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.

ENFORCEMENT AND COMPOUNDING COMMITTEE
MEETING MATERIALS
MARCH 2, 2016

Amy Gutierrez, PharmD, Chair, Board President
Greg Lippe, Public Member, Vice Chair
Stan Weisser, Professional Member
Allan Schaad, Professional Member
Greg Murphy, Public Member

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)]

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

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 and their families of a Sharp Hospital in San Diego, who opt in, may pick up their outpatient medications from this device located in a hospital, instead of having to go to the community pharmacy. Consultation will be provided via telephone before medication can be 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, collect and review the data during the third quarter of 2016, and report back to the board with their results during the last quarter of 2016.

Also at this 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 2015 Board Meeting, the board approved this recommendation.

At this meeting, Dr. Hirsch will provide an update via telephone and respond to questions from the committee.

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

Attachment 1

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. A copy of the post card can be found in **Attachment 1**. 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.

At this meeting, Ms. Herold, who sits on the DOJ/DCA Change Control Board for CURES, will provide an update on CURES 2.0 program.

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

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.

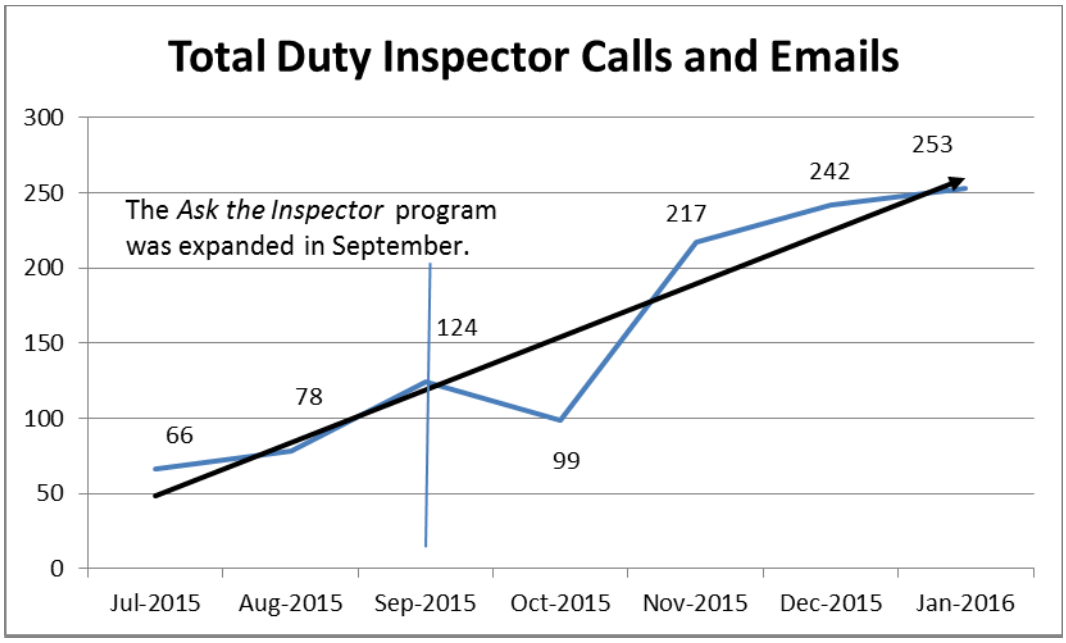
At the February 25, 2016 Board Meeting, the board approved the modified language. The new language will read as:

> 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.

d. Data Describing Duty Inspector Activities

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.

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**

These presentations will focus on the security features and reports available for pharmacists and others to review what has been removed from the machines. Additionally, these presentations will likely include how pharmacy staff is trained initially and over time, additional software or programs that track the medication that has been removed from the device and provided to the patient.

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 identifies 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.

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

The committee will discuss the information provided in the presentations.

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

Attachment 2

Ms. Herold will provide an update on the proposed regulation on reconciliation and inventory report of controlled substances. **Attachment 2** contains the proposed language.

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.

Ms. Herold will provide an update on the sterile compounding regulations.

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

Brian Warren, CPhA, and a microbiologist expert for USP will present testimony regarding alternative sterility testing methodologies.

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.

d. Overview of Compounding Inspections Performed and Violations Noted

At this meeting, Supervising Inspector Christine Acosta will provide a presentation on data compiled by the board from inspections of licensed compounding pharmacies.

IV. MEETING DATES FOR 2016

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

- June 1, 2016
- August 31, 2016

Attachment 1

BE AWARE AND TAKE CARE:
Talk to your pharmacist!
CALIFORNIA STATE BOARD OF PHARMACY

Dear California-Licensed Pharmacist,

Effective July 1, 2016, California law requires that all individuals holding active pharmacist licenses in California must establish and maintain registration to access California's prescription drug monitoring program, CURES. This notice is being sent to remind you of this obligation. There is no charge for you to register with CURES.

The California Department of Justice operates CURES. Registration and other information about CURES can be obtained from: **https://pmp.doj.ca.gov/pmpreg**

Their Help Desk telephone line is (916) 227-3843

The California State Board of Pharmacy urges you to complete this registration process soon, and in advance of the July 1, 2016 deadline.

Thank you.

Attachment 2

Title 16. Board of Pharmacy
Proposed Text

Adopt section 1715.65 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1715.65. Reconciliation and Inventory Report of Controlled Substances

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform reconciliation and inventory functions to prevent the loss of controlled substances.
(b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section.
(c) Perform a Periodic Inventory: A pharmacy or clinic shall compile an Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of federal Schedule II controlled substances and at least one additional controlled substance which may be specified by the board each year as based upon loss reports made to the board in the prior year. The Inventory Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist.
    (1) The original or copy of the signed controlled substances Inventory Report shall be kept in the pharmacy or clinic and be readily retrievable for three years.
    (2) 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:
        (A) A physical count of all controlled substances is performed, not an estimated count of how much medication is in a container.
        (B) The federal Drug Enforcement Administration biennial inventory was taken no more than three months from the last inventory required by this section.
(d) A new pharmacist-in-charge of the pharmacy shall complete an inventory as required by subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should complete an inventory as required in subdivision (c).
(e) Reconciliation with Inventory Report: The pharmacy or clinic shall review all acquisitions and dispositions of controlled substances as part of the inventory process to determine the expected stock of each controlled substance on hand, based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.
    (1) Losses shall be identified in writing and reported to the board and, when appropriate, to the Drug Enforcement Administration.
    (2) Likely causes of overages shall be identified in writing and retained.

(3) Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, the pharmacist-in-charge or consultant pharmacist shall determine there has been a loss of these controlled substances. These losses shall be reported in the manner specified by paragraph 1.

(f) Adjustments to the Inventory Report shall be made following reconciliation, only after the reporting and documenting of any losses or accounting made for overages.
   (1) Each adjustment to the Inventory Report made to correct the stock on hand count shall be annotated to show any adjustment in the number of controlled substances on hand in the pharmacy or clinic, and who made the annotation, and the date.
   (2) The pharmacist-in-charge or consultant pharmacist shall countersign the adjusted Inventory Report.
   (3) The original Inventory Report and amended Inventory Report following reconciliation shall be readily retrievable in the pharmacy or clinic for three years.

(g) The pharmacist-in-charge of a hospital pharmacy or of a pharmacy servicing skilled nursing homes where an automated drug delivery system is in use shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy. Any discrepancy or unusual access identified shall be investigated. Controlled drugs inappropriately accessed or removed from the automated delivery shall be reported to the board within 14 days.

(h) 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, including installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are continuing.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4104 and 4332, Business and Professions Code.