



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
ENFORCEMENT COMMITTEE MEETING
MINUTES**

DATE: July 25, 2011

LOCATION: Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Boulevard
Sacramento, CA 95834

COMMITTEE MEMBERS

PRESENT: Randy Kajioka, PharmD, Vice President
Greg Lippe, Public Member, Treasurer
Tappan Zee, Public Member

COMMITTEE MEMBERS

NOT PRESENT: Neil Badlani, RPh

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Joshua Room, Deputy Attorney General
Kristy Shellans, DCA Staff Counsel
Carolyn Klein, Legislation and Regulation Manager
Tessa Miller, Staff Analyst

Call to Order

Chair Randy Kajioka called the meeting to order at 9:45 a.m.

Chair Kajioka conducted a roll call. Board Members Lippe, Zee, and Kajioka were present.

Board President Stan Weisser was in attendance in the audience.

1. **Presentation from the California Pharmacists Association to Request Exemption from 16 California Code of Regulations Section 1707.5 Label Requirements for Prescription Drug Containers as Authorized by Section 4076.5 of the California Business and Professions Code for Skilled Nursing Facilities**

Chair Kajioka provided that at the December 2010 and March 2011 Enforcement Committee Meetings, the committee heard presentations from groups seeking exemption from the labeling requirements for their specialized patient populations. He advised that the board has not yet approved any waiver request.

Paige Talley, representing the California Pharmacists Association (CPhA) and Art Whitney, representing Pacific West Pharmacy, clarified that CPhA is requesting an exemption to the patient-centered label requirements for unit dose medications.

Dr. Kajioka discussed that because a health care professional will be administering the unit dose to the patient, an exemption is not required.

Deputy Attorney General Joshua Room clarified that this exemption is already written into the regulation (see Business and Professions Code section 4076.5 (d)).

Dr. Kajioka clarified that any drug that is dispensed or could go home with the patient upon discharge must be labeled according to the labeling requirements of Section 1707.5.

DCA Staff Counsel Kristy Shellans sought clarification regarding this exemption request. She provided that the meeting materials indicate that the request is being made for medications that will go home with patients upon discharge.

Chair Kajioka indicated that this initial request has been modified to seek an exemption for unit dose medications only.

Ms. Talley confirmed that this initial request has been withdrawn.

Executive Officer Virginia Herold asked whether bingo cards in skilled nursing facilities are being labeled in 10-point or 12-point font.

Ms. Talley provided that the bingo cards are labeled in a 10-point font.

No public comment was provided.

2. Discussion and Possible Action to Make Recommendations to the Board Regarding Changes to the Board's Disciplinary Guidelines at 16 California Code of Regulations Section 1760, Including to Incorporate Recommendations of the Substance Abuse Coordination Committee (Pursuant to SB 1441, Ridley-Thomas, Chapter 548, Statutes of 2008)

Background

The board has initiated a restructuring and updating of its Disciplinary Guidelines. To incorporate changes to the Disciplinary Guidelines, the board needs to initiate a rulemaking.

As part of this effort, the board has also determined to incorporate the recommendations of the DCA's Substance Abuse Coordination Committee into the Disciplinary Guidelines.

Senate Bill 1441 created the Substance Abuse Coordination Committee (SACC) and required that this committee, by January 1, 2010, formulate uniform and specific standards in specified areas that each healing arts board must use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program. To facilitate implementation of these standards, the DCA created a workgroup in 2009 consisting of staff from each of the healing arts boards to draft recommended standards for SACC consideration during public meetings. There are 16 standards that were developed.

The most recent version of the SACC standards was approved in April 2011.

In March 2011, a board subcommittee of Stan Weisser and Tappan Zee met in a first step toward incorporating these standards into the Disciplinary Guidelines.

At the May 2011 Board Meeting, the board directed staff to develop regulatory language to modify the disciplinary guidelines to incorporate the SB 1441 standards.

Discussion

Mr. Room provided an overview of the proposed changes that have been identified and drafted for board consideration for incorporation into the board's Disciplinary Guidelines. He indicated that the proposed draft (provided in the meeting materials) incorporates three levels of changes: SB 1441 Uniform Standards (shown in blue), reorganization (shown in red), and subcommittee edits (shown in green).

Mr. Room discussed that the following Uniform Standards do not fit within this framework and are more policy standards and/or standards of general application, rather than terms that must be negotiated as part of a settlement.

- Uniform Standard # 6, which sets up factors the board should consider in deciding whether to send a respondent to inpatient, outpatient, or other type of treatment. The Disciplinary Guidelines do not currently have a term whereby the board can send a respondent to treatment (PRP handles that, for those in PRP).

- Uniform Standard # 9, which defines a failed drug test as a major violation.
- Uniform Standard # 10, which defines major and minor violations.
- Uniform Standard # 11, which defines the criteria that must be met before a respondent can petition to return to full-time practice.
- Uniform Standard # 12, which defines the criteria that must be met before a respondent can "petition for reinstatement" to an unrestricted license (but is specifically defined as not the APA's petition for reinstatement in the Uniform Standards).
- Uniform Standard # 13 defines standards and specifications for contracts with and requirements of drug testing vendors/contractors.
- Uniform Standard # 14 defines what information about respondents/licensees who are in a diversion program (PRP) shall be publicly disclosed.
- Uniform Standard # 15 sets up auditing requirements for diversion services vendors.
- And Uniform Standard # 16 sets up board reporting requirements to the Legislature.

Ms. Shellans provided that the board's implementation of the Uniform Standards (standards) will be evaluated during the sunset review process. She indicated that other healing arts boards have been heavily scrutinized by the Senate Business and Professions Committee with respect to the implementation and noticing of the rulemakings that incorporate the standards into the disciplinary guidelines. Ms. Shellans advised that the board will also be subject to such elevated scrutiny.

Ms. Shellans indicated that the statute requires the boards to use the standards in their programs. She discussed that there are three different legal opinions regarding the boards' discretion regarding the implementation of the standards. Ms. Shellans explained that the Senate Business and Professions Committee believes that the standards are final and should be adopted as written by the boards; and, as such the board has no discretion to make modifications. She discussed that alternatively, the healing arts boards and their counsel have taken the opinion that they have discretion and the ability to make modifications in this area to conform to their respective practice. Ms. Shellans provided that certain department representatives have maintained that the boards have only the discretion to decide when to apply the standards.

Ms. Shellans recommended that the board notice the disciplinary guidelines with the standards as written by the SACC and consider making modifications during the formal rulemaking process pursuant to comments received during the public comment period. She stated that this will provide the board with a stronger legal argument that the standards were used and unaltered before they were noticed.

Ms. Shellans advised that the board should be prepared for criticism and disapproval by the Senate Business and Professions Committee should the standards be modified at this time.

The committee discussed how to proceed with its discussion and possible action in light of Ms. Shellan's recommendation.

Ms. Shellans provided that the board should review each standard and modify the disciplinary guidelines to incorporate the standards.

No public comment was provided.

MOTION: Recommend that the board initiate the rulemaking process to notice the version of the language as presented in the document as authored by Joshua Room reflecting the changes incorporating the SB 1441 Uniform Standards (shown in blue) and reorganization (shown in red). The changes in green should be maintained in a manner to document the subcommittee's work for historical record.

M/S: Lippe/Zee

Support: 3 Oppose: 0 Abstain: 0

Additional Discussion

The committee briefly discussed standards that were not included in the draft document.

Mr. Room provided an overview of standard #6 regarding whether to send a respondent to inpatient, outpatient, or other type of treatment. He indicated that the Disciplinary Guidelines do not currently have a term whereby the Board can send a respondent to treatment. Mr. Room explained that the clinical case manager for the Pharmacists Recovery Program (PRP) makes this determination. He discussed that the board can write a term in its guidelines to fit this language and can incorporate the standard as the criteria for the term.

Ms. Shellans discussed that other boards have linked standard #6 with standard #1 and have created a new optional term for alcohol or drug abuse treatment programs.

It was the consensus of the committee to recommend that the board hold a one-day board meeting to further discuss this item.

3. Review and Discussion of Enforcement Statistics and Performance Standards of the Board

Chair Kajioka referenced the 2010/11 enforcement statistics for the board's enforcement efforts provided in the meeting materials.

No public comment was provided.

4. Public Comment for Items Not on the Agenda

Steve Gray, representing Kaiser Permanente, discussed that many pharmacy organizations are experiencing problems when trying to obtain patient medication therapy records from other pharmacy organizations. He recommended that the board address and evaluate the professional standard in this area.

The meeting was adjourned at 10:27 a.m.