California State Board of Pharmacy
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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES

DATE:	November 8-9, 2017
LOCATION:	Department of Consumer Affairs 1st Floor Hearing Room 1625 North Market Blvd. Sacramento, Ca 95834
BOARD MEMBERS PRESENT:	Amy Gutierrez, PharmD, President Victor Law, RPh, Vice President Allen Schaad, RPh, Treasurer Greg Lippe, Public Member Ricardo Sanchez, Public Member Deborah Veale, RPh Albert Wong, RPh Amjad Khan, Public Member
BOARD MEMBERS NOT PRESENT:	Ryan Brooks, Public Member Valerie Muñoz, Public Member Lavanza Butler, RPh Stanley Weisser, RPh
STAFF PRESENT:	Virginia Herold, Executive Officer Anne Sodergren, Assistant Executive Officer Laura Freedman, DCA Counsel Joshua Room, Supervising Deputy Attorney General Laura Hendricks, Staff Analyst

Call to Order **10:06 a.m.**

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

Vice President Victor Law called the meeting to order at 10:06 a.m. Board members present: Gregory Lippe, Albert Wong, Deborah Veale and Allen Schaad, Ricardo Sanchez and Victor Law.

Note: Amjad Khan arrived at 10:48 a.m. and President Gutierrez arrived at 1:00 p.m.

As a quorum of the board was not present Mr. Law explained that the board would take the agenda out of order to handle items that did not require action by the board.

Below are statistics on the events.

Date	Location	Attendance: 6 Hour Program	Attendance: Naloxone Training
8/26/17	Northstate University School of Pharmacy	160	125
10/21/17	KGI School of Pharmacy	128	116

Ms. Herold reported that the evening of November 7, 2017, the board offered a three-hour presentation in conjunction with a two-day prescription drug abuse conference convened by the California Opioid Policy Summit that includes several sponsors, including the DEA and the Department of Public Health. She noted that 175 licensees attended the event and 150 of them stayed for the Naloxone training.

Ms. Herold stated that board staff will be hosting seven-hour event in San Francisco at UCSF on January 27, 2018. She added that details are being finalized as this packet is being prepared, and an alert will be released announcing the training after the board meeting.

f. Federal Re-evaluation of the Distribution of Controlled Substances

Ms. Herold explained that in recent weeks, there have been a number of announcements involving the regulation of controlled substances over the last years.

From the New York Times:
On October 16, 2017, President Trump directed the Department of Health and Human Services to declare the opioid crisis a public health emergency, an action to address a rapidly escalating epidemic of drug use. However, he did not declare "a national emergency" on opioids, which would have prompted the rapid allocation of federal funding to address the issue.

Among the President's statements:
"No part of our society — not young or old, rich or poor, urban or rural — has been spared this plague of drug addiction and this horrible, horrible situation that's taken place with opioids"

"This epidemic is a national health emergency."

Ms. Herold explained that according to media reports, the result of this declaration is that this will allow for some grant many to combat opioid abuse, permit the hiring of specialists to tackle the crisis, and expand the use of telemedicine services to treat people in rural areas where doctors are in short supply. Additional federal plans linked to the announcement include a policy to develop nonaddictive painkillers and efforts to stop shipments of fentanyl. However, the declaration does not link substantial increases in federal funding that some had hoped for, nor seek out government pressure to make naloxone available at lower prices.

Ms. Herold stated that meanwhile, some in Congress are reconsidering repeal of a 2016 law that made it substantially more difficult for the DEA to issue what amounts to suspension orders to

drug wholesalers when excessive/suspicious opioid sales to pharmacies are detected. The issues involving enactment of this law were highlighted in a recent Washington Post series and 60 Minutes segment that were based on the report of former head of DEA's Office of Diversion Control Joe Rannazzisi.

Ms. Herold explained that the new law limited the ability of the DEA to issue suspension orders to freeze drug shipments where the agency determined the shipments posed an imminent danger. Instead the standard was converted to "a substantial likelihood of an immediate threat," a much higher standard. She noted that the debate over the law and enactment occurred during a time when deaths due to opioid overdoses were escalating.

Note: The Washington Post article may be found using the following link: https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.d8ac603c2b6c

The board asked what action is taken when a pharmacy is suspected of dispensing too many controlled substances. Ms. Herold explained that an investigation would be conducted and if appropriate an accusation would be filed with the attorney general and disciplinary action would be taken.

Note: Board member Amjad Khan arrived at 10:48 a.m.

g. Board's Response to the State of Emergency Declared by Governor Brown Due to Multiple Wildfires

Ms. Herold reported that in early October, California was burning from a number of wildfires scattered throughout the state. Thousands of people were relocated to emergency shelters, in some cases in the middle of the night.

Ms. Herold explained that as the Governor issued state of emergency declarations, the board issued two subscriber alerts (October 9 and 16) to remind pharmacies and pharmacists how they could assist patients who sought emergency supplies of medications they could no longer access.

Ms. Herold reported that the board also issued three temporary licenses to pharmacies that were affected by the fires. She noted that the board was not advised of any destroyed pharmacies.

The board asked the Communication and Public Education Committee to look at additional ways by which the board can provide emergency information to licensees.

h. Personnel Update

Ms. Herold provided a brief personnel update as proved below.

Recent Hires/Transfers/Promotions

- Taydene Dalrymple was promoted to a SSM I over the Complaint Unit.
- Debi Mitchell was promoted to a SSM II over the Licensing and Administration.
- MaryJo Tobola was hired as the SSM II over the Enforcement, Complaint, and Criminal

Note: Below is inspection data for the prior four years.

Total Inspections: FY 13-14 thru FY 16-17 by Visit Type

Inspection Type	FY 13-14	FY 14-15	FY 15-16	FY 16-17	Total
Routine	287	342	235	300	1164
Investigation	875	926	1065	757	3623
Probation/PRP	139	227	208	311	885
Sterile Compounding	996	1067	1123	976	4162
Other	32	26	9	9	76
Grand Total	**2329**	**2588**	**2640**	**2353**	**9910**

Chairperson Schaad reminded that board that the education of licensees is an important part of the board's operations. He added that the board educates licensees in various ways as described below.

- **The Script:** The board's primary means of education for licensees is its newsletter, which is published once per quarter and is available on the board's website. http://www.pharmacy.ca.gov/publications/script.shtml

- **Presentations:** The board provides presentations at various events such as association meetings and schools of pharmacy. The presentations usually include updates to pharmacy law or board priorities. Often CE units are provided for attendees.

- **Subscriber alert system:** The board utilizes an electronic subscriber alert system to provide information directly to licensees about new laws or regulations as they take effect, and then provides links to the board website where licensees can learn more about a new requirement.

- **Self-assessment forms:** Completing the self-assessment forms allows licensees to identify key laws that impact their practice to ensure compliance.

- **"Ask an inspector:"** The board has reinstated the "ask an inspector" program to give licensees the opportunity to speak with a board inspector regarding questions of pharmacy law.

Chairperson Schaad stated that additionally, the board now requires every pharmacist to take at least two CE units of education provided directly by the board as a condition of license renewal.

Chairperson Schaad explained that a periodic inspection by a board inspector where compliance is the focus would further benefit the public through improved education of board licensees. It would also allow identification of violations before they come to the board's attention in other ways as well.

Chairperson Schaad reported that the Enforcement Committee discussed the statistics and directed staff to establish a means to ensure that all pharmacies will be inspected every four years. The committee emphasized that these inspections needed to be accomplished with

existing resources.

Chairperson Schaad stated that the board's staff will provide periodic reports to the committee and board on its progress to achieve the compliance inspections. Among the reports requested will be graphs to compare the activities of inspectors by number of inspections, investigations and other work. He added that staff will also research requirements in other states for inspections and their frequency.

Dr. Wong asked if an inspection done as part of a complaint investigation will count as a compliance inspection. Ms. Herold responded that this is a possibility, but ideally there will be two separate inspections.

d. Discussion and Consideration of Possible Statutory or Regulatory Changes to Expand the Use of Automated Drug Delivery Systems (ADDS)

Chairperson Schaad explained that there is increasing interest and demand for expanded use of ADDS in pharmacies, clinics and other environments to provide medications to patients. Generally, there are two major forms of these machines:

1. Storage of medication until a specific dose is needed for a patient (e.g., Pyxis machines in hospitals and skilled nursing facilities) where the medication is obtained by a health care provider after it has been ordered for a patient.
2. Storage of a full dosing regimen for a specific patient awaiting patient pick up (e.g., Asteres machine currently under study by UCSD, ADDS that comply with requirements established by California Code of Regulation section 1713 for refills that patients opt in to use from a machine adjacent to a pharmacy counter, use of ADDS via remote technology as authorized in clinics licensed by Business and Professions Code section 4186).

Chairperson Schaad reported that at a technology summit held by the board earlier this year, various forms of technology were demonstrated.

Chairperson Schaad stated that in 2017 there were two legislative proposals introduced in the California Legislature to allow for additional uses of the machines:

- A machine that can store medication in fire departments and EMSA offices to replenish ambulance supplies when convenient for the ambulance (sponsored by the board and enacted).
- A machine installed in clinics, operated by a pharmacy, to dispense 240B drugs to qualified patients (stalled in the Legislature).

Chairperson Schaad reported that during the year, board staff has been working to resolve various issues relating to the existing law we have in this area (see below):

- Under Health and Safety Code section 1261.6 (where medication can be stored for unit dose administration to patients by health care personnel after the medication is delivered to a skilled nursing facility by a pharmacy):
  - Who can refill the machines?
  - Who can deliver the medication to the facility? Should storage in vehicles be

prohibited? What type of security during transportation is required?
    - Can the medications be stored at the facility before loaded into the machine? If so, where?
    - How will expired medication be removed from an ADDS?

- Under Business and Professions Code sections 4105.5, 4186 and California Code of Regulations section 1713 (where patients will be dispensed their medication):
    - Is patient consent required to use the ADDS? How often does it need to be reviewed/reaffirmed?
    - Is patient consultation required? When, only on initial fills?
    - Is a phone connection adequate, or is a video camera also needed?
    - How can language interpretations be secured via ADDS?
    - Should ADDS be placed in non-pharmacy areas? If so, how should security of the medication and patient confidentiality be provided?
    - How long may a refill be provided?
    - Should all medication be available via an ADDS dispensing?
    - Should patients be reminded about the need for some drug therapy to be monitored periodically via testing? If so, how should this be meshed into patient care?

- General questions:
    - Who can own/operate an ADDS (A licensed pharmacy, a pharmacist, anyone)?
    - If a pharmacy must own the ADDS, can it do so from an out of state location?
    - Where can (or even if) drug stock that will be placed in the machine may be temporally stored outside the machine (in locked areas, in transport vehicles, etc.)
    - Should the board inspect the machines?
    - Authentication systems to ensure the appropriate patient gains access to the stored medication.

Chairperson Schaad reported that the committee directed staff to work with him on developing a framework for future regulation of ADDS and bring this to the next Enforcement and Compounding Committee.

Ms. Veale spoke in support of the use of ADDS.

There were no comments from the public.

e. Discussion and Consideration of the University of California San Diego's Experimental Program Regarding Access to Medications from an Automated Drug Delivery System (ADDS) (Pursuant to California Code of Regulations, Title 16, Section 1706.5)

Chairperson Schaad reported that at the July 2017 Board Meeting, the board heard and discussed the results of the UCSD experimental study involving the use of ADDS technology to dispense new and refill medications to outpatients in an area nonadjacent to a pharmacy counter. This study involves a waiver of California Code of Regulations Title 16, section 1713, in that it allows first-time fills to be dispensed via an ADDS machine, and the ADDS is not adjacent to a pharmacy counter but is installed in a hospital location.

Chairperson Schaad stated that during the July Board Meeting, the board heard the final report of this study and supported a request from UCSD to extend the study for one year to provide

additional data regarding the study and time for the board to consider a regulation modification involving ADDS to provide medication to patients.

Chairperson Schaad reported that following the discussion, the board approved the following motion: Extend the UC San Diego study for another 12 months (July 26, 2017 -July 25, 2018). Additionally, request that the data provided to the board include a distinction between new prescriptions (as defined by law) and previously dispensed prescriptions.

Chairperson Schaad reported that during the September Enforcement and Compounding Committee meeting, the committee again heard presentations from Asteres and UC San Diego. He added that during the presentation Dr. Hirsch requested that that following changes be made to the data collection parameters for the study moving forward.

- Return to Stock: continue to collect data
- Pick-Up Time: continue to collect data
- Kiosk Patient Survey Data: continue to collect data
- Counseling Logs: continue to complete the logs through the end of 2017 (note: all counseling will continue to occur; the log is the only part that stop)
- Truly New Prescriptions: add this manual data collection to the study
- Therapeutic Class: remove from study

Chairperson Schaad explained that the committee discussed whether the study should be extended longer than one year to build in time to gather more data and if appropriate to secure statutory or regulation changes. Staff counsel also requested that the amended IRB be provided to the board at its next meeting.

Chairperson Schaad noted that after consideration, the committee made the following motions.

Committee Recommendation: Approve the changes to the study as provided below and direct staff to work with UCSD to ensure that the changes made to the IRB are consistent with the committee's discussion.

- Return to Stock: continue to collect data
- Pick-Up Time: continue to collect data
- Kiosk Patient Survey Data: continue to collect data
- Counseling Logs: continue to complete the logs through the end of 2017 (note: all counseling will continue to occur; the log is the only part that stop)
- Truly New Prescriptions: add this manual data collection to the study
- Therapeutic Class: remove from study

Committee Recommendation: Direct UCSD to provide study updates to the Enforcement Committee every six months.

Ms. Herold stated that staff is requesting that the board consider amending the study time frame from one year to two years (July 2019) to allow UC San Diego to gather more patient data and to allow adequate time should the board decide to amend 1713. She explained that the Enforcement Committee discussed extending the study beyond one year; however, the committee did not vote to approve the extension.

The board agreed with the staff recommendation.

There were no comments from the public.

Motion: Extend the study to July 2019 to allow adequate time to gather more patient data and for the board to consider possible amendments to 1713. Approve the changes to the study as provided below and direct staff to work with UCSD to ensure that the changes made to the IRB are consistent with the board's discussion.

- Return to Stock: continue to collect data
- Pick-Up Time: continue to collect data
- Kiosk Patient Survey Data: continue to collect data
- Counseling Logs: continue to complete the logs through the end of 2017 (note: all counseling will continue to occur; the log is the only part that stop)
- Truly New Prescriptions: add this manual data collection to the study
- Therapeutic Class: remove from study

M/S: Gutierrez/Lippe

Support: 7 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Gutierrez	x			
Khan				x
Law	x			
Lippe	x			
Munoz				x
Sanchez	x			
Schaad	x			
Veale	x			
Weisser				x
Wong	x			

Motion: Direct UCSD to provide study updates to the Enforcement Committee every six months.

M/S: Gutierrez/Lippe

Support: 7 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Gutierrez	x			
Khan				x
Law	x			
Lippe	x			
Munoz				x
Sanchez	x			
Schaad	x			
Veale	x			
Weisser				x
Wong	x			

f. Status Report on Waivers Issued for Compounding Construction Compliance Delays Pursuant to California Code of Regulations, Title 16, Sections 1735.6 and 1751.4

Chairperson Schaad explained that Title 16 of 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. He added that there is a related provision in CCR section 1751.4 that provides the same allowances for sterile compounding facilities.

Chairperson Schaad stated that an 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.

Chairperson Schaad reported that initial review of the waiver is performed by staff led by the executive officer, who approves or denies the waiver request. Approval or denial of a waiver is provided to facilities in writing. He explained that 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.

Chairperson Schaad stated that the goal of the construction waiver process is to secure full compliance at the earliest possible time.

Chairperson Schaad reported that facilities that have been denied a waiver have been made aware that there is an appeal process. There have been no additional appeals made since July 1, 2017.

Chairperson Schaad noted that most request waiver sections are 1735.6(e) and 1751.4(g) for the

external venting requirement for compounding hazardous drugs.

Chairperson Schaad explained that until mid-October, the implementation date of USP <800> was July 1, 2018. The board had been using this date as the final end date for any waiver it issued. However, this time frame was recently extended until December 1, 2019, when modifications to USP <797> are also expected.

Chairperson Schaad stated that the board needs to explore how it will handle waiver requests for compliance that will occur beyond July 2018. He added that the board continues to receive requests for waivers well beyond even the December 2019 date, sometimes as long as 2022.

President Gutierrez recommended extending the final end date for any waiver to December 1, 2019, to match the new USP <797> date. The board agreed with this recommendation.

Chairperson Schaad reviewed the following statistics.

Status of Waiver Requests Received as of 6/27/17:

- Total Waivers Received: 609
- Total Waivers Processed: 607
  - Denied: 40 - 6.5%
  - Withdrawn: 100 - 16.5%
  - Approved: 380 - 62.6%
  - Non-responsive letters sent: 21 - 3.5%
  - In process: 66 - 10.8%
- Total Waivers Pending Review: 2
- Total Waiver Extensions Granted: 60

Since November 1, the 401 waivers have been approved.
Of these:

- 164 are hospital pharmacies (41%)
- 24 are nonresident pharmacies (6%)
- 213 are community/outpatient pharmacies (53%)

Of the 401 approved waiver are for facilities holding the following license

- 253 hold sterile compounding licenses (63%)
- 8 hold nonresident sterile compounding licenses (2%)
- 140 pharmacies with waivers do not have sterile compounding licenses

There were no comments from the public.

Motion: Authorize the Executive Officer to allow the extension of waivers to December 1, 2019 when necessary.

M/S: Gutierrez/Law

Support: 7 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Gutierrez	x			
Khan				x
Law	x			
Lippe	x			
Munoz				x
Sanchez	x			
Schaad	x			
Veale	x			
Weisser				x
Wong	x			

Ms. Herold noted that inspectors will continue to write corrections in their reports when a facility has an approved waiver. This will allow the board to ensure that the facility is continuing to move towards compliance by December 1, 2019. Mr. Room clarified that these corrections are not discipline; they are simply a note in the inspection report.

g. Enforcement Statistics

Chairperson Schaad stated that the enforcement committee statistics were provided in the meeting materials for review.

Ms. Herold noted that board staff is working on providing summaries of disciplinary actions that are reported in *The Script*.

h. Future Committee Meeting Dates

Chairperson Schaad announced that the next Enforcement Committee Meeting would be held on December 11, 2017. A member of the public requested that the committee meeting be webcast.

Chairperson Schaad announced the 2018 Enforcement Committee meeting dates as provided below.

- March 28, 2018
- June 7, 2018
- September 5, 2018
- December 13, 2018

President Gutierrez recessed the meeting to closed session at 10:51 a.m.

The board returned to open session at 10:55 a.m. and adjourned the meeting at 10:56 a.m.