delegated authority to the executive officer to process waiver requests with parameters from the board. The board further delegated authority for a committee assigned by the president to hear waiver requests.

Initially staff met with Chairperson Gutierrez, Mr. Schaad and usually representatives of the Office of Statewide Health Planning and the California Department of Public Health to normalize the reviewing and processing of the waiver requests. This process has now been refined to have the initial review performed by staff led by the executive officer, who approves or denies the waiver request. The California Department of Public Health and the Office of Statewide Health Planning also typically have staff participate. If a waiver is denied by the executive officer, there is an appeal process which will be reviewed by two board members, currently board members Schaad and Law.

Discussion

Chairperson Gutierrez has stepped down from the waiver committee, and Mr. Law was appointed to serve on the committee. Mr. Weisser voiced concern over whether the committee is being reasonable by denying waiver requests. Mr. Schaad had concerns about hardships to facilities with respect to denials and whether the right to an appeal process was communicated properly to those entities. Ms. Herold reported that the board continues to receive waiver requests. Mr. Schaad wants to ensure that any entity that was denied is aware that there is an appeal.

DCA Counsel Laura Freedman alerted the committee that the appeal process will require that a public meeting be noticed and be held in a public forum. Chairperson Gutierrez requested a written copy of the denial communication be brought to the committee for review at the next meeting.

c. Update on the Board's Progress in Implementing California Business and Professions Code sections 4129, et seq., regarding Licensure and Regulation of Outsourcing Facilities

Background

Effective January 1, 2017, the board received the authority to license in-state and nonresident outsourcing facilities. This is an entirely new function and type of. The board will receive three new staff (two inspectors, one supervising inspector) for this program beginning July 1. Currently interviews are being scheduled to hire the staff needed for this program, and an inspector has been recently promoted into the supervising inspector position.

Additionally, training is being created to train staff on inspecting outsourcing facilities. The board will be positioned to inspect and license outsourcing facilities before July 1, 2017.

Currently, the board has received 28 applications for outsourcers. (Five of these are in California.) There are currently 68 outsourcing facilities listed on the FDA's website.

Discussion

Outsourcers will be reviewed under cGMP standards. Travel will be extensive on the outsourcing team. The board has met with the FDA, CDPH's manufacturing section and has set up training modalities to be able to move forward. Inspections will begin within the next couple weeks. Staff funding and positions are not in place until the 2017/18 budget is in effect on July 1.

d. Discussion and Consideration of the United States Government Accountability Office's March 31, 2017, E-Supplement Report to Congressional Committees on *Drug Compounding: FDA Has Taken Steps to Implement Compounding Law, but Some States and Stakeholders Reported Challenges*

Background

At the last Enforcement and Compounding Committee meeting, the committee reviewed a GAO report on the FDA's implementation of compounding law titled: *Drug Compounding: FDA Has Taken Steps to Implement Compounding Law, but Some States and Stakeholders Reported Challenges* (GAO-17-64).

At the end of March 2017, the GAO released an e-supplement, which is a companion piece to the drug compounding report that was issued in November 2016.

The e-supplement is an internet-only product that provides selected results from the GAO survey of state regulatory bodies on drug compounding, including additional data that are not included in the original report.

The committee was advised of this supplemental report but had no comment.

e. Presentation by Road Runner Pharmacy Regarding Compounding for Veterinary Prescriber Office Use

Background

At a recent board meeting, Road Runner Pharmacy representatives requested the opportunity to address the board on compounding for veterinary office use. They were invited to make a presentation at the Enforcement and Compounding Committee meeting.

At the time Road Runner Pharmacy representatives approached the board requesting time to make a presentation, they read a statement seeking an exemption from the board's compounding regulations for veterinary compounding. Morgan McCloud, representing Road Runner Veterinary Compounding Pharmacy in Phoenix, Arizona, requested the board exempt veterinary compounding from some of the requirements in the compounding regulations. He stated the recent adoption of new BUD dating and testing for compounding medications was excessive and the veterinary community needed to be exempted from CCR section 1735.2. Method suitability tests and container closure integrity tests normally associated with sterile products are now mandated for nonsterile products if BUD dating extension is to occur. Additionally, stability studies can be interpreted differently. Using stability indicators, a common process used in manufacturing could add as much as \$20,000 to the BUD analysis and would significantly raise costs to pet owners, of whom most have no insurance, dramatically decreasing pet patient care. Mr. McCloud explained to the board the importance of the request for exemption and to ensure the board is aware of the impact of compounding medications within the veterinary community. He explained in the veterinary practice, it is expected for the veterinarian to have the appropriate medication for the

pets. Due to the wide range of patients seen by veterinarians and unavailability of select drugs and strengths, the treatments often come from compounded office stock.

Mr. McCloud also explained the newly required testing could add as much as \$30,000 annually per medication, leaving pets to go untreated due to the costs. Additionally, the requirement for the practitioner to explain why a compounded product over commercial product has been selected seems counterintuitive. Mr. McCloud continued that mandates requiring the office stock to indicate the number of patients the medication is to serve, the quantities expected to be administered in the clinic, and the average volume dispensed for a 120-hour supply are illogical in the typical veterinary practice.

Mr. McCloud requested veterinary medications be exempted for these additional requirements because the medical needs of animals are met differently from those of humans. Due to the on-demand service nature of veterinary medicine, the unique nature of veterinary medicines and dosages, and the unavailability of most commercial drugs to meet those needs, Road Runner Veterinary Compounding Pharmacy requested a consideration for exemption in veterinary practices or at least that the board place this item on the agenda for further discussion at the next meeting.

The board also has recently received several letters from entities indicating that the board's regulations are negatively impacting patients and their pets. Copies of these letters were provided. The board has also received a few recent complaints from patients indicating that the board's regulations should be removed for veterinary compounding.

Discussion

Rob Eaton, Road Runner Pharmacy, stated they have been inspected by the FDA as a 503A and that compounding from bulk ingredients was never brought up during their inspection. They will submit an outsourcing application to the board in the near future. He noted that veterinary medicine is different from human medicine. Patients and clients typically expect to receive treatment at a veterinary office immediately.

Dr. Dell, also from Road Runner Pharmacy, read a handout that outlined the impact of the California compounding regulations on the veterinary community. He commented that compounding is integral to animal health. The absence of clinic office stock often causes delays in proper treatment. Dr. Dell sees these regulations as cGMP like, which is not necessary. Forced degradation studies seem like the type of testing that the board wants, but the regulation is unclear. This type of test could cost up to \$20,000. Mr. Dell commented they are able to do different types of tests but it seems unclear as to what the board wants. They feel when they have asked what type of tests should be done, the board has not been forthcoming with information.

Mr. Eaton commented that the tests on nonsterile products as discussed by Dr. Acosta are over-the-top requirements. It is impossible to know how many pets you will treat and what the dose will be. Mr. Eaton commented they cannot provide this information. Many nonsterile treatments are being transferred to an oil based component versus a water based component to get the six month beyond use dating (BUD). Animals do not like oil-based products.

Some options he suggested were:

1. Eliminate requirements for BUD testing.
2. Allow water based solutions to continue without restrictions in BUDs for aqueous solution.

Mr. Room asked which testing is a problem. Dr. Dell commented that both the stability and sterility testing are issues. It is not the testing per se that is a problem; they are asking for guidance to provide clarity in the type of testing.

Mr. Eaton commented that they are compounding specialty forms of medication for special pets. He asked why we are testing this at all. He feels the board should tie elaborate tests to batch size and not require the testing on smaller batches. Maybe the board could consider batch size as a criterion.

Dr. Acosta and Dr. Panella-Spangler commented that the CCR section 1735.2 refers to the extension of a BUD. The testing is required for any extension of a BUD. BUDs for a patient specific prescription must be performed if practitioners want to extend the BUD past USP <797> requirements. One can achieve a longer BUD with an oil solution versus a water solution. Water based solutions only allows for a BUD of 14 days.

The definition of a batch in the board's regulations is more than one dose when compounding non-sterile to sterile medication. Capsules under California law allow for a BUD of 180 days for a patient, but if a longer BUD is desired then the compounder must prove that with BUD studies. A longer BUD is outsourcing or 503B practice: longer BUDs are not the practice of pharmacy. This is why the board has laws that speak to the requirements for office use. The veterinarian can give a five-day supply to the patient and then the patient can fill the prescription at a pharmacy or the patient can go to a compounding pharmacy. Dr. Acosta stated Road Runner is asking for an outsourcing license.

Public Comment

Dana Gordon of Central Avenue Pharmacy in Pacific Grove, California, commented that patients must have a choice to get their drugs from their vet or somewhere else. The rules are different for a manufacturer. The BUDs are outlined in USP <795>, but the BUDs in the California regulations are unattainable for pharmacies. Mr. Gordon has spent thousands of dollars on upgrading his pharmacy. Mr. Gordon said the stability studies that are now required will put him out of the compounding business. He wants to provide accessibility to compounded products to patients. For example, patient A pays \$75 for a 90 day supply. Mr. Gordon commented he can do a potency over time test on the product; however, if he is required to re-dispense the product every 14 days, the cost escalates. Mr. Gordon said he cannot comply with the board's requirements for testing.

Steve Edgar is a compounding pharmacist from Chico. Mr. Edgar has published data regarding his compounded products. Vets provide a 50-day supply versus 14 day supply. He said people are choosing to not provide medicine to their pets because it is too costly, and this is affecting patient care. He said the current regulations are stifling. Mr. Edgar states aqueous solutions are stable for more than 14 days. Mucosal products are given 30 day BUD assignments, but if the individual must swallow the product it has to be given 14 days, and this affects humans and vet patient care. Mr. Edgar said the BUDs are repressive to the industry.

Valerie Wiebe, director of pharmacy at UC Davis Veterinarian Hospital; and Margo Karricker, clinical pharmacist at UCD's Veterinarian Hospital, commented specifically on veterinarian compounding of

aqueous oral nonsterile products. They support stability studies versus potency studies when possible with respect to degradation. These tests are mandated by the FDA to be performed on all aqueous products past the 14-day limit. The studies are expensive and time consuming. They ask that a potency study be accepted for aqueous products when a stability study is not possible.

Dr. Acosta commented that if there is a published study and there is evidence supporting such study, CCR §1735.2 (i) (4) allows you to use the published study to support the BUD extension.

Jon Roth with the California Pharmacist Association commented that he is opposed to an exemption for Road Runner. He supports a discussion regarding section CCR §1735 with respect to BUDs, testing methods and batch definition revolving around the regulation.

Jenny Partridge, compounding pharmacist and consultant, commented that California is the only state in the nation that has requirements for nonsterile compounding stability testing and BUDs. She has seen nine inspections performed by the board recently that have corrections for section 1735.2(i). Licensees are being told they are not following the stringent BUDs.

Ranelle Larson, compounding pharmacist and consultant for PCCA, works with compounders across the United States. CCR section 1735.2 (l)(3) only allows an extended BUD when supported by the following:

1. Method Suitability Study
2. Container Closure Integrity Test and
3. Stability Studies

Dr. Larson asks that the board provide clarification on these regulations.

Grant Miller is with the California Veterinary Medical Association. His members are having a hard time getting vital medications for their animal patients. Compounding pharmacies have discontinued compounding product, specifically aqueous products. He said it is a burden to fill custom formulations. Animals are having a hard time getting a complete course of medication. Many animals are only getting five days of drugs from the veterinarian. Patient can't get more drugs from the pharmacies. The stock of medications with the 120 hour limit that go to the veterinarian is an issue in the aqueous formulation because by the time it gets to the veterinarian, it expires within two days of receiving the medication. Veterinarians are having a hard time keeping up with stock. Vets don't want to be caught with expired medications on their shelves. Oil-based products for animals are contraindicated.

Recommendation

The board will agendaize whether vet BUDs should be given different treatment and provide clarification on the issue. The BUDs for oral compounds for vet and human consumption will also be discussed.

f. Discussion and Consideration of the Proposed Food and Drug Administration Rule, "List of Bulk Drug Substances That Can Be Used to Compound Drug Products in Accordance with Section 503A of the Federal Food, Drug, and Cosmetic Act" and Proposed Lists

Background

Under section 503A of the Food, Drug and Cosmetic Act, a bulk drug substance that is not the subject of a USP or NF monograph or is not a component of an FDA-approved drug cannot be used in compounding

unless it appears on a list promulgated by the FDA. However, until the substance has been evaluated and either included or not included to the bulks list, the FDA does not intend to take action if the product fits specific criteria.

Committee Discussion

The specific guidance document establishes an interim list of bulk substances that may be used by compounding pharmacies. The proposed rule also proposes other bulk drug substances the FDA has reviewed and classified as not to be added to the bulks list. Since December 2013, over 2,000 substances have been nominated to the FDA for listing on the bulks list; many of these can be used without inclusion on the bulks because they are subject of an applicable USP or NF monograph or are a component of an FDA-approved drug.

The committee did not take action on this item but will make the information available on the board's website.

g. Discussion and Consideration of the Food and Drug Administration Rule “Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act –Guidance for Industry” and Proposed Lists

Background

A bulk drug substance cannot be used in compounding unless it is used to compound a drug that appears on the FDA drug shortage list at the time of compounding, distributing and dispensing, or it appeared on the drug shortage list within 60 days of compounding. According to this guidance document, the FDA is considering the following factors in developing a bulks list for outsourcers:

- Safety concerns about use of the bulk drug substance in compounding.
- Whether the bulk drug substances was nominated by multiple parties or identified as necessary by medical professional organizations.
- The efficiency with which the evaluation can be completed (ease of acquiring the information to conduct the review, available resources, and other logistical issues).

Committee Discussion

The FDA intends to publish in the *Federal Register* its proposed position on each substance it has evaluated and why it will or will not add each to the outsourcing bulks list. It will seek the federal Pharmacy Compounding Advisory Committee's review when it believes their input may be helpful.

Staff notes that the last pages of the guidance provide three lists: a list of substances that are under evaluation for the bulk drug substances list for outsourcers, bulk substances that raise significant safety risks, and a list of substances that were nominated “without adequate support.” This item will be added to the board's website.

Public Comment

Jenny Partridge asked if the board is enforcing this document. DCA Counsel Laura Freedman commented that the board is not required to comment on this item.

h. Discussion and Consideration of the Food and Drug Administration Rule “Guidance for Industry Compounding Animal Drugs from Bulk Drug Substances” and Proposed Lists

Background

Regulations developed by the FDA for animal drugs specify that bulk drug substances cannot be used to compound animal drugs. However, the FDA also notes that because either no drug is approved for a specific animal species or a drug is available under extra-label use provisions, an animal drug compounded from bulk drug substances may be an appropriate treatment option. Nevertheless the FDA states that the “unrestricted compounding of animal drugs from bulk drug substances has the potential to compromise food safety, place animals or humans at undue risk from unsafe or ineffective treatment, and undermine the incentives to develop and submit new animal drug applications to FDA containing data and information to demonstrate that the product is safe, effective, properly manufactured, and accurately labeled.” The guidance provides that the FDA does not intend to take action if a state-licensed pharmacy, licensed veterinarian or outsourcer compounds animal drugs from bulk drug substances if operating under specified conditions. These include:

- If in a pharmacy, is compounded under the direct supervision of a pharmacist, after receipt of a prescription from a vet or based upon prescribed prior experience.
- If the compounded product is not used for food producing animal,
- If the bulk substance is part of an approved animal or human drug, there is a change from the approved drug that produces a clinical difference for the animal.
- And numerous other factors detailed in the guidance.

Discussion

As part of its discussion, the committee discussed this guidance as part of the context of the Road Runner request. The committee heard concerns about the conflict between the board’s compounding regulations that allow for compounding for prescriber office use versus the guidance issued by the FDA that such compounding is outside operating as a 503A pharmacy.

Supervising Inspector Acosta discussed the Guidance for Industry Compounding Animal Drugs from Bulk Drug Substances. She commented while this is an older document, this is still guidance. California regulations are very closely aligned with the USP standard. California has a more thorough explanation of training and process validation in its regulations than does USP. The California standard has finally reached where USP has been for the last few years. Our minimum practice standard is what USP requires.

The board requires more testing than USP regarding the stability and the sterility. Those tests can be more extensive. California’s definition of a batch is also different from USP’s.

Beyond use date (BUD) is a compounding term for expiration date. Manufactured products have an expiration date. Compounded products have a beyond use date. For a sterile product the BUD should assess the sterility conditions under which a product is made. For a nonsterile product the BUD should assess the stability of the product.

The issue that Dr. Acosta believes the industry wishes to address is that animal drugs should not require the same testing as humans would. It is believed that industry is looking for leniency for sterility and stability testing on non-human compounded drugs.

Public Comment

Marie Cottman, Pharm D, compounding pharmacist and business owner, speaking on behalf of herself stated that she compounds veterinary medication on a daily basis, both sterile and non-sterile. She is being asked daily from other states for product for office use. If we are only looking for compliance with USP <795> and <797> she believes the board is being shortsighted. California compounders are putting themselves at risk by not following these federal guidelines. They are putting themselves at risk for a 483 report or a FDA warning letter. There are 12 requirements that the FDA says we must adhere to as compounders. Dr. Cottman referenced the FDA guidance document which mentions that the drug is dispensed with a valid prescription for an individually identified animal patient. No. 9 in the document addresses that the compounded drug cannot be transferred by an entity other than the entity that compounded the drug. A five-day supply is legal in California but not legal under federal law. No. 11 should indicate the species of the animal, name of animal and name of owner of the animal to compound. The FDA guidelines do not leave any room for a 503A to compound medication for prescriber office use. A pharmacy may compound for an unnamed animal patient by supplying drugs as an outsourcer. California rules and federal rules are not in congruence.

Dr. Cottman asked board to consider guidance for industry compounding of animal drugs from bulk substances, dated May 2015. She is being asked on a daily basis by individuals in other states if she can provide them with compounded product for office use. Dr. Cottman is requesting an even playing field in the market place but realizes that is not the function of the board.

Michael Blair commented that the FDA has no authority to regulate compounding. The FDA has never addressed compounded drugs for use in animals. In 2012 the FDA said it does not have the authority to regulate compounding and requested legislation that specifically addresses compounding. The FDA has no authority to regulate compounding. Mr. Blair stated the FDA guidelines are not a regulation; please do not refer to it as a federal regulation.

V. Enforcement Statistics

The board reviewed the latest enforcement statistics. During the first three quarters of the fiscal year, the board has initiated 2,231 investigations, closed 2,369 and had 2,241 pending. The board denied 55 applications, issued 370 letters of admonishment, issued 1,505 citations/citations and fines, and referred 252 investigations to the Office of the Attorney General. The board also secured one interim suspension order and one automatic suspension (based on a conviction). The board secured eight Penal Code section 23 restrictions and issued one cease and desist order for sterile compounding violations.

VI. Future Meeting Dates for 2017

- July 12, 2017
- October 17, 2017

Adjournment

The meeting was adjourned at 4:10 pm.

State Board of Pharmacy- Enforcement Committee
 Review- Pharmacy Automation Technology

Background: Multiple pharmacy automation vendors provided presentations at the February 17, 2017 Board meeting. These vendors provided an overview of existing technology, and dispensing/restocking workflow for their respective products. Each vendor also requested modification of existing pharmacy law to accommodate use of their technology. The Enforcement Committee was asked to review these requests and provide recommendations to the full Board of any changes needed to the law to enable technology that is believed to be safe, accurate, minimizes ability for drug diversion, and improves patient access.

In an effort to provide a framework for this discussion, a table was prepared that outlines the various technologies presented (so far) as well as policy discussion items for each.

CATEGORY 1: Medication dispensing technology that is accessed by Nursing at the remote site to obtain medications that are then administered to the patient at the remote site. Examples of remote sites include skilled nursing facilities and correctional settings.

Category I Technology	Description	Medication dispensing	Replenishment of medications	Transport of Medication	Who performs replenishment	Policy discussion items
A1	Automated Dispensing Cabinets- hosted by pharmacy not physically located at remote site	Nurse at remote site	Host Pharmacy replenishes medication in unit dose packets. Stock levels and reports are accessed from the pharmacy location to facilitate replenishment	Sealed tamper-proof sealed plastic container with a chip that identifies the canister. Container will not allow placement into technology if tampered with.	Various workflows described: Nurse at remote site Pharmacist physically places into ADC Pharmacy technician, under pharmacist supervision, physically places into ADC	<ul style="list-style-type: none"> Is the medication stored in the remote site ADC part of the pharmacy inventory? If the licensed clinic owns the ADC, what role does pharmacy play in restocking? Who should be allowed to place the sealed tamper-proof plastic container into the ADC? Is Nursing allowed to place the tamper-proof canister into the ADC after receipt from the pharmacy? If controlled drugs are supplied, does this require a DEA 222 form for each restock? Should the remote site be licensed?
A2	Automated Dispensing Cabinets- hosted by pharmacy not	Nurse at remote site	Host Pharmacy replenishes medication in unit dose packets. Stock levels and reports	Sealed medication delivery bags are utilized to transport medication	Various workflows described: Nurse at remote site Pharmacist	<p>Same as A1 above, plus:</p> <ul style="list-style-type: none"> Are there concerns for drug diversion due to less than secure transport workflow? How will pharmacy be assured that all medication arrived at location?

	physically located at remote site		are accessed from the pharmacy location to facilitate replenishment	from pharmacy to remote site. May or may not have tamper proof seal; no plastic container. Remote site replenishment involves placement of individual doses into ADC cell manually (no canister with chip)	physically places into ADC Pharmacy technician, under pharmacist supervision, physically places into ADC	
B1	Medication Canisters with patient-specific packaging that is performed at the remote site	Nurse at remote site-typically in 24-hour patient-specific plastic packets for oral solids	Host pharmacy replenishes drug-specific oral solid canisters that are placed into the device at the remote site. Stock levels and reports are accessed from the pharmacy location to facilitate replenishment	Sealed tamper-proof sealed plastic container with a chip that identifies the canister. Container will not allow placement into technology if tampered with.	Nurse physically places the drug-specific oral solid canister into the device.	<ul style="list-style-type: none"> • Is the medication stored at the remote site part of the pharmacy inventory? If the licensed clinic owns the technology, what role does pharmacy play in restocking? • Who should be allowed to place the sealed tamper-proof plastic container into the device? Is Nursing allowed to place the tamper-proof canister into the device after receipt from the pharmacy? • If controlled drugs are supplied, does this require a DEA 222 form for each restock? • Should the remote site be licensed?

CATEGORY 2: Medication dispensing technology that is accessed by healthcare providers in order to provide the patient at the remote site to access medications for at home self-administration

Category I Technology	Description	Medication dispensing	Replenishment of medications	Transport of Medication	Who performs replenishment	Policy discussion items
A1	Robot that dispenses medication through	Staff at remote site. Robot labels the patient	Host Pharmacy replenishes medication in drug specific	Various	Staff at remote site	<ul style="list-style-type: none"> • Is the medication stored in the remote site part of the pharmacy inventory? If the licensed clinic owns the technology, what role does pharmacy play in restocking? • Who should be allowed to place the containers into the

	direct real-time link with pharmacist	medication containers per information input by remote pharmacist.	containers. Stock levels and reports are accessed from the pharmacy location to facilitate replenishment			<p>technology? Is Nursing allowed to place the medication after receipt from the pharmacy?</p> <ul style="list-style-type: none"> • Some vendors cited the use of a wholesaler to replenish the inventory in the automated device. Should the board allow wholesalers to receive and restock medication on behalf of a pharmacy? • If controlled drugs are supplied, does this require a DEA 222 form for each restock? • Should the remote site be licensed? • How is patient counseling performed? Is the patient interaction conducive to patient teaching (screen size, technology, etc.) Is patient counseling always provided (some state only upon patient request) • Does the label meet state label requirements? • How is drug diversion detected if transport does not include tamper-proof sealed canisters? How is drug diversion detected from a wholesaler or other non-pharmacy replenishment?
A2	Robot that dispenses medication through direct real-time link with pharmacist	Staff at remote site. Staff must assemble medication container, and label printed separately and affix the label to the container at remote site	Host Pharmacy replenishes medication in drug specific containers. Stock levels and reports are accessed from the pharmacy location to facilitate replenishment	Various	Staff at remote site	<p>All of the above plus:</p> <ul style="list-style-type: none"> • Are there any patient safety concerns with someone other than a pharmacist affixing a medication label?
B	Technology that dispenses pharmacy-filled medications to facilitate patient access	Performed within the pharmacy	Host pharmacy places filled patient-specific medication bags into technology to facilitate patient pick-up from a remote location.	Pharmacy	Pharmacy	<p>Current pilot ongoing with UCSD; awaiting pilot results.</p> <ul style="list-style-type: none"> • How is patient counseling performed? • How is drug diversion detected? • Should the remote site be licensed?