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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
PUBLIC BOARD MEETING
MINUTES

DATE: May 3 and 4, 2011

LOCATION: Radisson Hotel Newport Beach
4545 MacArthur Blvd.
Newport Beach, CA 92660

BOARD MEMBERS PRESENT:
Stanley C. Weisser, President
Randy Kajioka, PharmD, Vice President
Greg Lippe, Public Member, Treasurer
Neil Badlani, RPh
Ryan Brooks, Public Member
Ramón Castellblanch, Public Member
Rosalyn Hackworth, Public Member
Kenneth Schell, PharmD
Deborah Veale, RPh
Shirley Wheat, Public Member

BOARD MEMBERS NOT PRESENT:
Tappan Zee, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer, 5/3 only
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

Board President Stanley Weisser called the meeting to order at 9:35 a.m.

President Weisser conducted a roll call. Board Members Schell, Lippe, Wheat, Brooks, Hackworth, Kajioka, Castellblanch, Badlani, Veale, and Weisser were present.

I. General Announcements

President Weisser recognized former board members John Tilley, Darlene Fujimoto, John Jones, and Stan Goldenberg who were in attendance in the audience. President Weisser also recognized Dawn Benton from the California Society of Heath-System Pharmacists and Kimberly Kirchmeyer, DCA Deputy Director of Board and Bureau Relations.

II. Approval of the Full Board Meeting Minutes of February 1 & 2, 2011

MOTION: Approve the minutes of the February 1 and 2, 2011 Board Meeting.

M/S: Schell/Hackworth

Support: 10 Oppose: 0 Abstain: 0

III. Approval of the Full Board Meeting Minutes of March 30, 2011

MOTION: Approve the minutes of the March 30, 2011 Board Meeting.

M/S: Hackworth/Lippe

Support: 10 Oppose: 0 Abstain: 0

IV. ENFORCEMENT COMMITTEE REPORT

Report of the Meeting Held March 29, 2011

a. Discussion and Possible Action Regarding Requests for Exemptions from 16 California Code of Regulations Section 1707.5 Label Requirements for Prescription Drug Containers as Authorized by Section 4076.5 (SB 1489, Negrete-McLeod, Chapter 653, Statutes of 2010)

Report

Board Member Randy Kajioka provided that effective January 1, 2011, the board's requirements for patient-centered labels went into effect as 16 California Code of Regulations section 1707.5.

Dr. Kajioka provided that also effective January 1, 2011, provisions enacted by SB 1489 (Senate Business and Professions Committee, Chapter 653, Statutes of 2010) as amendments to Business and Professions Code section 4076.5, allow the board to exempt from the labeling requirements prescriptions dispensed to patients in certain environments. He stated that the exemptions are provided as subdivisions (d) and (e) below.

4076.5. (a) The board shall promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California.
(b) To ensure maximum public comment, the board shall hold public meetings statewide that are separate from its normally scheduled hearings in order to seek information from groups representing consumers, seniors, pharmacists or the practice of pharmacy, other health care professionals, and other interested parties.
(c) When developing the requirements for prescription drug labels, the board shall consider all of the following factors:
(1) Medical literacy research that points to increased understandability of labels.
(2) Improved directions for use.
(3) Improved font types and sizes.
(4) Placement of information that is patient-centered.
(5) The needs of patients with limited English proficiency.
(6) The needs of senior citizens.
(7) Technology requirements necessary to implement the standards.
(**d) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) prescriptions dispensed to a patient in a health facility, as defined in Section 1250 of the Health and Safety Code. if the prescriptions are administered by a licensed health care professional. Prescriptions dispensed to a patient in a health facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility shall be subject to the requirements of this section and the regulations promulgated pursuant to subdivision (a). Nothing in this subdivision shall alter or diminish existing statutory and regulatory informed consent, patients' rights, or pharmaceutical labeling and storage requirements, including, but not limited to, the requirements of Section 1418.9 of the Health and Safety Code or Section 72357, 72527, or 72528 of Title 22 of the California Code of Regulations.**
(e) (1) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) a prescription dispensed to a patient if all of the following apply:
(A) The drugs are dispensed by a JCAHO-accredited home infusion or specialty pharmacy.
(B) The patient receives health-professional-directed education prior to the beginning of therapy by a nurse or pharmacist.
(C) The patient receives weekly or more frequent follow-up contacts by a nurse or pharmacist.
(D) Care is provided under a formal plan of care based upon a physician and surgeon's orders.
(2) For purposes of paragraph (1), home infusion and specialty therapies include parenteral therapy or other forms of administration that require regular laboratory and patient monitoring.

(f) (1) On or before January 1, 2010, the board shall report to the Legislature on its progress under this section as of the time of the report. (2) On or before January 1, 2013, the board shall report to the Legislature the status of implementation of the prescription drug label requirements adopted pursuant to this section.

Dr. Kajioka provided that this law directs that the board "may exempt;" thus to allow such an exemption, the board will need to promulgate regulations.

Dr. Kajioka provided that at the March 2011 Enforcement Committee Meeting, the committee heard three exemption requests:
1. to exempt radiologic pharmacies from GE Healthcare
2. to exempt parenteral nutrition labeling from Walgreens specialty pharmacies; and
3. to exempt long-term care labels from the California Pharmacists Association (CPhA).

Dr. Kajioka provided that a prior request from Medco to exempt infusion labels was dropped after the February 2011 Board Meeting.

Dr. Kajioka stated that there are three outcomes from the March Enforcement Committee that are being brought forward to the board at this meeting.

<u>Request 1: From GE Healthcare for Radiopharmaceuticals</u>
Dr. Kajioka provided an overview of the request by GE Healthcare to exempt labels prepared for radiopharmacy products compounded for specific patients for diagnostic evaluations and are not distributed directly to the patient. He discussed that Board Counsel Kristy Shellans advised the committee that in this case, the requirements for a patient-centered label do not apply if the medication is not dispensed directly to patients in California. Dr. Kajioka also stated that Deputy Attorney General Joshua Room also agreed that such products, when never dispensed to the patient, would not be required to be labeled according to the patient-centered regulation.

Dr. Kajioka provided that the committee took no action on the request because of this advice.

No public comment was provided.

Request 2: From Walgreens For Pharmacies Making Total Parenteral Therapy (TPN)
Dr. Kajioka provided an overview of the request to exempt total parenteral nutritional labeling. He discussed that Walgreens has specialized pharmacies that prepare total parenteral nutritional products. Dr. Kajioka stated that during the discussion it was learned that these Walgreens specialty pharmacies are not accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), but by the Accreditation Commission for Health Care or ACHC. He advised that the exemption language in Business and Professions Code section 4076.5(e)(1)(A) only exempts pharmacies accredited by JCAHO from consideration for the labeling exemption; as such, Walgreen cannot qualify.

Dr. Kajioka provided that the board needs to determine if it wishes to expand the list of accrediting agencies in the Business and Professions Code 4076.5(e)(1)(A) that could qualify as an entity seeking an exemption for the patient-centered labeling requirements. He stated that this would require a statutory amendment. Dr. Kajioka suggested that Walgreens may also want to pursue such an amendment on its own.

Dr. Kajioka indicated that there is no recommendation from the committee.

Executive Officer Virginia Herold advised that it may be too late in the legislative year to move forward in this area. She discussed that this issue can be pursued by Walgreens independently.

Board Member Greg Lippe offered a proposal to instruct the committee to move to pursue statutory change to incorporate the additional accreditation agencies approved by the board.

Ms. Veale offered support to Mr. Lippe's proposal.

Mr. Room discussed that this proposal would require both a bill to change the statute as well as a regulation to grant the exemption.

Mr. Lippe amended his proposal to also include pursuit of the necessary regulation.

Board Member Ken Schell spoke in opposition to the proposal stating that the board has some resource issues for implementation. He offered support of the idea, but indicated that there may be higher priority issues.

The board discussed the balance of board staff workload and other issues before the board. It was suggested that a broad exemption be sought rather than granting one exemption specifically for Walgreens.

Mr. Lippe again amended his proposal to direct that this issue be returned back to the committee for further consideration.

No public comment was provided.

MOTION: To refer this issue back to the Enforcement Committee to develop the language necessary to add the additional accreditation agencies with sponsorship to be decided at a later date.

M/S: Lippe/Veale

Support: 5 Oppose: 4 Abstain: 1

Request 3: From CPhA's Long-Term Care Academy for Skilled Nursing Facilities
Dr. Kajioka provided that the committee had a detailed discussion with CPhA long-term care members about the method of drug distribution within skilled nursing facilities (SNFs), continuing discussions started at the prior Enforcement Committee and February 2011 Board Meeting. He stated that of particular concern to the committee was that if the exemption were provided to pharmacies dispensing drugs to skilled nursing facilities, how will the pharmacies, particularly those dispensing medications in the bingo cards that are often used in SNFs, be able to ensure that these discharged patients can readily read the labels when they leave the facility.

Dr. Kajioka provided that the labels must adhere to the labeling requirements if there is any opportunity for the medication to go home with the patient.

Dr. Kajioka provided that when reviewing the bingo-type cards in use in SNFs, the committee generally concluded that these cards should be labeled according to the patient-centered requirement because they are potentially likely to be taken home with patients because they may contain a seven or 30 day supply of drugs. He stated that the committee noted that there appears to be adequate space on the bingo cards to label the product according to the patient-centered requirements.

Dr. Kajioka provided that the committee agreed that unit-dose medications dispensed via an automated dispensing machine in SNFs could be exempt from the patient-centered labeling requirements.

Dr. Kajioka reviewed the motion from the committee to recommend an exemption to the patient-centered label requirements for unit dose medications dispensed via an automated dispensing machine in SNFs pursuant to Business and Professions Code section 4076.5(d).

Discussion
Ms. Shellans clarified that the exemption is being sought for unit-dose medications that are administered to the patient by a licensed healthcare professional.

The board discussed the committee's recommendation in light of the request. Concern was expressed that the recommendation does not specify that the exemption is specifically for medication that will not go home with the patient. The board asked for clarification on CPhA's request.

Mr. Room clarified that CPhA's initial request was for an exemption for all medications dispensed by a pharmacy to a SNF. He indicated that the committee felt that the request was only appropriate for unit-dose medication that would not go home with the patient.

Stan Goldenberg, representing CPhA, and Scott Hahn, representing Omnicare, provided an overview of emergency medications dispensed in SNFs. He discussed that this medication, usually a unit-dose, can come from an automated system or an e-kit. Mr. Goldenberg clarified that in both cases, no medication will go home with the patient. He also provided comment regarding new technology that pre-pours medications, as programmed by the contracting pharmacy, into an envelope to be administered by nursing staff to patients. Mr. Goldenberg stated that the envelopes are labeled to the patient according to the labeling laws previous to the patient-centered label regulation.

Mr. Goldenberg provided that the labels on bingo cards will be in a 10-point font, in compliance with the regulation. He discussed that the committee indicated that the patient can request a 12-point font at the time of the next refill post discharge from a SNF. He requested that, in the event the exemption is granted, the next issue of *The Script* include an article to clarify the exemption for the industry.

Mr. Room discussed two legally defensible possibilities regarding dispensing: (1) dispensing to the patient happens only once during the initial dispensing or (2) dispensing to the patient happens when the patient has an opportunity to comment on the dispensing transaction. He recommended that the board clarify what it considers a dispensing transaction to be by way of regulation.

Mr. Goldenberg discussed additional challenges with the overlay of new federal and insurance requirements that require dispensing in smaller doses. He also discussed the need for uniformity in labeling for licensed staff and the challenges faced with the relabeling of medication prior to discharge.

Board Member Deborah Veale cautioned the board from overanalyzing this issue. She reiterated that bingo cards will be dispensed with a label in a 10-point font and the patient will have the opportunity to request a 12-point font at the time of the next refill.

Board Member Ramón Castellblanch discussed that the population being discharged from SNFs are at a greater need for understanding and reading the information on the label. He provided that any medication that could go home with the patient, including bingo cards, should comply with the requirements of the regulation.

Mr. Goldenberg provided comment regarding patient discharge from SNFs and indicated that requiring relabeling of medication in a 12-point font prior to discharge will result in significant delays. He discussed that requiring a 12-point label for all medications would result in larger, costly packaging and would disrupt the established systems inside SNFs to ensure that patients receive the appropriate medication.

Dr. Castellblanch provided that the pharmacy industry has expressed similar concern; yet, is complying with the requirements. He expressed concern regarding the board's jurisdiction with regards to discharge in nursing homes and suggested that the board hear input from nursing home advocates on this issue.

Mr. Room discussed the board's limited authority under section 4076.5(d) which states that the board may not exempt prescriptions dispensed to a patient in a health facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility. He stated that the only way the requirement for 12-point font upon request will not be required is if the board determines that dispensing only occurs at the time of the initial dispensing and the request for 12-point font can be ignored. Mr. Room indicated that this is an interpretation, not an exemption.

President Weisser encouraged the board to consider what interpretation is in the best interest of the patient. He discussed that patient protection could be compromised if it is determined that no medications can go home at discharge.

Discussion continued. Concern was expressed regarding ownership of the medication while the patient is in a SNF and possible unintended consequences in the event the medication is withheld.

Ms. Shellans provided that regulations will need to be promulgated before any exemption can be granted. She stated that this discussion will be used for development of such regulations.

Dr. Kajioka suggested that this issue be returned to the Enforcement Committee for further review.

MOTION: Table action on the recommendation from the Enforcement Committee.

M/S: Schell/Lippe

Support: 10 Oppose: 0 Abstain: 0

The board recessed for a break at 11:01 a.m.

The board reconvened at 11:30 a.m.

The board suspended the Enforcement Report in order to recognize pharmacists in service for 50 years – Agenda item VII.

President Weisser recognized Kenneth Wedule and his wife Kathleen Wedule. Mr. Wedul graduated from North Dakota State in 1956 and became a licensed pharmacist

in California in 1961. He has owned ten stores in Orange County and currently works at Leisure World Pharmacy in Seal Beach. President Weisser presented Mr. Wedul with a 50-year pin.

The board resumed the Enforcement Report.

b. Discussion and Possible Action to Implement DCA's Recommendations of the Substance Abuse Coordination Committee, Pursuant to SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2011), as Board of Pharmacy Regulations

Report
Dr. Kajioka provided that 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.

Dr. Kajioka provided that 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.

Dr. Kajioka referenced the following standards.

1. Clinical diagnostic evaluation
    - Specifies that if a licensee in a diversion program or on probation is required to undergo a clinical evaluation it shall comply with :
        i. Qualifications for the licensed practitioner performing the evaluation
        ii. Acceptable standards for such evaluations
        iii. Identified elements of the report
        iv. Timeframes to complete the process and prohibition of the evaluator having a financial relationship, etc. with the licensee.
2. Temporary removal of practice for clinical evaluation
    - Specifies that board will issue a cease practice order during the evaluation and review of the results by board staff.
    - Specifies that the licensee will be subject to random drug testing at least two times per week.
    - Sets forth the evaluation criteria that must be considered by the diversion or probation manager when determining if a licensee is safe to return to work and under what conditions.
3. Communication with a licensee's employer, if applicable
    - Requires a licensee to notify the board of the names, physical addresses, mailing addresses and telephone numbers of all employers.

- Requires a licensee to give written consent authorizing the board and employers and supervisors to communicate regarding the licensee's work status, performance and monitoring.

4. Drug testing
    - Sets forth a minimum testing frequency of at least 52 random drug tests per year for the first year and a minimum of 36 random drug tests per year (from then on) and establishes some exceptions to this including:
        i. Previous testing/sobriety
        ii. Violations(s) that occur outside of employment (e.g. DUI)
        iii. Not working in health care field
        iv. Tolling
        v. Substance use disorder not diagnosed
    - Specifies that testing shall be observed; conducted on a random basis, as specified; and may be required on any day, including weekends or holidays.
    - Requires licensees to check daily to determine if testing is required and specifies that the drug test shall be completed on the same day as notification.
    - Establishes criteria for the collection sites and laboratories processing the results.
    - Establishes data collection and reporting requirements on every drug screen collected.
5. Group meeting attendance
    - Sets forth the evaluation criteria that must be considered when determining the frequency of group support meetings.
    - Specifies the qualifications and reporting requirements for the meeting facilitator.
6. Type of treatment
    - Sets for the evaluation criteria that must be considered when determining whether inpatient, outpatient, or other type of treatment is necessary.
7. Worksite monitoring
    - Allows for the use of worksite monitors.
    - Specifies the criteria for a worksite monitor.
    - Establishes the methods of monitoring that must be performed by the worksite monitor.
    - Sets forth the reporting requirements by the worksite monitor; specifies that any suspected substance abuse must be verbally reported to the board and the licensee's employer within one business day; and specifies that a written report must be provided to the board within 48 hours of the occurrence.
    - Requires the licensee to complete consent forms and sign an agreement with the worksite monitor and board to allow for communication.
8. Positive drug test
    - Requires the board to issue a cease practice order to a licensee's license and notify the licensee, employee and worksite monitor that the licensee may not work.
    - Specifies that after notification, the board should determine if the positive drug test is evidence of prohibited use and sets forth the criteria the board must follow when making such a determination.
    - Specifies that if the board determines that it was not a positive drug test, it shall immediately lift the cease practice order.
9. Ingestion of a banned substance

- Specifies that when a board confirms a positive drug test as evidence of use of a prohibited substance, the licensee has committed a major violation.

10. Consequences for major and minor violations
    - Specifies what constitutes a major violation including: failure to complete a board ordered program or undergo a clinical diagnostic evaluation; treating patients while under the influence of drugs/alcohol, and drug/alcohol related acts which would constitute a violation of the state/federal laws, failure to undergo drug testing, confirmed positive drug test, knowingly defrauding or attempting to defraud a drug test.
    - Specifies the consequences for a major violation including: issuing a cease practice order to the licensee; requiring a new clinical evaluation; termination of a contract/agreement; referral for disciplinary action.
    - Specifies what constitutes a minor violation including: untimely receipt of required documentation; unexcused group meeting absence; failure to contact a monitor when required; any other violations that does not present an immediate threat to the violator or the public.
    - Specifies the consequences for a minor violation including: removal from practice; practice restrictions; required supervision; increased documentation; issuance of a citation and fine or working notice; re-evaluation/testing; other actions as determined by the board.
11. Return to full time practice
    - Establishes the criteria to return to full time practice, including demonstrated sustained compliance, demonstrated ability to practice safely, negative drug screens for at least six months, two positive worksite monitor reports and compliance with other terms and conditions of the program.
12. Unrestricted practice
    - Establishes the criteria for a licensee to request unrestricted practice including sustained compliance with a disciplinary order, successful completion of the recovery program, consistent and sustained participation in recovery activities, demonstrated ability to practice safely and continued sobriety of three to five years, as specified.
13. Private-sector vendor
    - Specifies that the vendor must report any major violation to the board within one business day and any minor violation within five business days.
    - Establishes the approval process for providers or contractors that work with the vendor consistent with the uniform standards.
    - Requires the vendor to discontinue the use of providers or contractors that fail to provide effective or timely services as specified.
14. Confidentiality
    - For any participant in a diversion program whose license is on an inactive status or has practice restrictions, requires the board to disclose the licensee's name and a detailed description of any practice restrictions imposed.
    - Specifies that the disclosure will not include that the restrictions are as a result of the licensee's participation in a diversion program.
15. Audits of private-sector vendor
    - Requires an external independent audit every three years of a private-sector vendor providing monitoring services.

- Specifies that the audit must assess the vendor's performance in adhering to the uniform standards and requires the reviewer to provide a report to the board by June 30 of each three year cycle.
- Requires the board and department to respond to the findings of the audit report.

16. Measurable criteria for standards
    - Establishing annual reporting to the department and Legislature and details the information that must be provided in the report.
    - Sets forth the criteria to determine if the program protects patients from harm and is effective in assisting licensees in recovering from substance abuse in the long term.

Dr. Kajioka reviewed the committee discussion and action on this item. He stated that the committee discussed in general the uniform standards as well as the process used to develop them. Dr. Kajioka provided that the committee was advised that some of the proposed changes to the Disciplinary Guidelines would facilitate implementation of portions of these standards.

Dr. Kajioka reviewed the recommendation from the committee to direct staff to develop regulatory language to modify the Disciplinary Guidelines to implement the SB 1441 standards.

Dr. Kajioka provided that the most recent version of the standards was approved in April 2011. He referenced a copy of the standards in their current form as well as the proposed changes that have been identified and drafted thus far for board consideration to incorporate into the board's Disciplinary Guidelines that were provided in the meeting materials.

Dr. Kajioka discussed that the board is seeking clarification regarding whether the new administration will have the same focus on this initiative.

Discussion

Mr. Room reviewed potential revisions to the board's Disciplinary Guidelines to incorporate the standards, staff proposals, and edits made by the subcommittee (provided as an attachment in the meeting materials). He advised that the document currently only covers four standards which have the most significant impact on the board's Disciplinary Guidelines. Mr. Room stated that the finalized document will be brought to the Enforcement Committee.

Ms. Herold commended Mr. Room for his work on this document. She recommended that the Enforcement Committee review the document upon completion. Ms. Herold advised that this will be a full day process.

Dr. Schell spoke in support of the committee's recommendation and reviewing the completed document in its entirety.

Kimberly Kirchmeyer, DCA Deputy Director of Board and Bureau Relations, also commended Mr. Room for his work on the document. She discussed the Legislature's

intent to set minimum standards and advised that some of the edits made by the subcommittee may be going below the minimum standards. Ms. Kirchmeyer stated that the board should maintain the minimum standards as intended by the Legislature. She advised that the subcommittee's edits to the drug testing standard does not meet the minimum standard.

Ms. Shellans provided that she has a different interpretation of how the board should incorporate the standards. She stated that the board is charged with setting the standards for its programs and has discretion in this area. Ms. Shellans stated that the statute only requires the board to use the standards that were developed by the SACC.

Ms. Shellans recommended that the board start its process with the standards as written by the SACC and assess how and if these standards could be implemented. She advised that the statute does not define a "substance abusing licensee." Ms. Shellans suggested that the board define this term for its program and determine when the standards could be used.

Dr. Schell recommended that the board leave the document as is for its review and as a means to provide a historical perspective of the work that has been completed.

Mr. Room discussed that if the board chooses to follow Ms. Shellan's recommendation, the committee edits can be deleted from the document. He suggested that the board operate from the initial presumption that anything edited by the subcommittee should revert to its initial drafting unless the board agrees to adopt the subcommittee's recommendation.

Dr. Schell discussed that the board has been advised not to implement any standard below the minimum standard approved by the SACC.

Ms. Herold suggested that maintaining the edits by the subcommittee in the document will help to identify standards that deserve careful consideration.

No public comment was provided.

MOTION: ENFORCEMENT COMMITTEE: Direct staff to develop regulatory language to modify the Disciplinary Guidelines to implement the SB 1441 standards.

Support: 10 Oppose: 0 Abstain: 0

Dr. Castellblanch left the meeting room at 11:52 p.m.

c. Questions and Answers from the Public on the Board's Implementation of 16 California Code of Regulations Sections 1735-1735.8, Pharmacies That Compound, and Sections 1751-1751.8, Pharmacies That Compound Sterile Injectable Medications

Report
Dr. Kajioka provided that effective July 7, 2010, new and amended regulations took effect regarding pharmacies that compound medications as well as pharmacies that compound sterile injectable medications.

Dr. Kajioka provided that since the approval of these regulations, board staff has been educating licensees on the requirements. He stated that additionally, during Enforcement Committee meetings, Supervising Inspector Robert Ratcliff has been providing a question and answer session on the new compounding regulations.

Dr. Kajioka provided that during the October 2010 Board Meeting, the board voted to create a subcommittee to further vet the questions and answers received thus far, as well as to respond to any new questions.

Dr. Kajioka provided that the subcommittee, comprised of Dr. Kajioka, Dr. Schell, Dr. Dang, Dr. Ratcliff and Ms. Herold met January 5, 2011.

Dr. Kajioka provided that the questions and answers are posted on the board's Web site.

Dr. Kajioka provided that the committee discussed the Q&A's and requested that future questions be submitted in writing and forwarded to the subcommittee to evaluate.

Dr. Kajioka provided that the committee did not take action on this item.

Dr. Kajioka advised that the board has not received any additional items.

No public comment was provided.

d. Minutes of the Meeting Held March 29, 2011

The minutes of the meeting held on March 29, 2011 are provided in the meeting materials.

There was no board discussion or public comment provided on this item.

Other Enforcement Committee Items

e. Discussion on the President's Comments to the Federal Food and Drug Administration Pursuant to Determination of System Attributes for Tracking and Tracing of Prescription Drugs; Public Workshop (Document ID FDA-2010-N-0633-001)

Report

Dr. Kajioka provided that California law has the strongest pharmaceutical supply chain security requirements of any state. He indicated that these provisions require that for almost any prescription drug sold in California, that an electronic pedigree be established that starts with the manufacturer and that traces any changes in ownership until the drug reaches a pharmacy. Dr. Kajioka stated that the requirements will take effect over a 2.5 year period from 2015 through 2017. Dr. Kajioka provided that California's laws in this area were enacted in 2004, and amended in 2006 and 2008. He discussed that California is viewed as the leader in this area, and the provisions in our law originate with a 2004 FDA Counterfeit Task Force Report.

Dr. Kajioka provided that during the March 2011 Board Meeting, the board discussed the opportunity to provide comments to the FDA on its proposal. He stated that during the meeting the board directed staff to draft a response to the FDA regarding the components of California's requirements for the tracking and tracing of prescription drugs to be reviewed by the board president, and upon completion, provide a copy to the members of the board.

Dr. Kajioka provided that comments were drafted and approved for release, however because of the timing, the comments were not submitted. He advised that the FDA needs to reopen the docket to allow for additional comments to be submitted because of some procedural issues. Dr. Kajioka indicated that the board's comments will be submitted when the docket is reopened.

Dr. Kajioka referenced the summary from the FDA detailing the comments from its February 2011 workshop as well as the comments the board will be submitting provided in the meeting materials.

No public comment was provided.

f. Discussion on CalRecycle's Report to the Legislature "Recommendations for Home-Generated Pharmaceutical Collection Programs in California"

Report

Dr. Kajioka provided that California's Senate Bill 966 passed in 2007 and required CalRecycle to work with other state agencies and stakeholders to develop voluntary Model Guidelines for home-generated pharmaceutical collection programs, then report to the Legislature with recommendations for the potential implementation of a statewide program and statutory changes.

Dr. Kajioka provided that during the February 2011 Board Meeting, the board discussed the previously released report from CalRecycle and decided not to submit comments to the legislature on this earlier report.

Dr. Kajioka provided that the DEA hosted a Drug Take-Back Day on April 30, 2011.

Dr. Kajioka provided that the report completed by CalRecycle is now available. He reviewed the following key findings noted by CalRecycle in its announcement including:

- Based on survey results (with an 86 percent response rate), CalRecycle found that local governments currently fund more than 80 percent of collection programs in California and pharmacies fund another 15 percent.
- CalRecycle found that only about one-third of existing programs in California met the voluntary Model Guidelines. Of the major types of programs (law enforcement collection, pharmacy collection, household hazardous waste collection, periodic collection "events," and mail-back programs), each has advantages and barriers in being able to meet the voluntary Model Guidelines.
- CalRecycle recommends the Legislature adopt a combination of two options:
  - "Establish Clear State Agency Roles and Responsibilities, Improve Model Guidelines and Enforcement, and Convert Guidelines to Regulation" and
  - "Implement Product Stewardship"

Discussion

Ms. Herold encouraged the board to read this report. She discussed provisions in SB 431 regarding the definitions for "reverse distributor" and "hazardous waste hauler." Ms. Herold discussed that there is concern from some in the waste management community that defining these terms in pharmacy law may inhibit the development of take-back programs.

No public comment was provided.

g. Selection of Enforcement Committee Meeting Dates for 2011

The members of the Enforcement Committee discussed their availability for the following dates. The final dates will be confirmed and posted on the board's Web site.

June 6, 2011 or June 20 – 24, 2011
September 6 – 9, 2011 or September 12-16, 2011
December 5 – 9, 2011

h. Review of Enforcement Statistics and Performance Standards of the Board

The board's enforcement statistics as well as the Department's performance standards report for the board are provided in the meeting materials.

There was no board discussion or public comment provided on this item.

i. Third Quarterly Update of the Committee's Strategic Performance Goals for 2010/11

The third quarter report on the committee's strategic plan are provided in the meeting materials.

There was no board discussion or public comment provided on this item.

V. REPORT OF THE DIRECTOR OF THE DEPARTMENT OF CONSUMER AFFAIRS

Kimberley Kirchmeyer, DCA Deputy Director of Board and Bureau Relations, provided an update on projects and matters of interest on behalf of Director Brian Stiger. She thanked the board and board staff for its continued support of department projects.

Ms. Kirchmeyer discussed the hiring freeze ordered by Governor Brown on February 15, 2011 and the exemption request process. She reported that the board has been approved for two freeze exemptions, totaling eight staff.

Ms. Kirchmeyer discussed the executive order restricting travel that was issued on April 26, 2011. She stated that the department is waiting for more guidelines from the Department of Finance and will work with the boards to comply with this order. Ms. Kirchmeyer advised that board and committee meetings are allowed as they are statutorily required and fit into the criteria of "mission critical." She encouraged the board to limit the number of staff attending meetings, to evaluate the most cost effective meeting locations, and to consider the use of video conferencing and teleconferencing.

Ms. Kirchmeyer discussed the Consumer Protection Enforcement Initiative (CPEI) and thanked the board for including its performance measurements in the meeting materials for this meeting. She indicated that the department is asking that all boards submit an enforcement program update. Ms. Kirchmeyer stated that the department will provide a more extensive enforcement report at a future meeting.

Ms. Kirchmeyer encouraged the board to implement the SB 1441 standards and to incorporate the necessary language into regulation.

Ms. Kirchmeyer discussed the vehicle reduction executive order. She stated that the department will work with board staff to ensure that this does not hinder the productivity of the board's inspectors. Ms. Kirchmeyer provided that the department believes that vehicles are necessary for Board of Pharmacy inspectors.

Ms. Kirchmeyer provided an update on the contract process for the BreEZe program. She advised that the department is undergoing negotiations with the vendor and the final contract should be secured between May and August 2011 for implementation in 2012.

Ms. Herold thanked Ms. Kirchmeyer for her support. She also thanked Ms. Sodergren for her role in securing hiring freeze exemptions for the board.

Ms. Herold discussed that board inspectors use state cars to conduct inspections and investigations. She advised that it is less expensive to purchase and maintain a car than to reimburse mileage for use of personal cars on state business.

No public comment was provided.

The board recessed for a lunch break at 12:25 p.m.

The board reconvened at 1:28 p.m. Dr. Castellblanch and Mr. Brooks were not present.

VI. LICENSING COMMITTEE REPORT

Report of the Meeting Held March 8, 2011

a. Update on the Board's Psychometric Evaluation of the ExCPT and PTCB Examinations

Report

Mr. Lippe provided that Business and Professions Code section 4202 establishes the requirements for licensure as a pharmacy technician. He discussed that there are several routes to licensure including the following:

- Obtain an associates degree in pharmacy technology
- Completion of a technician training course
- Graduation from a school of pharmacy recognized by the board
- Certification by the Pharmacy Technician Certification board

Mr. Lippe provided that Business and Professions Code section 139 requires a psychometric assessment description of the occupational analysis serving as the basis

for the examination and an assessment of the appropriateness of prerequisites for admittance to the examination.

Mr. Lippe provided that last year the board was advised that the department's Office of Professional Examination Services (OPES) will conduct these evaluations for the board which should be completed by June 30, 2011.

Mr. Lippe provided that the committee was advised that board staff recently signed an interagency agreement with the OPES. He stated that it will cost approximately $24,000.

No public comment was provided.

b. Continued Discussion About a Proposal to Specify Continuing Education Credit for Pharmacists in Specific Content Areas

Report

Mr. Lippe provided that Business and Professions Code section 4231 requires a pharmacist to earn 30 hours of approved continuing education credit every two years as a condition of renewal.

Dr. Castellblanch and Mr. Brooks returned to the meeting room at 1:31 p.m.

Mr. Lippe provided that Business and Professions Code section 4232 specifies that content of courses that will be acceptable including the following:

- Pharmacology
- Biochemistry
- Physiology
- Pharmaceutical chemistry
- Pharmacy Administration
- Pharmacy Jurisprudence
- Public health and communicable diseases
- Professional practice management
- Anatomy
- Histology

Mr. Lippe provided that at several prior meetings of the board or its committees, there has been general discussion about developing requirements for pharmacists to earn CE in specific subject matter areas. He advised that to establish such a requirement would take either a legislative or regulation change.

Mr. Lippe provided that prior discussions have included possible mandatory CE in emergency/disaster response, patient consultation, drug abuse or in maintaining control of a pharmacy's drug inventory.

Mr. Lippe provided that the committee heard a presentation from two pharmacy directors of California counties' emergency response team and how such a topic would be applicable as an appropriate mandatory CE course. He reviewed additional suggested topics also brought to the committee for consideration included the following:

- Emergency/Disaster Response
- Patient Consultation
- Maintaining Control of a Pharmacy's Drug Inventory
- Ethics
- Drug Abuse
- Defined Content Areas

Mr. Lippe provided that the committee will continue to review this issue. He stated that if appropriate, the committee will also determine if the CE course should mandate how the course is provided (e.g. live, web-based, journal, etc.).

Mr. Lippe referenced the information from the Accreditation Council for Pharmacy Education on continuing education for pharmacists as well as a CE comparison chart, developed by the Department of Consumer Affairs provided in the meeting materials.

Discussion

Ms. Herold discussed a bill that would have required physicians, regardless of their practice setting, to take units in general nutrition. She stated that this bill was not well received by the committee as there was concern that this specific topic may not be applicable to all practice settings. Ms. Herold advised that the board should be prepared to address similar concerns if it chooses to proceed in this area.

No public comment was provided.

c. Discussion About a Request to Modify 16 California Code of Regulations Section 1732.2 Regarding Continuing Education Credit for Pharmacists Gaining Certification by the Board of Pharmacy Specialties

Report

Mr. Lippe provided that CCR 1732.2 allows a pharmacist to petition the board to allow continuing education credit and specifies that coursework meeting the standard of relevance to pharmacy practice that has been approved by specified healing arts board is also acceptable to the board.

Mr. Lippe provided that the board voted to pursue amendment to California Code of Regulations Section 1732.2 to grant continuing education credit for various types of pharmacist activities, including attending a board or committee meeting, being certified by the Commission for Certification in Geriatric Pharmacy or for certain activities as a Competency Committee member.

Mr. Lippe provided that since that time, the executive officer was advised that there are other certifications that some pharmacists earn that perhaps should be considered as fulfilling portions of the CE requirements for renewal of a pharmacist license. He stated that if the board determines it wishes to add these components in the future, it will need to be done as a new rulemaking to section 1732.2.

Mr. Lippe referenced the following additional areas for board consideration that could also be incorporated into this section.

1. Menopause Practitioner Examination - interdisciplinary examination available from NAMS (The North American Menopause Society) (www.menopause.org)
2. Board of Pharmacy Specialties (BPS) has recognized six specialty practice areas: note –these certification examinations also require recertification every 7 years (re-certification by examination should also be permitted for credit) (www.bpsweb.org)
    - Ambulatory Care Pharmacy (2011)
      Includes the provision of integrated, accessible healthcare services by pharmacists who are accountable for addressing medication needs, developing sustained partnerships with patients, and participating in the context of family and community.
    - Nuclear Pharmacy (1978)
      Specialists seek to improve and promote the public's health through the safe and effective use of radioactive drugs for diagnosis and therapy.
    - Nutrition Support Pharmacy (1988)
      Specialists promote the maintenance and/or restoration of optimal nutritional status, designing and modifying treatment according to the needs of the patient.
    - Oncology Pharmacy (1996)
      Specialists recommend, design, implement, monitor and modify pharmacotherapeutic plans to optimize outcomes in patients with malignant diseases.
    - Pharmacotherapy (1988)
      Specialists are responsible for ensuring the safe, appropriate, and economical use of drugs in patient care and frequently serve as a primary source of drug information for other health care organizations.
    - Psychiatric Pharmacy (1992)
      Specialists address the pharmaceutical care of patients with psychiatric disorders.

Mr. Lippe referenced the copy of the proposed regulation language provided in the meeting materials. He stated that the 15-day comment period for this proposal concluded on February 21, 2011.

Discussion
Ms. Shellans provided that if the board would like to pursue any of these options it can direct staff to draft proposed regulatory language to further amend section 1732.2 to be brought back to the board for consideration.

Ms. Veale provided that the committee discussed that incorporating these additional areas would be consistent with the board's intent to amend this section. She proposed that the board move forward with adding these additional options.

Ms. Herold suggested that the board halt the existing regulation and instead pursue all of the modifications to this section after other higher-priority regulations are finalized.

Ms. Herold discussed that the board may also want to evaluate whether too many CE units are being awarded for attending board meetings.

Ms. Veale offered a proposal to refer this matter back to the committee for further consideration as well as to consider the board's current policy to award CE for attendance at board meetings.

Dr. Schell provided comment in support of the motion. He suggested that these programs be evaluated to ensure that the requirements are consistent.

Public Comment
Darlene Fujimoto, representing UCSD, sought clarification regarding the intent of this proposal.

Ms. Herold clarified that certification in one of these specialties would be considered as fulfilling portions of the CE requirements for renewal of a pharmacist license. She discussed that training in these areas, specifically in the area of geriatrics, has been recognized as beneficial to the public.

Dr. Schell clarified that it is not intended that the board will be accrediting these agencies.

MOTION: To direct staff to draft proposed regulatory language to further amend section 1732.2 to be brought back to the board for consideration and to evaluate the board's current policy to award CE for attendance at board meetings.

M/S: Veale/Lippe

Support: 10 Oppose: 0 Abstain: 0

d. Update on the Board's Efforts to Implement 16 California Code of Regulations Section 1702, Mandatory Submission of Fingerprints for Pharmacists

Report
Mr. Lippe provided that California Code of Regulations 1702 establishes new renewal requirements for pharmacists.

Mr. Lippe provided that the regulation specifies that as a condition of renewal, a pharmacist must disclose on the renewal form any arrest or conviction since the licensee's last renewal; that a pharmacist applicant must pay the actual cost of compliance with the submission of fingerprints; a requirement that the licensee retain proof of compliance, as specified; and that failure to comply with the fingerprint requirement will result in an application for renewal being considered incomplete. He stated that this regulation was approved by the Office of Administrative Law and took effect December 7, 2010.

Mr. Lippe provided that the board was previously advised that because of staff reductions with the Department of Justice, implementation on the electronic fingerprint submissions would be delayed until the necessary program changes could be implemented.

Mr. Lippe provided that the committee was advised that the necessary changes are now in place and that staff would draft letters that will be sent to all affected licensees advising them about the regulation change as well as providing them with the necessary forms. He stated that pharmacists will be advised to retain a copy of their livescan form or other receipt confirming compliance with this provision.

Mr. Lippe advised that implementation of the arrest and conviction disclosure requirements was not delayed.

Mr. Lippe provided that board staff developed the letter to be sent to affected licensees. He stated that this letter is currently undergoing review by the department.

No public comment was provided.

e. Discussion Concerning DCA's Focus on Continuing Competency

Report
Mr. Lippe provided that several months ago, DCA Director Stiger indicated that the Department of Consumer Affairs has an initiative underway to promote that all health care boards initiate periodic assessment of continuing competency in their licensed practitioners.

Mr. Lippe provided that continuing competency assessment requires periodic evaluation (and perhaps re-testing) of licensed providers to ensure they are maintaining their skills necessary to practice safely.

Mr. Lippe provided that during the meeting, Cindy Kanemoto, representing the DCA discussed different pathways to complete a continuing competency requirement. He indicated that Ms. Kanemoto stated that the competencies for a profession as well as the board certification requirements must first be identified. Ms. Kanemoto reviewed a five step model including a self evaluation, peer assessment, and a professional development plan. Mr. Lippe discussed that Ms. Kanemoto emphasized that this process is different than just earning CE credit.

Mr. Lippe provided that during the director's monthly conference call with board presidents and board chairs, Mr. David Swankin, CEO of the Citizen Advocacy Center (CAC) and Dr. Martin Crane, former Chair of the Federation of State Medical Boards (FSMB) provided information on this issue.

Mr. Lippe referenced a copy of the Proceedings from the Continuing Competency session at the CAC's annual meeting, held in November 2010, provided in the meeting materials.

Discussion

Dr. Castellblanch asked how this will be implemented.

President Weisser requested that Kimberly Kirchmeyer provide a synopsis of the conference call.

Ms. Kirchmeyer discussed that the board will need to determine how and if it will implement the continuing competency requirement. She advised that there is not a lot of research on how to implement requirements in this area for pharmacists. Ms. Kirchmeyer stated that the overall goal is that the licensee begin with a self-assessment, identify deficient areas, and then find courses that meet these deficient areas. She indicated that there are many others ways other than testing to implement continuing competency.

Board Member Ryan Brooks asked whether this initiative was developed in response to any identified deficient areas for pharmacists. He expressed concern that the board may be creating a solution for a problem that is unknown.

Ms. Kirchmeyer indicated that this initiative is not specific to pharmacy. She discussed study findings that indicated that course related continuing education may not be the most appropriate means for further educating licensees. Ms. Kirchmeyer provided that from her perspective, anytime disciplinary action is taken there is a need for education of licensees.

Mr. Lippe discussed that most of the board's disciplinary actions are regarding diversion and theft issues, and not necessarily issues regarding competency.

Dr. Schell discussed that the board should evaluate whether 30 hours every two years is an appropriate indicator of competency.

Ms. Herold provided that the National Association of Boards of Pharmacy (NABP) previously offered a practice/pharmacy knowledge self assessment to pharmacists on a voluntary basis. She stated that this assessment was discontinued due to a lack of use. Ms. Herold indicated that NABP is developing a new assessment mechanism that will be discussed at the July 2011 Board Meeting.

Ms. Kirchmeyer provided that NABP may be able to provide information regarding whether a continuing competency requirement is needed for pharmacists.

Public Comment
Larry Drechsler spoke in opposition to the retesting of pharmacists. He expressed concern regarding the CE requirements for new graduates. Mr. Drechsler also expressed concern regarding the certification and administration of a test to evaluate pharmacist competency as well as the cost involved.

f. Discussion of the Office of Statewide Health Planning and Development's Manpower Assessment and Survey of Licensees

Mr. Lippe provided that as part of Senate Bill 139 (Chapter 522, Statutes of 2007) the Office of statewide Health Planning and Development (OSHPD) was directed to establish the California Healthcare Workforce Clearinghouse (Clearinghouse) to serve as the central source for collection, analysis, and distribution of information on the healthcare workforce employment and educational data trends for the state.

Mr. Lippe stated that specifically the bill included a provision that OSHPD work with the Employment Development Department's Labor Market Information Division, state licensing boards, and state higher education entities to collect, to the extent available, all of the following data:

(a) The current supply of health care workers, by specialty.
(b) The geographical distribution of health care workers, by specialty.
(c) The diversity of the health care workforce, by specialty, including, but not necessarily limited to, data on race, ethnicity, and languages spoken.
(d) The current and forecasted demand for health care workers, by specialty.
(e) The educational capacity to produce trained, certified, and licensed health care workers, by specialty and by geographical distribution, including, but not necessarily limited to, the number of educational slots, the number of enrollments, the attrition rate, and wait time to enter the program of study.

Mr. Lippe provided that DCA Director Brian Stiger is encouraging all boards to collect the necessary information to assist OSHPD in their charge to, among other items, serve as the repository for comprehensive data and standardize data collection tools and methods.

Mr. Lippe provided that many of the boards within the DCA, including the Board of Pharmacy, do not collect several of the data elements being requested by OSHPD. He stated that the Medical Board developed a survey that is designed to collect several elements. Mr. Lippe indicated that the survey is provided to licensees along with their renewal application and the results will be provided to OSHPD.

Mr. Lippe provided that board staff indicated that mandating submission of this information would require either a regulation and/or statutory change. He stated that board staff suggested that the board consider development of a survey that could be accessed from the board's Web site. Mr. Lippe discussed that an on-line resource such as Survey Monkey, could serve as an easy collection method that would have minimal impact on board staff.

Mr. Lippe provided that Cindy Kanemoto, representing the DCA at the Licensing Committee Meeting, shared that she has recommended that OSHPD create the survey and also house the data. She stated that the board could provide a link on its Web site to the survey. Ms. Kanemoto had advised that the licensees would be directly inputting the information to OSHPD and the board would still have access to the data. She provided that the department is exploring this option as an interim solution until the implementation of the BreEZe system.

Mr. Lippe referenced a copy of a fact sheet on the Healthcare Workforce Clearinghouse as well as the draft survey that will be used by the Medical Board provided in the meeting materials.

No public comment was provided.

g. Discussion Regarding the Licensing Committee Presentation by the Emergency Management Services Agency on the Role and Involvement of Pharmacists in Emergency Response in California

Mr. Lippe provided that during the meeting, Patrick Lynch, representing the Emergency Medical Services Authority (EMSA), provided an overview of the Emergency System for the Advance Registration of Volunteer Health Professionals (ESAR-VHP), a registration system for healthcare professionals to volunteer in the event of a significant disaster or a public health emergency. He stated that Mr. Lynch discussed that volunteers are verified with the appropriate licensing board, assessed for whether or not they are actively practicing, and are added to the statewide registry. Mr. Lynch stated that during a disaster, state or local officials will determine what kind of health professionals are needed, search the database for available volunteers, and send an alert to selected members via email, telephone and pager.

Mr. Lippe provided that it was indicated that there are currently 515 pharmacists, 105 pharmacist interns, and 18 pharmacy technicians registered in the system.

Mr. Lippe referenced a copy of the board's emergency response policy as well as an informational brochure on registering to become an emergency responder provided in the meeting materials.

Discussion
Mr. Lippe discussed the lower number of technicians registered in the system.

Ms. Veale suggested that technicians may not know that this opportunity is available.

No public comment was provided.

h. Competency Committee Report

California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)
Mr. Lippe stated that effective April 1, 2011, the board instituted a quality assurance review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). He stated that this means that there will be a delay in the release of all CPJE examination scores. Mr. Lippe explained that this process is done periodically to ensure the reliability of the examination. He indicated that the board will release scores as soon as possible. Mr. Lippe stated that based on historical patterns, the board anticipates results being released approximately August 2011.

Mr. Lippe provided that the board encourages all qualified applicants to continue to schedule and take the CPJE exam. He stated that the greater the number of applicants who take the exam during this review period, the sooner results can be released.

CPJE Statistics

Mr. Lippe referenced CPJE statistics for April 1, 2010, through September 30, 2010, provided in the meeting materials. The CPJE statistics for October 1, 2010, through March 31, 2011, were available in the board meeting materials and will be placed online.

Examination Development

Chair Lippe provided that both Competency Committee workgroups had meetings in the spring of 2011 to work on examination development. He stated that the Competency Committee has ensured the new outline was used to develop examinations administered after April 1, 2011.

Chair Lippe provided that board staff has updated the CPJE Candidate Information Bulletin and board Web site to reflect the new content outline as well as notified candidates eligible to take the CPJE.

Ms. Herold reviewed the overall pass rates for the CPJE and NAPLEX.

No public comment was provided.

i. Minutes of the Meeting Held March 8, 2011

The minutes of the meeting held on March 8, 2011 are provided in the meeting materials.

There was no board discussion or public comment for this item.

Other Licensing Committee Items

j. Discussion Regarding the Joint Board of Pharmacy/Drug Enforcement Administration Conference on "Drug Security for Pharmacies" Held in Los Angeles April 12, 2011 in Los Angeles , and Discussion and Possible Approval to Award Continuing Education Credit for Future Joint Conferences in Southern California

Mr. Lippe provided that on April 12, 2011, the DEA and Board cosponsored a one-day conference in Los Angeles titled "Diversion of Controlled Substances, What Every Pharmacist Should Know to Prevent Diversion." He stated that the conference was held at the DEA Los Angeles Office in downtown LA. Mr. Lippe referenced a copy of the agenda provided in the meeting materials.

Mr. Lippe provided that at the March 2011 Board Meeting, the board awarded 5 units of CE credit for those who attended. He stated that the board released a subscriber alert after this meeting, with less than two weeks before the conference, the only publicity

really done. Mr. Lippe indicated that the conference had 120 participants who were able to fit, somewhat uncomfortably, within the conference room.

Mr. Lippe provided that the board developed the following learning criteria for the continuing education credit:

- Identify CII-V controlled substances commonly abused in the Los Angeles area
- Know how to access CURES data for a pharmacy's patients
- Identify ways to keep controlled substances more secure in a pharmacy
- Identify 3 new parameters for evaluating pharmacist's corresponding responsibility
- Identify responsibilities of dispensing prescription drugs via the Internet
- Articulate the dangers of the use, abuse and addiction of controlled substance by teenagers

Mr. Lippe provided that there were 71 evaluation responses received, and the comments were generally highly favorable. He reviewed the following evaluation results:

	1 Needs Work	2	3 Satisfactory	4	5 Great
Overall Conference		1	11	25	11
Topics Timely & Relevant			10	23	39
Facility	2	5	19	22	24
Quality of Speakers		2	12	20	39

Mr. Lippe provided that the DEA and board staff hope to hold additional sessions in the future in LA. He advised that the travel restrictions now in place may limit this.

Mr. Lippe provided that the board's staff request the board's approval to award 5 hours of CE credit should additional sessions of this conference be provided in the future. He offered a proposal to the board to grant this request.

Dr. Kajioka suggested that the board consider working with the northern California DEA to also offer a similar conference in northern California.

President Weisser provided that the conference was very educational and informational and is a good opportunity to award CE credits.

Ms. Herold discussed that a strong relationship with the DEA helps the board to fulfill its consumer protection mandate.

Public Comment
John Jones encouraged physician involvement and participation by the Medical Board in this process.

MOTION: To award 5 hours of continuing education credit for future joint Board of Pharmacy/Drug Enforcement Administration conferences on "Drug Security for Pharmacies."

M/S: Lippe/Kahoka

Support: 10 Oppose: 0 Abstain: 0

k. Selection of Licensing Committee Meeting Dates for 2011

The members of the Licensing Committee discussed their availability for the following dates. The final dates will be confirmed and posted on the board's Web site.

June 6, 2011 or June 20 – 24, 2011
September 6 – 9, 2011 or September 12-16, 2011
December 5 – 9, 2011

No public comment was provided.

l. Licensing Statistics for 2010/11

The licensing statistics for third quarter 2010/11 were provided in the meeting materials.

There was no board discussion or public comment on this item.

m. Third Quarterly Update of Strategic Plan for the Licensing Committee

The third quarterly report on the Licensing Committee's goals was provided in the meeting materials.

There was no board discussion or public comment on this item.

VII. RECOGNITION AND CELEBRATION OF PHARMACISTS LICENSED FOR 50 YEARS IN CALIFORNIA

This agenda item was taken out of order during the Enforcement Report due to time restraints.

VIII. LEGISLATION AND REGULATION COMMITTEE

PART I – REGULATIONS

a. For Board Discussion and Possible Action to Modify Proposed Changes
Amend Title 16 Sections 1715, 1784, 1735.2, and 1751– Update of Self-Assessment Forms for Pharmacies, Sterile Injectable Compounding Pharmacies, Hospitals and Wholesalers
[45-day comment period: March 11 – April 25, 2011]

Report
Dr. Schell provided that based on the comments received, staff recommends that the board adopt the proposed regulation to amend Title 16 Sections 1715, 1735.2, 1751 and 1784 and the self-assessment forms that are incorporated by reference; and direct staff to take all steps necessary to complete the rulemaking process, including filing of the final rulemaking package with the Office of Administrative Law, delegate to the Executive Officer the authority to make any non-substantive changes to the proposed regulations and forms incorporated by reference, and adopt the proposed regulations at Sections 1715, 1735.2, 1751 and 1784 as described in the Notice with general non-substantive changes described by staff at this meeting.

Dr. Schell offered a proposal to approve this recommendation.

Carolyn Klein, Legislation and Regulation Manager, provided an overview of the four comments received during the 45-day comment period. She indicated that a copy of each comment was provided in the materials provided to the board, and that the board's response to each will be provided in the Final Statement of Reasons. She stated that the board also received comments that were not specifically directed at the board's proposed action.

Regarding the patient-centered labeling requirements established in statute and in regulation, Ms. Klein indicated that one commenter objected to the references being included in Form 17M-39, asserting that proposed additions related to the patient-centered labeling regulations was not applicable to compounding. Another commenter objected to these same references being added to section 21 of Form 17M-14, stating the references were duplicative or unnecessary. Ms. Klein referenced the applicable regulatory and statutory references which supported the inclusion of the proposed language, and stated that the Final Statement of Reasons would indicate why the references were necessary.

Ms. Klein referenced a comment that pointed out a typographical or printing error, and another that provided suggestions for formatting changes to provide the reader with a way to easily identify items within a form. Ms. Klein indicated that changes related to renumbering, typographical errors, updating references, or revising grammar or

punctuation could be deemed to be without regulatory effect (i.e., non-substantive) and would be responsive to these types of comments.

No public comment was provided.

MOTION: Adopt the proposed regulation to amend Title 16 Sections 1715, 1735.2, 1751 and 1784 and the self-assessment forms that are incorporated by reference (Forms 17M-13, 17M-14, 17M-26 and 17M-39); and direct staff to take all steps necessary to complete the rulemaking process, including filing of the final rulemaking package with the Office of Administrative Law, delegate to the Executive Officer the authority to make any non-substantive changes to the proposed regulations and forms incorporated by reference, and adopt the proposed regulations at Sections 1715, 1735.2, 1751 and 1784 as described in the Notice with general, non-substantive changes described by staff at this meeting.

M/S: Schell/Veale

Support: 10 Oppose: 0 Abstain: 0

Ms. Herold stated that the requirement to complete the self-assessment form becomes effective July 1, 2011. She advised that in the event the rulemaking is not finalized by this date, a subscriber alert will be sent to licensees and the requirement will not be enforced until the rulemaking becomes final.

b. Board Approved Regulations – Rulemaking File Being Compiled
Amend Title 16 CCR Section 1732.2 – Board Accredited Continuing Education

Report
Dr. Schell provided that at the February 2010 Board Meeting, the board voted to initiate the rulemaking process to amend 16 CCR § 1732.2. related to board-accredited continuing education. He stated that the proposed text was formally noticed for comment on October 8, 2010, and the 45-day comment period concluded on November 22, 2010. Dr. Schell indicated that he board received one comment in support of the proposed amendments.

Dr. Schell provided that staff is compiling the final rulemaking file and anticipates submitting the rulemaking for review no later than May 13, 2011. He stated that following legal review, the file will be submitted to the department for review and, at that time, final rulemaking documents will be made available on the board's Web site. Dr. Schell indicated that given department and agency approval, the file will then be submitted to the Office of Administrative Law pursuant to the Administrative Procedure Act. He referenced a copy of the final text provided in the meeting materials.

No public comment is provided.

c. Board Approved Regulations – Recently Noticed

Amend Title 16 Section 1793.5 – Pharmacy Technician Application; Requirement for Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB)
[45-day comment period: April 8 – May 23, 2011]

Report

Dr. Schell provided an update on this rulemaking. He stated that the proposed rulemaking was noticed for a 45-day public comment period on April 8, 2011. He indicated that the board will accept comments on this proposed rulemaking through May 23, 2011. Dr. Schell referenced a copy of the proposed amendments to 16 CCR Section 1793.5 and the proposed Pharmacy Technician Application (17A-5) provided in the meeting materials.

No public comment was provided.

d. Board Approved – Awaiting Notice

1. Add Title 16 Section 1707.6 and to Amend Section 1707.2 Regarding Consumer Notices and Duty to Consult – Consumer Notice for Language Assistance Interpretive Services Provided in Pharmacies and the Ability to Request 12-Point Font on Prescription Drug Container Labels

Report

Dr. Schell provided that staff is developing the Notice for this rulemaking and hope to have it published in May 2011. He stated that in addition, Executive Officer Herold is working with staff to identify possible dates for the Regulation Hearing on this matter. Dr. Schell referenced a copy of the proposed text approved by the board provided in the meeting materials.

No public comment was provided.

2. Add Title 16 Section 1727.2 – Requirements for Pharmacist Interns – To Require Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB)

The board reviewed this item with the following agenda item.

3. Amend Title 16 Section 1728 – Requirements for Pharmacist Examination - Amend to Require Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB)

Report
Dr. Schell provided that the board filed a request to notice the proposal to add Section 1727.2. and to amend Section 1728. to Title 16 CCR and to initiate a rulemaking to require an applicant to submit with their application a Self-Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) with the Office of Administrative Law, and the Notice is scheduled to be published in the California Regulatory Notice Register on Friday, May 6, 2011. He indicated that the 45-day public comment period will commence upon notice and will conclude on June 20, 2011. Dr. Schell referenced a copy of the proposed text provided in the meeting materials.

No public comment was provided.

e. Board Approved – Under Development (Update Only)

1. Proposed Amendments to § 1746 – Emergency Contraception Protocol

Report
Dr. Schell provided that in 2004, the board adopted a statewide protocol for dispensing emergency contraception products, resulting in the codification of Title 16 CCR Section 1746. He indicated that the regulation became operative on December 2, 2004. Dr. Schell stated that the board has been working with the Medical Board to update the emergency contraceptive protocol. He explained that as part of the rulemaking, the board will need to update the patient information fact sheet, which is required to be provided to patients by the pharmacists using the protocol to dispense emergency contraception. He provided that it is anticipated that an updated manuscript will be brought to both the Medical Board and to the Board of Pharmacy at their respective meetings in July 2011.

Dr. Schell provided that this matter will also be addressed during the Public Education Committee Chair Report.

No public comment was provided.

2. Proposed Amendments to § 1751.9 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Report
Dr. Schell provided that this proposed regulation would specify the criteria the board will utilize to consider approval of accreditation agency requests. He stated that staff is continuing to work with counsel to develop language for consideration at a future meeting.

No public comment was provided.

3. Proposed Amendments to § 1780 – Update the USP Standards Reference Manual (Minimum Standards for Drug Wholesalers) [referred to subcommittee]

Report
Dr. Schell provided that section 1780 of the California Code of Regulations sets minimum standards for drug wholesalers. He stated that this regulation currently references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. Dr. Schell indicated that the USP Standards are updated and published annually. He explained that section 1780(b) requires amendment to reflect the 2005 version of the USP Standards and to hold wholesalers accountable to the latest standards, if determined appropriate.

Dr. Schell provided that because of stated concerns about whether referencing the 2005 USP Standards would be an unreasonable burden on wholesalers, at the October 2008 Board Meeting, the board voted to address the issue of updating the USP Standards reference materials within this section.

Dr. Schell provided that the board established a subcommittee for this purpose but, as a result of board vacancies, the subcommittee has not held any meetings and no action has been taken with respect to this regulation change.

No public comment was provided.

4. Proposed Amendments to § 1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer [referred to Licensing Committee]

Report
Dr. Schell provided that the Licensing Committee has not yet initiated a program review of the Veterinary Food-Animal Drug Retailer program. He stated that staff does not anticipate proceeding with this regulation until such time that the Licensing Committee completes its review.

No public comment was provided.

PART II – LEGISLATION

Dr. Schell referenced the following two-year bills and spot bills. The board did not discuss these items.

- AB 847 (Lowenthal, Bonne) Pharmacy: Clinics
- SB 632 (Emmerson) Pharmacy
- SB 847 (Correa) Medical Cannabis Licensing Act
- AB 958 (Berryhill) Regulatory Boards: Limitation Periods
- SB 544 (Price) Healing Arts
- SB 667 (Wyland) Naturopathic Doctors

Dr. Schell also referenced the following bills that are no longer being tracked by the board.

- AB 1328 (Pan) Clinical Laboratories
- AB 1003 (Smyth) Professional and Vocational Licenses
- SB 100 (Price) Healing Arts
- SB 227 (Wyland) Business and Professions: Licensure
- SB 231 (Emmerson) Regulatory Boards: Healing Arts
- SB 260 (Cannella) Controlled Substances: Ephedrine or Pseudoephedrine
- SB 538 (Price) Nursing
- SB 786 (Dutton) Controlled Substances

Dr. Castellblanch sought clarification regarding SB 847 and its potential impact on the board.

Assistant Executive Officer Anne Sodergren provided that this bill has been amended and now impacts residential zoning rather than licensing.

No public comment was provided.

a. Board Sponsored Legislation

1. SB 431 (Emmerson) Pharmacies: Regulation

Report

Dr. Schell provided that in January 2010, the board voted to pursue legislation to improve the board's enforcement tools as well as to better define the return of medicine via reverse distributors. He stated that these provisions are incorporated in SB 431. Dr. Schell referenced the following specific code sections:

Sections 4040.5, 4081 and 4126.5 – Proposal Regarding Return of Medicine to Reverse Distributors

- §4040.5 – Reverse Distributor

  Specifies that a reverse distributor may not accept previously dispensed medicine and that previously dispensed medicine returned to a pharmacy can only be handled by a licensed integrated waste hauler. Defines "dispensed" for purposes of this section only. This provision was approved by the board in January 2009.

- §4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory

  Specifies that records documenting the return of drugs to a wholesaler or reverse distributor must include the quantity or weight of the drug being returned, the date returned and the name(s) to which the drugs were provided. Specifies that records documenting the return of drugs to a licensed integrated waste hauler shall include a list of the volume in weight and measurement, and the date and name of the hauler. Defines "licensed integrated waste hauler" for purposes of this section only. This provision was approved by the board in January 2009.

- §4126.5 – Furnishing Dangerous Drugs by a Pharmacy

  Authorizes a pharmacy to furnish drugs to a licensed integrated waste hauler. Needs to authorize a pharmacy to accept returned product from a consumer in the event of a product recall.

Sections 4104, 4105 and 4112 – Enforcement Enhancements

- §4104 – Licensed Employee, Theft or Impairment, Pharmacy Procedure

  Amends existing law to clarify that a pharmacy shall provide the board, within 14 days, evidence of licensee's theft or impairment. The provisions also require a pharmacy to conduct an audit to determine the scope of a drug loss and to provide the board with a certified copy of the audit results.

- §4105 – Retaining Records of Dangerous Drugs and Devices on Licensed Premises;

  Temporary Removal; Waivers; Access to Electronically Maintained Records
  Amends existing law to specify the time period within which records shall be provided to the board when requested by an inspector or authorized representative of the board.

- §4112 – Nonresident Pharmacy; Registration; Provision of Information to Board; Maintaining Records; Patient Consultation

  Require that a nonresident pharmacy cannot allow a pharmacist, whose license has been revoked in California, to provide pharmacist related services to Californians.

Dr. Schell provided that board staff continues to advocate this legislation and is working with the author's office to address any concerns raised. He stated that this bill passed out of the Senate Business, Professions and Economic Development Committee. Dr. Schell indicated that the bill was referred back to Rules committee and will be sent to the Senate Environmental Quality Committee.

No public comment was provided.

2. SB 943 (Senate Committee on Business, Professions & Economic Development) Omnibus

Report
Dr. Schell provided that at the October 2010 Board Meeting, the board voted to pursue an omnibus provision to eliminate a reference to the previous pharmacists examination in Business and Professions Code Section 4200. He stated that this provision is contained in Senate Bill 943.

Dr. Schell provided that the bill was scheduled for a committee hearing in Senate Business, Professions and Economic Development on May 2, 2011.

No public comment was provided.

b. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

1. Board of Pharmacy/Licensing

AB 377 (Solorio) Pharmacy: Centralized Hospital Packaging
Version: As amended, April 14, 2011

Dr. Schell provided that this bill provides for centralized pharmacy packaging in a hospital, allowing the pharmacy to be located outside of a hospital on either the same premises or separate premises that is regulated under a hospital's license. He stated that the bill exempts from the definition of manufacturing, repackaging a drug for parenteral therapy, or oral therapy in a hospital for delivery to another pharmacy or hospital, as specified.

Dr. Schell provided that the committee had no recommendation. He explained that the public members of the committee wanted more information before offering a recommendation.

Dr. Schell spoke in support of the bill and indicated that the board has supported this bill in the past.

Dr. Schell provided that the bill was referred to the Assembly Appropriations Committee. He indicated that recently, the board received a letter from the California Society of Health System Pharmacists requesting the board take a position of support on this measure. He referenced a copy of this correspondence as well as the bill and analysis for this measure provided in the meeting materials.

Discussion
Dr. Schell offered a proposal to establish a position of Support on this bill. He discussed that the bill will add a measure of security and will allow the board an easier opportunity to check facilities.

Mr. Room discussed some drafting concerns with this bill. He stated that the bill does not fulfill the intent to provide a definition for "centralized hospital pharmacy."
Mr. Room also discussed that it is unclear whether common ownership or requiring that a hospital is within the same hospital system is the binding factor in determining whether packaging will be allowed by a centralized hospital pharmacy.

Dr. Schell discussed that these factors may be interchangeable. He suggested that the committee recommend to the author that this be clarified.

Public Comment
Darleen Furjimoto, representing UCSD, recommended that the board confirm that the barcode is linked to the hospital computer system record.

Ms. Shellans confirmed that each pharmacy will hold its own license.
Bob Miller, representing Scripts Health, San Diego, provided comment on the intent of the bill. He discussed that the barcode, which does not contain all of the information itself, can be scanned to provide all of the necessary information.

MOTION: Establish a position of Support if Amended on AB 377.

M/S: Schell/Lippe

Support: 10 Oppose: 0 Abstain: 0

AB 399 (Lowenthal, Bonnie) Corrections: Offender Pharmacies
Version: As introduced, February 14, 2011

Dr. Schell provided that this bill would require the Department of Corrections and Rehabilitation to license all distributions centers and facilities with the board as part of its comprehensive pharmacy services program.

Dr. Schell provided that the committee recommended that the board establish a position of Support.

Dr. Schell provided that the hearing is scheduled for May 3, 2011 in the Assembly Health Committee.

MOTION: Legislation and Regulation Committee: Establish a position of Support on AB 399.

Support: 10 Oppose: 0 Abstain: 0

2. Controlled Substances/Marijuana

AB 507 (Hayashi) Pain Management
Version: As amended, April 27, 2011

Dr. Schell provided that this bill repeals provisions in existing law which permit the Department of Justice (DOJ) to employ a physician to interview and examine any patient in connection with the prescription possession or use of a controlled substance, require the patient to submit to the interview and examination, and permit the physician to testify in prescribed administrative proceedings. He stated that the bill makes technical and conforming changes to existing law related to severe chronic intractable pain and to the California Intractable Pain Treatment Act (CIPT Act).

Dr. Schell provided that the committee recommended that the board establish a position of Oppose.

Dr. Schell provided that this measure has been amended twice since the committee reviewed it. He stated that the first amendments occurred on April 13, 2011 and removed the proposed changes to the board's unprofessional conduct statute, B&PC 4301. Dr. Schell indicated that the bill was again amended on April 27, 2011. He provided that these new amendments again propose a change to B&PC 4301(d). Dr. Schell indicated that this measure is scheduled for hearing before the Assembly Business, Professions and Consumer Protection Committee on May 3, 2011.

Discussion
Ms. Shellans sought clarification regarding why the author is pursuing the amendment to B&PC Section 4301(d) to remove the term “clearly excessive” from the board’s unprofessional conduct code. She discussed that this amendment will limit the board’s ability to pursue excessive furnishing cases.

Mr. Room provided that this amendment may be in response to pain advocates who see “clearly excessive” as a barrier to access to pain medication or an attempt to ultimately eliminate this section.

Ms. Shellans provided comment on the benefit of maintaining this provision as a basis for determining unprofessional conduct. She advised that striking “clearly excessive” from the statute will limit the board’s ability in this area.

No public comment was provided.

Mr. Brooks left the meeting room at 3:12 p.m.

MOTION: Legislation and Regulation: Establish a position of Oppose on AB 507.

Support: 9 Oppose: 0 Abstain: 0

3. Reporting Requirements/Records

AB 1280 (Hill) Ephedrine: Retail Sale
Version: As amended, March 25, 2011

Dr. Schell provided that this bill contains provisions requiring the secure storage and monitoring of products containing any amount of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, as specified. He stated that this bill proposed a realtime tracking system beginning in January 2013 through December 2018.

Dr. Schell provided that this measure was not previously brought to the committee.

Dr. Schell provided that the hearing is scheduled for May 3, 2011 in the Assembly Public Health Committee.
Discussion
Ms. Sodergren provided that this proposal would require retailers to report ephedrine sales as specified, but only for a five year-period. She provided that efforts to request clarification regarding how or why this timeframe was established have thus far been unsuccessful.

Dr. Schell offered a proposal to establish a position of Watch on this bill.

No public comment was provided.

MOTION: Establish a position of Watch on AB 1280.

M/S: Schell/Castellblanch

Support: 9 Oppose: 0 Abstain: 0

SB 315 (Wright) Ephedrine and Pseudoephedrine
Version: As introduced, February 14, 2011

Dr. Schell provided that this bill would classify pseudoephedrine as a prescription drug.

He provided the committee recommended that the board establish a position of Support.

Dr. Schell provided that the bill passed through the Senate Public Safety Committee and was referred to the Senate Health Committee.

Dr. Schell provided that recently, the board received from the Oregon Pharmacist Association urging the board to support this measure. He referenced a copy of this letter provided in the meeting materials.

Presentation
Craig Hammer, representing the Department of Justice, Bureau of Narcotic Enforcement, provided an overview of the methamphetamine problem in California. He explained that pseudoephedrine is the essential precursor for making methamphetamine.

Mr. Hammer discussed that pseudoephedrine purchased (smurfed) from retail outlets in California is the exclusive source of this precursor. He reviewed case examples of smurfing in California and reviewed the limited resources available to address this issue.

Mr. Hammer indicated that the best way to eliminate the production of methamphetamine is to control this precursor by requiring a prescription. He reviewed similar efforts by other states including Oregon and Mississippi which has resulted in significant reduction in methamphetamine production in those states.

Mr. Hammer requested that the board support SB 315.

Dr. Schell expressed concern that smurfers may seek pseudoephedrine from internet pharmacies.

Mr. Hammer provided that Oregon has not experienced this problem.

Dr. Castellblanch discussed that the bill is opposed by many industry organizations as well as by the Peace Officers Research Association of California (PORAC).

Mr. Hammer provided that money may be factor for the opposition to this bill. He stated that he would like the opportunity to discuss this issue with PORAC.

Ms. Veale provided comment on the effectiveness of pseudoephedrine as a decongestant. She discussed that placing this drug in a different fee schedule will have a cost impact for the consumer and insurance providers.

Ms. Wheat left the meeting at 3:35 p.m.

Public Comment
Mary Staples, representing the National Association of Chain Drugs Stores (NACDS), indicated that SB 315 is now a two-year bill. She spoke in opposition to the bill and provided that it would be more effective to adopt AB 1280 (Hill, 2011) which would require retailers to report ephedrine sales as specified and would aid in the prosecution of smurfers.

Mr. Hammer provided that rather than focusing on tracking and prosecuting, the goal is to eliminate the problem in its entirety.

MOTION: Legislation and Regulation Committee: Establish a position of Support on SB 315.

Support: 6 Oppose: 2 Abstain: 0

SB 360 (DeSaulnier) Controlled Substance Utilization Review and Evaluation System
Version: As amended, April 14, 2011

Dr. Schell provided that this bill would revise Schedule I and Schedule II to add additional opiates, revise Schedule III to add additional depressants, anabolic steroid products, and materials, compounds, mixtures, or preparations containing chorionic gonadotropin (a hormone), and Schedule IV to add additional depressants and stimulants.

Dr. Schell provided that the committee recommended that the board establish a position of Watch.

Dr. Schell provided that the hearing is scheduled for May 3, 2011 in the Senate Public Safety Committee.

Dr. Schell provided that the board has correspondence from the California Attorney General's Office requesting that the board support this measure. He stated that they

note that SB 360 strengthens the Controlled Substances Utilization Review and Evaluation System (CURES) and California Security Printer programs administered by BNE. Dr. Schell indicated that SB 360 improves the ability of BNE to deter prescription drug abuse and fraud, and the misuse of confidential CURES data.

Dr. Kajioka and Mr. Badlani left the meeting room at 3:40 p.m.

Discussion
Ms. Sodergren discussed that this bill will allow for a transition period to implement the changes on the prescription forms.

No public comment was provided.

The board recessed for a break at 3:42 p.m.

The board reconvened at 3:56 p.m. Dr. Castellblanch was not present.

MOTION: Legislation and Regulation Committee: Establish a position of Watch on SB 360.

Support: 7 Oppose: 0 Abstain: 0

4. Healing Arts/DCA

AB 675 (Hagman) Continuing Education
Version: As amended, April 5, 2011

Dr. Schell provided that this bill would specify that continuing education or competency courses that advance or promote labor organizing on behalf of a union, or that advance or promote statutory or regulatory changes, political candidates, political advocacy, or political strategy shall not be considered content relevant to the practice regulated by the board and shall not be acceptable for meeting requirements for licensure renewal.

Dr. Schell provided that the committee did not make a recommendation on this measure, but directed staff to seek clarification on the measure.

Dr. Schell provided that the hearing is scheduled for May 3, 2011 in the Assembly Business, Professions and Consumer Protection.

Dr. Schell provided that board staff requested clarification on this measure, but has not received a response from the author's office.

Discussion
Mr. Room provided that this may preclude the board from awarding CE for attending board meetings.

No public comment was provided.

The board took no action on this item.

SB 541 (Price) Regulatory Boards: Expert Consultants
Version: As amended, April 13, 2011

Dr. Schell provided that this bill would authorize boards to enter into an agreement with an expert consultant, subject to the standards regarding personal service contracts described, to provide enforcement and examination assistance. He stated that the bill would require each board to establish policies and procedures for the selection and use of these consultants.

Dr. Castellblanch returned to the meeting room at 3:59 p.m.

Dr. Schell provided that this measure was not previously considered by the committee.

Dr. Schell provided that this bill was amended April 13, 2011 to incorporate these provisions. He indicated that a hearing was scheduled for May 2, 2011 in the Senate Business, Professions and Economic Development Committee.

Ms. Sodergren discussed that this proposal will aid the board in meeting its consumer protection mandate by ensuring the board has the ability to quickly enter into an agreement with an expert in disciplinary matters.

No public comment was provided.

MOTION: Establish a position of Support on SB 541.

M/S: Veale/Lippe

Support: 8 Oppose: 0 Abstain: 0

5. Other

AB 389 (Mitchell) Bleeding Disorders: Blood Clotting Products
Version: As amended, March 30, 2011

Dr. Schell provided that this bill would impose specified requirements on providers of blood clotting products for home use for products used for the treatment and prevention of symptoms associated with bleeding disorders, including all forms of hemophilia.

Dr. Schell provided that the committee recommended that the board establish a position of Watch.

Dr. Schell provided that this bill was in the assembly for a third reading on April 26, 2011.

Dr. Schell provided that board staff received correspondence from the sponsor of this bill requesting that the board remain neutral. He indicated that the bill is currently in the Senate.

MOTION: Legislation and Regulation Committee: Establish a position of Watch on AB 389.

Support: 8 Oppose: 0 Abstain: 0

AB 604 (Skinner) Needle Exchange Programs
Version: As amended, April 5, 2011

Dr. Schell provided that this bill would authorize the State Department of Public Health to approve certain entities to provide hypodermic needle and syringe exchange services in any location where the department determines that the conditions exist for the rapid spread of HIV, viral hepatitis, or any other potentially deadly or disabling infections that are spread through the sharing of used hypodermic needles and syringes.

Dr. Schell provided that the committee recommended that the board establish a position of Support.

Dr. Schell provided that the bill was in the Assembly for a third reading on April 26, 2011.

MOTION: Legislation and Regulation: Establish a position of Support on AB 604.

Support: 8 Oppose: 0 Abstain: 0

SB 41 (Yee) Hypodermic Needles and Syringes
Version: As introduced, December 7, 2010

Dr. Schell provided that this bill would allow a physician or pharmacist to furnish 30 or fewer hypodermic needles and syringes solely for personal use to a person 18 years of age or older. He stated that the bill addresses the storage of products to ensure they would be available only to authorized personnel, would require that disposal options are provided to consumers, and would require pharmacies to provide written information or verbal counseling at the time of furnishing on how to access drug treatment.

Dr. Schell provided that the committee recommended that the board establish a position of Support.

Dr. Schell provided that the bill passed out of the Senate Public Health Committee on April 26, 2011 and was referred to Senate Appropriations.

Discussion
Mr. Room advised that this bill deletes Business and Professions Code section 4140. He discussed that this deletion is unnecessary and will have unattended consequences as it is currently utilized for cases regarding illicit possession of hypodermic needles. Mr. Room provided that maintaining Section 4140 would not alter the intent of the legislation.

Dr. Castellblanch offered a proposal to support the bill if amended to maintain Section 4140.

Mr. Room discussed that the board can communicate support of the policy and indicate that the amendment is in line with this policy.

Dr. Schell recommended that the unattended consequences for eliminating Section 4140 also be communicated to the bill's author.

MOTION: Legislation and Regulation: Establish a position of Support of SB 41.

Support: 0 Oppose: 8 Abstain: 0

MOTION: Establish a position of Support if Amended on SB 41 to maintain Business and Professions Code section 4140. Indicate support of the policy and explain why such amendment would strengthen the intent.

M/S: Castellblanch/Schell

Support: 8 Oppose: 0 Abstain: 0

SB 514 (Simitian) Dextromethorphan: Sale to Minors Prohibited
Version: As amended, April 25, 2011

Dr. Schell provided that this bill would make it illegal to sell dextromethorphan to a person under the age of 18 without a prescription.

Dr. Schell provided that committee recommended that the board establish a position of Support.

Dr. Schell provided that this measure was amended on April 25, 2011 and now requires the retailer to, in an over-the-counter sale without a prescription shall, if feasible, use a cash register that is equipped with an age-verification feature to monitor age-restricted items.

Discussion
Mr. Lippe sought clarification regarding the effect of dextromethorphan.

Dr. Schell discussed that dextromethorphan, a cough suppressant commonly found in over-the-counter cold medications, acts a hallucinogen and has been abused for many years as it is easily accessible. He indicated that this product has classified as a scheduled substance in England.

Ms. Sodergren provided that according to the author's office, Poison Control reports an 850 percent increase in the number of calls it has received over the last ten years resulting from dextromethorphan. The author's office also stated that one in ten high school students has abused this drug.

MOTION: Legislation and Regulation: Establish a position of Support on SB 514.

Support: 8 Oppose: 0 Abstain: 0

6. Additional Legislation Impacting the Board or Its Regulatory Jurisdiction

Dr. Schell provided that there is no additional legislation that affects the practice of pharmacy or the board's jurisdiction for review.

No public comment was provided.

The board took agenda item X out of order to accommodate a scheduling conflict.

X. PUBLIC COMMENT ON ITEMS NOT ON THE AGENDA/AGENDA ITEMS FOR FUTURE MEETINGS

No public comment was provided.

President Weisser provided that this will be the last board meeting for Dr. Schell. He thanked Dr. Schell for his leadership and dedication towards public protection during his time on the board.

Dr. Schell reflected on his experience as a board member and shared that it has been a great experience to work with the board.

The board recessed for a break at 4:19 p.m.

The board reconvened at 4:28 p.m. Mr. Brooks returned to the meeting room.

IX. ELECTION OF BOARD OF PHARMACY OFFICERS FOR 2011/12

President

MOTION: Reelect Stan Weisser as president of the Board of Pharmacy.
M/S: Lippe/Brooks
Support: 8 Oppose: 0 Abstain: 0

Vice President

MOTION: Reelect Randy Kajioka as vice president of the Board of Pharmacy.
M/S: Weisser/Brooks
Support: 8 Oppose: 0 Abstain: 0

Treasurer

MOTION: Reelect Greg Lippe as treasurer of the Board of Pharmacy.
M/S: Veale/Schell
Support: 8 Oppose: 0 Abstain: 0

Recess for Day

The board meeting was recessed at 4:32 p.m.

Wednesday, May 4, 2011

The board reconvened at 8:40 a.m. on May 4, 2011.

President Weisser conducted a roll call. Board members Schell, Lippe, Brooks, Hackworth, Kajioka, Castellblanch, and Weisser were present.

The board took agenda items XI and XII out of order.

XII. ORGANIZATIONAL DEVELOPMENT COMMITTEE REPORT

President Weisser provided that there was no meeting of the Organizational Development Committee this quarter.

a. Budget Update/Report

1. Budget Report for 2010/11

Report
President Weisser reviewed the following board revenue and expenditures for the first nine months of the fiscal year 2010-11.

Expenditures (as of March 2011):	$7,725,502 (actual)
Maximum spending authority for year:	$12,800,000
Revenue Collected (as of March 2011):	$10,331,726

President Weisser provided that the board has spent 56 percent of its budget to date on personnel expenses, 21 percent on AG and OAH expenses, and 1 percent on travel. He stated that the board has collected 88 percent of its revenue from fees, 3 percent from cost recovery and 9 percent from citations and fines.

No public comment was provided.

2. Fund Condition Report

Report
President Weisser reviewed the following fund condition report prepared by the department:

2009/10	$12,411,000	11.6 months in reserve (actual)
2010/11	$9,954,000	8.4 months in reserve
2011/12	$6,005,000	5 months in reserve
2012/13	$2,806,000	2.3 months in reserve

President Weisser provided that the board will continue to closely monitor its fund condition to ensure the fiscal integrity of the board's operations.

Discussion
Ms. Herold provided that the state took one million dollars from the board's fund last year. She discussed that the actual funds (as opposed to the estimates used to forecast the board's fund condition) should be higher as the board is not spending all of the projected funds due to the hiring freeze and travel restrictions. Ms. Herold also discussed the board's high AG costs. She indicated that funds can be redirected to cover this important enforcement expense.

Dr. Schell requested that future reports also include the board's actual funds.

Ms. Herold provided that she will submit this request to the department.

No public comment was provided.

3. Budget Change Proposals for the 2011/12 Budget

Report
President Weisser provided that the board did not receive approval for the BCP submitted for 2011/12. He stated that no additional information can be provided.

No public comment was provided.

4. Update on BreEZe, DCA's Plans for a New Computer System

Report
President Weisser provided that as indicated during the Director's Report, the board is about 2-3 years away from changing to the new licensing and computer system, BreEZe.

Discussion
Ms. Herold provided that the new system will allow for online renewal and application processing, and will also replace the board's Consumer Affairs Systems and the Applicant Tracking System. She discussed that BreEZe will ultimately allow for improved services for applicants and licensees as well as provide for a more robust internal computer system.

No public comment was provided.

5. Reimbursement to Board Members

President Weisser referenced the expenses and per diem payments to board members provided in the meeting materials.

No public comment was provided.

b. Future Development of a Strategic Plan for 2011/12 to 2016/17

Report
Ms. Herold provided that about every five years the board develops a new strategic plan that will guide the board for the following five years.

Ms. Herold provided that on March 25, 2011, all board staff participated in the development of a SWOT (strengths, weaknesses, opportunities, threats) analysis to be used in the development of the new strategic plan. She provided an overview of the analysis that was developed. (A copy of this analysis is attached, following this meeting summary.)

Ms. Wheat arrived at 8:54 a.m.

Ms. Herold provided that staff is currently soliciting bids for a consultant to guide the board and staff through the process during the July 2011 Board Meeting.

No public comment was provided.

c. Recognition Program of Pharmacists Who Have Been Licensed 50 Years

Report
President Weisser provided that this program was created by former board member, Stan Goldenberg. He indicated that since July 2005, the board has acknowledged 1,091 pharmacists with 50 or more years of licensure as pharmacists in California. President Weisser stated that there were 34 pharmacists who reached this milestone between January and April 2011. He explained that when a pharmacist reaches this milestone, the board sends a certificate and an invitation to attend a future board meeting for public recognition.

Ms. Herold requested permission from the board to recognize a pharmacist who was unable to attend the board meeting at a California Pharmacists Association (CPhA) event.

It was the consensus of the board to approve this request.

No public comment was provided.

d. Transition Issues of Governor Brown's Administration

Report
Ms. Herold provided that the State and Consumer Services Agency is now headed by Anna Cabellero, who was appointed by Governor Brown on March 22, 2011.

Ms. Herold provided that board staff is awaiting direction regarding implementation of the Governor's executive order curtailing travel. She discussed that alternatives such as video conferencing will be explored in order to comply with the board's obligation to hold public meetings.

Ms. Veale arrived at 9:00 a.m.

Ms. Herold reviewed the following areas within which the board has been asked to make cuts for budgetary reasons.

- The board's operating expenses were reduced by 15 percent in 2009/10.
- In 2010/11, the board's personnel budget was reduced by 5 percent, a cut that will be permanent in future years.
- Imposition of a hiring freeze in August 2010 preventing the filling of vacancies.

Ms. Herold provided that the board will continue to evaluate how it does business and will identify ways to further reduce expenditures despite increases in workload in both licensing and enforcement areas.

No public comment was provided.

e. Personnel Update

1. Board Member Vacancies

Report
President Weisser provided that as of today, the board has 11 board members, and two board member vacancies. He indicated that the vacant positions are governor appointments and are for pharmacist members.

President Weisser provided that on June 1, 2011, Ken Schell will end his tenure as a board member. He shared that Dr. Schell has seen a number of changes in the board over his eight years on the board and as president for two years and has led the board in various initiatives. President Weisser indicated that this will be Dr. Schell's last board meeting.

Mr. Badlani arrived at 9:02 a.m.

President Weisser provided that after June 1, without new appointments to the board, the board will be comprised of 10 members, and be short three professional members.

No public comment was provided.

2. Staff Changes

Report
Ms. Herold provided that effective August 30, 2010, a statewide hiring freeze was implemented which has prohibited the board from filling any vacancies. She indicated that at the time the freeze order was issued, the board was actively recruiting for several vacancies for office and inspector staff. Ms. Herold explained that these vacancies were as a result of employees transferring to other state agencies, retirements, and additional staff positions the board received through the BCP process.

Ms. Herold provided that since January 2011, the board has been allowed to hire staff currently employed by other DCA agencies (as transfers within the same "hiring authority").

Ms. Herold provided that the board recently received eight freeze exemptions for investigative staff from the Administration. She commended Assistant Executive Officer Anne Sodergren for her work to secure these exemptions. Ms. Herold explained that there are no other pharmacists who work for DCA, so the board has been unable to fill any of its 20 vacant inspector positions.

Ms. Herold reviewed the following remaining vacant positions:
- 12 - Supervising inspector and inspector positions
- 1.5 - Associate analysts for the enforcement unit
- 1 - Staff analyst who performs application investigations & fingerprint reviews
- 4 - Office technicians who perform processing duties in enforcement and licensing

Ms. Herold provided that these positions equate to over a 35 percent vacancy rate.

President Weisser provided that board staff continues to work diligently, focusing their efforts on the highest priorities and most essential functions. He commended board staff for their work and dedication to the board.

No public comment was provided.

f. Discussion and Possible Action Regarding the Future Sunset Review of the Board of Pharmacy by the California Legislature

Report
Ms. Herold provided that this summer, the board's staff will prepare the board's sunset report to the Legislature, responding to a number of questions asked by the Legislature about the board's activities, and reporting specific data requested.

Ms. Herold provided that the board last underwent a sunset review in 2002.

Discussion
Mr. Room discussed that this is a laborious program for both the board and the legislature.

Ms. Shellans discussed that the time lapsed since the last review is a good indicator of the respect the legislature has for the program.

Ms. Herold discussed that the review is an opportunity to showcase the board's program and to identify areas that would benefit from assistance. She reviewed the following typical process:

- Fall 2011: submission of the sunset report to the Legislature
- Fall to spring: legislative assessment of the board's performance, both in writing and during a hearing
- Ideally during the 2012 legislative year, a bill is introduced extending the board's sunset date and recommending specific modifications to the board's legislative provisions

No public comment was provided.

g. Third Quarterly Report on the Committee's Goals for 2010/11

President Weisser referenced the third quarterly report on the Organizational Development Committee's goals provided in the meeting materials.

The board recessed for a break at 9:45 a.m.

The board reconvened at 10:09 a.m.

XI. COMMUNICATION AND PUBLIC EDUCATION COMMITTEE REPORT AND ACTION

There was no meeting of this Communication and Public Education Committee this quarter

a. Update of the State's Emergency Contraception Protocol Regulation (16 California Code of Regulations Section 1746.) and Consumer Fact Sheet

Report
Mr. Brooks provided that the Board of Pharmacy has begun work to update the emergency contraception protocol authorized by California Business and Professions Code section 4052.3 and 16 California Code of Regulations section 1746.

Mr. Brooks provided that the current state protocol was developed by the Medical Board in 2004 and then later adopted by this board as a regulation.

Mr. Brooks provided that Executive Officer Herold met with the Medical Board's executive officer, and obtained comments from California Pharmacists Association's (CPhA) representative (a women's health specialist pharmacist), and a representative of the American College of Obstetricians and Gynecologists. An updated manuscript has been prepared and is currently being reviewed by the various parties.

Mr. Brooks provided that after this review, the manuscript will be shared with the Medical Board, which must approve the modified protocol. He stated that the board will then need to proceed with a rulemaking to update the requirements.

Mr. Brooks provided that as part of the rulemaking, the board will need to update the patient information fact sheet, which is required to be provided to patients by the pharmacists using the protocol to dispense emergency contraception.

No public comment was provided.

b. Public Education Campaign for Patient-Centered Prescription Drug Container Labels

Report
Mr. Brooks provided that in time for National Consumers Week in March 2011, the board released a press release announcing the new patient-centered labels and requirements for interpreter services within pharmacies. He referenced a copy of this release provided in the meeting materials.

Mr. Brooks provided that the next planned major publicity for these labeling requirements will occur in October 2011, which is pharmacy month. He stated that staff will again work with the DCA's Press Office on highlighting these new requirements.

Mr. Brooks discussed that according to the outreach plan developed by the department, promotion of the new requirements could include press releases, articles, speakers, and an informational video.

Discussion
Dr. Schell suggested that consumer feedback in response to such press releases be monitored. He also recommended that the board also pursue alternate means to disseminate information.

Ms. Herold provided that more aggressive public education is appropriate at this time as pharmacies have had time to implement the new requirements.

Mr. Brooks suggested that the DCA create a 30 second public service announcement to be sent to radio stations in California. He offered to work with CBS to help facilitate this effort.

No public comment was provided.

c. Development of Consumer Education Videos for the Board's Web Site – Viewing of a Short Public Education Video on Purchasing Drugs on the Internet, Developed by the Department of Consumer Affairs

Report
Mr. Brooks provided that the Department of Consumer Affairs in-house video staff has developed its first video for the board. He shared that it is a short video on buying drugs from the Internet.

Ms. Herold provided that the video has been modified from the original version viewed by the board.

The board viewed the modified video.

Discussion
The board provided comments for modifications to the video and whether the video should be placed on the board's Web site.

It was the consensus of the board to place the modified version on the board's Web site and to routinely update the video to provide new and fresh information.

Public Comment
Darlene Fujimoto, representing UCSD, suggested that the board also post the video on YouTube.

d. Update on Consumer Fact Sheet Series with California Schools of Pharmacy Interns

Report
Mr. Brooks provided that the board has advocated a proposal to offer pharmacy students an opportunity to work with the board on meaningful projects promoting consumer education, while the board benefits from production of the materials. He indicated that several years ago, multiple facts sheets were developed in collaboration with the UCSF Center for Consumer Self-Care, but funding issues prevented their further participation. Mr. Brooks stated that the board offered other schools of pharmacy the opportunity to have their students develop one-page fact sheets on various topics, and have the fact sheets reviewed by an expert. He indicated that Schools of Pharmacy have expressed interest in this project.

Mr. Brooks provided that the board previously provided a fact sheet template, guidelines, and potential topics to all schools of pharmacy. He indicated that five schools confirmed their interest in the project, and materials from two schools have been submitted to the board for review. Mr. Brooks stated that the committee reviewed the unedited copies of the materials sent to the board during the January 2011 Committee Meeting.

Mr. Brooks provided that staff will need to work on refining the fact sheets, and fully research the facts stated in them before they can be released to the public. He stated that over time, more specific instructions may provide the students and faculty with better guidance, but there will always be need for editing and reviewing by the board.

Discussion
Ms. Veale provided that the fact sheets were well done. She discussed that the board may want to standardize the sheets as they were drastically different from each other.

No public comment was provided.

e. Update on the Committee's Assessment of the Board's Public Education Materials

Report
Mr. Brooks provided that Board Members Debbie Veale and Ramón Castellblanch agreed to work as a subcommittee to assess the board's public education materials. He stated that this subcommittee has reviewed the number of publications produced by this board and compared it to all other US boards of pharmacy. Mr. Brooks discussed that the board has substantially more and diverse materials than any other board.

Mr. Brooks provided that the committee believes that the first priority is to find a better way to display the information on the Web site so that it is easier to find a specific item, rather than using an alphabetic list of each title. He stated that consumers would

benefit if the board highlights the resources already posted on its website by improving the way information is presented.

Mr. Brooks provided that the subcommittee will continue their review, and report back to the next Communication and Public Education Committee meeting.

Discussion
Dr. Castellblanch provided that the subcommittee met with the board's Web site coordinator to brainstorm possible redesign. He discussed that since all state agencies will be directed to modify their Web sites to the template design in use by the Governor's Office eventually, the board will take this opportunity to modify its Web site with respect to the listing of publications and informational materials for the public.

Board Member Neil Badlani provided comment on a previous agenda item. He suggested that the board request that pharmacy students develop consumer videos. Mr. Badlani discussed that the board can provide guidelines to help develop the videos and can select the top three videos to post on the Web site.

No public comment was provided.

f. Update on *The Script*

Report
Mr. Brooks provided that the February 2011 issue of *The Script* has been caught in the review process of the department until this week. He stated that this issue, which will now become the May 2011 issue, will focus on new pharmacy law and regulations for 2011. Mr. Brooks stated that the issue will also include an update for licensees about the requirements for patient-centered prescription labels, an article about medication errors reported to the board during 2009/10, and the board's citation and fines issued for those errors.

Mr. Brooks provided that work has already begun on articles for the on the next edition of *The Script*, and will highlight questions and answers regarding pharmacy law.

Discussion
The board discussed the relevance of the articles. It was discussed that licensees have provided positive feedback and often archive the articles for future reference.

Ms. Herold suggested that input be solicited during surveys conducted during the strategic plan process.

No public comment was provided.

g. Update on Public Outreach Activities

Report

Mr. Brooks reviewed the following public and licensee outreach activities performed during the third quarter of Fiscal Year 10/11:

- February 7, 2011 – Supervising Inspector Nurse provides information to students at Loma Linda's School of Pharmacy.
- February 9, 2011—Supervising Nurse provides training regarding the board's investigations and regulatory jurisdiction at Orange County Med Board and Drug Officer training.
- February 11 and 12, 2011 – the Board staffs a booth at CPhA's annual meeting, Outlook.
- February 12, 2011 – Board President Weisser and Executive Officer Herold provided an update about Board of Pharmacy activities and a Town Hall for questions and answers at Outlook. The two presentations comprised three hours of contact time.
- February 15, 2011 – Executive Officer Herold provides a presentation on California's e-pedigree requirements via video conference to FDA's Track and Trace Workshop.
- February 24, 2011 – Executive Officer Herold provides a presentation at a statewide annual meeting of California district and city attorney's offices that handle consumer protection cases about the types of cases investigated by the board including California's serious drug diversion and prescription abuse issues.
- March 1, 2011 – Executive Officer Herold participates as a trainer in the day-long DCA Board Member Orientation and Training.
- March 2, 2011 – Supervising Inspector Ratcliff provides a training about the board, clinics and Title X in Orange County.
- March 14 and 15, 2011 – Executive Officer Herold provides a presentation about California's identification of the heparin recall failures in 2008 and participates in a two-day workshop hosted by the PEW Trust in Washington DC.
- March 15, 2011 – Supervising Inspector Ratcliff provides a webinar to Providence Hospital pharmacists.
- March 16, 2011, Supervising Inspector Dang provides a presentation to Western University on acting as a PIC.
- March 30, 2011 – Inspector Bailey provides information about surviving a board inspector to the Korean Pharmacists Association.
- April 1, 2011 – Executive Officer Herold provides a presentation to UCSF students about Board of Pharmacy activities.
- April 5, 2011 – Executive Officer Herold meets with a delegation from Japan regarding California's e-pedigree requirements.
- April 12, 2011 – The Board of Pharmacy and Drug Enforcement Administration host a day-long seminar on Diversion of Controlled Substances "What every pharmacist should know to prevent diversion" in Los Angeles.
- April 15, 2011 – Assistant Executive Officer Sodergren provides an update to the CSHP Board of Directors about Board of Pharmacy activities.
- April 15, 2011 – Executive Officer Herold, Supervising Inspector Nurse and Inspector Sakamura provide information to the consumer law attorneys of Southern

No public comment was provided.

h. Third Quarterly Report on the Committee's Goals for 2010/11

Mr. Brooks referenced the third quarter's Committee Goals provided in the meeting materials.

No public comment was provided.

XIII. EXECUTIVE OFFICER'S REPORT

Ms. Herold provided an overview of executive orders and department projects impacting the board including the hiring freeze, fleet and cell phone reduction, travel restrictions, implementation of SB 1441, implementation of BreEZe, the Consumer Protection Enforcement Initiative (CPEI) and the Job Creation Initiative.

Ms. Herold discussed the board's resources. She stated that board staff will continue to work with the department to ensure that the board's field staff has the equipment (including cars and new iPads) needed to complete their work.

Ms. Herold provided that the board will be obtaining some additional office space which will help to address the board's need for more file and staff space.

Ms. Herold discussed the increase caseload for both the board's enforcement program and the attorney general's office regarding drug diversion and poor pharmacy practices. She also provided that the board will be resuming opening inspections in response to an increase in medical fraud issues as well as an increase in the number of new licenses issued to independent pharmacies despite the current economy.

Mr. Brooks requested licensing data from last year in this area.

Ms. Herold discussed joint projects with other agencies such as Drug Take-Back Days with the DEA.

Mr. Brooks and Dr. Castellblanch encouraged the board to further pursue the issue of drug take-back and to consider programs that will allow drugs to be destroyed in California rather than outsourced to out-of-state facilities.

Public Comment

Steve Gray, representing Kaiser Permanente, provided comment on drug take-back and destruction. He discussed that this issue is a major concern from a public policy point of view as well as for pharmacies who often don't want to participate in such programs. Dr. Gray indicted that Kaiser currently ships collected drugs to Texas and Utah for incineration or to North Carolina for ground burial.

Ms. Herold reported that the board continues to see a large number of drug recalls as well as a large number of inquiries on epedigree. She stated that it is anticipated that the board will resume its work in the area of epedigree in September 2011.

The board provided input regarding the current email voting for enforcement matters. Dr. Schell recommended implementation of a ftp model. Board Members Brooks, Lippe, Veale, and Badlani offered to participate in a pilot program to test a new voting process.

The board discussed the mailing of meeting materials via FedEx. Ms. Wheat requested that her materials be emailed as a zip file.

Ms. Herold indicated that she will send an email to Board Members regarding zip file requests for board meeting materials.

Board Member Rosalyn Hackworth recommended that more board functions be conducted electronically. She requested that board member reimbursement be sent regular mail to save on FedEx costs.

The board discussed the creation of a Web site dedicated towards board matters including enforcement decisions and meeting materials.

The board discussed formatting for board meetings.

Dr. Kajioka requested that PowerPoint presentations be provided to members in advance so that they can be viewed on laptops.

Mr. Badlani suggested that the board consider teleconference meetings.

Ms. Shellans provided that teleconferences are an option and are decided by the board president and executive officer. She explained that the location of each member would need to be posted on the meeting agenda.

Ms. Herold indicated that she will continue to provide the board with updates and relevant article clippings.

Ms. Herold provided an overview of the strategic plan process. She indicated that the consultant for this process will be selected by the Organizational Development

Committee. Ms. Herold discussed that the chosen consultant will also be asked to refine the board's report formatting.

Ms. Herold reviewed the SWOT (strengths, weaknesses, opportunities, threats) analysis developed by board staff as discussed during the Organizational Development Committee report. (A copy of this analysis is attached, following this meeting summary.) She explained that the analysis will be used in development of the board's strategic plan as well as for preparation for the Sunset Review process.

President Weisser requested that a copy of this analysis be provided to the board members.

No additional public comment was provided.

XIV. SELECTION OF BOARD MEETING DATES FOR 2012

Ms. Herold indicated that she will send suggested meeting dates for 2012 to the board for consideration via email. Finalized dates will be posted on the board's Web site.

The board discussed upcoming meeting dates for 2011. It was the consensus of the board to reschedule the October 2011 Board Meeting to October 19 and 20, 2011.

No public comment was provided.

XV. PUBLIC COMMENT FOR ITEMS NOT ON THE AGENDA/AGENDA ITEMS FOR FUTURE MEETINGS

No public comment was provided.

The board recessed for a lunch break at 10:59 a.m.

The board reconvened at 12:30 p.m.

XVI. PETITION FOR EARLY TERMINATION OF PROBATION

- All Med Drugs, PHY 49827

XVII. PETITION FOR REINSTATEMENT OF LICENSE

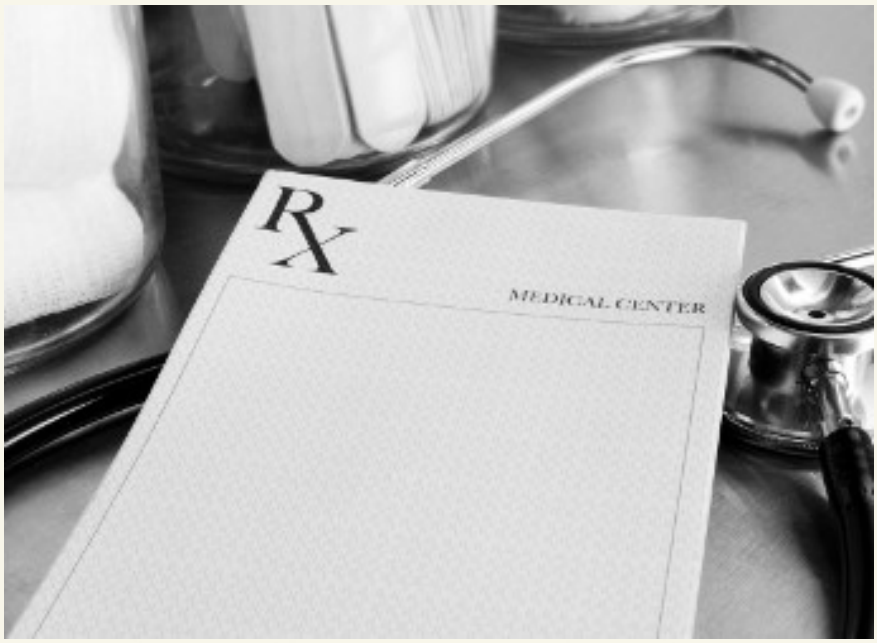
- Clifford Victor, RPH 41656

ADJOURNMENT

The meeting was adjourned at 3:09 p.m.

CALIFORNIA BOARD OF PHARMACY

2011 SWOT Analysis Report



ABOUT THE BOARD

The California State Board of Pharmacy (Board) protects consumers by licensing and regulating all aspects of the practice of pharmacy in California, including the pharmacist, the pharmacy, and prescription drugs and devices. The Board also regulates drug wholesalers, specialized facilities, and other practitioners such as pharmacist interns and technicians.

BACKGROUND

In preparation for the Board's upcoming Strategic Planning session, management and staff met on March 25th, 2011 in order to conduct a comprehensive environmental scan and S.W.O.T Analysis of the program. The meeting was facilitated by the Department of Consumer Affairs' Strategic Planning & Development Unit.

During the session, Board staff worked together to identify areas of particular strength and weakness within the California Board of Pharmacy. They also identified external threats and opportunities that could have a potential impact on the Board in the future. After completing the S.W.O.T analysis, staff reviewed the previous environmental scan that the Board conducted, and offered comments and suggestions on potential updates to the scan, based on recent changes in the marketplace.

The content from this session is designed to help Board members to understand the internal and external forces at play, as they are preparing to complete the upcoming Strategic Plan, which will drive the Board's actions over the next several years.

ELEMENTS OF THE S.W.O.T.

Strengths: characteristics of the board that give it an advantage over others.

Weaknesses: are characteristics that place the board at a disadvantage relative to others.

Opportunities: external chances to make a greater impact in the State.

Threats: *external* elements in the environment that could cause trouble for the Board.

"Our strength grows out of our weaknesses"

– Ralph Waldo Emerson

STRENGTHS

- Job security: The Board has workload, and lots of it!
- The Board is innovative. We strive for changes, and are always looking for a better way to improve our processes.
- The Board has fairly respectable resources – funds, equipment, PC, Telecom. BlackBerrys etc.
- The Board is not in the general fund, safeguarding it from some budgetary issues. Being self-funded often allows the Board to purchase some equipment necessary to perform our jobs efficiently.
- The Board enjoys a good reputation with the public & within DCA.
- The Board has a good mix of experienced and new employees, which allows for fresh ideas alongside traditions, knowledge and policies. The Board's diversity in education and skills make it more flexible.
- Good inter-office communication exists, which facilitates cross training & improved skills.
- The low turnover of staff means that the employees we have are more experienced.
- The Board fosters a team environment.

STRENGTHS

- The Board has field staff throughout the State. Our inspectors are more credible because they are also licensees. Their background also makes them more thorough and much more effective.
- The Board is active in legislationand law making to further protect consumers.
- Boardstaff are committed to doing their part to protect consumers, and have high standards of performance. A real enthusiasm exists for consumer protection within the organization, from the top, down.
- The Board enjoys extremely supportive management. Great leadership currently exists at the EO and AEO level. Executive and administrative management arevery experienced, with years in licensing, enforcement & legislation background.
- Being a small organization, we communicate effectively, people are available, and camaraderie exists. We are a family.
- The Board is result-oriented. We are the 1st line of defense. We also respond and use our enforcement effectively.
- The Board is utilizing the Deputy Attorney General and DOJ for fast legal action.
- TCT: the Board's spirit team is a definite strength.

WEAKNESSES

- Licensees currently feel they are overregulated.
- The Board is forced to use antiquated software programs, such as: TEALE, CAS and ATS. Antiquated equipment also delays the Board's ability to act.
- There has been a delayed implementation of new technology that may improve productivity, such as expanded online services (e.g. online license renewal).
- The Board is short staffed with a high rate of vacancies. Staff resources have not grown, while the licensing base has been steadily increasing.
- There is a major lack of support from DCA Headquarters. Problem areas include Legal, purchasing through BSO, Human Resources and Travel (CAL Aters).
- Chronic budget problems cause major issues:furloughs, lack of resources, purchasing freezes, the hiring freeze, and budget cuts all adversely affect the staff.
- Travel restrictions applied to the Board do not allow out-of-state travel, significantly reducing the number of industry meetings staff can attend.
- State vehicles for inspectors were lost due to governmental budget constraints, such as the 20% deduction in state vehicle fleet, significantly impacting the Board.
- There is a lack of special job training. Licensing and enforcement cross-training should be done more often.

WEAKNESSES

- Employees are being expected to do more with less equipment and staff. Overwhelming workload situations are occurring. In the front office, the volume of phone calls can be overwhelming to the staff
- The Board tends to be reactive opposed to proactive in terms of its approach to consumer protection.
- There are somewhat ambiguous laws for the board and licensees to adhere to.
- There's a clear lack of consumer awareness of what the board can do, caused by poor consumer education.
- Applicants, consumers, and licensees are unaware of the long time-frames involved in some of our processes and therefore become agitated.
- There is a lack of routine meetings or communication between field & office staff.
- Consumers are not always getting excellent service or information, primarily due to overworked staff.
- There is a time delay in prosecuting enforcement cases, originating in the AG office.
- The telephone system is inadequate, and the phone tree hasn't been updated in a long time.

WEAKNESSES

- Low staff morale, primarily caused by the State's chronic budget problems, coupled with a lack of positive feedback to employees, sometimes creates a negative work environment.
- Office temperature control within the building is extremely frustrating.
- There is a lack of communication and networking with outside boards.
- The Web site is not very consumer or licensee friendly.
- The Board needs more office space.Currently the office we are in is very cramped.

Opportunity is missed by most people because it is dressed in overalls and looks like work.
~Thomas Edison

OPPORTUNITIES

- Increase consumer and licensee outreach and education. Focus on teaching licensees & consumers what the Board does and the time-frames involved in those processes.
- Better working relationships, joint investigations with other boards and outside agencies such as the DEA, AG, courts, law enforcement arresting agencies, County Pharmacy Association, Department of Health, training tech schools, OSHPD, etc.
- Develop more alliances. (California's financial restraints on out of state travel have limited some interactions to conference calls).
- Publish *The Script* more often, and educate Registered Pharmacists (RPH) about subscriber alerts.
- Require e-mail addresses from RPH.
- The Board should look into getting access to California Law Enforcement Telecommunication System (CLETS) and LexisNexus databases.
- Outside Training such as: Council on Licensure, Enforcement and Regulation (CLEAR).
- Capitalize on the ability to utilize the AG, Board of Pharmacy CURES data
- Develop a well-rounded disaster response plan.
- Institute inspection ride-a-longs

THREATS

- Politicians with agendas, state bureaucracy, and conflicting interests at DCA and the SCSA.
- Public perception of state employees (we make too much, easy work, overcompensated benefits). Also, union busting efforts by politicians.
- Media sensationalism – Delivering inaccurate or incomplete information.
- Late budgets remove our authority to spend money.
- Increased attrition of staff.
- Pharmaceutical manufacturing lobbyists & corporations.
- The economic crisis will cause an increase in criminal activity due to financial hardship (i.e. increase in fraud).
- More people using and abusing prescription drugs, including some licensees.
- Pricing of pharmaceuticals in the states vs. out of country, and counterfeit drugs.
- Drug-related robberies are becoming more violent.
- Marijuana legislation and dispensaries could be a threat to the industry.
- Staff cutbacks are occurring in pharmacies due to the budget crisis.
- Potential environmental disasters.

THREATS

- AB 507: This pain med bill reduces ability to enforce CS diversion.
- Growth of Pharmaceutical industry and the inability to hire Board staff.
- Fraudulent qualifications such as fake diplomas are leading to unqualified licensees.
- The FDA is lacking resources & leadership.
- TCH Schools are unregulated and provide bad information .
- Increase in Pharmacy schools and licensed professionals, coupled with decreased jobs due to the economy.
- Special interests taking precedence over consumer protection.
- The Board is behind on applications and inspections.
- Budget cuts, furloughs and the hiring freeze have led to improper staffing, an inability to get technology i.e. breeze, proper equipment, etc.
- The complexity of the legislative process.
- Sunset Review.
- External resistance to our goals: manufacturers, chain stores, professional associations, etc.

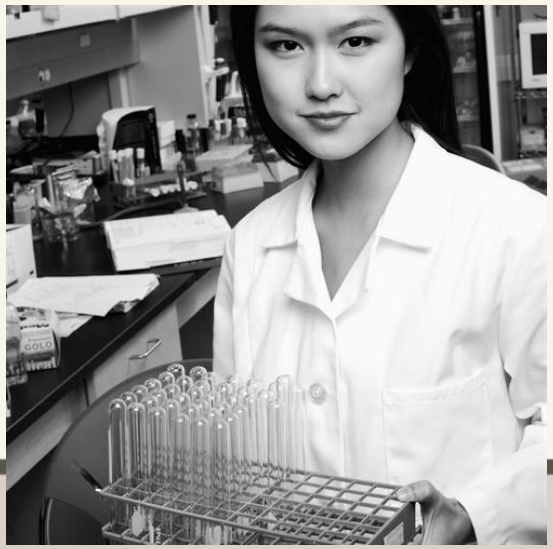
CA Board of Pharmacy, SWOT Analysis Report

ENVIRONMENTAL SCAN

An Environmental Scan is an analysis and evaluation of internal conditions and externaldata and factors that affect the organization.

Comprehensive Environmental Scans include the following:

- *Forecasting business trends.*
- *Conducting internal and external scans.*
- *Describing the current workforce.*
- *Projecting workforce supply and demand.*
- *Identifying current and needed competencies (knowledge, skills, abilities and behaviors).*



ENVIRONMENTAL SCAN

1. *Cost of medical/pharmaceutical care*

Providing necessary medication for all Californians is a concern; there is an increasing demand for affordable health care services. Also, spiraling medical care and prescription drug costs may influence people to take short cuts on their drug therapy or to seek medications from nontraditional pharmacy sources. Tiered pricing is a global reality. Due to global communication, patients can access drugs at different prices, worldwide. Patients seek lower cost medications from these sources because patients assume that prescription drugs are of the same quality as they are accustomed to obtaining from their neighborhood pharmacies. However, the cost of drugs drives unscrupulous individuals (such as counterfeiters and diverters) as well as conscientious health care providers to operate in this marketplace, the former endanger public health and confidence in the prescription drugs patients take.

Concepts for possible updates:

- Advocate color-coded prescriptions, for family members to avoid confusion in the household.
- Recognize the increase in over-the-counter medicinal use, herbal drugs, and the inherent interactions
- Global market drug suppliersare having an impact (china, etc.) 80% of drug ingredients are coming from overseas.
- Compounding is occurring in physician’s offices or out-of-state.
- Nurse Practitioners / Physician Assistants using andabusing drugs, and prescribing unethically.

ENVIRONMENTAL SCAN

2. *Aging Population*

There are increasingly more senior citizens, and that population is living longer. Aging consumers often have decreased cognitive skills, eyesight and mobility. Consequently as the senior population increases so will the volume of prescriptions and the impact on pharmacists and pharmacy personnel to meet the demand. Specialized training of pharmacists may be necessary to better serve the needs of aging patients.

Many senior citizens, who previously may not have had prescription drug insurance coverage, will benefit from the new prescription drug benefit of Medicare that started in January 2006. However, this new benefit has been implemented with significant problems for some seniors, and as a complicated new program, will require public education and perhaps statutory modification.

Concepts for possible updates:

- Increasing Baby Boomer population
- More opportunity for fraud with seniors.

ENVIRONMENTAL SCAN

3. *Pharmacists' ability to provide care*

The ability of pharmacy to provide optimal care for patients with chronic conditions is being challenged. Drugs are becoming more powerful and it is anticipated that more intervention by pharmacists will be required. The challenge is even greater when consumers fill multiple prescriptions at different pharmacies. The pharmacist shortage, increased consumer demand for prescription drugs, patient compliance in taking medications and polypharmacy are issues which will impact pharmacists' ability to provide care.

Concepts for possible updates:

- There is no more pharmacist shortage.
- In regards to consults, can family members sign off on them if they are picking up prescriptions?
- Changing role of the pharmacist. Pressure exists to to make unprofessional choices).
- Industry is a price driven market, less staff leads to problems, overworked pharmacists.
- Complex and powerful drugs being self-administered.

ENVIRONMENTAL SCAN

4. *Changing demographics of California patients*

The diversity of California's population is growing with respect to race, ethnicity and linguistic skills, as is the segment that seeks drugs and products from foreign countries. This requires greater knowledge, understanding and skills from health care practitioners. The increasing diversity of patients is coupled with culturally-based beliefs that undervalue the need for licensed pharmacists and pharmacies, and instead encourage purchase of prescription drugs from nontraditional locations and providers.

There also is widespread belief that there must be a medication solution for every condition or disease state.

Concepts for possible updates:

- Increase in offshoring to India. "Clerk" work is being done by for cheaper in another country. Phone banks are open before and after business hours in America.
- Wages have decreased, salary reductions continue.

ENVIRONMENTAL SCAN

5. *Laws governing pharmacists*

New laws enhancing pharmacists' roles as health care providers are needed. The laws must address several key issues including: expansion of the scope of pharmacy practice, the ratio of personnel overseen by pharmacists, delineation of the role of pharmacists relative to selling versus non-selling duties of personnel, and the responsibility for legal and regulatory compliance of the pharmacist-in-charge.

Concepts for possible updates:

- Discuss the criminal complaint unit.
- Schools are telling students to get pre-screened by the Board, which wastes time.Students are worried they aren't going to pass licensing application background check because of felonies, DUI's, etc.
- Auditing Tech applications requires regulation change
- CURES system data to read before prescribed drugs like OxyCotin.
- Consider changing over back to old vendor, information is ambiguous or not correct. No control at exists at DOJ.
- Renew a commitment to public education to consumers.

ENVIRONMENTAL SCAN

6. *Integrity of the drug delivery system*

Implementation of the e-pedigree for prescription drugs will reduce the growing incidence of counterfeit, damaged, adulterated or misbranded medications in California's pharmacies. Additionally the federal government has demonstrated an increasing interest in regulating health care to safeguard consumer interests. New legislation and regulation may be created in response to emergency preparedness, disaster response and pandemics. Changes in the prescription drug benefits provided to Medicare beneficiaries will continue to command attention.

Concepts for possible updates:

- Require photo ID to pick-up prescriptions to reduce identity fraud. Photo of alternative authorized pick up could be kept on file.
- Picture ID's for Pharmacist/Techs/interns.

ENVIRONMENTAL SCAN

7. *Technology Adaptation*

Technology will greatly impact the processing and dispensing of medication. Electronic prescribing and “channeling” to locations other than a traditional pharmacy may become the business model Automated pharmacy systems and electronic prescribing will impact pharmacy. New methods of dispensing medications raise additional liability issues. New medication, perhaps engineered for specific patients, will become available at high costs and require special patient monitoring systems.

Concepts for possible updates:

- False diplomas can be purchased online for $300. Address this issue.

EVIRONMENTAL SCAN

8.*Internet Issues*

The availability of prescription drugs over the Internet is on the rise. Multiple and easy access of drugs without pharmacist participation is dangerous. Entities promoting illegal drug distribution schemes have taken advantage of the Internet. Monitoring and protecting the public from improper drug distribution from these Internet pharmacies is severely impaired with continued resource constraints by both the federal and state agencies with jurisdiction.

Concepts for possible updates:

- Telemedicine should be incorporated.

EVIRONMENTAL SCAN

9. *Disaster Planning & Response*

Pharmacists need to be ready to be positioned to provide emergency care and medication in response to natural disasters, pandemics and terrorism. This requires specialized knowledge, advance planning and integration of local, state and federal resources that can be quickly mobilized. Specialized drug distribution channels will need to be authorized to permit emergency response.

Additionally, regulatory adjustments to the September 11 terrorism may affect persons' rights to privacy.

Concepts for possible updates:

- No comments

10. *Qualified Staff & Board Members*

The state's fiscal crisis has affected the board's ability to investigate customer complaints or hire staff. The board lost 20 percent of its staff positions during the prior five years due to the state's hiring freezes. Loss of these staff has altered the provision of services by the board. The salary disparity between the private and public sectors in compensation for pharmacists will make it difficult to recruit and retain pharmacist inspectors. Moreover, for all staff, if wages remain essentially frozen, the retention of current employees could be impacted.

The diversity and involvement of all board members in policy development is important for public health and protection. At least a quorum of board members is needed to ensure the board can make decisions and act timely.

Concepts for possible updates:

- No comments

EVIRONMENTAL SCAN

11. *Pharmacy and health care in the 21st century*

The state's health care practitioners (pharmacists, physicians, nurses) are being influenced by a variety of internal and external factors that affect and will continue to effect health care provided to patients. Improved patient care will result from improved integration among these professions. Also, a renewed emphasis on patient consultation will benefit patient knowledge about their drug therapy and thus improve their care.

Concepts for possible updates:

- National health care and its effect on regulators.
- Lack of pharmacist /customer relationship.
- Proliferation of special interests & lobbyists with alternative agendas.

ENVIRONMENTAL SCAN

12. *Information management*

Creation, maintenance and transfer of electronic patient records and prescription orders will be the norm in the future. Patient records need to remain confidential and secured from unauthorized access. Pharmacies and wholesalers need to ensure the availability of an e-pedigree for drugs obtained, transferred and dispensed. It is likely that all controlled drugs dispensed in California will be tracked electronically by the CURES system.

Concepts for possible updates:

- Utilize wholesalers to identify individuals who are selling massive quantities of specific drugs (potentially illegally).
- Increase of schools/ tech schools coupled with the current economic climate, has eliminatedshortage of pharmacists.
- Accreditation process not in place for tech schools.
- Required proof of diploma.Auditing certain % of diplomas submitted.
- Not enough control at Dept. of Education.
- Tech schools are misinforming students.