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STATE AND CONSUMERS SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES

DATE: July 28 and 29, 2010

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

BOARD MEMBERS PRESENT:
Stanley C. Weisser, President
Randy Kajioka, PharmD, Vice President
Ryan Brooks, Public Member
Ramón Castellblanch, Public Member
Rosalyn Hackworth, Public Member
Kenneth Schell, PharmD
Shirley Wheat, Public Member (7/28/2010)
Deborah Veale, RPh
Tappan Zee, Public Member

BOARD MEMBERS NOT PRESENT: Greg Lippe, Public Member, Treasurer

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

Call to Order

President Weisser called the meeting to order at 8:35 a.m.

I. Approval of the Full Board Meeting Minutes of April 21 and 22, 2010

Randy Kajioka requested clarification to his comment on page 23.

Ramón Castellblanch requested that clarification be added to his comment on page 13.

MOTION: Approve the minutes of the April 21 and 22, 2010 Board Meeting as amended.

M/S: Schell/Kajioka

Support: 7 Oppose: 0 Abstain: 0

II. Approval of the Full Board Meeting Minutes of June 10, 2010

Kristy Schieldge provided that she has submitted changes to staff to clarify statements on pages 21, 23, and 25. These changes are to be incorporated into the final version.

MOTION: Approve the minutes of the June 10, 2010 Board Meeting as amended.

M/S: Schell/Castellblanch

Support: 7 Oppose: 0 Abstain: 0

III. Communication and Public Education Committee Report and Action

Report of the Meeting Held July 14, 2010

a. Review of the 39th Annual Report of the Research Advisory Panel of California

Executive Officer Virginia Herold provided an overview of the Research Advisory Panel established by the California Health and Safety Code to oversee research involving use of controlled substances.

She indicated that the executive officer of the panel, Jennifer Ahn, will be invited to a future board meeting to provide more information about the work of the Research Advisory Panel.

No public comment was provided.

b. Development of Consumer Education Videos for the Board's Web Site

Ms. Herold provided that at the end of 2009, the Board of Pharmacy worked with the Department of Consumer Affairs (DCA) and a private vendor to develop a three minute video for consumers about how patients can prevent receiving a medication error. She indicated that this video is available from the board's Web site.

Ms. Herold provided that over the last six months, the board's staff has expressed an interest to the DCA in developing additional videos. She stated that DCA has hired video staff of its own, and thus could produce future videos in-house.

Ms. Herold provided that currently under development as a board/DCA collaboration is development of a new video on the dangers of buying drugs from the Internet.

No public comment was provided.

c. Update on the Development of the Consumer Fact Sheets with California School of Pharmacy Interns

Ms. Herold provided that several years ago, the board approved a proposal by the committee to integrate pharmacy students into public outreach activities. She explained that the intent was to offer students the opportunity to work with the board on meaningful projects promoting consumer education, while the board would benefit from the production of the materials.

Ms. Herold provided that initially the project was initiated with UCSF and their Center for Consumer Self-Care. She stated that over the course of several years, approximately nine fact sheets were developed; however, funding issues prevented UCSF from continuing to do the project without a stipend from the board.

Ms. Herold provided that the board decided to invigorate this program by offering other schools of pharmacy the opportunity to have their students develop one-page fact sheets on various topics, and then have the developed fact sheets reviewed by an expert.

Ms. Herold provided that earlier this year, board staff again contacted each of the California schools of pharmacy to initiate the project. She indicated that there are currently four schools, including Western University, USC, UCSD, and UOP, which have confirmed their participation or have actually developed some fact sheets, although none have been finalized.

Ms. Herold provided that Dr. Castellblanch has indicated that students in public health masters degree programs at San Francisco State would also be interested in developing fact sheets for the board.

No public comment was provided.

d. Public Education Materials Under Development and Proposed for the Future

Mr. Herold indicated that the board has one part-time staff person assigned to this function. She indicated that recently this part-time staffer has been reassigned to report disciplinary data to the Health Practitioner Data Bank. Ms. Herold reviewed the following Board of Pharmacy publications under development, review or revision:

- Revisions to an existing publication: "What you Should know Before Buying Drugs from Foreign Countries or Over the Internet," last revised in 2007, is targeted to be revamped into three publications – "Bringing Prescription Drugs into the Us From Foreign Countries," "Counterfeit Drugs" and "What You Should Know Before Buying Prescription Drugs on the Internet." Copies of the old brochure and the three fact sheets were reviewed by the committee during the meeting.
- Later this fall, the committee plans to release new fact sheets developed by California interns.
- For board licensees, the board has under development:
  - Questions and answers on the board's compounding regulations, following a discussion held at the June 2010 Enforcement Committee, and an ongoing number of questions being asked of the board regarding the compounding regulations.
  - Development of separate fact sheets from two articles published by the CPhA and CSHP in their newsletters -- on "The Pharmacists Recovery Program" and "Becoming a Licensed Pharmacist in California."
- Development of a public education and outreach campaign on the patient-centered prescription container labels is needed.

Public Comment

Mary Staples, representing the National Association of Chain Drug Stores, asked whether the current Notices to Consumers are provided by the board. She sought clarification on which languages the notices are provided in.

Ms. Herold stated that the notices are provided by the board. She stated that the notices are required to be posted in English and are available in several other languages.

Ms. Herold indicated that, if developed, the poster regarding patient-

centered labels will also be provided by the board in multiple languages.

Ms. Staples asked for clarification regarding tip cards.

Assistant Executive Officer Anne Sodergren provided that the example tip card that was referred to in the board packet is a card that is often kept in a wallet or purse to provide information regarding a person's medications and other pertinent information. She stated that the department has developed several tip cards to provide information and tips to consumers as part of its consumer outreach.

Ms. Herold provided that the board will provide these cards on the board's Web site for pharmacies to download and disseminate.

Ms. Staples sought clarification regarding the status of the rulemaking file for patient-centered label regulation.

Ms. Herold provided that the rulemaking file is being reviewed by the department's legal office. She indicated that the file has not yet been referred to the executive office.

Additional clarification regarding the rulemaking process and the intent of the attachments provided in the board packet was provided.

No public comment was provided.

e. Proposal to Assess the Board's Public Outreach Materials

Ms. Herold provided that the committee has determined that it is an appropriate time to assess the board's public outreach materials. She indicated that Chairperson Brooks designated Board Members Veale and Castellblanch to work with staff on this assessment and bring a report back to the committee for a thorough discussion.

No public comment was provided.

f. Update on *The Script*

Ms. Herold provided that work on the July 2010 issue of *The Script* has been completed by staff and the text is undergoing legal review. She stated that this issue will focus on implementation and questions and answers about pharmacy law as well as an update to licensees about the requirements for patient-centered prescription container labels.

Ms. Herold provided that from this point forward, publication of *The Script* will be done electronically, rather than in print. She indicated that licensees will be notified when new issues are released via the subscriber alert.

Ms. Herold provided that work will soon begin on the January 2011 edition which will highlight new pharmacy law that takes effect on January 1, 2011.

No public comment was provided.

g. Request of the California Pharmacists Association to Develop Readiness Announcements for Pharmacy Responders on Disaster Response

Cathi Lord, representing the California Pharmacists Association (CPhA), provided an overview of the Emergency Response Committee. She stated that the committee was created to engage pharmacists in emergency response efforts. Ms. Lord reviewed the following requests to the board to help facilitate efforts in this area:

1. First, can the committee provide the board with an emergency preparedness survey (rather than a link to it) that can be sent to your listserve (aka "subscriber alert")? The committee is trying to gauge what licensed pharmacists know and what actions they have taken to get prepared for emergencies, so the committee can better tailor its next set of messages.
2. Also, the committee would like to prepare some emergency response communications specifically for pharmacists on how to respond to specific disasters, such as fire, earthquake, etc. They are to be in advisory nature, and are intended to answer the inevitable questions that come up when disasters strike, such as "how can I help?." Since the board has direct access to all licensed pharmacists, the committee would like to provide the board with these messages that have been appropriately vetted with disaster response officials, to be sent out in times of need.

Ms. Herold recommended that the board develop a policy for use of the subscriber alert in this area. She advised that the board should also evaluate whether or not it wishes to permit outside agencies to use the subscriber alert.

It was the consensus of the board to discuss this matter at the next committee meeting.

Public Comment

Steve Gray, representing Kaiser Permanente, encouraged the board to consider requiring periodic mandatory continuing education for pharmacists in emergency preparedness. He recommended that the board reconsider its policy on mandatory subjects for continuing education. Dr. Gray advised that the two

pharmacists organizations in California only represent and educate a small percentage (10%) of pharmacists in California.

There was no additional board discussion or public comment.

h. Development of Policy for Activation of the Board's E-Mail Notification Subscriber Alert System

Ms. Herold provided that for at least four years, the board has had an email "subscriber alert" system, by which those interested in receiving email notices from the board about information the board believes is important can receive such notices. She stated that over the last few years, the board has used the subscriber alert system to advise licensees (and other interested parties) about:

- Drug recalls, where the drug is being recalled from the pharmacy or patient
- Emergency response declarations
- Board meeting agendas and meeting materials being released to the public
- Publication and availability of the board's newsletter, *The Script*
- New materials being added to the board's Web site
- "All Facility Letters" released by the California Department of Public Health
- Changes in the CURES program affecting board licensees

Ms. Herold provided that the board has also developed a special subscriber list of pharmacies that are able to compound drugs in emergency response or declared disaster areas, fulfilling a request of the California Department of Public Health for an immediate way to contact these pharmacies.

Ms. Herold provided that in July 2010, California law was amended to require that all sites licensed by the board become subscribers to the board's subscriber alert system. (Individuals who are licensed by the board can become subscribers voluntarily; they are not required to do so.) She stated that currently pending in the California Legislature is SB 1489, an amendment that would allow pharmacy "chains" with multiple pharmacies with the same owner to use a company's internal email notification system for the board's subscriber alert system so long as the headquarters becomes a subscriber, and immediately disseminates the board's subscriber alert message to all of its component pharmacies.

Ms. Herold provided that given the number of outside requests to use the board's subscriber alert system, staff requested the committee develop the following policy statement for approval by the board about the use of the subscriber alert system.

> The Board of Pharmacy's subscriber alert system is an email notification system used by the board to advise its licensees and other interested parties who are self subscribers about California State Board of Pharmacy

policies, publications and activities that impact the board's regulatory jurisdiction or public protection mandate. On occasion, the board will release notices about other matters impacting public health of wide appeal or urgency (such as drug product recalls, notices from other state or federal agencies, emergency declarations). Drug recall notices shall be the top priority for such notices and shall be denoted as a drug recall alert.

Under California law, all sites licensed by the board are required to become subscribers and maintain their current email addresses with this system so that they can receive these board notices. However, the board recognizes the potential to overload licensees and subscribers with less important or unwanted notices, with the ultimate impact that all subscriber alerts sent by the board become viewed with less focus and discernment. As such, the board's executive staff will approve each subscriber alert before release to ensure that the notice advances the board's public protection mandate or relates to the board's regulatory jurisdiction.

No public comment was provided.

MOTION: Communication and Public Education Committee: Approve the Modified Policy Statement, emphasizing drug recalls as a priority for such notices. Direct staff to learn how other boards communicate important notices to their licensees and report to the committee.

Support: 8 Oppose: 0 Abstain: 0

i. Policy Discussion Regarding Web Casting of Board Meetings

Ms. Herold provided that the department now has technology and staff to facilitate the web casting of board and committee meetings and is encouraging the board to web cast its meetings.

Dr. Castellblanch asked whether the web casts would be interactive.

Ms. Herold indicated that the web casts would be view only at this time.

Ken Shell provided comment in support of this option and stated that it is a tremendous opportunity for the board to provide access to the public throughout the state.

Public Comment

Lori Rice, representing the UCSF School of Pharmacy, asked whether continuing education credit would be given to those who watch the web cast.

Ms. Herold provided that the board will address this matter at a future meeting.

There was no additional board discussion or public comment.

Motion: Communication and Public Education Committee: Web cast Board Meetings (not Committee Meetings) whenever the meeting facilities will accommodate such technology.

Support: 8 Oppose: 0 Abstain: 0

j. Public Outreach Activities Conducted by the Board

Ms. Herold referred to the following public and licensee outreach activities performed during the fourth quarter of Fiscal Year 09/10:

- April 12, 2010 -- Executive Officer Herold presented information about the Board of Pharmacy and ongoing projects at a California Society of Health-System Pharmacists Board of Directors Meeting in Sacramento.
- May 5, 2010 - Executive Officer Herold and Supervising Inspector Ratcliff presented information about the Board of Pharmacy and answered questions about pharmacy law to 60 Costco Northern California pharmacy managers.
- May 13, 2010 – Board Member Kajioka provided presentations to students at the University of the Pacific about new pharmacy law and projects at the Board of Pharmacy.
- May 21, 2010 – Supervising Inspector Nurse made a presentation about drug thefts and robberies from pharmacies at a day-long San Diego Pharmacy Conference hosted by the federal Drug Enforcement Administration. Over 100 pharmacy representatives attended.
- May 23, 2010 -- Board President Schell and Executive Officer Herold hosted a booth at the annual National Association of Boards of Pharmacy Meeting in Orange County.
- May 29, 2010 -- Inspector Toevs provided a presentation about lowering drug costs at a community meeting hosted by Senator Liu in Los Angeles.
- June 2, 2010 - Executive Officer Herold presented information about the board's compounding requirements and other key board issues to a meeting of the Bay Area Pharmacy Directors at Stanford.
- June 7, 2010 - Executive Officer Herold attended a conference hosted by the California Endowment on Building Quality and Equitable Health Care Systems in Los Angeles.
- June 17, 2010 – Board Member Schell and Executive Officer Herold participated in a High Risk Drug Task Force Meeting, hosted by the California Hospital Association.
- June 25, 2010 – Executive Officer Herold attended a Medication Safe Alliance Conference in San Francisco hosted by the Pharmacy Foundation of California.

- June 29, 2010 – Executive Officer Herold presented information on the role of the executive officer at the Department of Consumer Affairs Board Member Orientation in Sacramento.

No public comment was provided.

k. Strategic Plan Update for the Communication and Public Education Committee for 2010/2011

Ms. Herold highlighted the committee's recent additions to the strategic plan.

No public comment was provided.

Motion: Communication and Public Education Committee: Add the following objectives to the committee's strategic plan:
- Number of communication venues developed for other health care professionals (e.g., physicians, nurses)
- Assessment of educational materials

Support: 8 Oppose: 0 Abstain: 0

l. Minutes of the Communication and Public Education Committee Held July 14, 2010

Ms. Herold referenced to the minutes of the July 14, 2010 Communication and Public Education Committee Meeting provided within the board packet.

No public comment was provided.

m. Fourth Quarterly Report on Committee Goals for 2009/10

Ms. Herold referenced the fourth quarterly report on the Communication and Public Education Committee's goals contained within the board packet.

No public comment was provided.

n. Public Comment

No additional public comment was provided.

IV. Recognition of Pharmacists Licensed with the Board for 50 Years

President Weisser recognized George MacMurphey. Dr. Kajioka presented Mr. MacMurphey with a 50-year pin. Mr. MacMurphey graduated from the first class of pharmacy graduates from the University of the Pacific in 1959. He worked in community pharmacy for six years and then operated independent pharmacies for nearly 30 years.

President Weisser recognized Don Myers. Dr. Kajioka presented Mr. Myers with a 50-year pin. Mr. Myers graduated from the University of Utah in 1960. He worked as a community pharmacist for 14 years, as a hospital pharmacist for 25 years, and is currently working as a fulltime community pharmacist.

President Weisser recognized Will Henry. Dr. Kajioka presented Mr. Henry with a 50-year pin. Dr. Henry graduated from the University of California, Berkeley with a bachelor's degree in 1960 and earned his doctorate degree from the University of California, San Francisco in 1961. He has owned three stores throughout his career.

President Weisser recognized Donald Lee. Dr. Kajioka presented Mr. Lee with a 50-year pin. Mr. Lee owned his own store for 30 years and also became a hospital pharmacist. He was recognized as the Orange County Pharmacist of the Year in 1980.

President Weisser recognized Howard Strause. Dr. Kajioka presented Mr. Strause with a 50-year pin. Mr. Strause was the owner and operator of Neighborhood Pharmacy and worked in assisted living and a skilled nursing facility. He is still working as a pharmacist today.

President Weisser recognized Harvey Swenson. Dr. Kajioka presented Mr. Swenson with a 50-year pin. Mr. Swenson worked in a variety of settings throughout his career including retail, hospital, long term care, and the Department of Health.

President Weisser recognized Charles Blogell. Dr. Kajioka presented Mr. Blogell with a 50-year pin. Mr. Blogell graduated from the University of Colorado and worked as a pharmacist at Thrifty Drug and Corner Drug in Woodland, California.

President Weisser recognized George Pennebaker. Dr. Kajioka presented Mr. Pennebaker with a 50-year pin. Mr. Pennebaker was the first pharmacy consultant for the Medi-Cal program and was the president of the California Pharmacists Association (CPhA). Mr. Pennebaker recognized fellow pharmacist and son, Tim Cutler.

V. Board Recognition of Mary Anne Koda-Kimble, PharmD, Dean UCSF School of Pharmacy, for Her Contributions to Pharmacy

Dr. Schell recognized Mary Anne Koda-Kimble and presented her with a certificate of appreciation with the following acknowledgment.

> The California State Board of Pharmacy awards its highest recognition to Mary Anne Koda-Kimble, Pharm.D, for her extraordinary accomplishments as a pharmacy educator, mentor, researcher, innovator, and administrator. Your exemplary efforts have produced the highest standards of pharmacist's care for patients, and made a positive and lasting impact worldwide in the education and training of pharmacists. Your leadership, recognized locally, nationally, and beyond in advancing the profession as an integral part of the healthcare process, has been unparalleled and laudable. We acknowledge and thank you for your tireless energy and successes in improving the public health.

Dr. Schell shared the following statement from the board.

> In March of this year, Dr. Mary Anne Koda-Kimble was awarded the pharmacy profession's highest honor, the 2010 Remington Honor Medal at the annual meeting of the American Pharmacists Association. The award recognizes distinguished service and/or outstanding achievement on behalf of American pharmacy.
>
> Dr. Koda-Kimble was nominated for the award for, "…not only the sheer quality and quantity of her accomplishments, but also her leadership, her steadfast dedication, and her sustained commitment to education, the public good and the advancement of the profession that make her a more than deserving nominee." She was also described as a "…major force in shaping, advocating and expanding clinical pharmacy practice in the U.S. and around the world."
>
> After graduating from UCSF in 1969, she joined the faculty in 1970, and was one of a small group of pioneering practitioners who blazed the trail for what was to become known as clinical pharmacy – now an established discipline in which pharmacists directly care for patients in all settings to ensure optimal and safe use of medications.
>
> Realizing that student pharmacists and practitioners needed a textbook uniquely designed for their emerging clinical roles, Dr. Koda-Kimble and colleague Lloyd Young, Pharm.D., led the 1975 publication of *Applied Therapeutics for Clinical Pharmacists*, the first textbook of its kind. The book, recognized as the standard here and abroad, has had eight additional editions and a change of titile, *Applied Therapeutics: The*

Clinical Use of Drugs. Few names in clinical pharmacy worldwide are as recognizable as Koda-Kimble.

In between accepting incalculable awards and delivering numerous lectures, Dr. Koda-Kimble has published 36 articles, 16 books and contributed 31 book chapters.

But the board, while recognizing her many accomplishments, at the same time is most pleased to acknowledge and honor her as one of our own. In 1976, she was appointed a professional member of the board, where she served almost eight years and functioned as president for two years. Also, as a member of the board's Competency Committee, she participated in the development of pharmacy board examination questions for many years.

VI. Presentation by the US Drug Enforcement Administration on Issues and Trends Involving Controlled Substances and Prescription Drug Abuse

- Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, US DEA, Arlington, VA

  Mr. Rannazzisi discussed items of mutual concern to the DEA and to the Board of Pharmacy including drug diversion from the supply chain (dangers to the public, who is doing it, who is buying the drugs from the diverters, strategies to stop it), prescription drug abuse, Internet drug sales, drug take back programs from consumers and e-prescribing of controlled substances.

  Mr. Rannazzisi reviewed the increasing prevalence of prescription drug abuse beginning in the 1960s. He discussed the importance of increased awareness and outreach in this area.

- Thomas Lenox, Group Supervisor, Tactical Diversion Squad, US DEA, San Diego, CA

  Mr. Lenox discussed prescription drug abuse by teenagers and Californians as well as issues involving controlled drugs in San Diego and drug take back programs.

  Mr. Lenox presented statistics and example cases of pharmaceutical and Oxycontin abuse in San Diego County. He highlighted the San Diego Oxy Task Force, a multi-agency task force created to address the issues of prescription drug abuse in San Diego County. Mr. Lenox reviewed the highly addictive nature of drugs like Oxycontin and discussed issues involving teens who start with Oxycontin and then shift to less costly heroin.

VII. Licensing Committee Report and Action

Report of the Meeting Held June 16, 2010

a. Request for Board Recognition of a School of Pharmacy with Precandidate Status with the Accreditation Council for Pharmacy Education Pursuant to 16 CCR § 1719 – New University of New England School of Pharmacy for Portland, Maine

Ms. Herold provided that the University of New England College of Pharmacy has requested that the Board of Pharmacy recognize its school of pharmacy for purposes of approving intern applications.

Ms. Herold provided that during its July 2010 Board of Directors Meeting, the ACPE Board voted to grant the University of New England College of Pharmacy candidate status through June 30, 2011. She stated that given this, this university now falls within the definition of a school of pharmacy recognized by the board in CCR section 1719.

No public comment was provided.

b. Discussion of Proposed Changes to the Intern Hours Requirements for California

Ms. Herold provided that the National Association of Boards of Pharmacy (NABP) will be evaluating how intern hours are earned and counted by each state. She indicated that this will most likely lead to a policy to be released at the next NABP meeting. Ms. Herold stated that the board would not have to adopt this policy.

Ms. Herold provided that over the last few years, the Licensing Committee has considered proposals to amend the intern hour requirements. She stated that the committee has also discussed major changes to intern experience requirements established by the Accreditation Council for Pharmacy Education (ACPE) in the last few years. Ms. Herold indicated that these new requirements added hours to the educational requirements students need as part of their intern training and are required as a condition for a school to maintain its accreditation status with the ACPE. She advised that each time the committee has decided not to recommend changes to the board.

Ms. Herold provided that under current law, an intern must possess 1,500 hours of intern experience under the supervision of a pharmacist before he or she can be made eligible to take the pharmacist licensure examinations in California. (Business and Professions Code Section 4200.)

Ms. Herold provided that additionally, Section 1728 of the California Code of Regulations specifies that a minimum of 900 hours of pharmacy experience must

be earned under the supervision of a pharmacist in a pharmacy. She stated that the remaining 600 hours can be granted for experience under the supervision of a pharmacist substantially related to the practice of pharmacy, but not specifically earned within a pharmacy. Ms. Herold explained that California pharmacy students typically earn the 600 "discretionary" hours for school-related experiential training (clinical clerkship).

Lori Rice, representing UCSF, presented a proposal to change the current intern hour requirement to allow 900 hours to be accrued within a school of pharmacy and reduce the minimum number of pharmacy experience hours to 600. She discussed 2 main reasons for the proposal:

1. Students are finding it more difficult to obtain the 900 required hours in a pharmacy. This may be due to budgetary constraints in chain or hospital practice and/or competition for intern sites (due to the addition of new pharmacy schools in California).
2. The practice of pharmacy has continued to expand. As such, there is a need to recognize experiences in other established pharmacy practice environments.

Ms. Rice provided that this modification would allow flexibility for pharmacy students and schools and would not have a negative impact on schools of pharmacy or the Board of Pharmacy.

Shirley Wheat sought clarification regarding how the 600 discretionary hours are currently obtained and how many graduates will actually practice in a pharmacy.

Ms. Rice provided that pharmacy graduates obtain at least 600 hours of experience in a pharmacy setting during the course curriculum. She stated that the vast majority of graduates will practice pharmacy in a pharmacy setting.

Dr. Castellblanch expressed concern that this modification will impact competency.

Ms. Schieldge provided that the current 900 hour requirement was established to emphasize that students need experience in a licensed pharmacy setting.

President Weisser expressed concern that the emphasis is shifting from community pharmacy to clinical pharmacy.

Ms. Rice provided that UCSF requires a clinical rotation in community practice as part of its curriculum.

Debbie Veale sought clarification regarding the actual time a pharmacy student spends in a clinical rotation.

Ms. Herold provided that the Accreditation Council for Pharmacy Education (ACPE) guidelines require a minimum of 1740 hours in a pharmacy to graduate from an accredited school of pharmacy. She indicated that most schools require either 1000 or 1500 hours of intern experience.

Dr. Kajioka discussed that the 900 hour requirement allows student the ability to hone their skills and to become strong technicians.

Public Comment

Dennis McAllister discussed the requirements established by the Accreditation Council for Pharmacy Education (ACPE) including the requirement for 1740 hours of live, experiential training that must be balanced between community and hospital practice. He indicated that the hour requirement was originally based on an academic year of work. Mr. McAllister suggested that the board consider adopting the 1740 hour requirement and place schools in charge of the experiential training.

Dr. Schell provided that there was no study conducted to establish the hour requirement. He indicated that the requirement was based on the academic year and has not been validated.

Mr. Brooks provided comment in support of the proposal. He indicated that it would provide flexibility for the students and schools.

Ms. Veale asked when the ACPE adopted the 1740 hour requirement.

Mr. McAllister provided that the requirement was adopted in the 2007 standards.

Steve Gray, representing Kaiser Permanente, provided that Kaiser is opposed to this change. He indicated that Kaiser finds that new graduates tend to be inadequately prepared and are often not able to recognize drugs. Dr. Gray discussed a postgraduate residency offered by Kaiser. He proposed that the board consider requiring a one year postgraduate residency prior to licensure.

Mr. Brooks discussed that an emphasis on curriculum and better teaching may better prepare students.

Darlene Fujimoto provided that she was informed that the 1500 hour requirement was based on the length of a one year practice experience. She provided comment in support of the proposal and the move towards more flexibility in this area. Dr. Fujimoto indicated that other schools have expressed similar interests for this change.

Dr. Fujimoto provided that both recent graduates and transferring pharmacists receive additional jobsite training.

Dr. Castellblanch discussed the importance of obtaining clinical practice experience. He stated that both clinical experience and quality curriculum should be a priority.

Tim Cutler, representing UCSF, provided comment in support of the proposal. He stated that ACPE does require standards that are followed by all schools of pharmacy. Mr. Cutler provided that the fourth year curriculum focuses on evaluating a student's competency in a variety of practice settings.

Melissa Kusaka provided that the curriculum has significantly changed since the 1500 hour requirement was established. She indicated that the current curriculum provides more hands on experience. Ms. Kusaka discussed that pharmacy students are faced with many academic demands which can make it difficult to fulfill the hour requirement.

Hilary Campbell provided that every pharmacy school in California requires at least one year of advanced pharmacy practice experience or rotations. She stated that the current 900 hour requirement focuses on dispensing instead of education. Ms. Campbell indicated that job availability is limited and may not provide meaningful on-the-job education. She provided that the proposed change will provide pharmacy schools with more time to educate students.

President Weisser provided that the board may wish to consider holding an informational hearing on this issue. He suggested that board staff conduct some research on the current requirements of other boards of pharmacy in this area.

Tappan Zee provided that the board received testimony on this issue at the last Licensing Committee Meeting which indicated that the pharmacy practice has changed. He proposed a motion to move forward with the proposed change.

Mr. Brooks provided comment in support of the motion. He discussed that the number of hours does not necessarily equate to a better education.

Dr. Schell provided that the motion reflects the tremendous changes in pharmacy curriculum.

Ms. Veale referred to Section 1728 (a)(1)(D). She suggested that the board may not want to specify required hours, and instead, follow the ACPE requirement.

Ms. Hackworth asked how long it will take for board staff to compile the information regarding the hour requirements of other boards of pharmacy.

Ms. Herold indicated that staff should be able to obtain this information relatively quickly.

Dr. Castellblanch expressed concern that the board may be moving too quickly on this issue. He suggested that the board hear more information on this issue including information regarding the safety impact of this change.

Ms. Wheat provided that the board needs to know how this change will impact the consumer.

Dr. Kajioka provided that the pharmacy practice experience provides students with the opportunity to encounter and participate in a variety of real life scenarios that may not be replicated within curriculum. He stated that time spent in pharmacy setting allows students to address a greater number of scenarios.

Mr. Brooks provided that the board needs more information in order to consider if this change will benefit and help the consumer.

Ms. Wheat stated that she would like more detail regarding how the shift in hours will be applied with respect to curriculum.

Dr. Castellblanch provided that more information on this issue is needed. He discussed the changes in pharmacy practice and stated that more training and higher standards may be necessary in order to adequately prepare graduates.

There was no additional board discussion or public comment.

MOTION: Direct staff to draft language for board consideration to amend Section 1728 (a)(1)(A) and (a)(1)(B) of the California Code of Regulations to reflect a minimum of 600 hours of pharmacy practice experience obtained in a pharmacy and a maximum of 900 hours of pharmacy practice experience which may granted at the discretion of the board.

M/S: Zee/Brooks

Support: 8 Oppose: 1 Abstain: 0

The board requested that the Licensing Committee discuss this topic at its next meeting.

The board suspended the Licensing Committee Report in order to hear the Department of Consumer Affairs Director's Report.

Department of Consumer Affairs Director's Report

Department of Consumer Affairs Director Brain Stiger thanked the board members for attending the department's board member training. Mr. Stiger recognized and thanked Ms. Herold for her continued efforts.

Mr. Stiger provided an update on the Consumer Protection Enforcement Initiative (CPEI). He indicated that the department has been approved for about 140 new positions in the Legislative Budget Change Proposal. Mr. Stiger asked the board to move forward with the recruitment process to fill these positions.

Mr. Stiger provided that all DCA boards and bureaus have been directed to begin collecting data on performance measures to be posted on their Web sites.

Mr. Stiger provided that DCA has received approval to implement the BreEZe automated system, providing DCA's customers with an integrated licensing and enforcement information technology solution that will replace the current outdated legacy systems.

Mr. Stiger asked the board to move forward with implementation of provisions from both SB 1111 and SB 1441. He also requested that the board work to streamline and reduce any backlog to ensure that Californians are able to obtain licenses needed for employment.

Mr. Stiger discussed the federal healthcare reform and the impact this will have on all healing arts boards.

Mr. Stiger encouraged the board to web cast as many of its meetings as possible.

No public comment was provided.

The board resumed its discussion of the Licensing Committee Report.

c. Review of Data Describing the Board of Pharmacy's Audits of Continuing Education Earned by Pharmacists as a Condition of Renewal

Ms. Herold provided that Business and Professions Code section 4231 requires a pharmacist to earn 30 hours of approved continuing education during each renewal cycle. She stated that in 2009, this section was amended to also allow the board to convert the renewal to an inactive license if the pharmacist fails to provide such documentation when requested. (A pharmacist with an inactive license cannot work as a pharmacist in California.)

Ms. Herold provided that at the time of renewal, every pharmacist must certify under penalty of perjury that he or she has completed the 30 units.

The exact language a pharmacist is asked to certify is:

> I certify that I have completed _____ hours of continuing education during my last renewal period. I declare under penalty of perjury under the laws of the state of California that the foregoing is true and correct.
>
> _____ _____
> Signature Date

Ms. Herold provided that the board periodically audits a few pharmacists each month to determine their compliance with this requirement. She indicated that if they are unable to provide 30 hours of CE for the renewal period, they are directed to immediately provide proof of completion of additional CE now (earned outside the renewal period, but to bring them into compliance) and then are cited and fined.

Ms. Herold provided that the results of recent board audits indicates that 16 percent of those audited could not provide proof of completion of continuing education credits earned during the last renewal period and, as a result, were cited and fined (fines range from $300-$600). She stated that of these, 5 (2 percent) ended up having their licenses converted to inactive status.

Ms. Herold provided that the Licensing Committee discussed the current CE process as well as possibly identifying target areas for such education at its last meeting. She stated that it was the consensus of the committee to recommend that the full board discuss the topic of targeted CE. Ms. Herold indicated that direction was given to staff to establish parameters in this area. She reported that work has not yet started on establishing these parameters.

Mr. Brooks suggested that the fine be increased in order to deter noncompliance.

Discussion continued regarding the auditing process and the possible increase of fines.

Joshua Room, Deputy Attorney General, cautioned the board from specifying a fine amount and instead suggested that the board provide direction to the executive officer that this is an area of concern and that the fines should reflect this concern.

Ms. Herold provided that this issue will be addressed in *the Script.* She encouraged licensees to maintain either paper or electronic record of their CE credits which must be retained for four years.

No public comment was provided.

d. Proposal to Modify Application Requirements for Intern Pharmacists and Pharmacists to Include "Self-Query" Reports From the Healthcare Integrity and Protection Data Bank (HIPDB)

Ms. Sodergren provided that the board currently reports information regarding its licensees who have been disciplined or otherwise had an adverse action to the Healthcare Integrity and Protection Data Bank (HIPDB) as required by law. She stated that in addition to this reporting, all adverse actions taken by federal or state agencies, exclusions of health care practitioners in federal or state programs, criminal convictions, and civil judgments are also required to be reported to the HIPDB. Ms. Sodergren indicated that the HIPDB serves as the repository of data for all such actions taken against healthcare practioners.

Ms. Sodergren explained that it is not unusual for a pharmacist applicant or intern to also be licensed in other jurisdictions. She indicated that as part of the application process for both the intern and pharmacist exam application, applicants are required to self-disclose several items. Ms. Sodergren provided that the intern application includes several questions surrounding prior disciplinary action taken in this state or any other.

Ms. Sodergren provided that board staff proposes a change to the application requirements to also include a "self-query" report to be required as part of the application process. She stated that requiring such a search will ensure that the board has all relevant information when making a licensing decision and does not inadvertently issue a pharmacist or intern license to an individual that has been disciplined in another state unless, after review of the information, it determines that such an issuance is consistent with the board's consumer protection mandate. Ms. Herold indicated that this requirement will cost the applicant $16.00.

Mr. Zee provided that this proposal is supported by the Licensing Committee.

Ms. Schieldge advised that regulations may be needed to modify the intern pharmacist application.

Public Comment

Steve Gray, representing Kaiser Permanente, provided that the applicant will also have to pay a notary fee. He asked why this requirement is not being proposed for pharmacy technicians.

Ms. Schieldge suggested that the board discuss this during the discussion of the pharmacy technician application.

MOTION: Direct staff to draft language for the board's consideration to initiate a rulemaking to adopt the "self-query" report requirement.

M/S: Hackworth/Veale

Support: 9 Oppose: 0 Abstain: 0

e. Emergency and Disaster Response Planning Update

Ms. Herold provided that in 2007, the board developed and released an emergency response policy, pursuant to California Business and Professions Code section 4062 to waive statutory requirements to benefit public safety in response to a declared emergency or disaster.

Ms. Herold provided that at the October 2009 Board Meeting, the board voted that in situations following a declared emergency or disaster where the board cannot convene a meeting timely, the board delegates its authority to waive statutory requirements to benefit public safety to a committee of three board members via teleconference.

Ms. Herold provided that recently the California Department of Public Health requested clarification on several issues surrounding the board policy.

1. How will the board know when to rescind its emergency suspension of the requirements under these provisions once the emergency has ended?
2. What is the trigger for the emergency to be dissipated and have the licensees return to practice?
3. Who initiates and when does it go into place?

Ms. Herold asked the board to review the following response to ensure it reflects the will of the board:

> There is not a definitive answer. Often there is a point where either the Governor or the Office of Emergency Services makes a statement that the emergency is over. The California Department of Public Health, I would suspect, would also be a likely agency to note when the emergency has dissipated. At some point, business and patients return to normal. This is the point when the board would advise entities to return to normal business practices. In the limited instances where the board used its emergency policy (several years ago during CA's wildfires), we did not need to issue notice about the end of the emergency. Things returned to normal on their own.

Ms. Herold provided that the committee has recommended that the board discuss this response to develop its policy about criteria for ending the emergency authorization and establish parameters for mobile pharmacies.

Mr. Brooks suggested that the board contact the Governor’s Office to seek clarification regarding how a declared emergency order is lifted.

Dr. Schell asked how enforcement is impacted during declared emergencies.

Ms. Herold provided that she is not aware of any significant enforcement problems during recent emergencies. She stated that the only problem she is aware of is where another agency attempted to shutdown services.

Discussion continued regarding the official end of declared emergencies. It was indicated that emergencies can be declared by local agencies, and not just the governor's office. It was the consensus of the board to refer this topic back to the committee for further discussion.

No public comment was provided.

f. Competency Committee Report

Ms. Herold provided that the Competency Committee oversees the board's examination program. She indicated that Board Members Kajioka and Veale have been appointed to the committee.

Ms. Herold referenced to the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) statistics provided within the board packet.

Ms. Herold provided that under the leadership of the board's psychometric consultant, the Competency Committee has worked on revising its content outline and the completed work was presented to the board at the April 2010 Board Meeting. She indicated that during this meeting, the board reviewed and approved the new content outline. Ms. Herold stated that the Competency Committee will begin working with the board's psychometric consultant to ensure the new outline will be used to develop examinations administered after April 1, 2011.

Ms. Herold provided that the new content outline will be available in January 2011.

No public comment was provided.

g. Review and Possible Approval of Accreditation Agencies for Licensed Sterile Injectable Compounding Pharmacies

Ms. Herold provided that the California Business and Professions Code section 4127 et seq. establishes a specialized category of pharmacy licensure for pharmacies that are 1) already licensed pharmacies, and 2) compound injectable sterile drug products. She stated that as a condition of licensure, these pharmacies must be inspected by the board before initial licensure and each year

before renewal of the license. Ms. Herold indicated that his is the only category of board licensure that requires annual inspections as a condition of renewal. Ms. Herold provided that there is 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

- the pharmacy is currently accredited by the Joint Commission on Accreditation of Healthcare Organizations or other private accreditation agencies approved by the board.

Ms. Herold provided that currently there are two accreditation agencies approved by the board: 1. Accreditation Commission for Health Care, Inc. (ACHC), and 2. Community Health Accreditation Program (CHAP).

Ms. Herold provided that during the April 2010 Board Meeting, the board directed that the following occur:

1. Review and assess the three accreditation agencies
2. Report the findings to the Licensing Committee
3. Bring committee recommendations to the full board

She indicated that the board also voted to extend the approval of the two already approved accreditation agencies, ACHC and CHAP, for one year until April 2011.

Ms. Herold provided that the following agencies are requesting approval by the board to serve as accreditation agencies approved by the board.

1. Det Norske Veritas (DNV)
2. Accreditation Commission for Health Care, Inc. (ACHC)
3. Community Health Accreditation Program (CHAP)
4. Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

Supervising Inspector Janice Dang provided a review of Det Norske Veritas (DNV) and her findings from the inspection of the one California licensed pharmacy accredited by DNV. She highlighted the process and criteria used to evaluate DNV as well as the other three agencies. Dr. Dang indicated that DNV meets all of the criteria and has integrated California Pharmacy law into its standards for pharmacies in California.

Ms. Herold provided that the board can determine how frequently it wishes to evaluate and recognize the agencies.

Patrick Horine, representing DNV, provided an overview of the DNV accreditation program. He indicated that DNV is currently recognized by the Centers for Medicare and Medicaid Services (CMS). Mr. Horine stated that there is an optional requirement that allows a hospital to choose accreditation by DNV in lieu of separate licensure by the board.

Ms. Schieldge asked whether DNV would be willing to make the inspections and evaluations available to the board. She advised that state agencies are not permitted to sign confidentiality agreements.

Mr. Horine stated that DNV would like to enter into a collaborative agreement to share information to the board. He indicated that the hospitals would need to be willing to allow DNV to share this information.

Ms. Herold suggested that the board may wish to consider a regulation requiring that accreditation agencies notify the board regarding any violations.

Dr. Schell expressed concern regarding inspection by non-pharmacists.

Dr. Dang indicated that she performed an independent inspection of the sites. She stated that DNV has indicated that pharmacists will conduct the inspections if requested by the board.

Mr. Horine provided that DNV would comply with this requirement and would expect that this requirement is also imposed on the other agencies. He indicated that all accreditation teams will include a physician or nurse as well as a "generalist," which could be a pharmacist.

Dr. Schell stated that the board should evaluate the need for an additional accreditation body.

Mr. Horine provided that DNV is looking for the opportunity to provide hospitals in California with a choice regarding accreditation or licensure.

No public comment was provided.

MOTION: Approve Det Norske Veritas (DNV) to serve as an accreditation agency for three years.

M/S: Brooks/Weisser

Support: 8 Oppose: 0 Abstain: 1

It was the consensus of the board to table the discussion on the other accreditation agencies for a future meeting.

h. Update of the Licensing Committee's Strategic Plan for 2010-2011

Ms. Herold provided that board staff has revised their recommended additions to the committee's strategic plan to better define each task. She stated that the

following tasks are being forwarded to the board for consideration and inclusion into the 2010-11 Strategic Plan and would be included under Objective 2.4 - - Implement 25 changes to improve licensing decisions by June 30, 2011.

20. Automate fingerprint background results with the Department of Justice
21. Evaluate pharmacy technician application process to identify areas for improvement
22. Implement fingerprint requirement for pharmacist renewal
23. Evaluate licensing requirements for businesses seeking licensure that are under common ownership

Public Comment

Steve Gray, representing Kaiser Permanente, sought clarification regarding when the board will discuss targeted continuing education credit.

Ms. Herold provided that the board will discuss this topic at a future meeting.

There was no additional board discussion or public comment.

MOTION: Approve the Licensing Committee's Strategic Plan for 2010-2011 and include the additions as recommended by board staff.

M/S: Hackworth/Schell

Support: 9 Oppose: 0 Abstain: 0

i. Minutes of the Meeting Held June 16, 2010

Ms. Herold referenced to the summary of the meeting held on June 16, 2010 provided in the board packet

No public comment was provided.

j. Licensing Statistics 2009/10

Ms. Herold highlighted the licensing statistics for 2009/10. She stated that the board has experienced significant growth in its individual licensing classifications ranging from 4 percent to 67 percent in the number of applications received, 12 percent – 95 percent in the number of licenses issued and 13 percent to 36 percent in the total number of licensees.

Ms. Sodergren provided that in some classifications of site licensing the board has seen growth, such as with non-resident pharmacies, however in other areas,

the workload fluctuates over the years. She indicated that this is most apparent in the number of applications received from and the number of licenses issued to pharmacies.

Ms. Herold provided that these spikes in workload are usually attributed to a chain store buyout.

No public comment was provided.

k. Fourth Quarterly Update on the Committee's Goals for 2009/10

Ms. Herold referenced to the fourth quarter's status of the Licensing Committee Goals contained within the board packet.

No public comment was provided.

l. Public Comment

No public comment was provided.

VII. Enforcement Committee Report and Action

Report of the Meeting Held June 16, 2010

a. Discussion Regarding the Drug Enforcement Administration's Proposed Regulation for the E-Prescribing of Controlled Substances

Dr. Kajioka provided that the federal Drug Enforcement Administration (DEA) released on March 22 proposed requirements to enable e-prescribing of controlled drugs. He stated that until June 1, 2010, federal law did not allow the electronic prescribing of written prescriptions for controlled drugs. Dr. Kajioka indicated that the comment period on the proposed interim final rule ended on May 31, 2010.

Dr. Kajioka provided that at the April Board Meeting, the board was led in a discussion of the proposed, highly technical requirements by Deputy Attorney General Joshua Room. He stated that after a short discussion, the board agreed to send a request to the DEA to extend the comment period another 120 days so that the board and others could carefully read and consider the more than 330 pages of requirements and policy statements released by the DEA.

Dr. Kajioka provided that e-prescribing of controlled substances is an important and significant change for prescribers, for pharmacies and for patients. He stated that the volume of material released by the DEA for this regulation is

extensive (334 pages), and fortunately, not all these pages are text of the requirements. Dr. Kajioka advised that the regulation is very technical and is difficult to readily digest.

Dr. Kajioka provided that the committee was advised that the DEA has not responded to the board's request for an extension to the comment period and has not trained staff field agents. He indicated that the committee voted to establish an ad hoc committee to review and provide guidelines on the DEA proposed rules.

No public comment was provided.

b. Request to Modify Title 16 California Code of Regulations Section 1713(d) Regarding the Requirement that Automated Dispensing Machines Be Adjacent to the Secure Pharmacy Area

Dr. Kajioka provided that in 2005 and 2006, the board discussed and eventually promulgated a regulation to allow automated dispensing machines in pharmacies to dispense refill medications -- if requested by the patient and approved by the pharmacist.

Dr. Kajioka provided that a number of conditions were built into the regulations to provide for assurance that patients would not be required to use these machines for refills if they were not supportive.

Dr. Kajioka provided that this regulation was promulgated cautiously. He indicated that throughout 2006, the board modified and adopted the regulation now in effect as section 1713. Dr. Kajioka stated that in January 2007, the regulation actually took effect.

During the January 2010 Board Meeting, Phil Burgess representing Asteres made a presentation to the board seeking a waiver from 1713(d) to allow automated dispensing machines to be located in areas other than the requirements of the section that restrict the automated dispensing machine to be adjacent to the secure pharmacy area. He stated that at that time the board asked Mr. Burgess to refine his request and return to the board so the board would more fully understand the proposal.

Dr. Kajioka provided that during the June 2010 Enforcement Committee Meeting, Mr. Burgess requested that the board waive regulation section 1713(d)(6) regarding the placement of automated medication dispensing machines in hospitals to allow for the installation of the ScriptCenter "pickup" system in a hospital environment whereby the unit is not directly attached to the pharmacy. He indicated that Mr. Burgess made a second request for a special waiver to allow for a pilot of this system to demonstrate that improved access

will increase medication adherence and indicated that he would like the waiver for a five year period.

Dr. Kajioka provided that the committee discussed the proposals and sought clarification on the potential impact of the request. He stated that in response Mr. Burgess specified that use of this machine would be limited to hospital employees that elect to use this system and detailed the security measures.

Dr. Kajioka provided that Mr. Burgess was advised that his request to allow for a pilot of this system must be done in a research project in conjunction with a school of pharmacy as provided for in CCR 1706.5. He indicated that the committee did not take action on this item.

Mr. Room requested that "automated delivery devices of previously dispensed medications" be used instead of the term "automatic dispensing machines" as there is a legal distinction.

There was no one present from Asteres to provide information about this proposal.

No public comment was provided.

c. Discussion of a Drug Distribution Model Proposed by Medco Health Solutions, Using Two Pharmacies, Each with Specialized Functions

Dr. Kajioka provided that Title 16, CCR section 1707.4 authorizes a licensed pharmacy to process a refill request received by another pharmacy.

Dr. Kajioka provided that under Medco's proposal, a patient comes into a community pharmacy and receives medication adjudicated by Medco. He stated that the prescription is then either filled by the community pharmacy, or filled by Medco and shipped to the community pharmacy for dispensing.

Dr. Kajioka provided that the committee was provided with a presentation from Medco highlighting a drug distribution model that is currently being pilot tested in several states. He stated that it was clarified that in instances where the medication is not picked up by the patient, the pharmacy will destroy the medication through a reverse distributor. Dr. Kajioka indicated that all documentation and records will be available for the board for inspection. He provided that the committee did not take action on this item. Dr. Kajioka stated that Medco was advised that the model appears consistent with pharmacy law.

Dr. Kajioka added that Medco indicated that they would provide both pharmacies' names and address on the prescription label.

No public comment was provided.

d. Update and Possible Action to Initiate Rulemaking on the Board's Efforts to Implement Components of the Department of Consumer Affairs' Consumer Protection Enforcement Initiative

Dr. Kajioka provided that since July 2009, the Department of Consumer Affairs has been working with the health care boards to upgrade their capabilities to investigate and discipline errant licensees to protect the public. He indicated that the proposed changes include three areas: 1) additional resources, 2) a new computer system and 3) legislative changes. Dr. Kajioka stated that the goal is to ensure the average case closure time for formal discipline, from receipt of the complaint to final vote of the board, occurs within 12 to 18 months.

Dr. Kajioka provided that many of the legislative changes were incorporated into SB 1111 (Negrete-McLeod). He stated that during the April 2010 Board Meeting, the board was advised that SB 1111 failed passage in a policy committee, so the board did not discuss SB 1111 in any detail during that meeting.

Dr. Kajioka provided that following this, the department identified provisions contained in the bill that could be implemented through regulations, and directed that all healing arts boards develop language and initiate the rulemaking process.

Dr. Kajioka provided that during the June 2010 Board Meeting, the board reviewed draft regulation language for some changes. He referred to the following identified sections:

- Amendment to Section 1760 – Disciplinary Guidelines. The proposed amendment would specify that any proposed decision that includes findings of fact that include that a licensee engaged in sexual contact with a patient, client or customer, or a licensee had been convicted of a sexual offense shall contain an order of revocation. The proposed change provides an exception to this and also defined sexual contact. The board took no action on this proposal.
- Amendment to Section 1762 – Unprofessional Conduct. The proposed amendment to this section would specify that certain acts would constitute unprofessional conduct including: gag clauses in a civil suit settlement; failure to provide requests as requested by the board; failure to comply with a court order or subpoena for records; and failure to notify the board of an arrest, indictment, conviction or discipline as specified. The section also specified that the board is authorized to revoke a license or deny an application for an act requiring an individual to register as a sex offender. It was the consensus of the board to bring this issue back to a future meeting for discussion.
- Amendment to Section 1769 – Application Review and Criteria for Rehabilitation. The proposed amendment would allow the board to request

that an applicant for licensure undergo an examination as specified to determine if the applicant is safe to practice. The board voted to require that once it has been determined that an applicant is to be evaluated; the evaluation shall be completed within 60 days. Within 60 days of the evaluation, the report shall be received from the evaluator.

- Amendment to Section 1770 – Substantial Relationship Criteria. The proposed amendment would specify that a crime or act that resulted in a licensee being required to register as a sex offender would be considered substantially related to the functions and qualification of the license. The board did not take action on this proposal.

Dr. Kajioka provided that additional items for consideration will be discussed at the next Enforcement Committee and will be brought to the board for consideration in October.

Ms. Sodergren provided that board staff recommends that this matter be referred to the Enforcement Committee for further deliberation and refinement.

No public comment was provided.

MOTION: Draft language for review and further discussion by the Enforcement Committee.

M/S: Kajioka/Brooks

Support: 9 Oppose: 0 Abstain: 0

e. Update on California's Drug "Take Back" Programs from Patients

Dr. Kajioka provided that Senate Bill 966 required CalRecycle to work with agencies including the Department of Toxic Substances Control, the State Water Resources Control Board, and the California State Board of Pharmacy to develop criteria and procedures for model pharmaceutical waste collection programs by December 2008. He stated that SB 966 also required CalRecycle to analyze model programs for effectiveness, cost, accessibility, and safety. Dr. Kajioka indicated that these findings must be included with recommendations in a report to the Legislature by December 2010.

Dr. Kajioka provided that since 2007 the board has been discussing drug take back programs. He stated that such programs are growing in popularity as consumers look for a safe, convenient and environmentally friendly ways to dispose of unused medicine. Dr. Kajioka added that environmentalists continue to advocate for such programs to reduce the amount of such medication that ends up in our water supply and land fills.

Dr. Kajioka provided that the board has heard presentations from vendors making collection containers for pharmacies, heard concerns from the Department of Public Health, and has worked with the California Integrated Waste Management Board (now CalRecycle) to establish parameters for these programs.

Dr. Kajioka provided that in the February 2010 *The Script,* the board promoted the take-back guidelines developed by the California Integrated Waste Management Board pursuant to SB 966 (Simitian, Chapter 542, Statutes of 2007).

Dr. Kajioka provided that since April, board inspectors have been directed to take pictures of drug take back programs in place in pharmacies, and to encourage compliance with the state's guidelines.

Dr. Kajioka provided that the Drug Enforcement Administration continues to be concerned about these programs nationally, and is working with counties that are establishing principally short-term take back programs for controlled drugs. He stated that in some communities, law enforcement is working under the DEA's preference to accept take back controlled drugs at law enforcement facilities.

Dr. Kajioka provided that during its meeting, the committee was advised that the CalRecycle Program was holding a workshop on home-generated pharmaceutical waste collection and disposal on July 20, 2010. He indicated that the committee took no action on this item.

Dr. Kajioka provided that board staff attended the July meeting with the committee chair. He explained that this meeting was convened to discuss a draft report assessing implementation of the proposed guidelines developed in late 2008 for California by the CIWMB/CalRecycle.

Dr. Kajioka highlighted the four proposals arising from the report:
1. Continue Current Practices
2. Improve Guidelines, Enforcement and Establish Clear State Agency Roles and Responsibilities
3. Implement Product Stewardship
4. Create a Statewide Collection Program Using an Advanced Disposal Fee and State Oversight.

Ms. Schieldge encouraged the board to submit comments to CalRecycle as these recommendations may result in legislative changes to model "take back" programs.

Mr. Brooks suggested that the board reach out to law enforcement agencies to encourage them to also submit comments.

Dr. Schell made a proposal for the board to submit comments to CalRecycle.

Ms. Herold stated that many interested parties are seeking the lowest cost solution with regards to drug take-backs. She discussed that promoting the guidelines is a good opportunity for the board to encourage safe, convenient, and environmentally friendly disposal of unused medicine.

Mr. Brooks discussed that this issue is complex and encouraged the board to focus on the elements within its jurisdiction.

Dr. Kajioka provided that the comments submitted to CalRecycle should indicate that "take back" programs are voluntary and are not mandated.

Public Comment

Steve Gray, representing Kaiser Permanente, provided that local ordinances are beginning to mandate drug take back programs. He suggested that the board request a briefing on the status of these ordinances from counsel as many pharmacies are struggling to determine what ordinances they must comply with.

Ms. Herold referred Dr. Gray to SB 762 by Senator Aanestad which would codify that the California legislature, the Department of Consumer Affairs (DCA), and the boards and bureaus overseen by the DCA, should have the ultimate authority over medical scope of practice issues for healing arts licentiates.

There was no additional board discussion or public comment.

MOTION: Direct staff to submit comments signed by the board president to CalRecycle by August 13, 2010 to encourage that elements from the Model Guidelines developed for drug take back be incorporated into legislation so that they can be enforced.

M/S: Schell/Hackworth

Support: 9 Oppose: 0 Abstain: 0

f. Question and Answer Session on the Board's Implementation of 16 California Code of Regulations Sections 1735-1735.8, Pharmacies That Compound, and Sections 1751-1751.8, Pharmacies That Compound Sterile Injectable Medications

Dr. Kajioka provided that beginning in 2004, the board facilitated meetings with industry to establish regulations for pharmacies that compound. He indicated that as a result, the board developed regulations to define the parameters under

which a pharmacy can compound. Dr. Kajioka stated that these regulations took effect on July 6, 2010.

Dr. Kajioka provided that during the meeting, Supervising Inspector Bob Ratcliff responded to questions submitted in advance of the meeting, as well as questions from attendees.

Dr. Kajioka provided that board staff will develop a fact sheet based on the questions and answers, and this fact sheet will be posted on the board's Web site. He indicated that board staff will continue to take questions and will update the Q&A's. Dr. Kajioka stated that the board or committee may wish to designate additional time for anther Q&A session at a future meeting.

Ms. Herold provided that there will continue to be an opportunity for comments and questions to be submitted. She indicated that a document will also be created to address case specific sets of questions.

Public Comment

Jenny Partridge provided comment on several areas that are causing confusion for licensees including end product testing. She discussed that licensees are being cited and fined for sterile compounding violations in this area.

Mr. Room stated that the board cannot discuss these specific cases as they are enforcement issues that may come back before the board.

Ms. Herold stated that the board is not citing and fining licensees for any of the compounding requirements that took effect in July 2010; any citations issued would be for violations in compounding requirements previously in place before the new requirements.

It was the consensus of the board to continue discussion on this topic at the next Enforcement Committee Meeting and to extend the comment period for questions regarding the compounding regulations.

There was no additional board discussion or public comment.

g. Pharmacies Dispensing Prescriptions for Internet Web Site Operators

Dr. Kajioka provided that California Business and Professions Code section 4067 prohibits a person from dispensing a drug on the internet without a prescription issued pursuant to a good faith medical examination.

Dr. Kajioka provided that California law allows the board to issue citations at $25,000 per invalid prescription delivered to patients in California. He stated that

these drugs are often controlled drugs or other non-controlled drugs of abuse (e.g., Soma, Tramadol).

Dr. Kajoka provided that over the last 18 months, the board has issued multiple million dollar fines to California pharmacies for filling such false prescriptions. He indicated that the Drug Enforcement Administration is also involved in some of these Web site investigations and has also fined California pharmacies for their participation.

Dr. Kajioka provided that the committee discussed this issue and was provided with a listing of significant fines issued in the last year to California pharmacies aiding internet providers in the distribution of prescription drugs with a valid prescription. He stated that it was suggested that additional legislation may be needed and that the Enforcement Committee could identify solutions and refer them to the Legislation and Regulation Committee.

Ms. Herold provided that the board has issued 28 citations in this area over the last 18 months for a total of $373,600,000 in fines.

Mr. Brooks asked how much of this total will actually be collected.

Ms. Herold stated that it is anticipated that 5-10 million dollars will be collected.

Mr. Brooks suggested that board inspectors can be used to collect these fines. He recommended that the board discuss collection of fines at a future meeting.

No public comment was provided.

h. Post Implementation Review of the Board's Criminal Conviction Unit

Dr. Kajioka provided that included as part of last year's budget, was a staff augmentation for the board to establish the Criminal Conviction Unit within the board. He stated that this specialized unit was created to address the significant increase in the number of subsequent arrest notifications that the board receives, in part because of an increase in our licensing population, but mainly because of the transition the Department of Justice made to an automated system.

Dr. Kajioka highlighted the significant progress of the unit after one year. He stated that on July 1, 2009, there were 1708 investigations pending and as of June 1, 2010, that number was reduced 629 investigations pending. Dr. Kajioka added that over 1900 cases have been completed. He reviewed the following snapshot of the final disposition of those cases.

Referred for Formal Discipline	190
Citation and Fine Issued	112

Letter of Admonishment Issued	152
B&PC 4301 Letter Issued	633
Closed No Further Action	785
Closed Referred to PRP	2
Closed Other	30
Closed No Violation	1
	1,905

Dr. Kajioka provided that this unit was envisioned to be a "beginning to end" unit, meaning that the staff would not only complete the investigation, but also complete the final processing as well, e.g., issue the citation and fine, refer the matter to the Office of the Attorney General, etc. (This workload is currently being processed by other staff but is impacting other workload priorities.) He stated that the committee was advised that as the board's staff continues to reduce the number of pending investigations, staff will begin training in these other functions to ensure the final resolution is achieved timely, consistent with our consumer protection mandate.

Ms. Herold noted that 10 percent of the cases have been referred for formal discipline and 25 percent of the cases resulted in citations or other notification.

No public comment was provided.

i. Update of the Committee's Strategic Plan 2010-11

Dr. Kajioka provided that each fiscal year, the board updates its strategic plan. The current plan was developed in 2006-07 with the assistance of a consultant. He indicated that since then, each year the board has reviewed and as necessary revised its strategic plan. Dr. Kajioka explained that these are typically minor adjustments and additions.

Dr. Kajioka provided that as part of the Organizational Development Committee Report scheduled for tomorrow, the board will be voting on the strategic plan in its entirety for 2010/11.

Dr. Kajioka provided that the committee voted to approve the 15 tasks identified in Objective 1.5 in the Enforcement Committee's Strategic Plan and to add the following additional tasks:

16. Complete review of pharmacies dispensing prescriptions for Internet web site operators
17. Provide updates on the board's reporting to the Healthcare Integrity and Protections Data Bank (HIPDB)

Dr. Schell sought clarification regarding the intent of the review of pharmacies in task 16.

Dr. Kajioka provided that this task will help to identify legislation and internet problems to be referred to the Legislation and Regulation Committee.
Ms. Sodergren provided that this task will evaluate what the board as an organization can do to address this problem.

Dr. Schell suggested that the task be clarified to indicate the desired outcome.

Public Comment

Steve Gray, representing Kaiser Permanente, suggested that the strategic plan include an evaluation of how to enforce the standards in Business and Professions code § 4052.2 regarding the practice of collaborative drug therapy management by pharmacists as well as a review and discussion on how to better enforce consultation requirements.

President Weisser provided that the board will be revising the plan overtime and can incorporate new changes at that time.

There was no additional board discussion or public comment.

j. Minutes of the Meeting Held June 16,2010

Dr. Kajioka referenced to the summary of the meeting held on June 16, 2010 contained within the board packet.

No public comment was provided.

Other Enforcement Items:

k. Discussion and Possible Action to Implement DCA's Recommendations of the Substance Abuse Coordination Committee, Pursuant to SB 1441, for the Pharmacists Recovery Program

Dr. Kajioka provided that in 2008, SB 1441 was enacted to direct health care boards with so called "diversion programs" for health care licensees to establish department-wide minimum standards for participation.

Dr. Kajioka provided that the board has its Pharmacists Recovery Program, which serves the board's public protection mandate by closely monitoring those with substance abuse or other specified conditions. He explained that the board encourages a licensee under investigation for a substance abuse problem to enter the program in advance of the board's formal discipline; thus, the licensee enters a strict monitoring program (not a diversion program) while the investigation and enforcement processes continue.

Dr. Kajioka provided that there are 16 of these standards under development by a committee comprised of board executive officers, including the board's executive officer. He indicated that the standards are not yet finalized, but are nearing completion.

Dr. Kajioka provided that at the request of the department, each health care board was to review and begin necessary actions to implement these standards. He stated that Board Counsel Schieldge identified whether each standard needs statutory and/or regulation modifications. Dr. Kajioka indicated that the standards were also reviewed for compliance with the board's contract with the vendor that administers the PRP.

Ms. Schieldge provided that the board reviewed the suggested changes at the April 2010 Board Meeting. She indicated that the Substance Abuse Coordination Committee has not finalized the recommendations. Ms. Schieldge recommended that the board wait to take any action until the recommendations become final.

No public comment was provided.

l. Enforcement Statistics 2009-2010

Ms. Herold highlighted the enforcement statistics for 2009/10 as well as the 5 year comparison charts detailing the growth of the board's enforcement activities. She stated that 264 accusations were filed in 2009; whereas, only 29 were filed in 2008. Ms. Herold indicated that $335,420.58 in cost recovery has been collected.

No public comment was provided.

m. Fourth Quarterly Report of the Committee's Goals for 2009/10

Dr. Kajioka referenced to the fourth quarter's status of Enforcement Committee Goals contained within the board packet.

No public comment was provided.

n. Public Comment

No public comment was provided.

Recess for Day

The board meeting was recessed at 6:03 p.m.

July 29, 2010

The board reconvened at 8:11 am on July 29, 2010.

IX. Legislation and Regulation Committee Report and Action

Including a Report of the Meeting Held July 14, 2010

Part 1: Regulation Report

a. For Board Discussion and Possible Action

1. Discussion and Possible Action Regarding a Regulation Specifying Consumer Notice for Language Assistance Interpretative Services Provided in Pharmacies and the Ability to Request 12-Point Font on Prescription Drug Container Labels

Dr. Schell provided that on June 10, 2010, the board adopted proposed regulation 16 CCR 1707.5 to establish requirements for a patient-centered prescription drug container label. He indicated that this regulation is currently undergoing administrative review.

Dr. Schell provided that during the rulemaking process to adopt the prescription drug labeling requirements, it was suggested that the board establish requirement(s) that consumers be notified of the availability of oral language interpretive services and of 12-point font, as specified in the adopted regulation.

1. Policy Discussion

Dr. Schell provided that staff is requesting that the board discuss whether it wishes to amend 16 CCR § 1707.2 (Duty to Consult; existing consumer notices) to move existing consumer notices from § 1707.2 to a new section that also includes notices re: language interpretive services and large font sizes.

Dr. Schell provided that this item was not reviewed by the Legislation and Regulation Committee for discussion at its recent meeting.

Ms. Herold highlighted the draft language for consideration. She indicated that the language incorporates the current notices with the proposed notices and places them under one code section. Ms. Herold stated that the language also includes a provision to allow notices to be displayed on a television screen.

The board discussed the relocation of the current notice provisions. It was suggested that this move would make it easier to locate the notice requirements.

Ms. Schieldge provided that it is her opinion that the board could not adopt this regulation until § 1707.5 – Patient-Centered Labels on Medication Containers is approved by the Office of Administrative Law (OAL). She stated that this proposal would be a contingency motion.

Ms. Herold provided that she believes the board has flexibility to adopt the language and to not advance the rulemaking file until the prior regulation is approved. She indicated that this will save the board a minimum of 6 months.

Mr. Brooks discussed possible alternatives to the notice to consumers poster including display of sample bottles exhibiting 10 and 12-point fonts.

Ms. Herold provided that § 4122 requires that the format and the wording of the existing notices be adopted by the board by regulation.

Dr. Kajioka discussed that standard posting requirements are needed for enforcement purposes.

Mr. Brooks expressed concern that requiring too many posters will hinder the ultimate goal of communicating vital information to consumers.

Dr. Schell recommended that the board continue discussion on the notice format at a future meeting.

No public comment was provided.

MOTION: Upon approval of § 1707.5 – Patient-Centered Labels on Medication Containers by the Office of Administrative Law, amend 16 CCR § 1707.2 to move existing consumer notices from § 1707.2 to a new section that also includes notices regarding language interpretive services and large font sizes.
M/S: Hackworth/Veale

Support: 8 Oppose: 0 Abstain: 0

2. Review draft text prepared by staff to establish consumer notices to advise patients of their right to the:

   - Availability of Oral Interpretive Services; and
   - Availability of 12-Point Font on Prescription Labels

   Dr. Schell provided that if the board approves the draft text and so chooses, it can direct staff to take all steps necessary to initiate the formal rulemaking process to add Section 1707.6 to Division 17 of Title 16 of the California Code of Regulations to specify the content of consumer notices related to the availability of interpretive language services for and of the availability of 12-point font on

prescription drug container labels. If no adverse comments are received during the 45-day comment period or at the regulation hearing, authorize the executive officer to adopt the proposed addition of Section 1707.6 as filed with the Office of Administrative Law.

Dr. Schell provided that this item was not before the Legislation and Regulation Committee for discussion at its recent meeting.

Dr. Castellblanch provided that the posters should be posted in an easily visible location and should be printed in a readable font. He suggested that the language on the current notices be assessed to ensure the information is current and straightforward. Dr. Castellblanch encouraged that if the board permits the notices to be displayed on television screens, it needs to ensure that the information appears on the screen frequently and for a long enough period of time for the consumer to read the information.

Mr. Room provided that the pricing information on the notices may be dated. He also stated that alternative methodologies for displaying the information could be permitted by amending proposed § 1707.6(a) in the draft language to include a provision allowing a pharmacy to seek a waiver while maintaining a poster as a baseline.

Mr. Brooks provided that consumers will not read the posters if they contain too much content.

Ms. Veale asked if there was a basis for specifying a 30 inch video screen and a minimum of a 30 second display in the draft language.

Mr. Room provided that there was no basis for the numbers included in the draft language. He said that he did try to imagine how much time a consumer would be standing in line before being helped at the counter.

Ms. Veale provided that she likes the idea of alternative methods to display the message. She stated that appropriate sequencing and time delays should be evaluated if the board chooses to move forward with this alternative. Ms. Veale cautioned the board from only emphasizing font information on the notices. She stated that the notices contain a lot of important information that also helps consumers to prevent medication errors.

Dr. Schell discussed that advertisements aim to engage the audience within the first 30 seconds.

Ms. Veale stated that having a variety of signs posted on the walls may not be effective. She cautioned the board from excluding other methodologies.

Discussion continued regarding the draft language. Concern was expressed that being overly prescriptive may hinder a licensee's ability to comply as all

pharmacies are not built and designed the same. It was clarified that the existing notices are required by statute.

Public Comment

Steve Gray, representing Kaiser Permanente, thanked the board for considering his suggestion to display the notice information on a video screen. He stated that he believes that the statute allows for this option as it does not require that a poster be posted.

Dr. Gray provided that the pricing information provided on the current notices derived from the controversy surrounding generic drugs in the 1980s. He stated that the notice language replaced a Board of Pharmacy requirement that pharmacies post a large poster providing a cost comparison for the top 100 drugs. Dr. Gray discussed that alternatives for posting the notices are needed as all pharmacies are not designed alike and building codes and local ordinances limit where signs can be posted.

Dr. Gray expressed concern regarding the effectiveness of the current notice to consumers with regards to the color, font, and size. He suggested that the committee reevaluate the design of the posters.

Nan Brasmer, representing the California Alliance for Retired Americans (CARA), discussed the findings of a survey she conducted of 10 pharmacies in her area with regards to design and ability to provide 12-point font on the label. She stated that those pharmacies surveyed did not have the space to post or hang a poster or television screen. Ms. Brasmer asked the board to consider design research, the variation in pharmacy design, and the needs of seniors including computer literacy when developing the notice format. She suggested that the notice be posted on the counter to increase accessibility instead of using a poster or screen on the wall. Ms. Brasmer expressed concern that pharmacists may not be aware of the impending requirement to provide 12-point font on the label upon request.

Marty Martinez, representing the California Pan Ethnic Health Network (CPEHN), suggested that the notice be available in a specified number of languages. He recommended that the board consider using the top 14 languages from the California census data.

Carol Baily, representing CARA, expressed concern regarding how information will be made available to consumers who use mail order or other services that do not require that the consumer enter the pharmacy.

Bob Hansen, representing Safeway, discussed that too much information is required on the notices. He suggested that a simple poster or a handout in a

large font be created to simply list the most important information and to provide references directing consumers to the complete information.

Jenny Partridge provided that high content labels are often affixed to the product box or container instead of the bottle. She stated that labels that comply with the requirements of §1707.5 may be too long and will be difficult to adhere the label to products such as eye drops.

Ms. Schieldge advised that the comment period for § 1707.5 is closed.

Missy Johnson, representing the California Retailers Association (CRA), asked whether the notice required by § 1707.6(e) regarding interpretive services would be provided by the board.

Mr. Room provided that as drafted, this notice would not be provided by the board.

Mary Staples, representing the National Association of Chain Drug Stores (NACDS), asked that a standardized poster for § 1707.6(e) be provided by the board. She recommended that the current "Know Your Rights" poster be updated and possibly include information regarding available interpretative services.

Ms. Johnson asked if a video screen can be used for all requirements in the draft language. She also questioned if the statute for the existing notices prevents updating or modifications.

Mr. Room provided that the video screen option is available for all sections of the draft language. He indicated that the text can be modified but must stay in line with the subject area as specified by the section.

Ms. Johnson and Ms. Staples presented a sample notice printed in languages in which services are commonly available. They indicated that requiring the posting of this notice would be cumbersome for pharmacies.

The board further discussed the draft language. It was the consensus of the board that the draft language needs further evaluation and refinement. A proposal was made to direct staff to develop a new proposal to be discussed at the committee level prior to the next board meeting.

Dr. Gray provided that there is uncertainty regarding whether the notices are required to be posted in pharmacies that are not open to the public. He requested that the Legislation and Regulation Committee address this issue.

Ms. Schieldge provided that Business and Professions Code § 4122 requires that the notices be posted in every pharmacy.

There was no additional board discussion or public comment.

MOTION: Direct staff to develop new draft language to be reviewed by the Legislation and Regulation Committee before being brought before the full board.

M/S: Castellblanch/Kajioka

Support: 8 Oppose: 0 Abstain: 0

2. Future Amendment of 16 California Code of Regulations Section 1793.5 Regarding Modifications to the Pharmacy Technician Application Form

Background

Dr. Schell provided that staff is requesting that the board review the proposed changes to § 1703.5 and to the Pharmacy Technician Application.

Dr. Schell provided that if the board concurs with the proposed changes and so chooses, they can direct staff to take all steps necessary to initiate the formal rulemaking process to amend Section 1793.5 to reflect the revision of the Pharmacy Technician Application (Form 17A-5, incorporated by reference) of Article 11 in Division 17 of Title 16 of the California Code of Regulations.

Ms. Sodergren provided that 50-60 percent of the pharmacy technician applications received are deficient. She indicated that the proposed changes have been developed to reduce these deficiencies. Ms. Sodergren stated that the changes have been reviewed by the board's council to ensure that the application is consistent with the legal requirements.

Ms. Schieldge provided that the board has discussed the addition of a self-query requirement to the Pharmacist and Pharmacist Intern Application. She asked whether the board would like to also add this requirement to the Pharmacist Technician Application.

Dr. Schell proposed that this requirement will enhance the application and should be added.

No public comment was provided.

MOTION: Direct staff to take all steps necessary to initiate the formal rulemaking process to amend Section 1793.5 to adopt the "self-query" report requirement and to reflect the revision of the Pharmacy Technician Application (Form 17A-5, incorporated by reference) of Article 11 in Division 17 of Title 16 of the California Code of Regulations. If no adverse comments are received during the 45-day public comment period and no hearing is requested, authorize the Executive Officer to adopt the proposed amendment of Section 1793.5 as filed with the Office of Administrative Law.

M/S: Schell/Hackworth

Support: 7 Oppose: 0 Abstain: 0

3. Future Update of the Self Assessment Forms for Pharmacies and Wholesalers (16 California Code of Regulations Sections 1715.5 and 1784)

Background

Pharmacy Law requires pharmacies and wholesalers to conduct self-assessments to promote compliance with various federal and state laws and regulations through self-examination and education. Self-assessment forms provide references to relevant laws and regulations, and also serve as an easy reference guide for the Pharmacist-in-Charge (PIC) or Designated Representative-in-Charge (DRIC).

Section 1715 of Title 16 Californian Code of Regulations applies to the self-assessment of a pharmacy by the Pharmacist-in-Charge. The regulation was established in 1997 and was last amended in 2009. The following self-assessment forms are incorporated by reference in § 1715:

- 17M-13 (Rev 10/08) "Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment"
- 17M-14 (Rev 10/08) "Hospital Pharmacy and Self Assessment"

Section 1784 of Title 16 Cal. Code of Regulations applies to wholesalers. This regulation was established in 2007 and was last updated in 2009. It incorporates by reference the following self-assessment form:

- 17M-26 (Rev 10/08) "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment"

Dr. Schell provided that the Legislation and Regulation Committee did not discuss this item. He indicated that after the conclusion of the 2009/2010 Legislative Session, board staff will draft changes to the self-assessment forms to reflect statutory changes for the board's consideration at a future meeting.

Public Comment

Steve Gray, representing Kaiser Permanente, requested that the self-assessment forms be formatted in a manner that will make it easier to reference specific sections.

Ms. Sodergren requested that Dr. Gray provide a sample format.

There was no additional board discussion or public comment.

b. Recently Approved
Adopt New Section at Title 16 California Code of Regulations Section 1702 – Fingerprint Submissions for Pharmacists

Background

The Office of Administrative Law approved and filed with the Secretary of State a new Board of Pharmacy regulation regarding fingerprint submissions for pharmacists. Title 16 California Code of Regulations Section 1702 is effective on December 7, 2010.

The regulation specifies that as a condition of renewal, a pharmacist must disclose on the renewal form any arrest or conviction, as specified, since the licensee's last renewal; that a pharmacist applicant must pay the actual cost of compliance with the submission of fingerprints; a requirement that the licensee retain proof of compliance, as specified; and that failure to comply with the fingerprint requirement will result in an application for renewal being considered incomplete.

Chair Schell advised that board staff will be developing an implementation plan and hopes to advise all affected licensees by late summer of the fingerprint requirements. He stated that an article also will be included in the next version of *The Script.*

Public Comment

Darlene Fujimoto asked whether a previous fingerprint report run for another agency can be submitted to the board.

Ms. Herold provided that the fingerprints need to be submitted with the board as the designated agency for reports.

There was no additional board discussion or public comment.

c. Board Approved – Undergoing Administration Review

1. Adopt Sections 1721 and 1723.1 in Division 17 of Title 16 of the Code of Regulation Regarding Dishonest Conduct During a Pharmacist's Licensure Examination/Confidentiality

Dr. Schell provided that the rulemaking was filed with the Office of Administrative Law on July 9, 2010, where it is currently undergoing administrative review.

No public comment was provided.

2. Adopt Section 1707.5 Patient-Centered Prescription Drug Container Label

Dr. Schell provided that the rulemaking was submitted to the department for review on July 12, 2010.

No public comment was provided.

d. Board Approved – Awaiting Notice

1. Amend Title 16 of the California Code of Regulations, Section 1746 of – Emergency Contraception Protocol (including Correct Typographical Error: Mcg instead of Mg)

Dr. Schell provided that at the January 2010 Board Meeting, the board voted to initiate the rulemaking process to correct an error in the 'chart' of Dedicated Emergency Contraception that is specified in 16 CCR § 1746(b)(11) to correct the heading of "Ethinyl Estradiol per Dose (mg)." He indicated that the heading should designate micrograms – not milligrams.

Ms. Sodergren provided that the committee recommended that a subcommittee or ad hoc committee be established to address additional drugs in the market that can be incorporated into the regulation.

Dr. Schell recommended to the board that a subcommittee be formed to address this area.

No public comment was provided.

2. Adopt Title 16 CCR Section 1732.2 – Board Issued Continuing Education Credit

Dr. Schell advised that at the February 2010 Board Meeting, the board voted to initiate the rulemaking process. He stated that board staff anticipates initiating the rulemaking for action at the October 2010 Board Meeting.
No public comment was provided.

e. Board Approved Regulations – Under Development

1. Title 16 CCR 1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

Dr. Schell provided that the committee was advised that this regulation has been tabled until the Licensing Committee completes its review of the Veterinary Food-Animal Drug Retailer program.

No public comment was provided.

2. Title 16 CCR Section 1751.9 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Dr. Schell provided that the board discussed the accreditation of agencies seeking board recognition during the first day of this meeting. This regulation would specify the criteria against which future agencies will be evaluated.

No public comment was provided.

3. Title 16 CCR Section 1780 – Update the USP Standards Reference Material

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

Dr. Schell indicated that a subcommittee had been established; but, as a result of recent vacancies, the subcommittee has not held any meetings and no action has been taken with respect to this regulation change. He advised that public comment suggested that the subcommittee seek some additional assistance in order to fully evaluate the standards.

No public comment was provided.

Part 2: Legislation Report

Dr. Schell provided an update on the following legislation.

a. Board-Sponsored Legislation
SB 1489 Omnibus Provisions (Senate Committee on Business, Profession and Economic Development)

Background
Last Amendment: June 17, 2010
Current Status: Assembly Appropriations

On January 20, 2010, the board voted to support the inclusion of several amendments in the Senate Business Professions and Economic Development

Committee's Omnibus measure for 2010. SB 1489 was introduced on March 11, 2010 and included the board's requested proposals.

- General Omnibus Provisions

  §4196(e) – Veterinary Food Animal Drug Retailer, Designated Representative in Charge

  At its October 2008 Board Meeting, the board approved provisions to be included in the 2009 Omnibus Bill (Senate BP&ED, SB 821). However, the chaptered version of SB 821 contained a drafting error and the section requires clarification (to be amended as previously approved by the board).

  §4200.1 – Retaking Examinations; Limits; Requirements (NAPLEX and CPJE 4 time failure)

  In October 2008, the board approved that the sunset provision within §4200.1 be eliminated. Though the Senate BP&ED committee did approve the proposal for inclusion in the 2009 omnibus bill, the proposed text was not printed in any omnibus measure. This language has been corrected to restore the provision to law without a sunset date.

- Provisions to Update References to the California Department of Public Health

  §4017 – Authorized Officers of the Law
  §4028 – Definition of Licensed Hospital
  §4037 – Definition of Pharmacy
  §4052.3(e) – Emergency Contraception Drug Therapy; Requirements and Limitations
  §4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions
  §4072(b) – Oral or Electronic Transmission of Prescription – Health Care Facility
  §4119(a) – Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies
  §4127.1(d) – License to Compound Injectable Sterile Drug Products Required
  §4169 – Prohibited Acts (also, strike operative date of 2008)
  §4181(a) – License Requirements; Policies and Procedures; Who May Dispense
  §4191(a) – Compliance with California Department of Public Health Requirements; Who May Dispense Drugs

- Provision to Update a Reference to the Physical Therapy Board of California (Formerly Known as the Physical Therapy Examining Committee of California)

  §4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions

- Provisions to Update References to the Department of Health Care Services

  §4425 – Pharmacy Participation in Medi-Cal Program; Conditions; California Department of Health Care Services Utilization Review and Monitoring
  §4426 – California Department of Health Care Services to Study Reimbursement Rates

- Other

  Dr. Schell suggested that the board may wish to discuss from a policy perspective the amendment to Business and Professions Code section 4013 as reflected in the June 17, 2010, version of the bill.

  Dr. Schell advised that board staff provided some technical input on the drafting of the language to allow chain store pharmacies to use intranet connections to disseminate board subscriber alerts instead of each pharmacy having separate internet access. The goal is to ensure that the intent of the section was not altered as a result of the proposed change, which was accepted by the Business, Professions and Economic Development Committee and subsequently amended into the bill. Dr. Schell stated that the board has not discussed this from a policy perspective and may wish to do so.

  Ms. Herold provided that the amendment has been incorporated at the request of industry, which had concerns about the implementation of the e-mail notification requirement that took effect July 1, 2010.
  No public comment was provided.

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

1. Board of Pharmacy

- AB 2104 (Hayashi) – California State Board of Pharmacy

  <u>Background</u>
  This bill would authorize the Department of Consumer Affairs to appoint the appointment of the executive officer of the board.

  The previous version of the bill would have authorized the Governor to appoint the executive officer and would have required the board to receive DCA approval before sponsoring or taking positions on legislation; and would have defined ex parte communications and established reporting requirements for board members that engage in such communications.

Dr. Schell provided that the department does not have a position on the current version of the bill. He advised that the committee recommends that the board maintain a position of oppose on this bill.

No public comment was provided.

- SB 1390 (Corbett) – Patient-Centered Prescription Labels

  Background
  The initial version of SB 1390 would have allowed the board to exempt from the patient-centered labeling requirements established in regulations, prescriptions dispensed to patients in a long-term health care facility if the medication is administered by a licensed health care professional.

  Dr. Schell advised the committee that SB 1390 was then amended June 15 to establish statutory requirements for patient-centered prescription drug container labels. The bill failed passage in the Assembly Committee on Business Professions and Consumer Protection. He advised that the committee did not take action on this item.

  No public comment was provided.

2. Sunset Review and Legislative Oversight Proposals

- AB 1659 (Huber) – State Government, Agency Repeals
  Background
  This bill creates a new Joint Sunset Review Committee charged with conducting a comprehensive analysis of every agency to determine if it is still necessary and cost effective. It establishes reporting elements that must be addressed by each agency including its purpose, budget information, programs and projects under its control, its successes and failures, and recommendations for changes to better fulfill its mission. The bill defines the committee composition and appointment authorities.

  Dr. Schell provided that the committee recommendation to the board is to not establish a position on this bill.

  Ms. Herold provided that a member of the Senate Business and Professions Committee has indicated that AB 1659 and its companion bill, AB 2130, are intended to put other state agencies under sunset review. She advised that the Senate Business and Professions Committee and the Assembly Business and Professions Committee will continue to have jurisdiction over the department.

  No public comment was provided.

- AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection

  Background
  AB 2130 is a related bill to AB 1659 (Huber). It abolishes the Joint Committee of Boards, Commissions and Consumer Protection and refers the charge of that committee to the proposed Sunset Review Committee established by AB 1659.

  Dr. Schell provided that the committee recommendation is to not establish a position on this bill.

  No public comment was provided.

3. Regulation of Dangerous Drugs and Devices

- SB 971 (Pavley) – Bleeding Disorders: Blood Clotting Products

  Background
  The bill sets forth requirements for entities that deliver blood clotting products and related equipment, supplies and services for home use. It authorizes the Department of Health Care Services to promulgate regulations necessary for the implementation of these standards and specifies that the Board of Pharmacy shall enforce the provisions established.

  Dr. Schell provided that the committee recommendation is to not establish a position on this bill.

  Ms. Schieldge expressed concern that this bill would authorize another agency to promulgate regulations that the board will enforce. She indicated that this may be problematic from an implementation perspective.

  Dr. Schell indicated that the department has taken an oppose position on this bill.

  No public comment was provided.

- SB 1071 (DeSaulnier) – CURES

  Background
  SB 1071 creates a fund to support the Controlled Substance Utilization Review and Evaluation System (CURES) and imposes a tax on every manufacturer, importer, or other person that makes the first sale of a controlled substance classified as Schedule II, III, or IV at the rate of $0.0025 for each pill sold.

Dr. Schell advised that the committee did not take any action on this bill as the hearing was canceled at the request of the author

No public comment was provided.

- SB 1106 (Yee) – Prescribers – Dispensing of Samples

Background
SB 1106 would require a prescriber, dispensing a drug sample or starter kit, to either (1) provide the patient with a copy of the FDA approved package insert for the drug sample or starter kit or (2) ensure that the manufacturer's warnings are affixed to the package containing the drug sample or starter kit.

Dr. Schell provided that the committee recommendation to the board is to maintain its current position of support if amended on this bill.

No public comment was provided.

4. Pharmacy Licensing Issues

- AB 2077 (Solorio) – Centralized Hospital Packaging Pharmacies

Background
AB 2077 makes findings and declarations regarding unit dose packaging and centralized packaging functions, and 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 under common ownership.

As amended on June 23, 2010, AB 2077 requires bar coding on the unit dose medication produced by the centralized pharmacy, allows for anticipatory unit dose packaging to ensure continuity of care, and also specifies that a hospital pharmacy utilizing the centralized packaging must notify the board in writing and in advance of utilizing a centralized packaging pharmacy and upon the closure or discontinued use of a facility.

Dr. Schell provided that AB 2077 passed out of the Senate Committee on Business, Professions and Economic Development and was referred to Senate Appropriations. He stated that the board supported key provisions now incorporated in the bill (those which were formerly contained in Solorio's AB 1370).

Dr. Schell provided that the committee recommendation to the board is to establish a position of support on AB 2077. Dr. Kajioka seconded the committee's recommendation.

No public comment was provided.

MOTION: Legislation and Regulation Committee Recommendation: Establish a position of support on AB 2077.

Support: 6 Oppose: 0 Abstain: 1

- AB 2551 (Hernandez) – Pharmacy Technician: Scholarship and Loan Repayment Program

Background
As amended on April 26, 2010, AB 2551 establishes the California Pharmacy Technician Scholarship and Loan Repayment Program within the Health Professions Education Foundation. This program will be administered by the Office of Statewide Health Planning and Development for the purpose of providing scholarships to pay for educational expenses of pharmacy technician school students and to repay qualifying educational loans to pharmacy technicians who agree to participate in medically underserved areas. The bill allows the Health Professions education Foundation to solicit and receive funds from business, industry, foundations and other private and public sources.

Dr. Schell provided that this bill is in Senate Committee on Appropriations and is scheduled for hearing August 2, 2010.

Dr. Schell provided that the committee recommendation to the board is to not establish a position on this bill.

No public comment was provided.

5. Distribution of Needles and Syringes

- AB 1701 (Chesbro) – Hypodermic Needles and Syringes

Background
AB 1071 removes the 2010 sunset date of the Disease Prevention Demonstration Project (a pilot launched in 2004) within the California Department of Public Health which allows a pharmacist, if authorized by a county or city, to furnish or sell 10 or fewer hypodermic needles or syringes at any one time, as specified.

The bill passed out of the Senate Committee on Health on June 23, as amended. However, as of July 21, amendments are not yet in print. The bill was referred to Senate Appropriations and is scheduled for hearing on August 2, 2010.

Dr. Schell provided that committee recommendation to the board is to maintain a position of support on this bill.

No public comment was provided.

- AB 1858 (Blumenfield) – Hypodermic Needles and Syringes: Exchange Services

  Background
  AB 1858 allows the California Department of Public Health to authorize entities to provide hypodermic needles and syringe exchange programs in any location where the department determines conditions exist for the rapid spread of deadly or disabling disease through the sharing of unclean hypodermic needles and syringes. As amended July 15, 2010, the bill requires an entity to submit an application to CDPH prior to implementing its program, and also requires that a 45-day public comment period lapse prior to approval of any program. Further, the bill specifies that a participant in a clean needle and syringe exchange program shall not be subject to criminal prosecution for possession of needles and syringes acquired under an approved program.

  Dr. Schell provided that this bill is currently in the Senate Committee on Appropriations and the hearing is scheduled for August 2, 2010.

  Dr. Schell provided that the committee recommendation to the board is to maintain no position on AB 1858, as amended June 15, 2010.

  No public comment was provided.

- SB 1029 (Yee) -- Hypodermic Needles and Syringes

  Background
  SB 1029 allows a physician or pharmacist, beginning January 1, 2011 through December 31, 2018, to furnish 30 or fewer hypodermic needles and syringes for human use to a person 30 years of age or older. The bill addresses the storage of products to ensure they are available only to authorized personnel; requires that disposal options are provided to consumers; and requires pharmacies to provide written information or counseling at the time of furnishing on how to access drug treatment.

  Dr. Schell provided that this bill is in the Assembly Committee on Appropriations and is scheduled for hearing on August 4, 2010.

Dr. Schell provided that the committee recommendation to the board is to maintain no position on this bill.

No public comment was provided.

6. General / Other

- SB 1172 (Negrete McLeod) –Diversion Programs

Background
This bill requires specified healing arts boards (including the Board of Pharmacy) to order a licensee to cease practice if the licensee tests positive for any substance that is prohibited under the terms of the licensee's probation or diversion program. This bill also allows a healing arts board to adopt regulations authorizing the board to order a licensee (on probation or in a diversion program) to cease practice for (1) major violations or (2) when the board orders a licensee to undergo a clinical diagnostic evaluation pursuant to uniform and specific standards, as specified.

Dr. Schell provided that the committee recommendation to the board is to maintain no position on this bill.

Ms. Schieldge provided that section 2 of SB 1172 authorizes the board to issue an order of cease practice. She expressed concern regarding the enforcement of this authority with regards to self referral participants in the diversion program. Ms. Schieldge advised that a consequence for noncompliance should be built into the bill and should constitute unprofessional conduct as grounds for disciplinary action.

Ms. Herold provided that she will discuss this issue at the next SB 1441 Substance Abuse Coordination Committee Meeting.

Dr. Schell provided that the department does not have a position on the bill. He stated that based on the available information the committee recommended that the board maintain no position on this bill. He recommended that the board direct the staff to incorporate the comments made by Ms. Schieldge or consider establishing a position of oppose.
Ms. Schieldge suggested that the board consider a position of support if amended if it thinks the idea of a cease practice is a good idea.

Public Comment

Steve Gray, representing Kaiser Permanente, suggested a discussion on the types of actions that are needed to be reported to the national database. He

suggested that the reporting of cease practice orders may discourage voluntary participation in the diversion program.

Ms. Schieldge provided that a cease practice order is not considered discipline under the statute.

There was no additional board discussion or public comment.

Part 3: Legislation and Regulation Committee

a. Strategic Plan Update for 2010/11

Dr. Schell reported that the Legislation and Regulation Committee is up-to-date on its strategic plan activities.

No public comment was provided.

b. Fourth Quarterly Update Report for 2009/10

Dr. Schell referenced to the fourth quarterly report on the Legislation and Regulation Committee's goals contained within the board packet.

No public comment was provided.

c. Public Comment

Missy Johnson sought clarification regarding the board's support position on AB 1701 and no position on SB 1029.

Ms. Sodergren confirmed these positions.

Darlene Fujimoto asked the committee to consider SB 971 at its next committee meeting. She stated that she does not believe that this bill is necessary and would be cumbersome to the board.

There was no additional public comment.

X. Organizational Development Committee Report

a. Proposed Meeting Dates for 2011

President Weisser provided that the board typically meets four times a year: January, April, July and October. He stated that because of pressing issues requiring more frequent board action, additional meetings have been scheduled.

President Weisser provided that it was suggested that the board's traditional schedule be adjusted to align better with the legislative cycle. He reviewed the following possible alternative schedule.

January 26 – 27, 2011
May 4 – 5, 2011
July 27 – 28, 2011
October 19 – 20, 2011

President Weisser advised that the locations for the meetings have not yet been determined.

Ms. Schieldge provided that she may have a scheduling conflict with the May meeting date.

It was the consensus of the board to approve the proposed meeting dates.

Public Comment

Steve Gray, representing Kaiser Permanente, advised that the October meeting dates interfere with the Membership Meeting of the National Pharmacists Association.

There was no additional public comment.

b. Approval of the Committee's Strategic Goals for 2010/11

President Weisser provided that the goals of each committee have been discussed. He made a proposal to approve the Committee's Strategic Goals for 2010/2011.

No public comment was provided.

MOTION: Approve the Committee's Strategic Goals for 2010/2011.

M/S: Weisser/Zee

Support: 7 Oppose: 0 Abstain: 0

c. Approval of the Board of Pharmacy's Strategic Plan for 2010/11

President Weisser provided that the board has reviewed the Strategic Plan for 2010/11.

Ms. Hackworth made a proposal to approve the plan.

Public Comment

Steve Gray, representing Kaiser Permanente, asked whether the motions made during yesterday's meeting have been incorporated into the plan.

President Weisser indicated that the approved committee's strategic plans have been incorporated.

There was no additional board discussion or public comment.

MOTION: Approve the Board of Pharmacy's Strategic Plan for 2010/11.

M/S: Hackworth/Schell

Support: 7 Oppose: 0 Abstain: 0

d. Budget Update/Report

1. Budget reports for 2009/10

President Weisser highlighted the estimated revenue and expenditure charts for 2009-10. He provided that as of July 1, 2010, the board has collected $11,103,581 in revenue.

Ms. Herold provided that the final budget figures for the fiscal year that ended June 30, 2010, will be available in August.

Mr. Brooks sought clarification regarding the collection of money for citation and fines.

Ms. Herold provided that this money is deposited into the board's fund.

No public comment was provided.

2. Fund Condition 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:

2008/09	$11,001,000	13.5 months in reserve (actual)
2009/10	$10,771,000	10.9 months in reserve
2010/11	$9,608,000	8.4 months in reserve
2011/12	$6,632,000	5.6 months in reserve

President Weisser provided that with the passage of the board's fee bill last year, AB 1071 (Emmerson, Chapter 270, Statutes of 2009), the board's reimbursements increased the last 6 months of the fiscal year with the higher fee schedule. He indicated that the board will continue to closely monitor its fund condition before increasing any additional fees, however with the new fee structure incorporated in AB 1071, the board does have the ability to raise fees via the regulation process when necessary.

Ms. Herold provided that there are no plans to raise fees in the immediate future.

No public comment was provided.

3. Budget Change Proposals for the 2010/11 Budget

President Weisser provided that the new fiscal year started July 1, 2010. He stated that included in the governor's proposed budget is a budget augmentation of $ 2,668,000 this year to establish 22.5 new positions in the board's enforcement unit and 2 new positions in the licensing unit. President Weisser indicated that these staff are necessary to meet the department established goal to ensure the average case closure time for formal discipline, from receipt of the complaint to final vote of the board, occurs within 12 to 18 months. He advised that this is a primary outcome of the Consumer Protection Enforcement Initiative (CPEI). President Weisser provided that the additional licensing staff are necessary to address the significant increase in pharmacy technician applications the board continues to receive as well as the increase in workload associated with processing several other types of applications (including change in pharmacist in charge forms and processing discontinuance of business forms.)

Ms. Herold discussed that these new positions will allow the board to address the growth in both its Licensing and Enforcement units.

No public comment was provided.

4. Reimbursement to Board Members

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

No public comment was provided.

5. BreEZe Program

President Weisser provided that for a number of years the department has worked to replace and/or enhance the legacy licensing and enforcement tracking systems. He stated that a few years ago, the department initiated an I-Licensing project which would offer online application and renewal of licenses (a much needed relief from mail-in renewals).

President Weisser provided that this project was recently replaced as a component in DCA's proposed Enforcement System upgrades with a new proposal, BreEZe, which will allow for online renewal and application processing, and will also replace the board's Consumer Affairs Systems and the Applicant Tracking System. He indicated that both systems are legacy systems. President Weisser explained that this new project will piggyback on the efforts of the initial I-Licensing system sought and will ultimately allow for improved services for applicants and licensees as well as provide for a more robust computer system internally.

President Weisser advised that the board is about 2-3 years away from changing to this new system.

No public comment was provided.

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

Since July 2005, the board has acknowledged 1031 pharmacists with 50 or more years of licensure as pharmacists in California. Ninety-four pharmacists reached this milestone between April and July 2010. Each was sent a certificate and invited to a future board meeting for public recognition.

There was no discussion on this item.

f. Personnel Update

Ms. Herold reviewed the following changes.

1. Board Member Changes

There are currently ten board members, and three board member vacancies. The vacant positions are all governor appointments and are for pharmacist members.

2. Staff Changes

The board has three staff vacancies remaining: two inspector positions and one staff position unfilled. Recent changes to the board's staff roster are provided below:

- Brenda Barnard, a board inspector, retired on June 30, 2010. The board is conducting the civil service exam, to establish of list of eligible candidates. This must be done prior to filling this vacancy.
- Victor Perez was promoted to an Associate Information Systems Analyst.
- Iran Serrano Borgmann transferred to the Bureau of Investigative and Security Services.
- Laura Hendricks was hired as the board's new budget analyst.
- Susan Williams accepted a position with the Department of Public Health.

Ms. Herold provided that the Governor has issued Executive Order S-12-10 that reinstitutes three furlough days per month until there is a 2010-11 fiscal year budget and the Director of the Department of Finance determines there is sufficient cash to allow the state to meet its obligations. She advised that the board's inspectors are exempted from the furloughs; however, the supervising inspectors are not included in this exemption.

Public Comment

Steve Gray, representing Kaiser Permanente, suggested that the board consider appointing a Chief Inspector to insure consistency with the growing number of board inspectors.

Ms. Herold provided that board staff have planned to make this appointment.

There was no additional board discussion or public comment.

g. Fourth Quarterly Report on the Committee's Goals for 2009/10

President Weisser referenced to the fourth quarterly report on the Organizational Development Committee's goals contained within the board packet.

No public comment was provided.

h. Public Comment

No public comment was provided.

XI. Public Comment for Items Not on the Agenda/Agenda Items for Future Meetings

Michael Negrete, representing Pharmacy Foundation of California, clarified a previous comment regarding suspect practices by mail order pharmacies. He stated that this activity is not specific to and does not apply to all mail order pharmacies.

Dr. Negrete provided an overview of the Safe Medication Use Alliance aimed at preventing medication errors specifically in the outpatient setting. He provided copies of the Report and Recommendations from the Alliance's June 25, 2010 Kick-Off Summit.

Steve Gray, representing Kaiser Permanente, expressed concern regarding the use of pharmacy technicians beyond the scope of practice. He requested that the board further discuss and provided outreach on this issue.

XII. Petition for Reinstatement

- David J. Ofstedahl

XIII. Petition for Early Termination of Probation

- Janice Ducotey

The meeting was adjourned at 12:32 p.m.

Attachment 2

Possible Text to Amend

16 CCR § 1793.5
re:
Pharmacy Technician Application

Title 16. Board of Pharmacy
Proposed Language

To Amend 1793.5. in Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.5. Pharmacy Technician Application.

The application for a pharmacy technician license (Form 17A-5 (Rev. ~~9/94~~ 08/10)) required by this section is available from the Board of Pharmacy upon request.

(a) Each application for registration as a pharmacy technician shall include:

(1) Information sufficient to identify the applicant.

(2) A description of the applicant's qualifications and supporting documentation for those qualifications.

(3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e). In addition, a signed statement whether the applicant has ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States, any state, or local ordinance.

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within 30 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete, the board will notify the applicant within 60 days of a license decision.

(d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in ~~Section 1749, subdivision (c)~~ Section 4400 of the Business and Professions Code.

Note: Authority cited: Sections 163.5, 4005, 4007, 4038, 4115, ~~and~~ 4202, and 4400 Business and Professions Code. Reference: Sections 163.5, 4005, 4007, 4038, 4115, ~~and~~ 4202, and 4400 Business and Professions Code.

WHAT MAKES AN APPLICATION COMPLETE (Please use the following checklist to assist you in ensuring your application is complete prior to submitting your application to the board.) If your application is incomplete, the board will notify you of any deficiencies. Failure to complete your application within 60 days after being notified by the board of any deficiencies will result in your application being deemed abandoned and you will be required to file a new application and meet all of the requirements in effect at the time of reapplication.

☐ **APPLICATION FEE $80**: Submit a check, money order, or cashier's check in the amount of $80, made payable to the Board of Pharmacy with your application. The application fee is non-refundable.

☐ **APPLICATION FOR REGISTRATION AS A PHARMACY TECHNICIAN** (form 17A-5 (rev. 7.10)): The application must be completed in its entirety. Failure to do so will result in an incomplete application and a deficiency letter being mailed to you. A passport style photo (2" x 2") must be taken within 60 days of filing the application, and must be attached to the front of the application. (Scanned images and Polaroid pictures are not accepted as the images decay over time.) You need to complete, sign, and date the application. Do not allow your school to complete page 1, 2, and 3 of the application.

☐ **FINGERPRINTS:** All applicants are required to have their fingerprints processed via Live Scan if they reside in California. If you reside outside of California and are unable to visit California to do the Live Scan, then you must have your fingerprints processed on the Board of Pharmacy issued fingerprint cards. DO NOT complete the Live Scan or fingerprint cards until you are ready to submit your application. The board will only accept current fingerprint clearances from Department of Justice (DOJ) and Federal Bureau of Investigation (FBI). Detailed instructions for fingerprints are provided below. Submit either A or B below with your application:

A. **Completed Live Scan receipt,** showing submission information.

OR

B. **Completed fingerprint cards** along with the additional $51 for the fingerprint card processing fee. Submit the fingerprint card processing fee with the application fee when submitting your application to the board.

☐ **QUALIFYING DOCUMENTATION:** You are required to include with your application the Affidavit of Completed Coursework or Graduation for Pharmacy Technician, a certified copy of your PTCB certification, or a certified copy of your military training. The Qualifying Method on page 1 of these instructions identifies which document you need to provide.

FINGERPRINT SUBMISSION INSTRUCTIONS

The board requires the applicant to have their fingerprints submitted at the time a pharmacy technician application is submitted to the board regardless of any prior fingerprint submission for other applications with the board.

A. **CALIFORNIA RESIDENT:** Complete a Live Scan Request form and take all 3 copies to a Live Scan site for fingerprint scanning. Please refer to the instructions for completing a "Request for Live Scan Service" form in this application package. The lower portion of the Live Scan Request form must be completed by the Live Scan operator verifying that your prints have been scanned and all applicable fees have been paid. Attach a completed copy of the Live Scan form to your application and submit to the board (this is your Live Scan receipt).

Live Scan sites are located throughout California. For more information about locating a Live Scan site near you, visit the Department of Justice Web site at:
http://ag.ca.gov/fingerprints/publications/contact.pdf

STEPS TO ENSURE YOUR LIVE SCAN FORM IS COMPLETED ACCURATELY BY THE LIVE SCAN OPERATOR

It is the applicant's responsibility to ensure that the information the Live Scan operator types into the computer system is correct before to the Live Scan operator submits the transmission. Please verify the following information is correct:

- The Live Scan operator selects BOTH the **DOJ and FBI** prior to submitting the request. If FBI is not selected at the time of original transmission, you may be required to have your Live Scan redone at another time and have to repay for the DOJ and FBI levels of services again. The board has been notified by the DOJ that effective 9/1/07; if the FBI level of service is not requested at the time of original transmission both DOJ and FBI levels of service will have to be redone. Any issue of cost for resubmission should be handled at the Live Scan Site level.
- Verify on the Live Scan operator's computer that the below information has been typed correctly.
  - **Full Name** is spelled correctly and matches your I.D (Jr., II, etc must be included in the name). Your name must match your full name on your application.
  - **Date of Birth** is correct.
  - **US Social Security Number** is entered and correct. This is required and must be entered.
  - **License type** needs to be entered as: Pharmacy Tech-Sect 4015.

The board has seen an increase in the number of Live Scan transmissions where the name, date of birth, or the US social security number has been entered incorrectly or does not IDENTICALLY match the applicant's identification and the full legal name on the application. If such information is entered incorrectly, the applicant will be required to redo the Live Scan process again. This is usually at the expense of the applicant. This will result in a delay in processing your application.

B. **NON-CALIFORNIA RESIDENTS:** If you reside outside California, you must submit rolled fingerprints with your application on Board of Pharmacy fingerprint cards along with fee fingerprint card processing fee of $51 made payable to the Board of Pharmacy ($32 DOJ fee and $19 FBI fee). You may contact the board to request the fingerprint cards at (916) 574-7900 or email your request to rxforms@dca.ca.gov.

Fingerprints submitted on the fingerprint cards must be taken by a person professionally trained in the rolling of prints. Fingerprint clearances from cards take longer than the Live Scan process, by approximately six weeks. Poor quality prints may result in rejection of the card and will substantially delay licensing since additional fingerprint cards will be required from you for processing.