



**California State Board of Pharmacy**

1625 N. Market Blvd, N219, Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

www.pharmacy.ca.gov

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:** December 17, 2014

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

**COMMITTEE MEMBERS**

**PRESENT:** Amy Gutierrez, PharmD, Chair, Professional Member  
Rosalyn Hackworth, Public Member  
Greg Lippe, Public Member  
Greg Murphy, Public Member  
Allen Schaad, RPh, Professional Member

**COMMITTEE MEMBERS**

**NOT PRESENT:** None

**STAFF**

**PRESENT:** Virginia Herold, Executive Officer  
Anne Sodergren, Assistant Executive Officer  
Robert Ratcliff, PharmD, Supervising Inspector  
Janice Dang, PharmD, Supervising Inspector  
Michael Santiago, DCA Staff Counsel  
Rob Buckner, Investigations Manager

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**Call to Order**

Dr. Gutierrez, chair of the committee, called the meeting to order at 10:18 a.m.

Dr. Gutierrez welcomed those in attendance. Roll call of the board members present was taken and a quorum of the committee was established.

**I. PUBLIC COMMENT FOR ITEMS NOT ON THE AGENDA/AGENDA ITEMS FOR FUTURE MEETINGS**

No public comments were received.

**II. ENFORCEMENT MATTERS**

**a. PRESENTATION: San Mateo County Supervisor Adrienne Tissier on the San Mateo County Safe Medicine Drop-off Program**

Background

At this meeting, San Mateo County Supervisor Adrienne Tissier requested the opportunity to provide information about their county's drug take back program.

Launched in 2006, San Mateo County's Pharmaceutical Disposal Program provides a convenient, environmentally sound way for citizens to dispose of both human and veterinary pharmaceutical drugs by providing disposal sites at law enforcement agencies throughout the county. Background from their website is provided in **Attachment 1**.

Discussion

Supervisor Tissier stated that San Mateo County began using surplus mailboxes for medication drop off in law enforcement offices. In its inaugural year, 2007, four law enforcement agencies were involved in the program and the county collected over 5000 pounds of unused or expired medication. In 2013, the program involved 14 agencies and the county collected over 21,000 pounds of medication with a disposal cost of \$1.61 per pound.

Heather Forshey, San Mateo Environmental Director, indicated that the drop-off program has been very successful and the county would like to expand and make it more accessible. Using Alameda County as a model, San Mateo is debating creating their own ordinance that would require pharmaceutical companies to be logistically and financially responsible for taking back their unused medications. Benefits of expanding their program would include reducing the amount of medications in the landfills and keeping unused medications off the black market and out of the hands of children. Ms. Forshey asked for the Board's support as San Mateo County continues to examine the possibility of shifting the responsibility for collecting unused and expired medications to the pharmaceutical companies.

Dr. Gutierrez verified that the cost to the County of San Mateo is less than \$40,000 annually and indicated CVS and Target both have mail back programs for medications.

Ms. Herold stated that the DEA now requires liners for collection bins. She said the board will be writing regulations and will most likely be looking at liner materials that are sufficient to protect people from a needle stick. Supervisor Tissier was not sure whether San Mateo's

collection bins have liners. Ms. Herold indicated that San Mateo is probably out of compliance with new DEA requirements if they do not have liners that are numbered and controlled from collection to disposal.

Heidi Sanborn, Executive Director of the California Product Stewardship Council, spoke about the Alameda County ordinance and the subsequent lawsuits that were based on three Pharmaceutical Associations' contention that the ordinance violated the Interstate Commerce clause. In Federal Court, and again in the Appeals Court, the judges ruled in favor of Alameda County.

**b. DISCUSSION: The Drug Enforcement Administration's Regulations for the Take Back of Prescription Medication**

Background

On Tuesday, September 9, 2014, the DEA released its regulations on the take back of drugs from the public – specifically the take back of controlled substances.

The final rule authorizes certain DEA registrants (manufacturers, distributors, reverse distributors, narcotic treatment programs, retail pharmacies, and hospitals/clinics with an on-site pharmacy) to modify their registration with the DEA to become authorized collectors. All collectors may operate a collection receptacle at their registered location, and collectors with an on-site means of destruction may operate a mail-back program. Retail pharmacies and hospitals/clinics with an on-site pharmacy may operate collection receptacles at long-term care facilities. A copy of the final rule is provided in **Attachment 2**.

The board will need to develop regulations for this program for California. At this meeting the committee reviewed the components of the federal requirements and initiated discussion to develop proposed regulations.

Also in **Attachment 2** is a newspaper article providing information about one of the country's largest reverse distributors and criminal arrests.

Discussion

Mr. Lippe referenced the article in the meeting materials that mentioned a Walgreens bag that renders medications unusable and safe to discard in the trash. Bill Reily, Broadway Pharmacy, stated he had seen the bags although he had not used one. He stated that it appeared to be a charcoal-based product which renders drugs useless. Heidi Sanborn indicated that the EPA had not evaluated this method of drug disposal. She also reminded everyone that these types of bags would add more plastic waste to landfills.

Ms. Herold gave an overview of the DEA's new drug take-back regulations.

During the presentation, Mr. Lippe asked if the DEA had established criteria for the thickness of the inner liners for collection bins. Ms. Herold indicated that criteria had been omitted from the new regulations.

Ms. Hackworth asked how the average citizen would know which drugs are acceptable for disposal. Ms. Herold was not sure whether there would be labeling on prescriptions or on the collection bin, but felt there would be some sort of informational signage to educate the public.

Steve Gray, speaking as an individual, suggested that the board be conscious of USP 800. He mentioned that hazardous chemotherapy drugs, for example, might be dropped off at collection sites which would cause compliance issues with USP 800. He also mentioned that there are a lot of chemotherapy infusion centers that don't qualify because they're not licensed.

Tony Wong, speaking as an individual, asked the board to consider not placing the collection burden on pharmacists.

**c. PRESENTATION: New York's E-Prescribing Requirements for Controlled Substances**

E-prescribing will be required for all New York State prescriptions effective March 27, 2015, pursuant to regulations adopted by New York State. At this meeting, the committee heard a presentation by New York's Board of Pharmacy Executive Officer Larry Mokhiber. A copy of the regulation is provided in **Attachment 3**.

Provided as background on this topic is a 2013 project report of two locations in California that were pilot testing e-prescribing. This report is provided in **Attachment 3**.

Discussion and Comment

Mr. Mokhiber stated New York's e-prescribing requirements slowly became reality due to a few factors including diversion of drugs, pharmacy robberies, prescription errors, and theft of prescription forms.

New York's e-prescribing provisions include requiring providers to check the prescription monitoring program. This has resulted in an 85 percent reduction in the number of patients who see five or more providers and five or more pharmacists in a month.

Beginning March 27, 2015, all prescriptions will need to be transmitted electronically. Research shows 97 percent of New York pharmacies are currently receiving electronic prescriptions; however, only 55 percent of New York pharmacies had activated the DEA-

approved software to receive controlled substance prescriptions and the prescriber community was lagging far behind. Most pharmacies are projected to be compliant by the March start date.

Mr. Mokhiber warned that New York has seen one technological problem with the current software. Once a pharmacy receives an electronic prescription there is no way for the pharmacy to respond to the prescriber or transfer a prescription to another pharmacy if the medication is out-of-stock, discontinued, or a critical shortage drug.

Steve Gray, speaking as an individual, said that the DEA allows electronic prescribing of controlled substances but requires the prescriber to actually send the transmission. He sees difficulty in not allowing a prescriber to delegate.

d. **DISCUSSION: Evaluation of 16 CCR section 1744 Regarding Required Warning Labels on Prescription Container Labels**

Background

Prior to July 1, 2014, Pharmacy Law required a pharmacist to inform a patient orally or in writing of the harmful effects of a drug: (1.) if the drug posed a substantial risk to the person consuming the drug, when taken in combination with alcohol, or if the drug could impair a person's ability to drive a motor vehicle, and (2.) the drug was determined by the Board of Pharmacy to be a drug or drug type for which the warning shall be given.

Assembly Bill 1136 (Levine), signed by the Governor on September 9, 2013, amended existing law to require a pharmacist on or after July 1, 2014, to include a written label on a prescription drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel, if in the pharmacist's professional judgment, the drug may impair a person's ability to operate a vehicle or vessel. The required label may be printed on an auxiliary label that is affixed to the prescription container. The revised version of Business and Professions Code section 4074, which AB 1136 amended, is provided in **Attachment 4**.

Section 1744 of the board's regulations provides the specific classes of drugs which trigger a pharmacist's verbal or written notice to patients where a patient's ability to operate a vehicle (and now a vessel) may be impaired. This section has not been revised in a number of years, so recently the schools of pharmacy were asked to provide comments to the list of medications listed in this regulation.

A number of California's schools of pharmacy provided comments. These comments are integrated into the draft below.

1744. Drug Warnings.

Pursuant to Business and Professions Code Section 4074, a pharmacist shall inform the patient or his or her representative of the harmful effects of certain drugs dispensed by prescription.

(a) The following classes of drugs may impair a person's ability to drive a motor vehicle or operate machinery when taken alone or in combination with alcohol:

- (1) Muscle relaxants.
- ~~(2) Analgesics with central nervous system depressant effects.~~
- (3) Antipsychotic drugs with central nervous system depressant effects including phenothiazines.(one commenter left the strike out in)
- (4) Antidepressants with central nervous system depressant effects.
- (5) Antihistamines, motion sickness agents, antipruritics, antinauseants, anticonvulsants and antihypertensive agents with central nervous system depressant effects.
- (6) All Schedule II, III, IV and V central nervous system depressant or narcotic controlled substances opioids or sedative-hypnotic as set forth in Health and Safety Code at Section 11055 et seq. prescribed in doses which could have an adverse effect on a person's ability to operate a motor vehicle.
- (7) Anticholinergic agents and other drugs which may impair vision.
- (8) Ramelteon (Sedation)
- (9) Minoxidil (Hypotension)
- (10) Phosphodiesterase V inhibitors (hearing and visual impairment)
- (11) Bromocriptine (dizziness and fatigue exacerbates alcohol)

(b) The following are examples of drugs which may have harmful effects when taken in combination with alcohol. These may or may not affect a person's ability to operate a motor vehicle.

- (1) Disulfiram and other drugs (e.g. ~~chlorpropamide~~, sulfonylureas, cephalosporins, trimethoprim, isoniazid, isotretinoin, griseofulvin, ketoconazole, metronidazole) which may cause a disulfiram-like reaction.
  - (2) Mono amine oxidase inhibitors.
  - (3) Nitrates.
  - (4) Cycloserine
  - (5) Verapamil (enhanced alcohol intoxication)
  - (6) Insulin (hypoglycemia) antidiabetic agents including insulin and sulfonylureas (due to risk of hypoglycemia)
  - (7) Niacin (increased risk of flushing and pruritis)
  - (8) Erythromycin (may increase absorption of alcohol)
- Or/and
- (b)(2) Monoamine oxidase inhibitors (due to the risk of hypertensive crisis if the alcohol contains significant amounts of tyramine (some beer, red wine)
  - (b)(3) Nitrates due to the risk of additive cardiovascular effects.

Or/And

- (c) Corticosteroids (BEERS list to avoid in the elderly)
- (d) Dipyridamole (BEERS list to avoid in the elderly)

At the September 16, 2014 committee meeting, the committee revised these comments into the version below that was referred to the board for action.

#### 1744. Drug Warnings.

Pursuant to Business and Professions Code Section 4074, a pharmacist shall inform the patient or his or her representative of the harmful effects of certain drugs dispensed by prescription. If a pharmacist exercising his or her professional judgment determines that a drug may impair a person's ability to operate a vehicle or vessel, the pharmacist shall include a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel.

- (a) The following classes are examples of drugs that may impair a person's ability to drive a motor vehicle, vessel or operate machinery when taken alone or in combination with alcohol:
  - (1) Muscle relaxants.
  - ~~(2) Analgesics with central nervous system depressant effects.~~
  - (3) Antipsychotic drugs with central nervous system depressant effects including phenothiazines.
  - (4) Antidepressants with central nervous system depressant effects.
  - (5) Antihistamines, motion sickness agents, antipruritics, antinauseants, anticonvulsants and antihypertensive agents with central nervous system depressant effects.
  - (6) All Schedule II, III, IV and V agents with central nervous system depressant effects. ~~or narcotic controlled substances as set forth in Health and Safety Code at Section 11055 et seq. prescribed in doses which could have an adverse effect on a person's ability to operate a motor vehicle.~~
  - (7) Anticholinergic agents and other drugs which may impair vision.
- (b) The following are examples of drugs which may have harmful effects when taken in combination with alcohol. These may or may not affect a person's ability to operate a motor vehicle:
  - (1) Disulfiram and other drugs (e.g., chlorpropamide, metronidazole) which may cause a disulfiram-like reaction.
  - (2) Mono amine oxidase inhibitors.
  - (3) Nitrates.
  - (4) Cycloserine.
  - (5) Insulin (hypoglycemia) antidiabetic agents including insulin and sulfonylureas (due to risk of hypoglycemia).

However, at the October Board Meeting, the board sent the language back to the committee for further discussion and review. An excerpt of the comments from this meeting is provided in the draft minutes of the October Board Meeting in **Attachment 4**.

### Discussion and Comments

Dr. Gutierrez asked Mr. Santiago for guidance. Mr. Santiago stated the board needs to update the list in 4074(a) by determining the drugs or drug types that will require a warning label for posing a substantial risk when taken with alcohol, or for impairing one's ability to safely operate a vehicle or vessel.

Dr. Gutierrez asked whether the specific drugs could be removed to include only classes. Mr. Santiago said that would be acceptable.

Mr. Lippe asked whether the board would be open to any liability issues if the board fails to list a drug which may poses a risk or impairs one's ability to operate a vehicle or vessel. Mr. Santiago answered that there should be no liability concerns.

### **Committee Recommendation:**

**Motion:** Recommend that staff revise the language and bring it back to the full board for review/approval.

**M/S: Lippe/Hackworth**

**Support: 5          Oppose: 0          Abstain: 0**

There was no public comment.

### **e. DISCUSSION AND POSSIBLE ACTION: Proposed Regulation for Pharmacies Aimed at Reducing Losses of Controlled Substances**

At the March 2014 Enforcement and Compounding Committee meeting, Chairperson Gutierrez led a discussion of losses of controlled substances reported to the board as required by California Pharmacy law. A pharmacy or a wholesaler must report any loss of controlled substances to the board within 14 days.

The board's staff compiled some statistics regarding drug losses reported to the board over the last few years. The following tables display the losses of controlled substances reported to the board.

**California State Board of Pharmacy Data Captured from Controlled Substance  
Drug Loss Reports**

Year	2009	2010	2011	2012	2013	2014 (6 mo.)
Number of Reports	614	749	536	639	1224	678
<b>Loss Type</b>	<b>Total Count Reported</b>					
Armed Robbery		70,786	35,773	106,787	80,464	
Customer Theft		9,550	4,598	5,684	13,175	
Employee Pilferage		252,225	452,877	372,926	125,305	
Lost in Transit		13,239	412,168	*1,657,875	22,310	
Night Break In		505,016	80,971	689,925	154,156	
Other		121,635	532,441	518,432	94,267	
<b>Totals</b>		<b>972,450</b>	<b>1,518,828</b>	<b>3,351,628</b>	<b>489,677</b>	

\* In transit losses

**DEA 106 Reports by License Category**

<b>Category</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>
Pharmacy	376	460	943	551
Hospital	115	104	230	97
Wholesaler	33	35	58	35
Out of State				
Distributor	1	6	8	4
Correctional Facility	10	5	2	5
Clinic	1	2	0	0
Non Resident				
Pharmacy	0	1	0	0
Drug Room	0	0	1	0
Other	0	0	2	1
<b>Total</b>	<b>536</b>	<b>613</b>	<b>1244</b>	<b>693</b>

2013 Losses

	No. of Reports	Dosage Units Lost
Chain Store:	652	564,061
Community:	291	533,045
Hospital:	230	28,073

2014 Losses (6 months only)

Chain Store	443	226,866
Community	108	289,751
Hospital	97	990

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In 2013, 3.06 million dosage units of controlled substances were reported to the board as lost. This includes 1.7 million units that were from a major manufacturer who had a truck stolen.

Note: these numbers are only estimates provided by the entity when they first realize there has been a loss. As such, the reported numbers are most likely significantly less than actual losses.

The committee expressed concern about the significant losses and the need for more stringent inventory controls in pharmacies to identify losses resulting from employee pilferage. Comments from the committee included developing steps for inventory controls, which could be done either by regulation, statute or policy and perhaps reconciling the top ten drugs for the pharmacy.

At the committee's September 16, 2014 meeting, the committee voted to recommend that the board adopt the following proposed language:

**1715.65 Monthly Inventory Counts of Fastest Moving Controlled Substances**

- (a) Every June 30<sup>th</sup>, each pharmacy and clinic licensed by the board shall identify its top 10 controlled substances dispensed by the licensee as measured in dosage units in the prior 12 months (July 1 – June 30).
- (b) Effective July 1 and each month thereafter until the next June 30 (for a total of 12 months), the pharmacy or clinic shall count and reconcile the inventory of the top 10 controlled substances identified pursuant to subdivision (a). This reconciliation shall include for each of the controlled substances:
  - (1) The inventory recorded on the first of the preceding month
  - (2) The additions to inventory made in the preceding month (e.g., purchases, transfers in, will-call items that were never handed out that were counted as dispositions the prior month)

- (3) The dispositions (e.g., dispensing, saleable returns to a wholesaler, drugs provided to a reverse distributor for destruction) from inventory made in the preceding month
  - (4) The drugs in quarantine waiting for the reverse distributor,
  - (5) The final inventory count on the first of the month
  - (6) The pharmacy shall attempt to reconcile overages or shortages. Shortages must be reported to the board.
  - (7) The name of the individual conducting the inventory and date the inventory required by this subdivision was performed
- (c) Losses of controlled substances identified from the monthly audit shall be reported to the board as required by section 1716.5 and Business and Professions Code section 4104.
- (d) The pharmacist-in-charge or consultant pharmacist for the clinic shall sign each monthly inventory performed under this section indicating he or she has reviewed the inventory taken.
- (e) The pharmacist-in-charge or consultant pharmacist shall perform a quality assurance review of the monthly and annual inventories to establish secure methods to prevent losses of all dangerous drugs.

At the October 28-29, 2014 board meeting, the board voted to oppose the committee's recommendation and send the matter back to the committee for additional discussion (an excerpt of the minutes of this part of the board meeting is provided in **Attachment 5**).

Among the concerns expressed were:

- Monthly inventory would cause undue hardships for small community pharmacies
- Employees could purposely divert non-top ten drugs in order to avoid detection
- Conducting inventory on controlled substances purchased each month rather than dispensed each month would be more effective as drugs are often diverted at the time of delivery or prior to delivery

Enforcement Chairperson Gutierrez worked with the executive officer to create the following proposed language for discussion:

**1715.65 Monthly Inventory Counts of Fastest Moving Controlled Substances**

- (a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall maintain a perpetual inventory for all controlled substances acquired by the licensee.
- (b) As an alternative to the maintenance of a perpetual inventory, a pharmacy or clinic must have a policy that identifies a monthly reconciliation process for the ten highest volume controlled substances purchased by the licensee. This policy shall address reconciliation of all purchases and acquisitions, dispenses, pharmacy inventory, including inventory in quarantine for the reverse distributor for the previous 30-day period.

- (c) Losses of controlled substances identified from the monthly audit shall be reported to the board as required by section 1716.5 and Business and Professions Code section 4104.
- (d) The pharmacist-in-charge or consultant pharmacist for the clinic shall sign and date each monthly reconciliation within 14-days of completion.
- (e) The pharmacist-in-charge or consultant pharmacist shall perform a quality assurance review of all inventories and reconciliations to establish and maintain secure methods to prevent losses of all dangerous drugs.

### Discussion and Comment

Steve Gray, speaking as an individual, commented that California law, unlike DEA law, requires the reporting of all losses of controlled substances regardless of significance. He suggested that the board consider revising the proposed language to only require that significant losses be reported. He said the DEA defines significant losses and he recommended the board mirror the DEA definition.

Ms. Herold responded that the board is able to distinguish between significant losses and will not usually investigate small losses. The concern is that different pharmacies may not consider the same loss amount as significant. The board wants to know about every loss.

Lynn Paulsen, speaking as an individual, indicated that hospitals report based on the DEA regulation which defines a significant loss, in part, as a percentage of overall purchases. Ms. Paulsen recommended requiring hospitals to provide an annual report of losses which would provide the data the board wants without placing a burden on hospitals to continuously report.

Supervising Inspector (SI) Ratcliff verified that current law requires the reporting of any loss within 30 days.

Dr. Gutierrez stated that the proposed regulation language doesn't change reporting requirements. The proposed regulation would require more frequent inventory counts in an effort to identify losses before they become too large.

Robert Stein, speaking as an individual, stated that pharmacies are already required to maintain an inventory, but that the proposed language refers to a "perpetual inventory." He asked if "perpetual inventory" was defined anywhere. Additionally, he observed that if there's a perpetual inventory and asked whether a monthly inventory would be necessary. If a monthly inventory was not necessary, subsections (c) and (d) would not apply.

Dr. Gutierrez read the DEA's definition of a "significant" loss:

- The actual quantity of controlled substances lost in relation to the type of business

- The specific controlled substance lost
- Whether the loss of a controlled substance can be associated with access to the controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances
- A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known
- Whether the specific controlled substances are likely candidates for diversion
- Local trends and other indicators of the diversion potential of the missing controlled substance

Brian Warren, of the California Pharmacists Association, commented that the proposed language does not include a timeframe regarding the 10 highest volume controlled substances and thinks the time period needs to be clear.

During committee discussion, it was decided that the board should not designate a timeframe for choosing the 10 highest volume controlled substances. Instead, the board should allow some flexibility and let each pharmacy determine the time period. The pharmacy would have to identify and defend the period when inspected.

Holly Strom, speaking as an individual, asked about the definition of “purchases” regarding the reconciliation of the top 10 controlled substances as mentioned in subsection (b) of the proposed language.

**Committee Recommendation:**

**Motion:** Work to define “perpetual inventory” and direct staff to revise the proposed language to reflect that pharmacies may choose subsection (a) or (b) and that subsections (c), (d), and (e) apply to all.

**M/S: Lippe/Murphy**

**Support: 5      Oppose: 0      Abstain: 0**

- f. **DISCUSSION: Board Comments Regarding the FDA’s Guidance on the Effect of Section 585 on the Food, Drug, and Cosmetics Act on Drug Product Tracing, and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements**

**Attachment 6**

On November 14, 2014, the board provided comments to the Food and Drug Administration regarding the aforementioned draft guidance on the effect of section 585 Federal Food, Drug, and Cosmetic Act. These comments and a copy of the guidance document itself are provided in **Attachment 6**.

There was no public or committee comment.

**g. DISCUSSION: NABP Report Highlighting the Proliferation of Rogue Online Drug Sellers and the Drug Abuse Epidemic**

**Attachment 7**

On October 31, 2014, the NABP issued a report highlighting a connection between the proliferation of rogue online drug sellers and the prescription drug abuse epidemic. This report is provided in **Attachment 7** and is for information.

There was no public or committee comment.

**h. DISCUSSION: Medication Error Reduction Continuing Education Online Course Developed by Oregon State University**

**Attachment 8**

On November 17, 2014, Oregon State University released a new online continuing education course titled Patient Safety and Medication Error Reduction for Pharmacists. A copy of this document is provided, for your information, in **Attachment 8**.

There was no public or committee comment.

**Dr. Gutierrez recessed for a 30-minute lunch break at 12:33 p.m.**

**The meeting reconvened at 1:03 p.m.**

**i. PRESENTATION: Omnicell's Presentation and Proposal For Restocking Automated Dispensing Cabinets in Post-Acute Care Settings**

**Attachment 9**

Omnicell requested an opportunity to provide a presentation of their software for restocking of automated dispensing by technicians in a post-acute care setting.

They have provided background for this presentation in **Attachment 9**.

One relevant code section regarding the use of automated devices in skilled nursing facilities is Health and Safety Code section 1261.6. A copy of this section is provided also in **Attachment 9**.

Representatives from Omnicell appeared before the committee to discuss the restocking of automated dispensing cabinets (ADCs) in the post-acute care environment and who can restock based on current regulations. Omnicell stated that California is only one of three states that require pharmacists to restock automated delivery cabinets. All other states allow technicians or nurses to restock.

Omnicell was able to demonstrate their technology and the restocking process to a few board members at ASHP during the previous week.

Omnicell had previously made a presentation before the committee in March 2014 regarding their technology for automated dispensing. At that time, they were asked to come back and present additional information regarding their policies, procedures, and workflow.

Omnicell cited a study conducted by Managed Healthcare Associates which showed that in 2013 the average pharmacy contract with long term care (LTC) facilities serviced less than 2,000 patients but dispensed over 11,500 prescriptions, averaging 11 prescriptions per patient. This was an increase from 9 prescriptions per patient two years prior.

Dr. Gutierrez asked what the CMS recommendations were for first doses at LTC facilities. Omnicell responded that the CMS study found widespread borrowing by nurses taking medications from one patient's drawer to use for another. The issue had to be addressed because it had created too many medication errors.

Omnicell clarified that their request was to allow pharmacy technicians to restock ADCs in LTC facilities from an institutional pharmacy when used as an e-kit and first dose. He claimed the benefits of using their software for electronic supervision include accountability, inventory control and safety/security.

Dr. Gutierrez asked whether the request was allowable under current law. SI Ratcliff responded that it was not allowed pursuant to current statute. Dr. Gutierrez stated that she believed the law needed to be updated.

Omnicell asked how the Board defines supervision of a technician for restocking. SI Ratcliff responded that the definition is that a pharmacist is on the premises and must have knowledge of the activities occurring in the pharmacy. The policy that had been adopted for the restocking of ADCs is that a camera must be installed for real-time observation by the pharmacist.

SI Dang stated that inspectors refer to Health and Safety Code section 1261.6 and California Code of Regulations section 1793.7 when reviewing new technology. She explained that the law doesn't require a pharmacist to physically restock a device if the pockets or drawers are removable and brought back to the pharmacy where a pharmacist or intern can restock, inspect, and sign-off on the drugs. The drawers can be returned to the ADC provided the drawers are secure until they are placed back in the device.

Additionally, SI Dang indicated that the law only provides that a technician can only use a removable pocket where the technician can't manipulate or tamper with the medication.

Omnicell asked for the definition of a "card" as cited in Health and Safety Code section 1261.6, subsection (g)(2), and noted that the Omnicell workflow includes pre-packed drugs which can be checked by a pharmacist prior to delivery. Omnicell indicated their cards are pre-packed unit dose blister packs.

SI Dang reviewed the Omnicell process card would be filled at the pharmacy, checked off a by a pharmacist, placed in a tamper-evident container, transferred to an LTC facility, then placed into the device by pharmacy technicians. Under current law, a pharmacist has to put the card into the device. Under CCR 1793.7, in order to meet the direct supervision requirement, a camera must be installed.

Omnicell indicated that the cards are pre-packed by a pharmacist, placed in a tamper-evident container, and that container is placed inside the device. Omnicell displayed a photo of their card on the large screen. The card can be used to transport and dispense either a unit dose or a single dose and has 16 individual bar codes.

SI Dang stated that if the medications were sent as a unit dose, the device would be allowed; however, if it were transported as a single unit dose, it would not be allowed. Health and safety Code section 1261.6 states a pharmacist shall restock an ADC.

SI Ratcliff stated that if the cameras are not sufficient for direct supervision by a pharmacist, then what happens to the existing devices. The board needs to discuss with counsel and might need to require a pharmacist for all devices.

The interpretation of the board is that a pharmacy technician can fill a cart but can't make the delivery to the LTC facility and re-stock even with pharmacist supervision via video.

Ms. Herold stated the current law does not provide for a waiver or for any other reasonable solutions to accommodate new technology. She encouraged Omnicell to speak with the legislature and attempt to get the law changed.

Robert Stein, speaking as an individual, stated that another vendor currently has technology that is filled within the pharmacy, closed and locked, and electronically interfaces with the ADC so there can be no error regarding drug identification once it is put back into the ADC.

j. **DISCUSSION: Use of Automated Technology in Hospitals and Skilled Nursing Facilities and the Tools for identification of Medication Diversion from These Units**

At the September 16, 2014 Enforcement Committee meeting, the committee discussed the need to schedule a future agenda item to learn about drug storage security features of automated devices already in use in California health care facilities and how many of these features can be used to deter diversion.

Several board members attended the American Society of Health-System Pharmacists meeting in Anaheim on December 8, 2014, and received demonstrations of the new technology by two vendors.

The committee discussed how to ensure that these security systems are used to identify and stop drug diversion at the earliest possible time.

Dr. Gutierrez provided background. There was no public or committee comment.

k. **DISCUSSION: Proposed Regulations for Third-Party Logistics Providers; Proposed Amendments to 16 California Code of Regulations Sections 1780 -1786**

**Attachment 10**

In 2014, the board sponsored legislation to enact provisions to license third-party logistic providers as a separate class and not as the board had previously done under the category of wholesaler. This legislation was enacted by AB 2605 (Bonilla, Chapter 507, Statutes of 2014). This legislation was needed because federal law enacted in 2013 prohibited licensure of third-party logistics providers as wholesalers.

The board now needs to amend its regulations to ensure that third-party logistics providers also must adhere to board regulations for all drug distributors, whether they are a wholesaler or third party-logistics provider.

**Attachment 10** contains a proposed mock-up of existing requirements for drug wholesalers that has been amended to include third-party logistics providers. This document is not yet completed as a self-assessment process is proposed much like the process required of drug wholesalers. Additionally the third-party logistic provider community needs to be advised of the developing regulations as well so that they may participate in the process.

Ms. Herold indicated the board has to develop and refine requirements and adopt regulations in this area. This item will be placed on the next enforcement committee agenda.

There was no public comment.

**Breaking News: At this point, the committee saw a news video regarding the arrest of 14 people associated with New England Compounding Pharmacy. Contaminated drugs — produced with expired ingredients under unsterile conditions — have been tied to the deaths of 64 people and to illnesses in about 700 patients in 20 states.**

### III. COMPOUNDING MATTERS

#### a. **PRESENTATION: Dynalabs on Their DVx Testing Device**

At this meeting, Dynalabs provided information about the benefits of their testing programs and devices.

An unknown member of the public commented that the Dynalabs device is not an approved test for extending BUD. Dynalabs agreed that the device was not to be used for stability testing.

Dr. Gutierrez stated that the presentation was for information only and that each person and organization should review the information and make their own determinations. The board is not in a position to confirm or require any technology.

#### b. **INFORMATION: Report of Sterile Compounding Pharmacy Inspections Conducted**

##### **Attachment 11**

Supervising Inspector Robert Ratcliff provided information about sterile compounding inspections and violations identified since the last meeting.

**Attachment 11** contains a list of FDA sterile compounding recalls.

Christine Versichele, with Dynalabs, stated she had been in many California Hospitals recently and had heard the same question regarding the State's recommendation for testing.

Supervising Inspector Ratcliff stated that there are two testing requirements. For quality assurance of all compounding, the requirements are found in 16 CCR 1735.8. For sterile compounding, the requirements are found in 16 CCR 1751.7(c) and mandate that testing be done for sterility and endotoxins.

**IV. MEETING DATES FOR 2015**

Dr. Gutierrez stated that the committee has established the following enforcement committee dates:

March 26, 2015

June 24, 2015

September 2, 2015

December to be determined

**Dr. Gutierrez adjourned the meeting at 2:47 p.m.**