California State Board of Pharmacy
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ENFORCEMENT AND COMPOUNDING COMMITTEE MEETING MINUTES

DATE:	April 3, 2018
LOCATION:	Department of Consumer Affairs Building Two 1747 North Market Blvd, Room 186 Sacramento, CA 95834
COMMITTEE MEMBERS PRESENT:	Allen Schaad, Licensee Member, Chair Amy Gutierrez, PharmD, Licensee Member, Vice Gregory Lippe, Public Member Stan Weisser, Licensee Member
COMMITTEE MEMBERS NOT PRESENT:	Valerie Munoz, Public Member
STAFF MEMBERS PRESENT:	Virginia Herold, Executive Officer Anne Sodergren, Assistant Executive Officer Christine Acosta, PharmD, Supervising Inspector Laura Freedman, DCA Staff Counsel Kelsey Pruden, DCA Staff Counsel Laura Hendricks, Staff Analyst MaryJo Tobola, Senior Enforcement Manager

1. Call to Order and Establishment of Quorum and General Announcements

Chairperson Allen Schaad called the meeting to order at 10:00 a.m.

2. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings
Note: The board may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code sections 11125, 11125.7(a)]

No public comments on items not on the agenda or for future meetings.

3. Update from 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 introduced Jan Hirsch, BPharm, PhD and UCSD researcher who provided a presentation on the status and direction of the University of California San Diego's experimental program regarding access to medications from an ADDS. UCSD provided a PowerPoint presentation, Study of Expanded Use of an Automated Delivery Device Extension Update.

As part of the discussion, Dr. Hirsch acknowledged a slight decline in ScriptCenter kiosk activity. Board staff inquired about actual ADDS holding capacity and the ability to expand capacity, and UCSD introduced a new category of data collected only after October 2017, "Truly New Patient."

4. Presentation, Discussion and Consideration of the Board's Citation and Fine Program

Chairperson Schaad stated that the pharmacy profession deserves a degree of transparency. The committee realizes that the expense of defending a violation can mean thousands of dollars in legal fees, and often times respondents have no alternative but to pay the fine, rather than incurring more legal expense. Additionally, the amount of time lapsed should be considered; it sometimes takes years to resolve a case, which is neither proficient nor fair. There is a professional concern that fines are simply punishment and have little effect on public safety. The committee wants to ensure that public safety is safeguarded by the use of these fines. The actual number of cases the board members see is relatively few, and as a result, the members do not have a true idea of what is happening statistically. Chairperson Schaad stated the board collects about $2 million in fines, and the committee wants a higher level of transparency.

At the request of the committee, Chiefs of Enforcement Julia Ansel and Tom Lenox provided an informational presentation on board-issued citations and fines. The presentation provided general enforcement information on board investigations, as well as information regarding citations and fines issued by the board during 2017.

As part of the discussion, the committee was advised that most programs within the DCA have a citation and fine program. However, it was noted that the board's authority to issue the letters of correction and the letters of admonishment is unique to the board. Ms. Herold added that the Board of Pharmacy has its own inspectors, staffed with licensed pharmacists, which also differ from other boards.

Legal staff clarified that the authority to issue citations comes directly from the Business and Professions Code. Additionally, counsel added there are very few programs that do not have a citation and fine program within the DCA and noted that the board itself adopts regulations and is the policy-setting authority; amendments are made through a formal rulemaking process. Unique to the Board of Pharmacy are the letters of correction and the letters of admonishment.

As part of the discussion, the committee and board staff discussed issues pertaining to the implementation of routine inspections next month and the proactive effect that could result from more routine inspections.

The committee was informed by board staff that through the years the citation and fine program has transitioned. There has been deliberate action by policy makers, which staff has implemented.

As part of the discussion, Chairperson Schaad stated that the profession must have an understanding of the types of discipline. The committee seeks transparency in the policies and procedures guiding the use of citations and fines.

The public commented, in part, on issues regarding the use of education in lieu of citation, the presence of board staff at more professional educational events, and the possible refocus of the California Practice Standards and Jurisprudence Examination (CPJE) with more emphasis on pharmacy law.

The committee asked that the citation and fine presentation be provided to the full board at the next board meeting.

5. Discussion and Consideration of Possible Board Policy Relating to Disclosure of Enforcement Actions Involving Board Members

In an effort to encourage consistent transparency, Chairperson Schaad stated that during Board Member Orientation, members are provided with the Department of Consumer Affairs' list of the "Top 10 Traits of an Effective Board Member." One of the traits on the list is being aware of conflicts of interest, whether conflicts are real or perceived.

Chairperson Schaad reminded the committee that one area where board members should be transparent is in enforcement actions involving themselves (whether they are directly or indirectly involved). Board members should determine whether recusal from a vote or discussion should occur based on the real or possible appearance of self-interest. For example, an enforcement matter involving a board member could influence a member's objectivity in future decision making when the case involves fact patterns similar to his or her enforcement matter.

Chairperson Schaad informed the committee that at the December 2017 committee meeting, a motion was made to recommend to the full board that board member involvement in disciplinary or administrative action would be reported in the Organizational Development Report.

Chairperson Schaad added that most recently, during the January 2018 board meeting, the board voted to send this issue back to the Enforcement and Compounding Committee for further discussion and reconsideration.

Chairperson Schaad recommended for committee discussion and consideration the areas of concern addressed by the board members at the January meeting. The committee shall determine the types of actions that should be reported for disclosure, the purpose of such reporting, and whether there is currently a problem with the current reporting system and determine reporting parameters.

Board staff provided information about how other DCA boards handle transparency in the area of citations, fines and disciplinary actions for all licensees. Board staff stated that a review of a few boards disclosed that some boards posts citations as an attachment to license searches. The degree of disciplinary transparency varies amongst the boards. Decision points are based differently depending on the needs of the specific board.

The committee was informed that currently, Board of Pharmacy only posts accusations and pleadings; citations and fines are not disclosed.

Staff was directed to survey all healing arts boards to examine how each healing arts board handles transparency in all areas of discipline. The results will be brought back to the next committee meeting.

The committee recommended changing the agenda item to Determining General Transparency Involving the Area of Cite and Fines.

There was no public comment.

6. Update on the Substance Abuse Coordinating Committee, and the Department of Consumer Affairs' Reconvening of it Pursuant to Business and Professions Code Section 315.

Chairperson Schaad informed the committee that Senate Bill 1441 established in the Department of Consumer Affairs the Substance Abuse Coordination Committee (SACC). The bill required the SACC to formulate uniform and specific standards in specified areas that each healing arts board would be required to use in dealing with the substance-abusing licensees.

Chairperson Schaad stated that Senate Bill 796 requires the Department of Consumer Affairs to reconvene the SACC to specifically review the existing substance abuse testing criteria. The committee must determine whether the existing criteria should be updated, and a report is due to the Legislature by January 1, 2019.

Chairperson Schaad announced that the first SACC meeting is scheduled for Monday, April 23, 2018 from 10 a.m. to 3 p.m. in the DCA HQ2 Hearing Room.

Ms. Herold informed the committee that she is a member of the SACC panel. Ms. Herold

stated that the SACC meeting should discuss, in part, a modification to the frequency of fluid testing. Ms. Herold reminded the audience that this is a public meeting.

No public comment

7. Update on the Status of the Proposed Regulations Undergoing Pre-Review to Amend Title 16 CCR Sections 1735.1, 1735.2, 1735.6, 1751.1, and 1751.4 Related to Compounding

Chairperson Schaad provided a timeline of the proposed emergency regulations approved in July 2017. The board's emergency regulation expires on June 19, 2018 and readoption of the emergency regulation will most like be necessary as the permanent regulation package has not been submitted to OAL to initiate the formal rulemaking process.

Legal recommends that the committee readopt the emergency regulation. Re-adoption is valid for 180 days.

No public comment.

Motion: Recommend to readopt emergency regulations.

M/S: Schaad / Gutierrez

Support: 4 Oppose: 0 Abstain:0

8. Discussion and Consideration of the Pew Charitable Trusts "State Oversight of Drug Compounding" Report

Chairperson Schaad provided background information on the Pew Charitable Trusts State Oversight of Drug Compounding Report. The Pew Charitable Trusts' drug safety project has identified more than 50 reported compounding errors or potential errors from 2001 to 2017 linked to 1,227 adverse events—undesirable experiences associated with the use of a medical product—including 99 deaths. Because many such events may go unreported, this number is likely to be an underestimation. Chairperson Schaad informed the committee that in November 2013, Congress passed and President Barack Obama signed into law the bipartisan Drug Quality and Security Act (DQSA), which established clear lines of oversight accountability for two categories of businesses that can compound drugs. While the majority of states have taken action to strengthen sterile compounding oversight policies since the outbreak, it is essential to follow through with strong implementation and enforcement of these laws and rules—including the federal DQSA.

Chairperson Schaad stated that this report is intended to highlight the significant progress on public health policy that has occurred and to identify the most fruitful opportunities for action to help ensure a safe supply of compounded drugs. This remains a period of flux for

drug compounding oversight: A number of states have pending policy changes, and implementation of the federal DQSA is ongoing. This continuing progress is one key finding of this study.

Ms. Herold confirmed that California is one of the 10 states that are compliant with USP.

The committee requested that the report be shared with the Medical Board to support oversight. The board shall offer guidance and support to the Medical Board.

The committee heard public comment. A member of the public requested that the report also be shared with the Veterinary Board.

Motion: Advocate at the federal level to allow for office-use compounding.

M/S: Lippe / Weisser

Support: 4 Oppose: 0 Abstain: 0

9. Discussion and Consideration of the Anticipated Release of Updates to United States Pharmacopeia Chapter (USP) 797, USP 800, and Other USP Chapters and the Impact on the Board's Regulation of Compounding

Chairperson Schaad stated that for several years this committee and the board have discussed the regulation of compounding, both sterile and nonsterile, and most recently hazardous compounding. The results of these discussions were comprehensive regulations promulgated to ensure compounded drug preparations are safe. Although not totally consistent, relevant USP chapters covering compounding served as part of the framework for these regulations.

Chairperson Schaad reminded the committee that during the February 2018 board meeting, counsel was directed to research the feasibility of incorporation of USP standards into the board's regulation of compounding practice rather than creating its own requirements.

Chairperson Schaad informed the committee that USP is currently working on revisions to several chapters including 795 and 797. The proposed revisions for Chapter 795 are scheduled to be released in the coming week.

Chairperson Schaad recommended for committee discussion a potential solution if the committee and board determined to accept USP's compounding standards as the appropriate minimum standards. Chairperson Schaad recommended that the board could seek a statute requiring the board to adopt or enforce USP standards, but still allowing the board to strengthen the standards by regulation where the board deems appropriate. Taking such an approach would mean the board would not need to update the regulation

if the USP is updated.

Chairperson Schaad offered, as an alternative, that that the board could also incorporate the USP standards by reference into its regulations. Chairperson Schaad stated that such an approach would require that the board still explain in its initial statement of reasons (ISR) the substance (purpose) of each rule or standard being adopted, and why. With OAL's close scrutiny of regulations, this would be a fairly detailed review. It would require that the standards adopted be specific to a single USP version. Any updates would have to be readopted through a subsequent rulemaking. Finally, it would require that the board analyze and address the cost of purchasing the standards in the regulation process. This is similar to OAL's requirement that an agency adopt specific equipment as a minimum standard, and would require the cost impact to be reported in the rulemaking file. Thus, the board would need to explain why it is clearer to use USP standards rather than have a parallel set of regulations. To the extent that the board can show that all, or all responsible, compounders already have copies of USP standards, that would significantly minimize that impact. The board can start to lay some groundwork now by asking for public feedback at board or committee meetings if compounders already own the relevant USP standards.

The committee discussed, in part, whether the board could adopt USP 797, whether USP 795, 796 and 797 could all be included, and following adoption, whether regulations would be used to identify higher California standards.

Supervising Inspector Acosta suggested that all referenced USP chapters should be included in the recommended language. The committee directed SI Acosta and board staff to draft recommended language to present to the committee.

Public comment was heard. A member of the public stated that all sections are not applicable to compounders. He also stated that it is very unclear which sections compounders are required to comply. He also recommended that USP 797 be adopted as a minimum set of standards. A member of the public provided examples of conflicts that might arise between USP and regulations. In general, the public members requested that regulatory language be clear and enforceable.

Motion: Board staff will review 797, 795, and 800 and draft language for board to review.

M/S: Gutierrez / Lippe

Support: 4 Oppose: 0 Abstain:0

10. Enforcement Statistics

Enforcement statistics for the first three quarters of FY 2017/2018 were provided to the committee.

11. Future Committee Meeting Dates

Chairperson Schaad reported that the future remaining Enforcement Committee dates for 2018 are:

June 7, 2018
September 5, 2018
December 13, 2018

Chairperson Schaad adjourned the meeting at 2:15 PM.