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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: March 2, 2016

LOCATION: DCA Headquarters, Building Two
1747 North Market Blvd., Room 186
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT:
Amy Gutierrez, PharmD, Chair, Professional Member
Greg Lippe, Public Member, Vice Chair
Stan Weisser, Professional Member
Allen Schaad, Professional Member

COMMITTEE MEMBERS NOT PRESENT:
Greg Murphy, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Janice Dang, PharmD, Supervising Inspector
Christine Acosta, PharmD, Supervising Inspector
Laura Freedman, DCA Staff Counsel
Susan Cappello, Enforcement Manager
Kelli Williams, Complaint Unit Manager
Debbie Damoth, Administration Unit Manger

Call to Order

Dr. Gutierrez, chair of the committee, called the meeting to order at 10:16 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

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

No public comments were received.

II. ENFORCEMENT MATTERS

a. Update by the University of California, San Diego on Its Pilot Program to Permit Patients to Access Medication from an Automated Storage Device not Immediately Adjacent to a Pharmacy

Background

At the Board of Pharmacy's April 2015 Board Meeting, the board approved an 18-month pilot study under the auspices of the UCSD School of Pharmacy involving use of an automated storage device for prescription medication for which staff of Sharp Hospital in San Diego and their families, who opt in, may pick up their outpatient medications from this device which is located in a hospital, instead of having to go to the community pharmacy. Consultation will be provided via telephone before medication is dispensed to a patient.

This study was planned to start in June or July, 2015; however, at the September 9, 2015 Enforcement Committee meeting, Dr. Jan Hirsch, BS Pharm, PhD, spoke via telephone and anticipated the pilot study would not begin until December.

At the December 14, 2015 Enforcement Committee Meeting, Dr. Jan Hirsch, BS Pharm, PhD, reported that they would launch the device, enroll patients and refine data collection tools and processes during the first quarter of 2016. During the third quarter of 2016, they will collect and review the data and report back to the board with their results.

Also at the December Enforcement Committee meeting the committee recommended that the board ask UCSD to collect drug classification data as part of the study.

At the Board of Pharmacy's February 2016 Board Meeting, the board approved this recommendation.

Discussion and Comment

At this meeting, via telephone, Dr. Hirsch delivered a presentation on the progress of the implementation and reported that the program launched on January 20, 2016. Dr. Hirsh indicated that there are about 120 patients enrolled that want to use the ScriptCenter kiosk and confirmed that the device was located in the secured, ground floor employee entrance at Sharp Memorial Hospital.

Dr. Hirsch also indicated that the kiosk is getting some activity during the morning hours but most of the activity is during pharmacy hours with a little activity on the weekends when the pharmacy is closed.

Mr. Weisser asked for information on consultations and how often consultations are requested and provided. Mr. Weisser was advised that if it was a new prescription, consultation was delivered. No information was available at the time detailing how many prescriptions were new versus refills.

Mr. Weisser also asked how many potential users there could be and if the 120 that were enrolled so far was what was expected. Mr. Weisser further asked how Sharp felt about the current results. Dr. Hirsch indicated that she'd have to report back on the number of potential users but indicated that Sharp was pleased so far with the results.

Dr. Hirsch was advised that the board approved the recommendation to include the drug classification data in the study. Dr. Hirsch indicated that she would submit the Institutional Review Board (IRB) amendment.

Steve Gray, representing Kaiser, congratulated UCSD and Sharp Memorial for implementing this study.

Dr. Gray sought clarification on whether "delivery" meant "picked up" and was advised that it did. Dr. Gray further asked for the ratio of employees and the overall number of employees on duty or finishing duty after hours versus those finishing duty during regular pharmacy hours to better understand how and when employees are utilizing the kiosk.

Laura Freedman, legal counsel, clarified that a member of the public requested that the number of employees be reported as part of the study. Ms. Freedman further stated that the committee would need to request that information from UCSD for it to be reported as part of the study and that committee could make a recommendation to the full board.

Committee Recommendation:
Motion: Recommend that the board ask UCSD for the number employees and work hours of those who utilize the kiosk as part of the study.

M/S: Lippe/Weisser
Support: 4 Oppose: 0 Abstain: 0

There were no questions or comments.

A copy of this presentation can be found at the end of this document.

Reports on this study will be provided at each quarterly Enforcement and Compounding Committee meeting while the study is underway.

b. Update on the CURES 2.0 Prescription Monitoring Program

Background

The Department of Justice (DOJ) recently announced another milestone in its conversion to CURES 2.0. Specifically, the DOJ announced that beginning January 8, 2016, the upgraded prescription drug monitoring program is available. As part of this transition, on or after January 8, 2016, all current registrants are required to update their registration in the new 2.0 environment to ensure access to the system. This can be done electronically.

According to the DOJ, CURES 2.0 will be available to all registrants that use Microsoft Internet Explorer Version 11.0 or greater, Mozilla FireFox, Google Chrome, or Safari when accessing the system. Registrants that do not currently have access to one of those specified internet browsers will be able to continue to access the prior version of CURES until the legacy system's retirement, at that time the updated browser must be used.

The board is working with the DOJ to develop "Frequently Asked Questions" to assist registrants with understanding CURES 2.0. The board will send out updates via its subscriber alert system as it learns additional information from the DOJ. Questions regarding these changes should be directed to cures@doj.ca.gov .

On February 8, 2016, the board sent post cards to all licensed California pharmacists as a reminder that California law requires that all individuals holding an active California pharmacist license must register with CURES by July 1, 2016. Another post card will be sent by the board in May 2016.

It has been reported that 25,132 pharmacists have registered for CURES 2.0. Additionally, over 344,000 patient activity reports (PARs) were run in the last 30 days.

Discussion and Comment

At this meeting, Ms. Herold, who sits on the DOJ/DCA Change Control Board for CURES, provided an update on CURES 2.0 program. Ms. Herold stated that DOJ indicated that there are 23,168 pharmacists currently registered in the old system, CURES 1.0, and there are 3,678 pharmacist currently registered in new system, CURES 2.0.

Ms. Herold also reported that users registered in CURES 1.0 will be able to log into 2.0 but will have to go through the first time profile update. Ms. Herold also indicated that online registration is the only method by which to register as paper registration is no longer available.

Mr. Lippe stated that everyone was required to register in CURES 2.0 but not required to access it.

Ms. Herold further stated that DOJ does not have staff to answer phone inquiries and indicated that pharmacy board would do everything it could to help the licensees get registered.

It was also noted that not being registered in CURES 2.0 would not hold up licensure renewal.

Dr. Gray commented that the enrollment process is difficult when someone has a license as a pharmacist and as a prescriber and encouraged the board to seek help from DOJ to help facilitate this process.

Dr. Gutierrez requested that the board send subscriber alerts out that include the percentage of registered users so that licensees could monitor the progress.

There were no further questions or comments.

c. Discussion and Update to the Board's Procedures to Waive Requirements During a Declared Emergency Pursuant to Business and Professions Code section 4062

Background

On September 15, 2015, the board held an Emergency Board meeting in response to the wildfires in Lake and Napa counties. In light of the recent use of the policy it was brought to the board for evaluation and assessment to determine if changes to the policy are necessary.

At the October 28-29, 2015 board meeting, this item was referred to the enforcement committee for discussion.

At the December 15, 2015, Enforcement Committee meeting, the committee recommended that the board modify the policy to delegate its authority pursuant to Business and Professions Code section 4062 to the board president for a period of 30 days.

At the February 25, 2016 Board Meeting, the board approved the modified language. The new language will read as:

> In the event that the board is not able to convene a public meeting on regular notice or pursuant to the emergency meeting provisions of the Open Meetings Act, the board president may, on behalf of the board, exercise the powers delegated to full board pursuant to Business and Professions Code section 4062 for a period of 30 days.

Discussion and Comment

At this meeting, Dr. Gutierrez reported that the board modified the policy language. Ms. Freedman clarified the board's intent with the policy language and indicated that the policy should read as:

> In the event that the board is not able to convene a public meeting on regular notice or pursuant to the emergency meeting provisions of the Open Meetings Act, the board president may, on behalf of the board, exercise the powers pursuant to Business and Professions Code section 4062 for a period of 30 days.

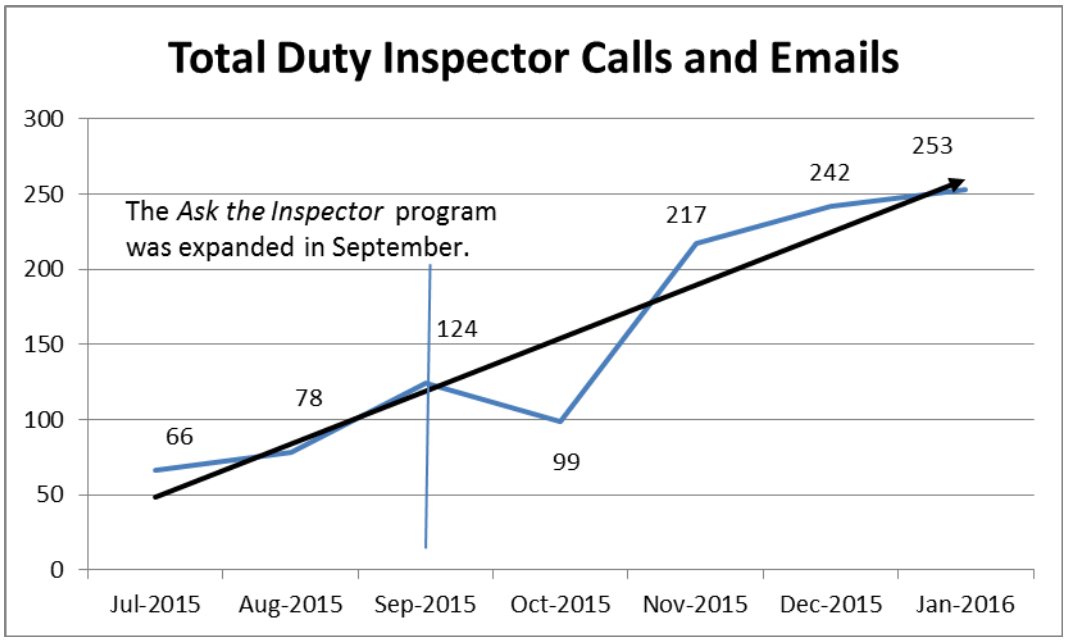
There were no questions or comments.

d. Data Describing Duty Inspector Activities

Background

From July 2015 through January 2016, the Complaint Unit resolved 166 *Ask the Inspector* inquiries. This is an average of 23 resolutions per month, with July being the lowest with 7 resolutions and January the highest with 40 resolutions. In addition, the Complaint Unit has screened 916 *Ask the Inspector* inquiries before escalating them to the weekly duty inspector for a response. This is an average of 130 inquiries per month.

Chart 1: *Ask the Inspector* Inquiries, by Month



Note: This graph includes inquiries resolved by the analyst as well as inquiries screened by the analyst and transferred to the weekly duty inspector for resolution.

The trend line shows the steady increase in calls and emails, an overall increase of 283%, from July 2015. The expansion of the *Ask the Inspector* service has caused a significant spike in activity for the Pharmacy board.

The board will continue to provide these statistics at future meetings.

Discussion and Comment

At this meeting, Dr. Gutierrez asked about the turnaround time for inspectors to respond to inquiries and was advised that responses are usually provided within the same week of receiving the inquiry.

Dr. Acosta stated that the board is receiving a lot of complex questions, legal questions and questions that could have been found in the law book by the caller.

Dr. Gutierrez asked if the board was compiling these questions into an FAQ document to be posted on the board's website and was advised that the board has compiled the top five questions received from pharmacists and the top five received from the public. Dr. Gutierrez was also told that the FAQs would be posted to the board's website in the next few months.

There were no questions or comments.

e. Automated Dispensing Machines – Available Drug Diversion Tools, Assessing Features Available, Training Provided to Pharmacy and Health Facility Staff. Presentations by:

1. **Kaiser Permanente**
2. **BD CareFusion/Pyxis & Rx Auditor**
3. **Omnicell/Aesyent**
4. **Cerner Automated Cabinets**
5. **Talyst**

Background

At the September 9, 2015, Enforcement Committee meeting, staff suggested that a simple registration be established for pharmacies that operate each of these machines that identify their locations as a beneficial step in board oversight and enforcement. The list could be updated as needed via form submission to the board by a pharmacy adding, moving or removing a machine. This registration could operate much like the off-site storage waivers for records waivers. Then at annual renewal of the pharmacy, the pharmacy would update or confirm the list of machines it operates and where each is located. Staff has drafted proposed language for requiring every pharmacy that owns or provides dangerous drugs dispensed through an automated drug delivery system to provide the board, in writing, the location of each device.

Presentations

These presentations provided information on the secured log on features as well as the various types of reports that are available with each device. It was also noted that training and consultation is provided initially and over time.

1. Kaiser Permanente

   Representatives from Kaiser Permanente provided an overview of their business operations and indicated the following as it relates to the automated delivery devices in their facilities which is only available in Kaiser facilities:

   - Currently there are 2,388 Pyxis machines enterprise wide
   - Able to create their own reports in addition to what comes standard with the Pyxis/Pandora reports
   - Kaiser uses biometrics to log on to the system in addition to being able use a password
   - Automated reports are delivered daily to the inpatient pharmacy director in the north and south
   - Able to perform trending reports

   Kaiser's National Special Investigations Unit (NSIU) investigates all suspicious behavior. The NSIU looks for signs of potential diversion such as poor job performance, appearance, behavior, complaints, and medication centered problems.

Discussion and Comment

Mr. Schaad asked if there was a way to reconcile the medication taken out of Pyxis machine and given to the patient. He was advised that Kaiser figured out a way to marry the removal to the Electronic Medication Administration Record (eMAR).

Dr. Gutierrez asked if Kaiser begins the tracking of the drug when it's placed in the machine and was advised that the tracking starts once it's placed in the machine.

Mr. Lippe asked if the nurses know that Kaiser has the capability to detect diversion activity and was advised that they did.

Comments included whether the devices had the capability to detect diversion activity as well as track the drugs from the time they are placed in the device to the time when they're dispensed to the patient and it was confirmed that it could.

It was also noted that processes are needed to ensure analytics are available for criteria-based best practices, understating behaviors and controlling the processes.

Dr. Gutierrez recessed for a break at 12:03 p.m.
The meeting reconvened at 12:18 p.m.

2. BD Carefusion
   Crystal Woodward, RPh, of BD/Carefusion provided an overview of the Pyxis MiniDrawer system, Pyxis Cubie pockets and medication management options available with the Pyxis machines. The options included the types of reports available, tracking, training, continuing education, consultation services and security features.

   Each cubie has a computer chip to track from when it leaves the pharmacy to be placed in the machine. The Pyxis machine uses biometrics (fingertip access) and scanning of a bar code from the employee's identification badge if the fingerprint doesn't work.

   Also available is a Pyxis CIISafe system that manages controlled substances for the pharmacy when receiving medications from manufacturers, and restocking of the Pyxis machines at the nurse's station.

Dr. Gutierrez recessed for lunch at 12:55 p.m.
The meeting reconvened at 1:16 p.m.

3. CUBEX
   Karen Nishi of Cubex Solutions provided an overview of the Pyxis hardware and Cubex software that included the automated technology available, security features, and reports.

4. Omnicell
   Representatives from Omnicell provided an overview of the automated dispensing cabinet's security features, including hardware, software, reporting capabilities, training and analytic options.

5. Cerner
   Steve Ward of Cerner provided an overview of the drug diversion strategies which included physical security and access control, including, software, reporting capabilities, analytics, and training.

6. Talyst
   Representatives of Talyst provided an overview of the technology, medication dispensing and administration, safeguards to ensure accuracy and security, reports and the training available.

f. Discussion on Technology Available to Detect Drug Diversion within Automated Cabinets

Discussion for this item can be found in the previous section.

g. Discussion on the Proposed Reconciliation and Inventory Report of Controlled Substances Regulation, Proposal to Add Title 16 California Code of Regulations Section 1715.65

This topic was not discussed at the committee meeting due to lack of time.

III. COMPOUNDING MATTERS

a. Update on the Status of the Sterile Compounding Regulations, Title 16 California Code of Regulations Sections 1735 et seq., and 1751 et seq.

Discussion and Comment
At this meeting, Ms. Herold stated that board staff is compiling all the responses received and putting together the rulemaking file to be submitted for DCA legal review by mid-March. The board has set January 1, 2017 as the date for implementation.

Ms. Herold indicated that one USP 797 has been released and that the committee will review those comments.

Rita Shane, Cedars Sinai, brought to the committee's attention that CSHP released comments to USP 797.

There were no further questions or comments.

b. Presentation on FDA-Approved Alternative Testing Technologies to Assess Sterility and Potency In Compounded Medications in use by Drug Manufacturers

Discussion and Comment
At this meeting, the committee heard a presentation by Dr. Tony Cundell on the Alternative Sterility Testing of Compounding Sterile Preparations.

A copy of this presentation can be found at the end of this document.

c. Discussion Regarding The Pew Charitable Trust Reports: "Best Practices For State Oversight of Drug Compounding" and "National Assessment of State Overnight of Sterile Drug Compounding"

The goal of these reports is to establish a baseline describing state policies today, and promote best practices in order to ensure that patients are safeguarded regardless of the state in which they receive treatment.

- ***Best Practices for State Oversight of Drug Compounding*** proposes best practices that are most meaningful to patient safety and the most achievable -- while recognizing that state funding may place limits on oversight systems
- ***National Assessment of State Oversight of Sterile Drug Compounding*** looks at the compounding landscape across the states to see how regulation and oversight vary in a number of categories (e.g., inspection, tracking, licensing).

A complete copy of these reports and more information regarding The Pew Charitable Trust organization can be found at: http://www.pewtrusts.org/en/projects/drug-safety-project.

This topic was not discussed at the committee meeting due to lack of time.

d. Overview of Compounding Inspections Performed and Violations Noted

This topic was not discussed at the committee meeting due to lack of time.

IV. MEETING DATES FOR 2016

The Enforcement Committee will meet on the following dates during 2016:

- June 1, 2016
- August 31, 2016