



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

Minutes

California State Board of Pharmacy LEGISLATION AND REGULATION COMMITTEE

Meeting Date:

June 25, 2012

Location:

Department of Consumer Affairs

1625 N. Market Blvd.

El Dorado Conference Room – 2nd Floor

Sacramento, CA 95834

Committee Members Present:

Shirley Wheat, Chair

Debbie Veale, RPh

Ramon Castellblanch, Ph.D.

Committee Members Not Present:

Tappan Zee

Staff Present:

Virginia Herold, Executive Officer

Anne Sodergren Assistant Executive Officer

Carolyn Klein

Kristy Shellans, DCA Sr. Staff Counsel

Ms. Wheat called the meeting to order at 10:09 a.m.

Agenda Item A. Legislation Report

The committee members discussed the following legislative measures:

Board Sponsored Legislation

1. **SB 1575**.(Price) – Omnibus. Ms. Wheat summarized the current status of the board’s sponsored legislation. No change in position was recommended.

Legislation Impacting the Practice of Pharmacy or the Board’s Jurisdiction

2. **AB 389** (Mitchell) – Bleeding Disorders: Blood Clotting Products. Ms. Wheat provided an overview of the status of the measure and reminded the committee of the board’s current position (Oppose), as well as a basis for the position. No change in position was recommended.
3. **AB 1442** (Weickowski) – Pharmaceutical Waste. Ms. Sodergren summarized the status of the bill, stating that the author has taken some of the board’s amendments, but staff is continuing to work with the author’s office to negotiate additional amendments. Because the author has addressed the board’s concerns, staff recommended that the board’s position be changed from Oppose Unless Amended to Neutral. There was no public comment.

M/S: Veale/Castellblanch – Recommend that the board change its position from Oppose Unless Amended to Neutral

Vote: 3-0-0

4. **AB 2348** (Mitchell) – Registered Nurses: Dispensation of Drugs. Ms. Wheat summarized the current status of the bill, noting that staff continues to watch this measure. There was no committee recommendation on this measure.
5. **SB 419** (Simitian) – Solid Waste: Home-Generated Sharps. Ms. Wheat noted that the board does not have a position on this measure, and that the bill remains on the Assembly Inactive File. There have been no changes to this bill since 2011. The committee made no recommendation on this measure.
6. **SB 1301** (Hernandez) 0 Prescription Drugs: 90-Day Supply. Ms. Wheat provided an overview of the bill and reminded the committee of the board’s position: SUPPORT. The committee made no recommendation on this measure.
7. **SB 1329** (Simitian) – Prescription Drugs: Collection and Redistribution Program. Ms. Wheat noted the board’s position of SUPPORT IF AMENDED, and that the author’s office has addressed some of the board’s concerns. Ms. Herold noted that staff continues to work with the author’s staff to negotiate amendments. She added that a few areas that remain to be addressed include the transferring of drugs between county program, the frequency of reporting and some of the facilities that would be able to donate medications. No change in position was recommended. There was no public comment.

Sunset Review and Legislative Oversight

8. **SB 1237** (Price) – Pharmacy Sunset. Ms. Wheat noted the board’s current position of SUPPORT. There was no committee or public discussion of this bill.

Licensing and Pharmacy Operations

9. **AB 377** (Solorio) – Pharmacy (Hospital Central Fill). Ms. Wheat noted the board’s current position of Support if Amended (April 2011). Philip Swanger representing the California Society of Health-System Pharmacists (the sponsors) stated that they are looking to amend the bill in the coming week or so. He said stakeholders are reaching consensus. Ms. Herold advised the committee of the anticipated scope of the expected amendments, and the committee discussed the benefits of the bill’s provisions. Mr. Swanger told the committee that the board could likely see amendments by the July Board Meeting.
10. **AB 1588** (Atkins) – Reservist Licensees: Fees and Continuing Education. Ms. Wheat summarized the status of this bill, noting that the committee has never discussed this measure before, and that the board does not have a position. Ms. Wheat noted that this bill would require the board to waive a licensee’s renewal fee and continuing education requirements, if applicable, for any licensee who is a reservist called to active duty. Sr. Staff Counsel Kristy Shellans noted that this bill would not require that the status of the license to be “inactive,” nor does the bill define the term “good standing.” Ms. Shellans recommended that staff seek clarification of the meaning “in good standing.” Public comment included that if someone is only licensed in California and is serving as a pharmacist, placing them on an Inactive status would cause a concern. In addition, the public comment indicated that the military provides training that is not ACPE or CAPE approved and, as such, that training would not count towards CE under current law. Staff will clarify the intent of the law as well as other concerns.

11. **AB 1896** (Chesbro) – Tribal Health Programs: Health Care Practitioners. Ms. Wheat summarized the status of this bill, and reminded the committee that the board has not taken a position on this measure. Staff share concerns and counsel advised the committee of her concerns including that it is unclear what legal standing the board would have. Staff will clarify the intent of the language.

M/S (Veale/Castellblanch) Recommend that the board establish a position of Oppose Unless Amended and offer amendments to require licensure if the tribal health program will be providing services to Californians outside of the tribal lands.

Vote 3-0-0

12. **AB 1904** (Block) Military Spouses: Expedited Licensure. Ms. Wheat noted that the board established a position of SUPPORT at the May Board Meeting. Ms. Shellans stated her concern with the bill language “shall expedite the licensure process,” indicating the language sounds like the board would *have* to give the applicant a license. The committee discussed Ms. Shellans concerns and directed staff to alter the language so as to clarify the term “current license.”

13. **AB 2570** (Hill) – Licensees: Settlement Agreements. Ms. Wheat provided an overview of the measure and reminded the committee that the board has a position of OPPOSE UNLESS AMENDED. Ms. Shellans expressed concern with the restitution provision and explained why this provision of the measure is problematic. The committee did not make a recommendation to change the board’s position.

14. **SB 1095** (Rubio) – Pharmacy: Clinics. Ms. Wheat summarized the current status of the bill, reminding the committee that the board currently has a position of OPPOSE UNLESS AMENDED. The committee was advised by the sponsor that amendments should be in print by tomorrow and they have asked that the committee hearing (ASM Health) be postponed to July 3 so that the amendments would be in print. Ms. Herold noted that the expected amendments address the board’s concerns. Ms. Wheat indicated the board will continue discussion of the measure at the July Board Meeting.

15. **SB 1481** (Negrete McLeod) Clinical Laboratories: Community Pharmacies. Ms. Wheat noted the current status of the bill, and the board’s current position of SUPPORT. No change in position was recommended.

Other

16. **AB 2369** (Valadao) – Prisoners: Pharmacy Services. There was no committee or public discussion of this measure.

17. **SB 1185** (Price) – Centralized Intelligence Partnership Act. There was no committee or public discussion of this measure.

Agenda Item B. REGULATION REPORT

Board Approved – Undergoing Review by the Administration

- a. Ms. Wheat advised the committee that the Office of Administrative Law recently approved the board's rulemaking and that the regulation will be effective on July 18, 2012:

Add Title 16 Section 1727.2 – Requirements for Pharmacist Interns and
Amend Title 16 Section 1728 – Requirements for Pharmacist Examination

To Require Specified Applicants to Submit a Self-Query from the National Practitioner Data Bank –
Healthcare Integrity & Protection Data Bank (NPDB-HIPDB)

Board Approved – Regulations Currently Noticed

- a. Proposed Amendments to Title 16 Section 1746 – Emergency Contraception Protocol

Ms. Wheat advised the committee on the status of the regulation, as well as the action that will be required by the Medical Board of California. Ms. Herold advised the committee that one amendment is necessary, noting the scope of the amendment related to two screening items that will be added to the protocol.

- b. Proposed Amendments to Title 16 Starting at Section 1735.1 Related to Compounding Drug Products

Ms. Wheat provided the committee with an update on the status of the regulation. Public comment from the California Society of Health-System Pharmacists expressed gratitude for the board's efforts and commented that the Frequently Asked Questions (FAQs) document may be a bit out of sync. Ms. Herold encouraged CSHP to submit comments to the board on the FAQs.

Board Approved – Awaiting Notice (*Information Only*)

- a. Proposed Addition of Section 1762 – Additional Grounds for Unprofessional Conduct
- b. Proposed Addition of Section 1769 – Addition of Application Review to Criteria for Rehabilitation
- c. Proposed Amendment of Title 16 Section 1745 – Partial Fill of Schedule II Controlled Substance

Ms. Wheat advised the committee that the three regulations noted above are currently being developed for release of the notice.

Proposed Regulations Being Discussed By Committees (*Not for Action - Update Only*)

Ms. Wheat highlighted the regulations that are currently being reviewed for possible action by other committees.

- a. Licensing Committee
 - Updates to the USP Standards Reference Manual
 - Standards for Agencies that Accredite Licensed Sterile Injectable Compounding Pharmacies
 - Continuing Education
 - Accreditation Agencies for Continuing Education
 - Self-Assessment of a Veterinary Food-Animal Drug Retailer

- b. Enforcement Committee
 - Requirements for Unique ID Numbers for Rx / E-Pedigree
 - Development of “Grandfathering” Provisions for Non-Pedigree Dangerous Drugs
- c. Communication and Public Education Committee
 - Notice to Consumers Posters / Video Display Format Option / Interpreter Availability

There was no additional public comment.

Ms. Wheat adjourned the meeting at 11:25 a.m.

Adjournment (Note: Adjournment time is approximate)