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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: January 31 and February 1, 2012

LOCATION: Embassy Suites San Francisco Airport
150 Anza Boulevard
Burlingame, CA 94010

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
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
Janice Dang, Supervising Inspector
Joshua Room, Deputy Attorney General
Kristy Shellans, DCA Staff Counsel
Tessa Miller, Staff Analyst

I. CLOSED SESSION

Pursuant to Government Code section 11126(c)(3), the board convened in closed session to deliberate on disciplinary matters.

II. GENERAL ANNOUNCEMENTS

President Stan Weisser called the open session to order at 10:33 a.m.

President Weisser recognized former board president Darlene Fujimoto.

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

III. APPROVAL OF THE FULL BOARD MEETING MINUTES OF OCTOBER 18 & 19, 2011

MOTION: Approve the minutes of the October 18 and 19, 2011 Board Meeting.

M/S: Hackworth/Lippe

Support: 9 Oppose: 0 Abstain: 0

IV. APPROVAL OF THE FULL BOARD MEETING MINUTES OF DECEMBER 6, 2011

MOTION: Approve the minutes of the December 6, 2011 Board Meeting.

M/S: Hackworth/Lippe

Support: 9 Oppose: 0 Abstain: 0

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

Jason Spears, representing Talyst, requested that the board add an agenda item for a future meeting to discuss the use of Talyst's automated dispensing systems in long-term care and correctional facilities.

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

President Weisser recognized Forest Van Vleck from Novato. Dr. Kajioka presented Mr. Vleck with a 50-year pin. Mr. Van Vleck shared that he began his practice as a pharmacist in Mill Valley, worked with Long's for six years, and worked as a pharmacy manager for Safeway in Santa Rosa until his retirement.

President Weisser recognized Bob Betti from Santa Cruz. Dr. Kajioka presented Mr. Betti with a 50-year pin. Mr. Betti graduated from the University of Pacific, School of Pharmacy in 1961 and was the owner of Escalon Drug from 1969 to 2002. Mr. Betti is currently still working as the pharmacy manager at Rite Aid Pharmacy in Santa Cruz.

VII. PRESENTATION BY EDWARD O'BRIEN, CHAIR, RESEARCH ADVISORY PANEL OF CALIFORNIA, ON THE 40TH ANNUAL REPORT OF THE RESEARCH ADVISORY PANEL OF CALIFORNIA

Edward O'Brien provided an overview of the Research Advisory Panel of California and indicated that the board's representative, Peter Koo, has retired and resigned as a member of the panel.

Mr. O'Brien requested that the board consider a recommendation by Dr. Koo to appoint Kirby Lee as his replacement.

Executive Officer Virginia Herold indicated that Dr. Lee's resume has been submitted to the board for consideration.

VIII. LICENSING COMMITTEE REPORT

Report of the Meeting Held December 14, 2011

a. Discussion and Possible Action on Requests for Approval by the Board as Accreditation Agencies for Licensed Sterile Injectable Compounding Pharmacies

Report

Mr. Lippe provided that California Business and Professions Code section 4127.1 establishes a specialized category of pharmacy licensure for pharmacies that compound injectable sterile drug products and sets forth the requirements for licensure including:

1. Licensure as a pharmacy
2. Inspection by the board prior to issuance of a license and prior to renewal of a license

Mr. Lippe provided that Section 4127.1(d) creates an exemption in existing law from this specialty category of board licensure for pharmacies if the pharmacy is:

- licensed by the board or the Department of Public Health
  AND
- currently accredited by the Joint Commission on Accreditation of Healthcare Organizations or other private accreditation agencies approved by the board.

Mr. Lippe advised that an exemption from the specialty license does not exempt the pharmacy from complying with all board laws and regulations surrounding the compounding of sterile injectable products. Rather, such entities must comply with all CA laws, including the compounding regulations established by the board in 2010.

Mr. Lippe provided that consistent with the statute, the board has approved three accreditation agencies:

1. Accreditation Commission for Health Care, Inc (ACHC)

2. Community Health Accreditation Program (CHAP)
3. Det Norske Veritas (DNV)

Mr. Lippe provided that during the September 26, 2011 meeting, the committee heard presentations from representatives of the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) and representative from Pharmacy Compounding Accreditation Board (PCAB). He stated that Supervising Inspector Janice Dang provided the results of her evaluation of the applications submitted by the two agencies as well as the outcomes of her inspections of pharmacies accredited by these two agencies.

Mr. Lippe provided that both organizations were asked to respond to the following requirements:

Survey teams will include a pharmacist.

- HFAP would need to restructure its survey teams to include a pharmacist.
- PCAB surveyor teams consist of all pharmacists.

Agency agrees to provide the board access to accreditation reports.

- HFAP will report deficiencies, serious noncompliance and denial or withdrawals of accreditation to the board.
- PCAB will notify the board regarding noncompliance and situations where a pharmacy's accreditation is denied or revoked.

Agency agrees to conduct an annual inspection of each pharmacy.

- HFAP will conduct annual inspections if required by the board but routine inspections will impact efficiency and lead to additional costs for the pharmacies.
- PCAB annual inspections would increase costs for accreditation and suggested that the board consider random inspection of ten percent of the pharmacies each year.

Mr. Lippe provided that the committee requested clarification regarding these requirements and the commitments agreed to by other accreditation agencies recognized by the board.

Mr. Lippe provided that during the October 2011 Board Meeting, the board discussed the requests and committee recommendations. He stated that the board did not take action on this item; however it was the consensus of the board that this issue be referred back to the committee for further evaluation and consideration of requirements for accreditation agencies.

Mr. Lippe provided that the committee discussed the requests and the results of the evaluation conducted by Supervising Inspector Dang as well as the appropriate duration of approval should the board approve the agencies. He stated that the committee

determined that a two year approval is appropriate to put these agencies on the same track for reconsideration as the other three agencies.

Mr. Lippe referenced the survey results as well as the information submitted by HFAP and PCAB provided in the meeting materials.

Mr. Lippe provided that the committee has recommended that the board approve HFAP and PCAB as accreditation agencies for two years.

Discussion
Ms. Veale spoke in support of the committee's recommendation. She indicated that pursuant to Section 4127.1 and 4127.2, the board is required to recognize JCAHO as an accreditation agency. Ms. Veale suggested that the board consider establishing standards for accreditation agencies to follow.

Public Comment
Steve Gray, representing Kaiser Permanente, sought clarification regarding whether completion of the self assessment form is required for sterile compounding pharmacies accredited by an accreditation agency.

Mr. Lippe advised that these pharmacies must comply with all board laws and regulations.

The board voted on the following motion from the committee. Ms. Veale seconded the motion.

MOTION: Licensing Committee: Approve the Pharmacy Compounding Accreditation Board (PCAB) and the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) as accreditation agencies for two years.

Support: 9 Oppose: 0 Abstain: 0

b. Update on Survey Results on Manpower Assessment Data Collected from the Board's Web site as Required by the Office of Statewide Health Planning and Development

Report
Mr. Lippe provide 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 provide that 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 the DCA has been 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. He stated that in addition, as part of the board's Sunset Report, the board needs to discuss its efforts to collect the information and provide it to OSHPD**.**

Mr. Lippe provided that as the board has neither a statutory or regulatory mandate to collect this data, nor are licensees required to provide this information as a condition of licensure or renewal, implementation efforts are limited.

Mr. Lippe provided that after the October 2011 Board Meeting, the board placed online a survey to encourage submission of data. He stated that a subscriber alert was sent out after this survey was added to the website, and 897 people have responded to date.

Mr. Lippe provided that board staff is working with OSHPD on the appropriate means to share this information.

Mr. Lippe referenced the early results obtained from the survey provided in the meeting materials.

Mr. Lippe advised that the survey can be accessed by going to www.pharmacy.ca.gov and clicking on information for "Licensees."

There was no board discussion or public comment.

c. Summary of a Presentation to the Committee by TCGRx on a Remote Tablet Packager

Report

Mr. Lippe provided that James Spernow, representing TCGRx, provided a presentation to the committee on remote tablet packaging technology. He stated that Mr. Spernow reviewed the capabilities of the automatic tablet packager (ATP) which facilitates the automation and verification of both unit and multi-dose packaging to be dispensed to patients in skilled nursing facilities.

Mr. Lippe provided that Mr. Spernow discussed that although the ATP is housed inside the skilled nursing facility, the medication dispensed by the ATP is owned, controlled and managed by the pharmacy. He stated that it was indicated that the pharmacy is responsible for filling the canisters that will be loaded into the machine with medication and stated that a nurse and a second representative from the facility will load the canisters into the machine. Mr. Lippe provided that Mr. Spernow reviewed safeguards, including the use of barcodes, to ensure accuracy and reduce risks such as diversion.

Mr. Lippe provided that Mr. Spernow reviewed the packaging and labeling of the medication dispensed by the ATP and advised that the pharmacy will ensure that the medication is labeled to comply with the patient-centered requirements with the use of an auxiliary label.

Mr. Lippe provided that the committee discussed the ATP technology in light of pharmacy law. He stated that it was clarified that any medication that may go home with the patient must be labeled according to the patient-centered label requirements pursuant to California Code of Regulations section 1707.5. Mr. Lippe shared that the committee was advised that if the system operated in California, it must be done in compliance with Business and Professions Code section 4119.1, which allows for the use of automated dispensing machines in health facilities.

Discussion

Ms. Veale requested that the meeting summary for the committee meeting be revised to clarify that an auxiliary label will be added to the medication dispensed by the ATP to comply with California's labeling requirements.

No public comment was provided.

d. Summary of Discussion to Develop Regulation Requirements to Specify Standards for Agencies that Accredit Licensed Sterile Injectable Compounding Pharmacies (Proposed as 16 California Code of Regulations Section 1751.9)

Report

Mr. Lippe provided that in 2003, the Licensing Committee developed criteria for the evaluation of applications by accrediting entities for board approval. He stated that it was decided that the evaluation of accrediting agencies for board approval under Business and Professions Code section 4127.1 should be based on the accrediting agency's ability to evaluate the pharmacy's conformance with California law and good professional practice standards and the following factors. Mr. Lippe reviewed the following general criteria that the board initially established in 2003.

1. Periodic inspection -The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years.
2. Documented accreditation standards -The standards for granting accreditation and scoring guidelines for those standards must reflect both applicable California law and sound professional practice as established by nationally recognized professional or standard setting organizations.
3. Evaluation of surveyor's qualifications -The surveyors employed to perform site inspections must have demonstrated qualifications to evaluate the professional practices subject to accreditation.
4. Acceptance by major California payers -Recognition of the accrediting agency by major California payers (e.g., HMOs, PPOs, PBGH, CalPERS).
5. Unannounced inspection of California accredited sites -The board must conduct unannounced inspections of two or more accredited sites and find those sites in satisfactory compliance with California law and good professional practice.
6. Board access to accreditor's report on individual pharmacies.
7. Length of time the accrediting agency has been operating.
8. Ability to accredit out-of-state pharmacies. Non-resident pharmacies are eligible for licensure under the sterile compounding statutes and accreditation should be equally available to both resident and non-resident pharmacies**.**

Mr. Lippe provided that over the past two years the board has reviewed and approved several new accreditation agencies. He stated that during the course of its discussion and evaluation, the board has expressed some hesitation in the approval of accreditation agencies that do not incorporate the following items:

1. A pharmacist as a member of the survey team
2. Perform annual inspections
3. Willingness to share information with the board on findings
4. Ensuring conformance with California’s requirements for LSCs

Mr. Lippe provided that to facilitate implementation of these requirements, regulation language needs to approved and ultimately adopted by the board.

Mr. Lippe provided that the committee discussed the draft language provided as well as comments made by committee members, staff, and counsel. He stated that in addition, the committee discussed the process for implementing the regulations once approved by the board and if current agencies should be grandfathered in. Mr. Lippe advised that several changes were requested to the current draft of regulation. He indicated that the committee requested that the changes be incorporated and brought back to the committee for additional consideration and possible action.

Discussion
Ms. Herold provided that the regulation will be brought to board following the committee's next review.

Mr. Badlani sought clarification regarding the requirements for non-resident pharmacies in this area.

Ms. Herold discussed that the board may wish to consider a requirement that non-resident pharmacies that dispense sterile compounded medication into California be accredited to ensure that they are inspected. She advised that a statutory amendment will be needed to implement this requirement.

e. Discussion and Possible Action on a Proposal to Specify Continuing Education Credit for Pharmacists in Specific Content Areas

Report
Mr. Lippe provided that for some months at 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 stated 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. He stated that any topic the board determines as appropriate for mandatory CE should have generally broad-based applicability for pharmacists.

Mr. Lippe provided that during the October 2011 Board Meeting, the board directed the committee to continue its discussion about such a requirement and specified that if the recommendation is approved, to authorize staff to investigate implementation.

Mr. Lippe provided that during the meeting the committee spoke generally about the board's current policy to award continuing education for attending board and committee meetings. He stated that in addition, the committee discussed the proposal to require continuing education in specific content areas.

Mr. Lippe reviewed the following committee recommendation. Ms. Veale seconded the committee's motion.

> MOTION: Modify the current amount of continuing education awarded to a pharmacist or pharmacy technician for attendance at a full day board meeting to six hours per renewal period. No continuing education credit will be offered for attendance at committee meetings.

Discussion

Ms. Veale reflected on the committee's discussion. She discussed that the committee is seeking to update the board's CE policy by modifying the amount of credit earned for attendance at board meetings and establishing specific content areas for CE. Ms. Veale provided that the committee felt that earning 20 hours for attendance at board meetings out of the 30 required CE hours per renewal period was not balanced and does not add to a pharmacist's competency.

Dr. Castellblanch discussed that he believes it is valuable for pharmacists to see the board's policy process by attending board meetings. He also expressed concern that the committee is recommending that no credit be offered for attendance at committee meetings.

Ms. Veale discussed that committee meetings are often only a few hours to a half day long. She stated that the committee was unsure of how much credit to award given this variance. Ms. Veale discussed that managing attendance at theses meetings may also be an administrative burden for board staff.

DCA Staff Counsel Kristy Shellans discussed that the board's current CE policy would change if the committee's motion is adopted by the board. She stated the board will also have to amend the board's current regulatory proposal that has been filed with the Office of Administrative Law (OAL).

Mr. Brooks spoke in support of awarding prorated credit for committee attendance.

Dr. Kajioka also provided comment in support of awarding some CE credit for attendance at committee meetings as it is an opportunity for licensees to observe the board's regulatory process.

MOTION: Licensing Committee: Modify the current amount of continuing education awarded to a pharmacist or pharmacy technician for attendance at a full day board meeting to six hours per renewal period. No continuing education credit will be offered for attendance at committee meetings.

Support: 0 Oppose: 8 Abstain: 1

Mr. Lippe offered a proposal to accept six hours per renewal period earned for attendance at a full day board meeting and two hours per renewal period for attendance at a committee meeting.

Dr. Castellblanch seconded the proposal.

Public Comment
Mary Ann Sullivan asked how many pharmacists are actually satisfying their CE requirement by earning 20 hours from board meeting attendance. She expressed concern regarding whether or not this change is needed.

Ms. Herold provided that the committee is recommending this change to improve education and competency of licensees.

Dennis McAllister, representing the Arizona Board of Pharmacy, provided that Arizona has also discussed this issue and determined that its licensees can satisfy 10 percent of their CE requirement by attending board and committee meeting.

Ms. Veale provided that the committee did evaluate how much CE was being awarded by other boards of pharmacy and indicated that 20 hours was very high in comparison.

MOTION: Modify the current amount of continuing education awarded to a pharmacist or pharmacy technician for attendance at a full day board meeting to six hours per renewal period and two hours per renewal period for attendance at a committee meeting.

M/S: Lippe/Castellblanch

Support: 9 Oppose: 0 Abstain: 0

Ms. Herold recommended that the board withdraw its current rulemaking that is with the OAL and begin a new rulemaking.

MOTION: Withdraw the current rulemaking filed with the Office of Administrative Law and renotice a new rulemaking consistent with the board's approved modifications for a 45-day public comment period.

M/S: Lippe/Hackworth

Support: 9 Oppose: 0 Abstain: 0

The board discussed the committee's recommendation to establish specific content areas for CE.

Ms. Shellans advised that if approved by the board, staff will draft language consistent with this concept for board consideration to pursue a rulemaking. She stated that the language will clarify that 6 hours total is to be earned within the specific area.

No public comment was provided.

MOTION: Licensing Committee: Initiate a rulemaking to require six hours of mandatory CE per renewal period in the following specific content areas:

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

Support: 9 Oppose: 0 Abstain: 0

f. Discussion on Implementation of AB 2699 (Bass, Chapter 270, Statutes of 2010) on the Board of Pharmacy and Discussion to Develop Regulation Requirements

Report

Mr. Lippe provided that Business and Professions Code section 901 provides the statutory framework for health care offering free care to uninsured or underinsured individuals. He discussed that included in this authority is the ability for health care practitioners licensed in another state, to provide services in CA for such events. Mr. Lippe stated that these provisions were incorporated into SB 2699 (Bass, Chapter 270, Statutes of 2010) and took effect January 1, 2011. He advised that the provisions will sunset January 1, 2014, unless a later enacted statute extends this section. Mr. Lippe provided that while it appeared initially that pharmacists would not be participating in such events, recent information received indicates otherwise.

Mr. Lippe provided that the committee discussed some of the challenges including need to evaluate the scope of an out-of-state pharmacist's participation in health care events as dangerous drugs and controlled substances must be maintained in a licensed pharmacy. He stated that additional information will be obtained about the intent of the legislation and the role board licensees would have at such events. Mr. Lippe indicated that this additional information will be brought back to the committee for future discussion and possible action. He advised that the committee did not take action on this item.

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

g. Competency Committee Report

California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE).

Mr. Lippe provided that the board instituted a quality assurance review of the CPJE effective December 1, 2011. He stated that this process is done periodically to ensure the reliability of the examination. Mr. Lippe indicated that on January 4, 2012, the quality assurance review was removed and results have been released.

Examination Development

Mr. Lippe provided that the Competency Committee workgroup will continue to meet in the spring of 2012 for examination development.

h. Licensing Statistics

Mr. Lippe referenced the licensing statistics for the second quarter of 2011/12 provided in the meeting materials.

i. Workload and Processing Statistics

Mr. Lippe provided that as the board anticipates a reduction in processing times as vacant positions are continued to be filled. He stated that board staff will continue to document progress in reducing backlogs and processing times.

j. Summary of the Meeting Held December 14, 2011

Mr. Lippe referenced the meeting summary provided in the meeting materials.

k. Second Quarterly Report on the Committee's Goals for 2011/2012

Mr. Lippe referenced the second quarterly report on the Licensing Committee's goals provided in the meeting materials.

New Licensing Committee Items Not Discussed During the December 14, 2011 Meeting

l. Discussion on the Implementation of AB 1424 (Perea, Chapter 455, Statutes of 2011) Regarding Franchise Tax Board and New Requirements for Denying or Suspending a License for Delinquent Tax Debt

Report

Mr. Lippe provided that this bill requires the State Board of Equalization and the Franchise Tax Board to each make available a list of the 500 largest tax delinquencies described above at least twice each calendar year. He stated that this bill requires the Franchise Tax Board to include additional information on the list with respect to each delinquency, including the type, status, and license number of any occupational or professional license held by the person or persons liable for payment of the tax and the names and titles of the principal officers of the person liable for payment of the tax if that person is a limited liability company or corporation. Mr. Lippe explained that this bill specifies that a license may be suspended for failure to pay tax delinquencies.

Mr. Lippe provided that the bill included notice requirements advising applicants and licensees of these provisions. He stated that as of December 31, 2011, the below language was inserted into all the board's site and individual initial and renewal applications on the board's web site with the exception of the pharmacy technician initial application, which has a separate notice between the instructions and the first page of the application. Mr. Lippe indicated that his language is also included as an insert to the renewal application mailed to all licensees.

> NOTICE: Effective July 1, 2012, the State Board of Equalization and the Franchise Tax Board may share taxpayer information with the board. You are obligated to pay your state tax obligation. This application may be denied or your license may be suspended if the state tax obligation is not paid.

Mr. Lippe provided that the pharmacy technician application is incorporated by reference into California Code of Regulation section 1793.5. He stated that to include the above notice in the application, a Section 100 regulation change must be pursued.

President Weisser recommended that the board pursue this change.

Public Comment

Steve Gray asked whether the notice includes any indication of what the effect is if the tax liability is under dispute.

Ms. Herold provided that this information is not included in the notice.

Ms. Shellans advised that any dispute would need to be addressed with the tax authority.

Darlene Fujimoto, representing UCSD, sought clarification regarding the board's process for implementing this new requirement and asked whether licensees will be notified of its implementation.

Ms. Shellans provided that the department is working to implement this process across the entire department. She stated that all DCA boards and bureaus have been asked to

post this notice on their website and notify licenses through outreach in addition to the requirement to include the notice on all applications.

MOTION: Direct the executive officer to take all steps necessary to initiate and complete the rulemaking process pursuant to Title 1, California Code of Regulations section 100 to amend Title 16, California Code of Regulations section 1793.5 to change the pharmacy technician application to add the text of the notices required by AB 1424 and authorize the executive officer to adopt these changes upon approval by the Office of Administrative Law.

M/S: Lippe/Veale

Support: 9 Oppose: 0 Abstain: 0

m. Selection of Licensing Committee Meeting Dates for 2012

Mr. Lippe reviewed the following proposed dates for committee consideration:
- April 16, 17 or 19, 2012
- July 12 or 13, 2012
- November 27, 28, or 29, 2012

Confirmed dates will be posted on the board's website.

IX. DEMONSTRATION OF WALGREEN'S NEW PHARMACY DESIGN MODEL TO PROMOTE PATIENT ACCESS TO PHARMACISTS

Al Carter presented a demonstration of Walgreen's new pharmacy design. He indicated that the new format, which has been implemented in several states, is designed to enhance the patient's interaction with the pharmacist.

Mr. Carter reviewed the following features of this new model:
- An open, redesigned layout with no view in the dispensing area. Pharmacists will monitor the dispensing area and activity with video surveillance.
- A pharmacist desk area in front of the pharmacy counter to provide greater accessibility for consultation about medications and to provide additional clinical services. Pharmacists will verify each prescription digitally before it is dispensed to the patient.
- Confidential consultation areas for patient consultation and other services such as immunizations, blood pressure and blood glucose testing, etc.
- A designated Health Guide – a Walgreens employee who is available to answer product and service questions.
- A centralized data entry and data review call center.

Mr. Carter discussed that the new environment is more comfortable, less stressful, and improves patient access to the pharmacist. He stated that patient counseling has increased by 40 percent since its implementation in 100 stores throughout the country.

Mr. Carter provided that Walgreens would like to implement this new model in 60 stores in California by May 2012. He asked whether approval by the board is needed for this implementation.

Ms. Herold expressed concern regarding the lack of direct pharmacist supervision of the dispensing area and the impact this may have on potential risks for diversion. She stated that this model needs further evaluation by the board and its inspectors.

Mr. Carter provided that the pharmacists will remain in the dispensing area until approval is given by the board.

The board recessed for a lunch break at 12:30 and resumed at 1:30 p.m.

Dr. Castellblanch and Mr. Brooks were not present.

X. BOARD DISCUSSION AND POSSIBLE ACTION ON PROPOSED REGULATIONS

a. Regulation Hearing to Amend the Board's Disciplinary Guidelines at Title 16 California Code of Regulations Section 1760, Including to Incorporate Recommendations of the Substance Abuse Coordination Committee (Pursuant to SB 1441, Ridley-Thomas, Chapter 548, Statutes of 2008)

President Weisser called the hearing to order at 1:30 p.m.

No oral testimony was provided on the proposed amendments to amend Section 1760.

Mr. Brooks returned to the meeting room at 1:33 p.m.

President Weisser closed the hearing at 1:35 p.m.

b. Review and Discussion of Comments for Noticed Rulemaking

Assistant Executive Officer Anne Sodergren reviewed the written comment submitted during the 45-day comment period. She reviewed that the commenter has made suggestions regarding definitions, use of business day versus calendar day, epedigree, the board's citation and fine program, public reprimand, tolling provisions, and costs imposed on respondents as a result of a board investigation. Ms. Sodergren stated that the comment included suggestions that are outside the scope of the regulation and do not need to be considered by the board.

Ms. Sodergren advised that board staff does not believe that the board should adopt the proposed changes suggested by the commenter as they are not necessary or not appropriate for the Disciplinary Guidelines.

Ms. Shellans discussed that administrative law judges follow applicable case law to determine the appropriate cost recovery allowable to a state agency.

Dr. Castellblanch returned to the meeting room at 1:40 p.m.

No public comment was provided.

MOTION: Reject the changes suggested in the written comment submitted during the 45-day public comment period to amend Section 1760 and the Disciplinary Guidelines.

M/S: Lippe/Hackworth

Support: 9 Oppose: 0 Abstain: 0

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

Ms. Sodergren requested that the board authorize staff to correct typos within the proposed language.

Ms. Shellans provided that in addition to the proposed updates to the Disciplinary Guidelines, the proposed language also incorporates applicable uniform standards developed by the Substance Abuse Coordination Committee (SACC). She stated that she believes that the board has discretion on whether or not to incorporate these standards.

Deputy Attorney General Joshua Room discussed that implementation of some of the uniform standards into the guidelines may create some challenges with respect to

settling board disciplinary cases. He indicated that there are varying views as to whether the board can deviate from the standards developed by the SACC.

The board discussed the proposed changes to the Disciplinary Guidelines. The board provided support to the proposed changes resulting from the reorganization of the guidelines.

The board proceeded with its discussion by focusing on the following specific terms within the proposed guidelines.

Mr. Brooks left the meeting room at 1:50 p.m. and returned at 1:52 p.m.

Term 8 - Restrictions on Supervision and Oversight of Licensed Facilities (Pharmacists or Designated Representatives only)

Mr. Room reviewed the new options that have been added to this term to now allow pharmacists or designated representatives to supervise ancillary staff with specific restrictions. He advised that these options will benefit the settlement process and potentially reduce costs.

No changes were offered for this term.

Term 20 - Clinical Diagnostic Evaluation

Mr. Room discussed that under option 1 of this term, the respondent is automatically suspended from practice until completion of the evaluation. He stated that this option incorporates recommendations from the SACC.

Ms. Shellans provided that the current guidelines allows for suspension after the evaluation if a practice safety issue is identified.

Ms. Sodergren expressed concern that this option limits the executive officer's discretion to determine when it is appropriate to suspend a licensee. She discussed that individuals are often at varying levels of recovery and do not pose the same risks to public safety.

Mr. Brooks spoke in opposition to this term. He expressed concern that this term limits the board's flexibility and grants discretion to the administrative law judge instead.

Ms. Shellans advised that it is the Department's view that this language must be added to the guidelines. She stated that the board's adoption of this language may be considered during the board's sunset review.

The board took no action on this term.

Term 24 - Drug and Alcohol Testing

Mr. Room discussed that this term has been revised to incorporate the SACC standard regarding the following frequencies for testing:

- At least 52 test dates during the first year of probation
- At least 36 test dates during the second, third, fourth, and fifth years of probation
- At least 1 test per month in each year of probation after the fifth so long as there have been no positive test results during the previous five years.

Mr. Room provided that the term also includes SACC language regarding specimen collectors. He expressed concern regarding whether this language is appropriate for the guidelines and recommended that it be removed.

Ms. Sodergren discussed that an individual's clinical picture should be considered when determining the testing frequency. She also discussed that specified testing frequencies may present a challenge for the board when negotiating settlements.

Mr. Room advised that striking the SACC standard will be a clear deviation from the SACC recommendation and may be considered during the board's sunset review.

The board discussed possible amendments to the language to eliminate the testing frequency and to authorize the board to determine the appropriate level of testing to ensure the safety of the public with increased testing that can be decreased as a licensee advances in his or her recovery. It was suggested that the sections regarding the testing frequency on pages 46 and 47 and the section on specimen collectors on page 48 be stricken from the language.

MOTION: Modify term 24 of the proposed amendments to the Disciplinary Guidelines to strike the testing frequency and replace with more general language consistent with the board's discussion and to strike the section regarding specimen collectors.

M/S: Lippe/Hackworth

Support: 9 Oppose: 0 Abstain: 0

Mr. Room discussed that various terms within the proposed language include minimum standards developed by the SACC regarding the qualifications for evaluators and health group facilitators. He referenced term 39 regarding the

qualifications for facilitators that can be selected by the board and stated that it is unusual for Disciplinary Guidelines to place restraints on the regulatory body.

Ms. Shellans discussed that the SACC established this standard to address some quality issues with facilitators.

Mr. Room suggested that this policy would be more appropriate in a memorandum to the executive officer or within DCA Guidelines as it is direction to the board and not to licensees.

Ms. Sodergren provided that this standard can be incorporated into the scope of service for contracts with facilitators.

MOTION: Strike all language regarding the minimum requirements for facilitators or evaluators within the proposed language.

M/S: Brooks/Wheat

Support: 9 Oppose: 0 Abstain: 0

Mr. Room discussed that the language also includes timelines for which various reports (i.e. clinical diagnostic evaluation) must be completed and submitted to the board. He stated that this also may not be appropriate to include in the guidelines and may subject the board for risk of litigation by respondents.

Ms. Shellans discussed that the board can address deviations from the SACC standards by explaining to the Senate Business and Professions Committee that it has received varying opinions on the board's discretion to implement the standards. She advised that clarification and additional information on this issue may be available to the board by the May 2012 Board Meeting.

Ms. Herold provided that staff will make changes to the proposed language as directed by the board for board consideration at the May 2012 Board Meeting.

The board recessed for a break at 2:41 p.m. and resumed at 2:58 p.m.

XI. DISCUSSION AND POSSIBLE ACTION TO CONVENE A PAIN MANAGEMENT SUMMIT JOINTLY WITH THE MEDICAL BOARD OF CALIFORNIA LATER IN 2012 FOR PRESCRIBERS AND PHARMACISTS

Report

Ms. Herold provided that in the last few years, the board has been struggling to deal with an enormous volume of drug diversion from pharmacies and wholesalers. She discussed that during the board's enforcement discussions and when taking formal discipline, the board has witnessed that huge quantities of prescription medication are being lost. Ms. Herold stated that today prescription drug abuse kills more people than automobile accidents. She provided that the DEA has hosted four national drug take back days for the public to dispose of unwanted medication in consumers' homes as one solution. Meanwhile consumers purchase medication from internet websites, without medical supervision. And until a few years ago with enactment of the federal Ryan Haight Act, many of these websites sold controlled pain medications.

Ms. Herold provided that AB 507 (Hayashi) was introduced in 2011 and sponsored by the American Cancer Society. She stated that the rationale behind this bill was that existing laws prevent patients from getting adequate pain management and relief. Ms. Herold indicated that an early version of this bill was opposed by this board for provisions it contained that would have eliminated provisions that are referenced in case law involving excessive dispensing and a pharmacist's corresponding responsibility. She explained that Assembly Member Hayashi agreed to remove this provision once the board's opposition was expressed and the board's executive officer agreed to work with the American Cancer Society on pain management issues.

Ms. Herold provided that the Board of Pharmacy joined with the Medical Board of California and the DCA to convene a pain management summit over 10 years ago. She stated that one of the outcomes of this conference was a Pain Management Health Notes that was developed and published by this board.

Ms. Herold provided that in the last few months, the executive officers of this board and the Medical Board of California have discussed hosting another pain summit to discuss appropriate pain treatment and how pharmacists and prescribers can work together to provide better patient care.

Ms. Herold recommended that the board develop a new pain summit. She advised that if the board is interested, she will be addressing the Medical Board at its upcoming meeting to discuss joining the board in hosting such a conference later in the year.

Mr. Brooks left the meeting room at 3:06 p.m.

Discussion

Dr. Castellblanch spoke in support of this recommendation and suggested that the board further pursue this issue.

Ms. Veale offered a proposal in support of Ms. Herold's recommendation.

Public Comment

Steve Gray, representing Kaiser Permanente, spoke in support of the summit. He encouraged the board to broaden the scope of those involved to also include other boards. Dr. Gray suggested that the summit include a discussion on pharmacists specialized in pain management.

Jenny Partridge, representing the California Pharmacists Association and the Academy of Compounding Pharmacists, stated that pain management is about 20 percent of the compounding pharmacy practice. She suggested a discussion topic for the summit to focus on the appropriate prescribing, dispensing, and reimbursement of pain management medication.

Mr. Brooks returned to the meeting room at 3:06 p.m.

Laura Myers, Assistant District Attorney, San Francisco, provided comment in support of the summit and stated that it is a good opportunity to bring together all of the stakeholders involved in this issue.

Kathleen Black, Director of Pharmacy, Emanuel Medical Center, Turlock, also provided comment in support of the summit and encouraged that all care areas be represented. Dr. Black suggested that the board consider several topics including transition of care, drug supply and shortages and also consider offering live webinars for CE.

Lugina Mendez-Harper, representing the Board of New Mexico, provided that the Board of New Mexico is also struggling with this issue. She thanked the board for the idea to convene a pain summit and indicated an interest in developing a similar summit for New Mexico.

MOTION: Develop and convene a pain management summit in conjunction with the Medical Board of California.

M/S: Veale/Castellblanch

Support: 9 Oppose: 0 Abstain: 0

XII. REPORT OF THE COMPOUNDING REGULATION SUBCOMMITTEE MEETING HELD JANUARY 4, 2012, AND POSSIBLE ACTION TO RECOMMEND INITIATION OF A RULEMAKING TO MODIFY ARTICLE 4.5 AND ARTICLE 7 OF TITLE 16 OF THE CALIFORNIA CODE OF REGULATIONS

Report

Dr. Kajioka provided that the Compounding Regulation Subcommittee was formed to respond to inquiries regarding implementation of the board's compounding regulations, sections 1735-1735.8 and 1751-1751.8. He stated that these regulations were developed following formation of the board's Committee on Compounding in 2004, and the regulation provisions have gone through various iterations since and before they took effect (although some of the provisions existed as long as the 1980s).

Presentation

Ms. Herold provided an overview of the origins of the compounding regulations as well as a review of the timeline for the evolution of the regulations. A copy of the presentation is attached, following this meeting summary.

Ms. Herold discussed that the new regulations were initiated in response to a letter from the Department of Health Services in July 2002 asking for collaboration with the board to develop comments to the FDA on differentiating between compounding and manufacturing. She provided that in 2004 the board formed a workgroup which developed a legislative proposal as well as regulation proposals in 2005. Ms. Herold explained that this ultimately led to the board's final approval in 2009 and implementation of the regulations effective July 6, 2010.

Discussion

Dr. Kajioka provided that for 18 months, the board has been discussing implementation of these requirements. He stated that a series of questions and answers to aid licensees in understanding the requirements were developed in response to questions licensees were asking. However, questions remain from some of the board's licensees.

Dr. Kajioka provided an overview of the following questions that have been addressed by the subcommittee. The public was provided an opportunity to address each question with the board.

1. What does quality assurance assessment of compounding require?

(1735.8) Summarized: The more frequent or voluminous the compounding, the greater the need for a structured QA for the compounded product. (See questions and answers below). Generally:

1. For medication compounded routinely or periodically -- there should be a process in place
2. For medication compounded for the first time, or almost never, there is less need for structure, unless compounding from non-sterile to sterile.

Subcommittee Recommendation
Dr. Kajioka discussed that the pharmacist-in-charge, using his or her professional judgment, is to determine the component of the QA program and to ensure that the program is being utilized.

Public Comment
Steve Gray, representing Kaiser Permanente, suggested that the board's Q&A document be revised to reflect the subcommittee's review of this question.

Joe Cabaleiro, representing PCAB, discussed challenges with the subcommittee's recommendation and indicated that PCAB is considering a minimum percentage for testing.

Kent Martyn provided comment on the issue of complexity versus volume. He stated that making a lot of a certain product does not necessitate quantitative or qualitative testing.

Lucy Power, representing Power Enterprises, provided comment on USP 797. She advised that USP 797 is not the only chapter that effect sterile compounding.

2. Sterile Injectable Labeling Requirements (1751.2): Labeling of Compounds that are Cytotoxic or Used for Chemotherapy

Issue: Not all cytotoxic agents are chemotherapeutic drugs. In such case, labeling should not alarm patients.

Subcommittee Recommendation:
Dr. Kajioka reviewed the following recommendation from the subcommittee:

Amend section 1751.2(d) to read:

All cytotoxic agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "Cytotoxic product – Dispose of Properly."

Dr. Kajioka provided that this amendment will require a regulation change.

Ms. Veale seconded the subcommittee's motion.

No public comment was provided.

MOTION: Compounding Regulation Subcommittee: Initiate a rulemaking to amend section 1751.2(d) to read:

All cytotoxic agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "Cytotoxic product – Dispose of Properly."

Support: 9 Oppose: 0 Abstain: 0

3. Equipment Used in Compounding

1. Definition of equipment: Problem -- Board Q and A # 23 was too broad in its initial definition of equipment that must be recorded whenever a product is compounded.

Subcommittee Recommendation
Dr. Kajioka reviewed recommendations from the subcommittee.

No public comment was provided.

MOTION: Compounding Regulation Subcommittee: Initiate a rulemaking to amend Section 1735.1 to add a definition of equipment:

(a) "Equipment" means items that must be calibrated, maintained or periodically certified.

Support: 9 Oppose: 0 Abstain: 0

MOTION: Compounding Regulation Subcommittee: Initiate a rulemaking to amend Section 1735.3(a)(7) to remove equipment from the list of items that must be recorded in the daily log when compounding.

Support: 9 Oppose: 0 Abstain: 0

MOTION: Compounding Regulation Subcommittee: Initiate a rulemaking to amend Section 1735.2(d) to require that equipment be added to and recorded in the master formulary:

(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:
(1) Active ingredients to be used.
(2) Inactive ingredients to be used.
(3) Equipment to be used.
(4) Process and/or procedure used to prepare the drug.
(45) Quality reviews required at each step in preparation of the drug.
(56) Post-compounding process or procedures required, if any.
(67) Expiration dating requirements.

Support: 9 Oppose: 0 Abstain: 0

4. Expiration Date of the Components

Issue: One key item missing from recording in the daily log is the expiration date of the components. The subcommittee believes this is an important addition. For compounding of products in hospitals for administration within 24 hours, the committee recommends that expiration date be exempted from recording.

Subcommittee Recommendation
Dr. Kajioka reviewed the subcommittee's recommendation to amend Section 1735.3 to require recording of expiration dates of the components.

Mr. Lippe seconded the committee's motion.

Public Comment
Rita Shane, representing the Cedars-Sinai Medical Center, spoke in opposition to the subcommittee's recommendation. She questioned why compounded medication is the sole focus for expiration dating and expressed concern that this amendment may not lead to better patient safety.

Ms. Herold discussed that cases regarding expiration dating are prevalent in all settings and are not unique to compounding pharmacies.

Discussion continued. It was the consensus of the board to suspend this discussion and to proceed with the next item.

5. Exemption for Hospitals From Recording Lot Number, Manufacturer (and proposed expiration date of components) from the Daily Log for One-time Administration in 24 Hours

Presentation
Rita Shane, representing Cedars-Sinai Medical Center, provided an overview of her presentation given to the subcommittee regarding sterile compounding and related safety strategies in hospital pharmacies to ensure patient safety.

Dr. Shane reviewed a proposal to exempt hospitals that compound any medication on a one-time basis from recording the elements in Section 1735.3(a)(6), and to extend the expiration date to the date that would be appropriate based on USP standards (24 hours if stored at room temperate and three days if refrigerated.

Dr. Shane discussed that complying with the documentation requirements often takes longer that the time it takes to prepare the compounded medication.

Discussion
Dr. Kajioka provided that the subcommittee is offering this issue for discussion by the board.

Ms. Veale sought clarification as to why expiration was not originally included in the regulation.

Ms. Herold provided that she believes this was an oversight.

Ms. Veale offered a proposal to amend Section 1735.3(a)(6) to include the expiration date and an exemption for sterile products compounded on a one-time basis for administration within twenty-four seventy-two hours and stored in accordance with USP standards to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

Ms. Wheat seconded the proposal.

Ms. Herold spoke in support of including the expiration as a requirement. She discussed that this requirement will not only aid the board's investigations, but will also add an additional check to prevent expired medication from reaching patients.

Public Comment
Dave Givants, representing Kaiser Permanente, provided comment on recall response as well as adverse drug events within the hospital setting. He discussed that expired medications are more of a regulatory compliance process issue rather than a patient harm outcome issue and shared that he has never had a patient harm event resulting from expired medications in his experience in managing health system pharmacies. Mr. Givants stated that adding additional steps will increase the potential for error and shifts the pharmacists' focus from appropriate and safe therapy.

Joe Guglielmo, representing the Department of Clinical Pharmacy, UCSF, expressed concern as to whether there is actually a problem in this area. He stated that he is not aware of any evidence to indicate a rate of error attributed to lack of expiration dating. Dr. Guglielmo suggested that the current requirements are sufficient.

Danny Vera, provided that he concurs with his colleagues and discussed that there was a lack of hospital participation when the regulation was developed. He stated that better participation would have perhaps eliminated the problem today.

Rich Sakai, Pharmacy Director at Children's Hospital, Central California, suggested that the board focus efforts and resources to an area with a known benefit to patient safety and proposed that manufactures be required to include the lot number, expiration, and other pertinent information on the product barcode.

Joanna Miller sought clarification regarding question number 7 on the board's Q&A document.

Dr. Dang reviewed that if all the information is not recorded (as provided by the exemption in 1735.3(a)(6)) then there is a lack of complete traceability and accountability for the compounded drug product and thus it cannot be used. She stated that if the proposed amendment is adopted, the product can be reused.

Kent Martyn provided comment regarding the differences between manufacturing and compounding in the hospital setting.

MOTION: Initiate a rulemaking to amend 1735.3(a)(6) to read:

1735.3. Recordkeeping of Compounded Drug Products

(a) For each compounded drug product, the pharmacy records shall include:

(1) The master formula record.

(2) The date the drug product was compounded.

(3) The identity of the pharmacy personnel who compounded the drug product.

(4) The identity of the pharmacist reviewing the final drug product.

(5) The quantity of each component used in compounding the drug product.

(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within ~~twenty-four~~ seventy-two hours and stored in accordance with USP standards to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

M/S: Veale/Wheat

Support: 7 Oppose: 0 Abstain: 2

Ms. Shellans provided that there will be additional opportunity for public comment after the rulemaking has been filed with the Office of Administrative Law.

6. In the interests of patient safety when compounding stock solutions from nonsterile to sterile ingredients, do the stock solutions need to undergo sterility and pyrogen testing?

1751.7(c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogrens.

Discussion

Dr. Kajioka provided that the subcommittee suggests that the board discuss and determine its interpretation of the regulations regarding end-product testing of non-sterile to sterile injectable compounds and whether this requires sterility and pyrogen testing of stock solutions.

Dr. Kajioka advised that the subcommittee did not offer a recommendation.

Dr. Kajioka provided an overview of the following problem:

> Many compounding pharmacies are compounding a stock solution made from one or more non-sterile ingredients. The stock solution is used over a period of time to compound multiple prescriptions by withdrawing an amount from the stock solution to be compounded with other non-sterile or sterile ingredients as prescriptions are received. The compounding pharmacies are filtering the stock solution and the final compounded drug product that has the additional ingredients added. The compounding pharmacy considers the product with all the ingredients to be the "end product." The compounding pharmacy is also considering, once the stock solution is filtered, that it is sterile and does not consider it to be a nonsterile ingredient, even though it is not tested to confirm sterility.
>
> Because the compounding pharmacy is adding additional ingredients with an amount from the stock solution as they receive a prescription, the compounding pharmacy does not consider the final compounded drug as being "batch produced" and therefore, not subject to end-product testing for sterility and pyrogens. This practice of compounding can result in multiple patients being affected by a stock solution that is not tested to confirm sterility.

Dr. Kajioka proposed that the subcommittee continue to discuss this issue and to review best practices in this area.

It was the consensus of the board to allow the subcommittee to further discuss this issue and to proceed with the rulemaking.

Public Comment

Steve Gray, representing Kaiser Permanente, provided that the standard of practice is to test the stock solution. He stated that this is an urgent issue and recommended that the board define stock solution.

Jenny Partridge provided that the Academy of Compounding Pharmacists will be submitting information and research to the subcommittee on this issue. She discussed that there has been no adverse events or deaths from California licensees since the implementation of the sterile compounding regulations in 2004. Ms. Partridge urged the board to not make any decisions in this area until more information is provided.

RECESS FOR THE DAY

The open session of the board meeting was recessed at 5:52 p.m.

XIII. CLOSED SESSION

Pursuant to government code sections 11126(c)(3) and 11126(a)(1), the board convened in closed session to deliberate on disciplinary matters and to evaluate the performance of the board's executive officer.

Wednesday, February 1, 2012

XIV. CLOSED SESSION

Pursuant to Government Code section 11126(c)(3) and 11126(a)(1) the board convened in closed session to deliberate on disciplinary matters and to evaluate the Performance of the board's executive officer

The open session reconvened at 9:01 a.m. on Wednesday, February 1, 2012. Dr. Castellblanch was not present at the call to order.

XV. ORGANIZATIONAL DEVELOPMENT COMMITTEE REPORT

There was no meeting of the Organizational Development Committee this past quarter.

a. Budget Update/Report

1. Budget Report for 2011/12

Report

President Weisser provided that the budget year began July 1, 2011 and will end June 30, 2012. He stated that the Governor's budget for this fiscal year included $14.4M spending authorization for the board. President Weisser indicated that specific line item authorizations for fiscal year 2011/12 and projections for this fiscal year indicate that the board will need to redirect from other budget line items to address the underfunding in the Attorney General line item. He advised that this will be the third consecutive year that the board has significantly overspent on this budget item. President Weisser discussed that such spending is necessary and consistent with the board's consumer protection mandate and underscores the board's significant efforts to discipline errant licensees.

President Weisser referenced various graphs depicting board revenue and expenditures for fiscal year 2011-12. He stated that 91 percent of the board's revenue thus far this year is coming from licensing fees. He also stated that the board's largest expenditures are personnel services (58 percent) and enforcement costs (17.8 percent).

There was no board discussion or public comment.

2. Fund Condition Report

Report
President Weisser provided that according to a fund condition report prepared by the department, the board will have the following fund conditions at the end of the identified fiscal years:

2010/11*	$13,678,000	11.5 months in reserve
2011/12	$11,484,000	9.1 months in reserve
2012/13	$8,423,000	6.6 months in reserve
2013/14	$5,053,000	3.9 months in reserve

* FY 2010/11 includes actual fund

President Weisser provided that the board will continue to closely monitor its fund condition to ensure the fiscal integrity of the board's operations and pursue a fee increase only when necessary.

There was no board discussion or public comment.

Dr. Castellblanch returned to the meeting room at 9:04 a.m.

3. Governor's Proposed Budget for 2012/13

Report
President Weisser provided that every January, as part of the budget process, the Governor releases the budget for the upcoming fiscal year. He stated that this year the Governor released his budget on January 5, 2012. President Weisser stated that included in this budget was $15.289,000 in authorized spending for the board, a slight increase from the board's current year authorization.

There was no board discussion or public comment.

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

Report
Ms. Herold discussed that work continues towards the implementation of the department's new computer system, BreEZe. She stated that based on the current timeline for implementation, the board will be in the second phase of programs transitioning to the new system. Ms. Herold indicated that given this timeline, the board is now less than two years away from changing to this new system.

Ms. Herold provided that BreEZe will allow for online renewal and application processing, and will also replace the board's Consumer Affairs Systems and the Applicant Tracking System.

Ms. Herold provided that the board continues to commit a significant amount of resources and staff time to this project to ensure the board's operational needs are met.

There was no board discussion or public comment.

5. Reimbursement to Board Members

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

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

President Weisser provided that since July 2005, the board has acknowledged 1,175 pharmacists with 50 or more years of licensure as pharmacists in California. He stated that there were 24 pharmacists who reached this milestone between November 2011 and January 2012.

Ms. Herold provided that when a pharmacist reaches this milestone, the board sends a certificate and an invitation to attend a future board meeting for public recognition.

c. Personnel Update

1. Board Member Vacancies

Ms. Herold provided that the board has 10 board members, and three board member vacancies. She stated that the vacant positions are Governor Appointments and are for professional members.

Ms. Herold announced that in December 2011, Stan Weisser and Randy Kajioka were both reappointed to the board.

2. Staff Changes

Ms. Herold provided that the board has been aggressively recruiting to fill vacant positions. She stated that the board has filled 8 inspector positions and will continue recruitment for an additional 15 inspector positions. Ms. Herold advised that travel restrictions have impacted training of the new inspectors.

Ms. Herold introduced new inspectors Catherine Hodnett and Manisha Patel to the board.

Mr. Badlani left the meeting room at 9:11 a.m.

d. Second Quarterly Report on the Committee's Goals for 2011/12

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

Mr. Badlani returned to the meeting room at 9:13 a.m.

XVI. DISCUSSION AND POSSIBLE ACTION TO APPROVE THE STRATEGIC PLAN OF THE BOARD OF PHARMACY FOR 2012-2017 PRESENTATION BY DANIEL IOCANFANO, MOORE IACOFANO GOLTSMAN (MIG)

President Weisser provided that the new strategic plan is being finalized and is not yet ready for review by the board. He stated that the plan will be presented to the board for review and adoption at the next board meeting.

There was no board discussion or public comment.

XVII. ENFORCEMENT COMMITTEE REPORT

There was no meeting of the Enforcement Committee in the past quarter.

a. Presentation of an Overview of California's Pharmacists Recovery Program as Provided in Business and Professions Code Sections 4360 et. seq

Report

Dr. Kajioka provided that Business and Professions Code, Chapter 9, Division 2, Article 21, Sections 4360 et seq., establishes the board's mandate to operate a pharmacists recovery program to rehabilitate pharmacists and intern pharmacists whose competency may be impaired due to abuse of alcohol, drug use, or mental illness. He stated that this article also sets forth the general parameters for this program.

Presentation
Ms. Sodergren provided an overview on California's Pharmacists Recovery Program (PRP). She reviewed the statutory requirements for the program as well as the program parameters and typical treatment for participants. A copy of this presentation is attached, following this meeting summary.

Ms. Sodergren discussed that the PRP is a comprehensive program that allows for immediate intervention by the board to protect the public.

Discussion
Mr. Brooks sought information regarding the recidivism rate of the program.

Ms. Sodergren provided that the current vendor for the PRP is tracking this rate; however, statistics are not yet available.

No public comment was provided.

b. Discussion of the Future of CURES Following Budget Reductions to the Department of Justice, Bureau of Narcotic Enforcement

Report
Dr. Kajioka provided that part of the Governor's 2011-12 budget included substantial reduction to the Department of Justice's Bureau of Narcotic Enforcement (BNE). He explained that this is the unit that house's California's CURES program, a prescription monitoring program for controlled substances in schedules II-IV.

Dr. Kajioka advised that this reduction resulted in the dissolution of the BNE and some services have been lapsed. He stated that the Department of Justice (DOJ) will now temporally operate the CURES program in its information unit.

Dr. Kajioka provided that this is an important program to this board and is used in drug diversion enforcement actions. He stated that for the last several months the board has received inquiries about the status of the program and licensees have reported problems in reaching the board. Dr. Kajioka indicated that board staff also have had difficulty in contacting program staff.

Ms. Herold discussed that there are plans for the DOJ to permanently run the program internally and discontinue use of a contractor to operate the program.

Ms. Herold advised that licensees must continue to report to the CURES program as required. She indicated that updated CURES contact information is available on the board's website and was also sent to licensees in a subscriber alert.

Mr. Lippe left the meeting room at 9:52 a.m.

Public Comment

Steve Gray provided comment regarding the use and benefits of the CURES program with respect to both enforcement and quality of care. He reviewed problems with the program including a lack of acknowledgment from the program when data is submitted and requiring that reporting be according to the federal schedule of controlled substances rather than the California schedule.

Dr. Gray suggested that the board address the schedule problem with an omnibus bill.

Mr. Lippe returned to the meeting room at 9:55 p.m.

Darlene Fujimoto discussed that the California schedule should also be required in the CURES program. She also indicated that pharmacies continue to have problems contacting the program.

Ms. Herold suggested the CURES program be discussed during the Pain Management Summit.

Ms. Sodergren advised that the CURES program will no longer respond to written requests for patient activity reports.

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

Dr. Kajioka referenced the board's enforcement statistics provided in the meeting materials.

d. Second Quarterly Update of the Committee's Strategic Performance Goals for 2010/11

Dr. Kajioka referenced the second quarter's update report on the committee's strategic plan provided in the meeting materials.

XVIII. LEGISLATION AND REGULATION COMMITTEE REPORT

PART I – REGULATIONS

a. Board Adopted Regulations – Approved by the Office of Administrative Law

1. Add Title 16 Section 1707.6 and 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 [Effective Date: February 16, 2012]

Ms. Wheat provided that on January 17, 2012, the Office of Administrative Law approved the board's proposal to amend Section 1707.2 and to Adopt Section 1707.6 of Title 16 of the California Code of Regulations. She advised that the regulation becomes effective on February 16, 2012.

b. Board Approved – Undergoing Review by the Administration

1. Amend Title 16 CCR Section 1732.2 – Board Accredited Continuing Education [45-Day comment period: October 8-November 22, 2010; February 4-21, 2011. Pending Review at the Office of Administrative Law.]

Ms. Wheat provided that this rulemaking will be withdrawn and a new rulemaking will be initiated.

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) [45-day comment period: May 6-June 20, 2011. Pending Review at Department of Finance.]

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) [45-day comment period: May 6-June 20, 2011. Pending Review at Department of Finance.]

Ms. Wheat provided that on May 6, 2011, the board initiated a rulemaking to add Title 16 CCR § 1727.2 and to amend Title 16 CCR § 1728. She stated that the board did not receive any comments during the 45-day comment period and in July 2011 the board directed staff to complete the rulemaking process. Ms. Wheat indicated that the Executive Officer adopted the text as proposed in the Notice for the 45-day public comment period. She stated that staff compiled the final rulemaking file and submitted it to the Department of Consumer Affairs for administrative review on November 10, 2011. Ms. Wheat provided that board staff has been advised that the DCA and the State and Consumer Services Agency have completed their review; the file is now at the Department of Finance awaiting approval. She indicated that once all administrative approvals are

received, the board will make available on its web site additional documents associated with the rulemaking and file the completed file with the Office of Administrative Law for final review.

c. Board Approved - Undergoing Initial 45-Day Comment Period

1. Proposed Amendments to § 1746 – Emergency Contraception Protocol [45-day comment period: January 6 – February 20, 2012]

Ms. Wheat provided that the board has noticed for a 45-day public comment period, proposed amendments to 16 CCR § 1746 related to update the board's Emergency Contraception protocol. She stated that the 45-day public comment period began on January 6, 2012 and will conclude on February 20, 2012.

Ms. Klein provided that one comment has been submitted. She stated that all comments received will be brought to the next board meeting for review.

d. Possible Action – Update Building Standards References
Discussion and Possible Action to Initiate a Rulemaking to Amend Building Standards (Title 24) References in Title 16 CCR Section 1751 and Section 1751.4 For Inclusion in the California Building Standards Commission's 2012 Triennial Code Adoption Cycle

Ms. Klein provided that pharmacy regulations at 16 CCR § 1751 reference various Title 24 regulations related to building standards pharmacies that compound sterile injectable drug products. She stated that the board has been recently advised that updates to Title 24 do not need to go through the California Building Standards Commission (CBSC) and this item no longer requires action by the board.

e. Board Approved – Under Development or Awaiting Notice (Update Only)

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

Ms. Wheat provided that board staff is continuing to work with counsel to develop language for consideration at a future meeting.

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

Ms. Wheat 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.

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

Ms. Wheat provided that the Licensing Committee has not yet initiated a program review of the Veterinary Food-Animal Drug Retailer program. She advised that Staff does not anticipate proceeding with this regulation until such time that the Licensing Committee completes its review.

4. Proposed addition of Section 1762 – Additional Grounds for Unprofessional Conduct

Ms. Wheat provided that staff is working to prepare a rulemaking package for a 45-day public comment period.

5. Proposed addition of Section 1769 – Addition of Application Review to Criteria for Rehabilitation.

Staff is working to prepare a rulemaking package for a 45-day public comment period.

PART II – LEGISLATION

a. Board-Sponsored Legislation for 2012

1. Omnibus Proposal to Amend Section 4209 of the Business and Professions Code related to Intern Pharmacist Applicants and Applicants for the Pharmacist Licensure Examination

Discussion

Ms. Wheat referenced language approved by the board in October 2011 to amend Business and Professions Code section 4209 which would provide the board with the authority to accept intern hours earned in another state, as specified, and to specify requirements for certifications of intern hours earned. She stated that the proposed language is being provided to the Senate

Committee on Business, Professions and Economic Development for consideration in an Omnibus bill for this session.

2. Proposal to Enable the Board to Complete Discipline of a License That Becomes Cancelled Before Completion of the Investigation

Discussion

Ms. Herold provided that staff is bringing the following legislative proposal to the board for consideration for board sponsorship.

Ms. Herold provided that during board investigations, board inspectors typically interview licensees who are the subjects of investigations. She explained that in some cases, knowing that an investigation is underway and hoping to avoid future board discipline (in some cases to prevent other states from learning about board enforcement actions), these licensees will then not renew their licenses or ask that their licenses be cancelled. Ms. Herold advised that this occurs for both individual and site licensees. She stated that for all license types except pharmacists, the law provides for cancellation of the license if it is not renewed within 60 days after expiration.

Ms. Herold provided that once a license is cancelled, the board has no jurisdiction over the former licensee and cannot take any enforcement action against the individual or business to put serious violations on record.

Ms. Herold provided that to ensure the board can put the discipline on record, staff is suggesting an amendment to California Pharmacy Law that is similar to California accountancy law:

> **Board of Accountancy – Section 5109 of the Business and Professions Code**
>
> The expiration, cancellation, forfeiture, or suspension of a license, practice privilege, or other authority to practice public accountancy by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of or action or disciplinary proceeding against the licensee, or to render a decision suspending or revoking the license.

Mr. Lippe offered a proposal to pursue a statutory amendment.

Mr. Room provided that Business and Professions Code section 118(b) generally limits the department's boards and bureaus ability to institute or continue a disciplinary proceeding against a canceled license. He stated that this language

is poorly drafted and should be changed. Mr. Room discussed that it is the board's decision if it would like to also address this statute.

Ms. Shellans provided that section 118(b) has been brought to the department's attention and it has been recommended that the department carry the bill. She suggested that the board pursue its own amendment as proposed.

Mr. Badlani left the meeting room at 10:16 a.m.

Mr. Brooks recommended that this amendment be done with an omnibus bill.

No public comment provided.

MOTION: Authorize the executive officer to pursue statutory amendment to add Section 4300.1 to the Business and Professions Code.

> The expiration, cancellation, forfeiture or suspension of a board-issued license by operation of law or by order or decision of the board or court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of or action or disciplinary proceeding against the licensee, or to render a decision suspending or revoking the license.

M/S: Lippe/Veale

Support: 8 Oppose: 0 Abstain: 0

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

Mr. Badlani returned to the meeting room at 10:19 a.m.

1. AB 389 (Mitchell) Bleeding Disorders: Blood Clotting Products

Summary: AB 389 imposes 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. The board has expressed its opposition to the bill, citing concerns regarding jurisdiction and challenges in enforcing some of the provisions. Recent amendments (1/17/12) remove the definition for and references to "*home nursing services*," and make other technical changes.

Board Position: Oppose (Ver. March 30, 2011)
Amended: January 17, 2012

Discussion
Ms. Wheat provided an overview of the board's opposition letter in which it is explained that the board is unaware of such a problem in this area and is hesitant to endorse unnecessary requirements that could lead to a plethora of additional specialized requirements in law for patients with other conditions.

Ms. Wheat provided that there have been no substantive changes to the bill.

Ms. Herold provided that the board has not received a complaint in this area.

Mr. Lippe suggested that the board retain it current position of oppose.

It was the consensus of the board to maintain its position of oppose on AB 389.

2. AB 1442 (Wieckowski) Reverse Distributors

Introduced January 4, 2012

Summary: AB 1442 amends the Medical Waste Management Act to define, for purposes of the act, "pharmaceutical waste" and "common carrier"; to provide for a pharmaceutical waste hauling exemption; to allow the use of common carriers to transport pharmaceutical waste for disposal, and to specify what information must be maintained regarding the disposal and transporting of pharmaceutical waste. The measure excludes from the definition of "pharmaceutical waste" drugs that must be returned via a reverse distributor pursuant to section 4040.5 of the Business and Professions Code. Staff continues to review the provisions of the bill and may provide additional information at the Board Meeting.

Discussion
Ms. Wheat provided an overview of the bill. She stated that it may be heard in committee on February 4, 2012.

Ms. Herold provided that the board does not have expertise in this area. She suggested that the board take a watch position on the bill at this time.

The board discussed the importance of this issue as it relates to drug take-back programs and risks for diversion. It was suggested that the board invite a reverse distributor to provide a presentation at a future meeting on this issue.

Public Comment
Darlene Fujimoto, representing UCSD, encouraged the board to make this issue a priority. She discussed that many pharmacies have obtained a waiver from their local water district to flush controlled substances down toilets as there is no better option for disposal at this time.

Mark Harvey, representing EXP Pharmaceutical Services, offered support to the board on this issue and provided comment regarding the role of reverse distributors and common carriers. He stated that the goal is to be able to help customers safely eliminate their product.

Danny Vera, Director of Pharmacy at Community Regional Medical Center, provided comment on the disposal of waste pursuant to the Resource Conservation and Recovery Act (RCRA). He discussed how is institution currently disposes of medical waste and stated that proper management and disposal of medical waste is very expensive.

Steve Gray, representing Kaiser Permanente, discussed that according to CalRecycle, expired medication is considered waste and can no longer be transported by common carrier. He provided comment on the various parties involved in this issue and stated that requirements at the state level are needed.

Mr. Badlani suggested that the board request 2 or 3 companies to conduct research in this area and report back on cost effective measures in this area.

Mr. Brooks recommended that the board contact the Governor to encourage all relevant parties to come together to address this issue.

Dr. Castellblanch discussed that this issue is also a serious problem for health plans.

MOTION: Establish a position of watch on AB 1442.

M/S: Wheat/Lippe

Support: 7 Oppose: 2 Abstain: 0

3. AB 377 (Solorio) Hospital Central Fill Pharmacies

Amended: April 14, 2011
Board Position: Support if Amended (Ver. 4/14/11)

Summary: AB 377 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. 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. The board has conveyed its concerns with the bill (to move the new centralized packaging provisions away from the definition of consolidated hospital license). The sponsor has agreed to make this amendment. The bill is moving forward in 2012.

Discussion
Ms. Wheat provided an overview of the bill.

Ms. Herold discussed that this bill will allow for the bar-coding of unit-dose medication produced from a centralized pharmacy location for hospitals under common ownership. She stated that bar-codes can be verified at the patients' bedside and significantly reduce serious dispensing errors.

Ms. Hackworth left the meeting room at 10:56 a.m. and returned at 10:58 p.m.

4. AB 369 (Huffman) Health Care Coverage: Prescription Drugs

Introduced: February 14, 2011
Status: Assembly Second Reading File (1/19/2012)

Of interest. AB 369 addresses health care plan coverage of medications used in pain management therapies.

Discussion
Ms. Wheat provided that this bill does not amend Pharmacy Law provisions and is being provided for information only.

PART III LEGISLATION AND REGULATION COMMITTEE

a. Second Quarterly Report on the Committee's Goals for 2011/12

Ms. Wheat referenced the second quarterly report on the Legislation and Regulation Committee's goals provided in the meeting materials.

XIX. COMMUNICATION AND PUBLIC EDUATION COMMITTEE REPORT

Summary of the Committee Meeting Held January 19, 2012

a. Discussion on Existing Requirements for Patient-Centered Prescription Drug Container Labels and Review of Labels in Use

Report

Mr. Brooks provided that the board has a legislative requirement to provide a report to the Legislature by January 1, 2013 on implementation of the patient-centered labels.

Mr. Brooks provided that the board's staff has begun activities aimed at compiling formation for this report. He added that beginning January 1, 2012, board inspectors have been directed to pick up sample prescription container labels from every pharmacy they enter.

Mr. Brooks encouraged the board begin preparing for this report.

There was no board discussion or public comment.

b. Discussion Surrounding the Developed Translations of Directions for Use for Patient Medication as Specified in16 California Code of Regulations Section 1707.5

Report

Mr. Brooks provided that translations of the standardized directions for use listed in the labeling requirements of section 1707.5 were developed by nationally know researchers who vetted them in field studies through a grant to the researchers funded by the California Endowment. He stated that the translations, which have been developed in Spanish, Russian, Chinese, Vietnamese, Korean, also underwent a second review by Carmazzi Global Solutions, a translation service contracted by DCA**.**

Mr. Brooks provided that these translations have been posted on the board's website.

Mr. Brooks urged licensees to also review the translations before implementing them for use.

There was no board discussion or public comment.

c. Discussion Regarding the Future Design of New Notice to Consumers Posters

Report
Mr. Brooks presented several poster designs that have been reviewed by the committee. He indicated that board staff is working to refine the posters based on comments provided by the committee.

Discussion
Ms. Wheat discussed that the goal of the committee is to produce only one poster rather than two.

Mr. Brooks provided an overview of the elements discussed by the committee including the size of the poster, color, graphics, readability, inclusion of the Board of Pharmacy seal and information to emphasize on the poster such as “Talk to your pharmacist.”

Ms. Hackworth discussed that the committee is aiming to balance inclusion of graphics to attract the attention of consumers while also including pertinent information to inform consumers of their rights.

Ms. Veale discussed that the notice should be designed to facilitate interaction and communication between pharmacists and their patients by emphasizing key information. She indicated that the Notice of Interpreter Availability will be provided as a separate document that is to be posted in an accessible area in which patients can point to their language.

Dr. Castellblanch provided comment in support of including information regarding the right to prescription drug labels in 12-point font on the poster.

Public Comment
Steve Gray, representing Kaiser Permanente, stated that the board has the opportunity to tie the poster to the board’s goal to improve the frequency and quality of consultation as identified in the board’s Strategic Plan. He suggested that the board emphasize the consultation requirement to both patients and pharmacists and limit the use of distracting graphics.

d. Discussion of Video Display Template for Notice to Consumers

Mr. Brooks provided that staff has also begun work on the video format option of the new Notice to Consumers. He referenced the following requirements for this format:

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§ 1707.6. Notice to Consumers.

(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by a prescription drug consumer, a notice

containing the text in subdivision (b). Each pharmacy shall use the standardized poster-Sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval. As an alternative to a printed notice, the pharmacy may also or instead display the notice on a video screen located in a place conspicuous to and readable by prescription drug consumers, so long as:

(1) The video screen is at least 24 inches, measured diagonally;

(2) The pharmacy utilizes the video image notice provided by the board;

(3) The text of the notice remains on the screen for a minimum of 60 seconds; and

(4) No more than five minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or only page of that notice re-displays.

The pharmacy may seek approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

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Mr. Brooks provided that staff has identified a text and graphics format produced by the Patient Education Institute for the National Institutes of Health (NIH) that conveys a video notice in an easily readable format.

A sample video from the NIH can be viewed at the link below. Note: the Board's video messaging will not include audio, only text/graphics on screen.
http://www.nlm.nih.gov/medlineplus/tutorials/takingacetaminophensafely/htm/_yes_50_no_0.htm

Mr. Brooks provided that staff will continue work on this format.

No public comment was provided.

e. Format for Notice of Interpreter Availability

Report
Mr. Brooks provided that the board also has begun work on the notice about the availability of a free interpreter in the pharmacy. He reviewed the following relevant section of the new notice to consumers regulation:

_____

> 1707.6 (c) Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text:
>
> Point to your language. Interpreter services will be provided to you upon request at no cost.
>
> This text shall be repeated in at least the following languages: Arabic. Armenian. Cambodian. Cantonese. Farsi. Hmong. Korean. Mandarin. Russian. Spanish. Tagalog, and Vietnamese.
>
> Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.
>
> The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches.

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Discussion
Ms. Veale discussed that the regulation specifies that the notice must be positioned so that consumers can actually point to and touch it. She discussed that the committee encouraged that the notice be easily accessible to the patient in order to easily and clearly indicate to pharmacy staff that interpreter services are needed.

No public comment was provided.

f. Fortieth Annual Report of the Research Advisory Panel of California

Report
Ms. Herold provided that Ed O'Brien, chair of the Research Advisory Panel, submitted a request to the board to appoint a replacement member to the panel in agenda item VII and provided copies of the Fortieth Annual Report. She stated that she and Board President Weisser will work together on this appointment.

There was no board discussion or public comment.

g. Update on an Assessment of the Board's Public Education Materials

Report
Mr. Brooks provided that an assessment of the board's public educational materials is underway. He stated that drafts will be made available to the board at future meetings.

There was no board discussion or public comment.

h. Discussion of New Webpage Design for the Board of Pharmacy

Report
Mr. Brooks provided that the board has been waiting for approval from the department to institute a new webpage that conforms to a new state format for websites. He stated that the State and Consumer Services Agency and the Department of Consumer Affairs must first convert to the new design before the Board of Pharmacy is given approval to convert.

There was no board discussion or public comment.

i. Update to the Board's Webpage about Implementation of SB 41 (Yee, Chapter 738, Statutes of 2011) regarding Needle Exchange

Report
Mr. Brooks provided that SB 41 (Yee, Chapter 738, Statutes of 2011) requires the board to post or maintain a link to information developed by the California Department of Public Health Office of AIDS on accessing sterile syringes and other health information on HIV and viral hepatitis drug testing and treatment.

He stated that the board now has two links to the Access to Sterile Syringes website that is maintained by the California Department of Public Health Office of AIDS.

Public Comment
Darlene Fujimoto, suggested that this information be sent out via a subscriber alert issued by the board.

Mr. Brooks suggested that the information can also be included in The Script.

Ms. Sodergren advised that pursuant to the requirements of SB 41, the board is required to post this information on its website.

Ms. Herold indicated that a subscriber alert was released in early January 2012 to ensure the board's compliance with the new statutory requirements.

j. Update on The Script

Report
Mr. Brooks provided that the next issue of The Script is pending legal review.

There was no board discussion or public comment.

k. Public Outreach Activities Conducted by the Board

Report
Mr. Brooks referenced the following public and licensee outreach activities performed during the second quarter of the fiscal year 2011/12:

- October 24: Supervising Inspector Hunt represented the board at a public fair for seniors convened by Assembly member Hayashi in San Leandro.
- November 4 and 5: Executive Officer Herold and Supervising Inspector Coyne staffed a board information booth at CSHP's annual meeting Seminar in Orange County.
- November 5: Executive Officer Herold provided a major presented on 2012 Pharmacy Law changes to attendees of CSHP Seminar.
- December 7: President Weisser, Executive Officer Herold and Assistant Executive Officer Sodergren represented the board at a meeting to discuss standardized directions for use and translations of directions for use on prescription container labels, a follow up to the California Endowment's funding of the translated labels.
- December 8: Executive Officer Herold provides a presentation at the Sacramento Valley Society of Health Systems Pharmacists meeting on 2012 changes to California pharmacy law and major current initiates before the board.

Discussion
Ms. Herold discussed that travel restrictions has restricted board operations in all areas, including public and licensee outreach.

Mr. Brooks requested that staff talk with the DCA director regarding the board's special funding. He discussed that this funding should exempt the board from such restrictions.

No public comment was provided.

l. Minutes of the Communication and Public Education Committee Meeting Held January 19, 2012

Mr. Brooks referenced the meeting summary of the January 19, 2012 provided in the meeting materials.

m. Second Quarterly Report on the Committee's Goals for 2011/12

Mr. Brooks referenced the second quarterly report on the committee's goal provided in the meeting materials.

n. Selection of Licensing Communication and Public Education Committee Meeting Dates for 2012

Mr. Brooks stated that the committee will select future meeting dates via email. He advised that confirmed dates will be posted on the board's website.

XX. EXECUTIVE OFFICER'S REPORT

Report

Ms. Herold provided that the board's 2011 Sunset Report is complete. She indicated that the hearing for this review has been tentatively scheduled for March 19, 2013.

Ms. Herold indicated that the board will be working with the Medical Board of California to develop a pain summit. She reviewed several potential topics including advocating that the purpose of a medication be included on the prescription order to be included on the prescription label.

Ms. Herold advised that the mail vote process will be modified to a smaller, weekly batch. She discussed that a mail ballot may also be used in lieu of electronic voting.

Ms. Herold provided an overview of the board's enforcement cases. She stated that board staff will be working with the FDA and other agencies regarding the security of the drug supply across state lines. Ms. Herold discussed that the board will be working with the National Council for Prescription Drug Programs (NCPDP) in the area of epedigree.

Ms. Herold reviewed the board's current licensing timeframes. She advised that the renewal operations of the DCA are delayed about four weeks. Ms. Herold stated that a Subscriber Alert was sent urging that licensees renew timely.

Ms. Herold provided that the board's licensing staff has moved to the additional office space that was recently vacated by the Board of Registered Nursing. She commended board staff for working diligently during this move.

Ms. Herold provided that the board's inspection staff will be holding video/audio conference meetings as travel restrictions have impacted the ability of staff to travel. She also indicated that interviews have been scheduled to fill the board's new inspector positions.

Ms. Herold provided that Denise Brown has been appointed Director of the Department of Consumer Affairs. She also announced that Reichel Everhart has been appointed as the Deputy Director for Board and Bureau Relations.

Ms. Herold advised that board members will need to complete sexual harassment and ethics training.

Discussion
Mr. Brooks sought clarification regarding the implementation of wifi capabilities in the DCA headquarters.

Ms. Herold provided that wifi has been secured and will be available for use during the board's next meeting at the DCA headquarters in Sacramento.

Ms. Wheat requested that board staff develop a summary document regarding the medical waste and reverse distribution for future discussions in this area.

Dr. Castellblanch suggested that staff also identify any reports by other government agencies in this area.

The board recessed for a lunch break at 11:34 a.m. and reconvened at 12:36 p.m.

XXI. PETITION FOR EARLY TERMINATION OF PROBATION

- John Jeleti, Pharmacist License 49954

The board recessed for a break at 1:56 p.m. and reconvened at 2:20 p.m.

Dr. Castellblanch left the meeting for the day at 1:56 p.m.

- James Chinn, Pharmacist License 27782

The open session of the board meeting was adjourned at 3:29 p.m.

XXII. CLOSED SESSION

Pursuant to Government Code section 11126(c)(3), the board convened in closed session to deliberate on the petitions for reinstatement and early termination of probation.

Regulation History

Origins

- 2004 Work group on Compounding develops statutory and regulation changes
- Legislation introduced in 2005
- Legislation died in the fall of 2006
- Board begins working on compounding regulations in January 2007 at its Licensing Committee Meetings

2007

- March – Licensing Committee discusses draft regulations
- May – Licensing Committee reviews regulation subdivision by subdivision
- July – Licensing Committee recommends initiation of rulemaking during board meeting

2008

- January: Board has regulation hearing on proposed requirements. No final action taken
- April: Start new notice based on comments from January
- August 22: new notice begins.
- October: Reg. hearing: Board meeting forms subcommittee to review comments

2009

- January Board Meeting: Board modifies text to specify 2 hours for non recording of lot number and mfg.
- April Board Meeting: board discusses three options: exempt for 24 hours or 12 hours or 2 hours

  Board amends language to 24 hours and releases for (final) 15- day comment
- May: Final 15 day comment period

2009

- July 2009 Board Meeting: board approves language and adopts

2010

- January 6: OAL approves rulemaking
- July 6: Regulations take effect

California's Pharmacists Recovery Program

Statutory Mandate

- B&PC 4001.1
  - Protection of the public shall be the highest priority for the Board.
- B&PC 4360
- Establishes the PRP for pharmacists and interns to rehabilitate those whose competency may be impaired.
- Intent is to allow safe return to practice without compromising public protection

Statutory Mandate

- B&PC 4362
  - As part of probation
  - In lieu of discipline
  - Informal referral
  - Self referral
- B&PC 4363
- B&PC 4365
- Contract with one or more qualified vendors

Statutory Mandate

- B&PC 4366
  - Evaluate those requesting participation
  - Develop treatment contracts
  - Monitor compliance
  - Provide reports
  - Notify participants
- B&PC 4369
- Termination
- Notification to the board

Statutory Mandate

- B&PC 4371
  - Program manager
  - Quarterly review of participants
  - Work with the contractor
- B&PC 4372
- Confidentiality
- B&PC 4373
- Immunity from civil damagers when acting in good faith

Program Scope

- Mental health referral
- Substance abuse
- Dual Diagnosis

Program Overview

- Nonstandard terms
  - Inpatient treatment
  - CDIOP
  - Aftercare
  - Individual therapy
- Standard contract terms
  - Health Support Group
  - AA/NA
  - Worksite monitoring
  - Random drug screens
  - Self-reports

Enrollment Process

- Initial Contact
- Phone Intake interview
- Self-intake package
- Inperson assessment
- Paperwork, including release

Monitoring Participants

- Pharmacists Review Team
- Quarterly review quarterly
- Changes approved by EO or designee
- Inspector staff

Typical Treatment Contract

- New participant
  - Inpatient or CDIOP
  - 90 AA/90 Days
  - Cease practice
  - 2 HSG/week
  - Self-reports
  - Random Drug Screen
    - Hair test
    - Urine

Typical Treatment Contract

- Transition
  - Worksite monitoring
  - Reduction in requirements
  - 12 step essays
  - Gorski Workbook
  - Transition application

Typical Treatment Contract

- Transition
  - Drug testing
  - Quarterly review
  - Inspector review
- Successful completion

Advantages

- Comprehensive Program
- Immediate intervention
- Mandatory reporting to board
- Expertise
- Trends