



**California State Board of Pharmacy**  
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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:** October 21 and 22, 2009

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

**BOARD MEMBERS  
PRESENT:**

Kenneth Schell, PharmD, President  
Randy Kajioka, PharmD, Vice President  
Stanley C. Weisser, RPh, Treasurer  
Ramón Castellblanch, Public Member  
Rosalyn Hackworth, Public Member  
Greg Lippe, Public Member  
Robert Swart, PharmD  
Shirley Wheat, Public Member

**BOARD MEMBERS  
NOT PRESENT:**

Ryan Brooks, Public Member

**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  
Tessa Fraga, Staff Analyst

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**Call to Order**

President Schell called the meeting to order at 9:03 a.m.

## **I. Ethical Decision Making for Regulators**

### **Presentation – Kristy Schieldge, DCA Senior Staff Counsel**

Kristy Schieldge, DCA Senior Staff Counsel, provided an overview of ethical decision making. She also reviewed major provisions of the Bagley–Keene Open Meeting Act. A series of hypothetical scenarios were highlighted and discussed.

### **Board Discussion**

The board discussed the requirements of the Bagley-Keene Open Meeting Act as well as proper conduct for board members. Disqualification and abstention issues were addressed.

There was no additional board discussion. No public comment was provided.

### **Announcements**

President Schell recognized former board members Bob Graul and Darlene Fujimoto who were attending the meeting and in the audience.

## **II. Approval of the Full Board Minutes of July 15 and 16, 2009**

**MOTION:** Approve the minutes of the July 15 and July 16, 2009 Board Meeting..

M/S: Weisser/Swart

Approve: 8   Oppose: 0   Abstain: 0

## **III. Approval of the Full Board Minutes of August 19, 2009**

**MOTION:** Approve the minutes of the August 19, 2009 Board Meeting.

M/S: Weisser/Wheat

Approve: 8   Oppose: 0   Abstain: 0

#### **IV. Enforcement Committee Report and Action**

*Report of the Enforcement Committee Meeting Held September 16, 2009 and Recent Updates in Enforcement Activities*

##### **A. Overview of Proposals to Strengthen the Enforcement Programs of the Health Care Boards of the Department of Consumer Affairs**

###### **1. Proposals of the Department of Consumer Affairs**

Dr. Robert Swart provided that over the prior 10 months, the Department of Consumer Affairs has initiated a number of initiatives aimed at strengthening the enforcement activities of the health care boards. He advised that the Board of Pharmacy is one of these agencies.

Dr. Swart provided that these changes were initiated following problems identified at the Board of Registered Nursing (BRN) by the *Los Angeles Times*.

Dr. Swart provided that the first major change was prioritization of fingerprinting of all licensees. He explained that fingerprinting allows a board to obtain federal and state background checks of applicants with respect to arrests and convictions entered into federal and state data bases by the courts and law enforcement agencies. Dr. Swart added that it also enables boards to obtain "subsequent" arrest and conviction information if a licensee is arrested or convicted in California.

Dr. Swart provided that the second major problem reported in the *LA Times* was the time it was taking the BRN to investigate complaints and complete enforcement actions, which exceeded 3.5 years. He indicated that the BRN uses the department's Division of Investigation to investigate its complaints, and problems with recruitment and retention of investigators has been a problem. Dr. Swart advised that this delayed investigations. He stated that additionally the time it takes to secure complete work by the Attorney General's Office and Office of Administrative Hearings further added delays.

Dr. Swart provided that DCA has responded with a series of proposals to strengthen the BRN's enforcement program as well as that of other health care boards. He added that board executive staff are working with the department on these changes.

No public comment was provided.

2. Proposals of the California Business, Professions and Economic Development Committee

Dr. Swart stated that the Senate Business, Professions and Economic Development Committee developed a series of proposals. He stated that the overall goal is to complete formal investigations from the time a complaint is received, through investigation and through final action on the stipulation or proposed decision by the board within 18 months. Dr. Swart advised that this goal is a very aggressive standard, but one that the public deserves.

No public comment was provided.

3. SB 294 - 2009 Legislative Proposal of the Administration and Senate Business, Professions and Economic Development Committee

Dr. Swart stated that a joint legislative proposal, SB 294, was amended ("gutted and amended" in the parlance of the Legislature) on September 4, 2009 to carry some of the Administration's and Senate's proposals for improving DCA's enforcement programs. He stated that whereas initial hopes for the bill were to have it reach the Governor by the end of the legislative year on September 11, 2009, the bill has become a two-year bill.

No public comment was provided.

4. Enforcement Priorities of the Department of Consumer Affairs

Dr. Swart referenced members to the Department of Consumer Affairs (DCA) Guidelines for Complaint Prioritization contained within the board packet.

**Presentation – Anne Sodergren, Assistant Executive Officer**

Assistant Executive Officer Anne Sodergren provided an overview of the board's enforcement program. She stated that the Governor has established a goal for all investigation cases to be closed between 12 to 18 months. Ms. Sodergren explained that DCA has designed a new enforcement model to aid all boards with this timeline.

Joshua Room, Deputy Attorney General, provided an overview of preponderance of evidence, reasonable doubt (the criminal standard), and clear and convincing evidence. He explained that clear and convincing evidence is less than reasonable doubt.

Ms. Schieldge provided that the standard for license disciplinary action is clear and convincing evidence to a reasonable certainty.

## **Board Discussion**

Dr. Swart sought clarification regarding the proposal that additional counsel would be assigned to the board under the DCA's proposal.

Ms. Sodergren provided that the administration is recommending that each board have its own in-house litigators.

Discussion continued regarding various aspects of the new enforcement model and the legislation required to implement it. It was clarified that there will be opportunity for public comment on the model in the future.

## **Presentation Continued**

Ms. Sodergren provided an overview of the total processing times and closure statistics for categories of cases investigated by the board.

Ms. Sodergren stated that there has been significant growth in the number of licensees that the board regulates. She stated that there has also been growth in investigations, the number of complaints received, and application investigations. Ms. Sodergren reviewed the enforcement statistics for fiscal years 2004/2005, 2006/2007, and 2008/2009.

Mr. Room provided that, when compared to other boards, the board is very timely in its processing of investigations.

Ms. Sodergren provided that the board's performance statistics are publicly reported on a quarterly basis in the board packet.

Ms. Sodergren provided that the board is working to identify internal improvements. She stated that these improvements include a reduction in total case closure time by: routing of complaints on-line (instead of mailing), routing draft pleadings on-line for review, using on-line mail ballots by the board when voting on decisions, and the in-house preparation of default decisions (instead of the Attorney General's office preparing these).

## **Board Discussion**

Dr. Swart discussed several occurrences where the respondent did not understand the accusation served upon them; and, consequently had a default decision rendered against them.

Mr. Room provided that this is a rare occurrence. He stated that it is at the discretion of the board to vacate the default.

## Public Comment

Dr. Steve Gray, representing Kaiser Permanente, provided comments on the increased access to records proposal by the DCA and challenges for current pharmacy to provide records to all law enforcement without a subpoena.

There was no additional board discussion or public comment.

## B. Enforcement Program of the Board of Pharmacy and Proposals to Strengthen Board Operations

*Proposed Regulation for Pharmacists to Report on License Renewal Applications Prior Convictions and To Require Electronic Submission of Fingerprints for Pharmacists With No Prior History of Electronic Fingerprints On File*

Dr. Swart provided that at the Enforcement Committee Meeting, the committee discussed the board's enforcement program. He stated that whereas the board has better timelines than the Board of Registered Nursing (BRN), they are not 12-18 months for most formal discipline, which is the average timeline targeted by the director and Administration. Dr. Swart advised that the board needs to strengthen its enforcement program, and provide faster resolution time. He indicated that the board will need additional staff. Dr. Swart provided that since August 2009, staff has been working on program changes and budget change proposals to augment staff so we can improve our program.

Dr. Swart stated that the Enforcement Committee recommends: Initiate a rulemaking on a regulation for pharmacists to: (1) report on license renewal applications prior convictions during the renewal period, and (2) to require electronic submission of fingerprints for pharmacists with no prior history of electronic fingerprints on file.

Dr. Swart provided that for years, the Board of Pharmacy has been fingerprinting applicants for individual licenses (pharmacists, pharmacist interns, technicians, designated representatives), and the officers and owners of board-licensed facilities (pharmacies, wholesalers, clinics, etc.).

Dr. Swart provided that pharmacists have been fingerprinted as a condition of licensure since September 1947 – only 150 individuals with active licenses do not have prints on file with the California Department of Justice. He advised that other boards only began fingerprinting applicants in the late 1980s and later.

Dr. Swart provided that the number of arrest and conviction reports (rap sheets) sent to the board on applicants and licensees is strongly dependent upon the speed with which local jurisdictions enter this information into the reporting system. He stated that in recent years, the number of these reports sent to the board has dramatically increased, and has exceeded the board's ability to

respond timely to these cases. As a result, the board submitted a budget change proposal early this year to ensure that it can timely review and investigate reports of criminal convictions and arrests. He advised that the board received 6.5 new positions effective July 1, 2009. Dr. Swart stated that the last two of these positions were filled in mid-September. He added that staff is now working to investigate a backlog of rap sheets awaiting review.

Dr. Swart provided that currently, the board's ability to ensure it has all information about the arrests and convictions of its licensees is not complete for two reasons:

1. Licensees who submitted fingerprints before 2001 submitted them on fingerprint cards, and the Department of Justice has not automated this process. Those who have been licensed since 2001 have submitted their fingerprints electronically through "LiveScan." Staff is concerned that it may not receive or receive timely rap sheets of those whose fingerprints are not electronically on file with the Department of Justice.
2. Licensees of the Board of Pharmacy are not required to certify at time of license renewal that they have not been convicted of anything. This is standard for other boards, and is a recommendation of the department for all health care boards.

Dr. Swart provided that in 2009, SB 389 was introduced to ensure all departmental agencies had fingerprints on file for all licensees, and that at each renewal, all licensees would certify that they had not been convicted of any crime during the renewal period. He advised that SB 389 was stalled in a policy committee of the Legislature.

Dr. Swart provided that staff recommend that the board move forward to secure these two elements for pharmacists, and then as this is completed for pharmacists, to move forward with technicians and designated representatives who were fingerprinted before 2001.

Dr. Swart provided that at the September Enforcement Committee Meeting, the committee recommended that the board move forward with this regulation.

## **Board Discussion**

The board discussed the timeline and the inclusion of an implementation date for the regulation. Licensees were encouraged to renew in a timely manner to ensure efficient processing.

Stan Weissner expressed concern over the traffic infractions that are required to be reported. He suggested the \$300 traffic fine standard may be too low, and result in a barrage of rap sheets.

The board discussed the workload impact with regards to the reporting of citations resulting in a \$300 fine versus a \$500 fine.

Executive Officer Virginia Herold provided that the fine standard is at the discretion of the board. She discussed the importance of the board's ability to review and investigate criminal convictions and arrests in order to protect the public. Ms. Herold indicated that the standard on the application is \$500.

Dr. Swart provided that there should be consistency between fine standards on the application and the renewal forms.

There was no additional board discussion. No public comment was provided.

**MOTION:** Initiate rulemaking on proposed regulation for pharmacists to: (1) report on license renewal applications prior convictions during the renewal period, and (2) to require electronic submission of fingerprints for pharmacists with no prior history of electronic fingerprints on file. This rulemaking will go into effect 6 months after the approval of the Office of Administrative Law (OAL).

M/S: Schell/Wheat

Approve: 8    Oppose: 0    Abstain: 0

**MOTION:** Direct board staff to take all steps necessary to initiate the formal rulemaking process to adopt the proposed text at 16 CCR Section 1702 and to authorize the executive officer to make any non-substantive changes to the rulemaking package and to insert the effective date in subdivision (a).

M/S: Schell/Wheat

Approve: 8    Oppose: 0    Abstain: 0

**MOTION:** Change the renewal disclosure requirement in subdivision (b) from traffic infractions under \$300 to traffic infractions under \$500.

M/S: Swart/Weisser

Approve: 8    Oppose: 0    Abstain: 0



## Proposed Language

**To Add Section 1702 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

### Section 1702. Pharmacist Renewal Requirements

(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's renewal date that occurs on or after (IOAL insert effective date).

(1) A pharmacists shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, omitting traffic infractions under \$500 not involving alcohol, dangerous drugs, or controlled substances.

(c) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

Note: Authority cited: Sections 4001.1, 4005 Business and Professions Code.  
Reference: Sections 490, 4036, 4200.5, 4207, 4301, 4301.5, 4311, and 4400,  
Business and Professions Code; and Sections 11105(b)(10), and 11105(e),  
Penal Code.

**C. Discussion of the Actions of the Department of Consumer Affairs Health Care Boards to Develop Regulations Required by SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) for Practitioner Recovery/Monitoring Programs**

Dr. Swart stated that at the June Enforcement Committee Meeting, the committee heard a presentation on SB 1441. He stated that Senate Bill 1441 created the Substance Abuse Coordination Committee (SACC) and required that this committee, by January 1, 2010, formulate uniform and specific standards in specified areas that each healing arts board shall use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program. Dr. Swart advised that this committee is subject to the Bagley-Keene Open Meeting Act and is comprised of executive officers and bureau chiefs from specified boards and bureaus. He indicated that the Board of Pharmacy is one of these participating boards.

Dr. Swart provided that given the timeline to develop these standards, the DCA created a workgroup consisting of staff from each of the healing arts boards. (The process is similar to process the board uses to promulgate a regulation.) He stated that the workgroup is responsible for developing recommended standards. Dr. Swart explained that the recommended standards will be vetted during a Uniform Standards Workshop, a public meeting akin to an informational hearing. He indicated that the draft standards will then be presented during a public meeting to the SACC for consideration and action. Dr. Swart announced that the last meeting is scheduled for November 16, 2009.

Dr. Swart provided that there have been public meetings to agree on the program standards for the monitoring programs; these have been held:

- May 6
- July 15
- September 22

Dr. Swart provided that the last meeting is proposed for November 10, 2009.

Dr. Swart provided that the SACC meetings were held:

- May 18
- September 2
- And the last meeting is set for November 16, 2009

*The board suspended the Enforcement Report in order to recognize pharmacists in service for 50 years.*

#### **V. Recognition of Pharmacists Licensed with the Board for 50 Years**

President Schell provided that the recognition of pharmacists in service for 50 years was a program initiated by former board member Stan Goldenberg several years ago. He noted that it is the board's honor to be able to continue the tradition.

President Schell recognized Katherine Owyong. Ms. Owyong was the only female in the first graduating class of the University of the Pacific in 1959. She served 40 years at St. Joseph Hospital where she served as the director of pharmacy. Ms. Owyong highlighted some of the changes she has seen throughout her years as a pharmacist. President Schell presented Ms. Owyong with a 50-year pin.

President Schell recognized Danny Chen. Mr. Chen graduated from the University of California, San Francisco in 1955. He served 34 years with Thrifty Drugstores. Ramón Castellblanch presented Mr. Chen with a 50-year pin.

President Schell recognized Jim Choi. Mr. Choi graduated from the University of Washington in 1954. He served two years in Korea and owned his own store for 23 years. Randy Kajioka presented Mr. Choi with a 50-year pin.

President Schell recognized Richard Mortensen. Mr. Mortensen discussed the enjoyment he has experienced throughout his practice as a pharmacist. He commended new pharmacists who are entering the practice. Greg Lippe presented Mr. Mortensen with a 50-year pin.

*The board resumed the Enforcement Report.*

#### **D. Implementation of the Board of Pharmacy's Ethics Regulation, 16 CCR Sections 1773 and 1773.5**

Dr. Swart provided that earlier this year, the board adopted a regulation to establish an ethics course as an enforcement option for those whose violations and resultant discipline involved at least an ethics issue. He stated that the ethics course is designed to be ethics counseling, done by individual introspection, working one-on-one with a consultant, and in a group setting.

Dr. Swart provided that the board will work with the Institute for Medical Quality to establish this course. He stated that the IMQ is a foundation of the California

Medical Association that operates a similar program for the Medical Board, and was the model the board used to develop the components for its ethics program.

Dr. Swart provided that when the board was considering options for ethics violations, it formed a subcommittee of Board Members Rob Swart and Susan Ravnan. He stated that now in implementing the program, as the parameters for the course are developed, President Schell has indicated that he would like to form a subcommittee to work with senior board staff in developing the program. Dr. Swart indicated that he has appointed Enforcement Chair Rob Swart to this subcommittee and will appoint one additional member.

Dr. Swart provided that the subcommittee will identify administrative discipline files where the violation, in part, had an ethical component (e.g., fraud, dispensing medicine without a prescription), and work with the course provider in establishing the parameters.

Dr. Swart provided that the goal is to have the course ready for administration at the end of the year.

President Schell added that Rosalyn Hackworth has been appointed to the subcommittee.

No public comment was provided.

#### **E. Ongoing Discussion and Presentations About Prevention of Medication Errors**

Dr. Swart provided that during this meeting, Dr. Michael Negrete of the Pharmacy Foundation of California will provide information on medication errors. He stated that this presentation is part of a CE presentation that Dr. Negrete has developed.

Dr. Swart stated that recently Consumers Union published an update of the 1999 Institute of Medicine (IOM) report of "To Error is Human – to Delay is Deadly." The initial IOM report documented the large number of medication errors in hospitals, where as many as 98,000 people die annually, needlessly, due to preventable errors.

Dr. Swart provided that the conclusion of the 2009 Consumers Union report is that if anything, things have gotten worse in the last 10 years.

Dr. Swart provided that California regulators did initiate action based on the initial IOM report. He stated that since the 1999 report, the board secured legislation and underlying regulations to ensure that any medication error that reaches the patient must be subjected to a quality assurance review by the pharmacy to

prevent a reoccurrence. Dr. Swart advised that this is a standard component checked during all board inspections of pharmacies.

Dr. Swart provided that according to preliminary data from 2008-09, over 10 percent of the board's investigations involve medication errors. He stated that last fiscal year (as of June 1, 2009) the board closed 316 medication error complaints; 75 percent of these were substantiated.

Dr. Swart stated that the California Department of Public Health has implemented statutory requirements to improve the care in hospitals. He stated that a presentation is planned for the January 2010 Board Meeting on this subject. Dr. Swart explained that generally the law required hospitals to develop an error reduction plan by 2002 that was submitted to the Department of Public Health, hospitals then had until 2005 to implement the plan, and in 2009 the Department of Public Health began inspections of hospitals for compliance.

#### **Presentation – Dr. Michael Negrete, Pharmacy Foundation of California**

Dr. Michael Negrete, representing the Pharmacy Foundation of California, provided an overview on medication errors. He reviewed elements of medical care including adverse events, preventable adverse events, and medical errors.

Dr. Negrete addressed statistics and the increase in medication errors as well as factors contributing to this increase. He encouraged consumers to demand that their doctors and pharmacists be given the time and information they need to ensure the safety of their therapies.

#### **Board Discussion**

Dr. Swart provided comment regarding the education process for both the providers and the patients.

Dr. Kajioka discussed the importance for the patient to be proactive. He questioned if the medication error statistics include data on prescription drug abuse.

Dr. Negrete provided that the statistics do not differentiate between drug use and drug abuse.

Dr. Castellblanch asked if current research has addressed any correlation between medication errors and the adequacy of prescription drug labels.

Dr. Negrete discussed the importance of the consumer actually reading the information provided on the label.

Discussion continued regarding the information provided on a prescription label and information provided during a consultation. Concern was expressed regarding patient medical literacy and patient comprehension.

President Schell discussed the expansion of the term medication errors to medication therapy errors and the promotion of a partnership between prescribers, dispensers, and patients.

Ms. Herold provided that the board will be producing a brief video to demonstrate the importance of patient consultations. She stated that this video will be available on the board's Web site.

There was no additional board discussion. No public comment was provided.

#### **F. Other Items from the September 16, 2009 Meeting**

1. Discussion Regarding a Request to Use Pharmaceutical Manufacturer Patient Assistance Programs for Indigent Patients Receiving Care from County-Run Pharmacies

Dr. Swart provided that the Enforcement Committee heard a request from LA County to permit it to better benefit from the use of patient assistance programs for indigent patients. He stated that LA County believes that they recoup \$2 million in drug value from their current participation in these programs, but hope to find a means to more fully use these programs to save \$8 million. Dr. Swart advised that they approached the Enforcement Committee hoping to find a way to replace the medication the County provides to medically indigent patients when receiving care in LA County facilities with the patient-specific medication later received from mail order pharmacies who distribute a manufacturer's drugs under a patient assistance program. He indicated that currently such returns to stock are not permitted, and it is difficult for patients to wait to receive the medication from mail order (some patients do not have addresses).

Dr. Swart provided that at the end of the presentation, board staff agreed to work with attorneys to develop some proposals. He advised that there are no proposals to present at this time. Dr. Swart indicated that board staff will have some approaches available at the next committee meeting in December.

No public comment was provided.

2. Presentation by Daichi Sankyo on Third Party Logistics Providers (Licensed Wholesalers) and Drug Manufacturers

Dr. Swart provided that the Enforcement Committee heard a presentation by Daiichi Sankyo on the operations of third party logistics providers.

No public comment was provided.

3. Presentation of the 2008 Report of the Research Advisory Panel of California

Dr. Swart provided that the California Health and Safety Code establishes the Research Advisory Panel to oversee research involving use of controlled substances. He stated that section 11213 provides that:

Persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purposes of research, instruction, or analysis, may lawfully obtain and use for such purposes such substances as are defined as controlled substances in this division, upon approval for use of such controlled substances in bona fide research, instruction, or analysis by the Research Advisory Panel established pursuant to Sections 11480 and 11481.

Dr. Swart provided that the Board of Pharmacy has one representative on this panel, Dr. Peter Koo of UCSF.

Dr. Swart provided that the Enforcement Committee had no comment on this report.

No public comment was provided.

#### **G. Minutes of the September 16, 2009 Meeting**

Dr. Swart provided that the minutes of the Enforcement Committee Meeting are contained within the board packet.

No public comment was provided.

#### **H. Update on the Status of Drug and Sharps Take Back Programs in California Pharmacies**

Ms. Herold provided that there are many take back programs operating throughout California. She advised that the majority of these programs do not follow the guidelines established by the California Integrated Waste Management Board (CIWMB). Ms. Herold provided that the next issue of *The Script* will promote and encourage the use of these guidelines.

#### **Presentation – Bill Anderson, Curbside Inc.**

Bill Anderson, representing Curbside Inc., provided an overview of a home generated non-controlled pharmaceutical collection program. He stated that the program consists of three main elements: (1) a secure drop-box container used for the collection of unwanted prescription drugs from patients, (2) witnessed on-site destruction of the drugs, and (3) final incineration of the materials.

#### **Board Discussion**

Dr. Swart asked if the container is leak proof.

Mr. Anderson provided that the container is completely sealed and consists of a heavy plastic liner to prevent leakage.

Mr. Room questioned if the containers are only installed in pharmacies.

Mr. Anderson provided that the containers are currently in a variety of public facilities including police stations, city halls, and senior centers.

Ms. Herold provided that in order to promote confidentiality and security, pharmacy staff should not assist patients with depositing drugs into the container.

#### **Public Comment**

Douglas Barcon sought clarification regarding the disposal of ointments and creams that are in full or partial tubes.

Ms. Herold provided that hazardous waste must be picked up by a licensed hazardous waste hauler.

Mr. Room provided that any aggregation of waste is classified as hazardous waste.

Discussion continued regarding the proper disposal and incineration of hazardous waste.



There was no additional board discussion or public comment.

**I. Controlled Substances Utilization Review and Evaluation System (CURES) Implements Changes to Allow Pharmacies and Prescribers to Obtain Via the Internet Dispensing Histories of Patients**

Dr. Swart stated that when the Board of Pharmacy first funded the CURES program back in the mid-1990s, the goal was to prevent patients with drug-seeking behavior from receiving controlled substances from pharmacies for drugs that should not have been prescribed. He stated that over the years, in part due to the costs of technology, it was not feasible to permit prescribers and pharmacies from reviewing the real-time dispensing of controlled substances to patients. Dr. Swart advised that pharmacies and prescribers who wanted such information on patients had to request written reports from the Department of Justice and to wait weeks for this information.

Dr. Swart provided that in September 2009, the Department of Justice announced that it could now provide online access to prescribers and pharmacies about the dispensing histories of controlled drugs to patients. He indicated that the data would be as old as three weeks.

Dr. Swart provided that at the next Board Meeting, staff from the DOJ's Bureau of Narcotic Enforcement will provide the board with a presentation on this system.

No public comment was provided.

**J. Enforcement Statistics 2009-10**

Dr. Swart referenced to the 2009-10 enforcement statistics contained within the board packet.

No public comment was provided.

**K. First Quarterly Report on Enforcement Committee Goals for 2009/10**

Dr. Swart referenced to the first quarterly report on the Enforcement's Committee's goals contained within the board packet.

No public comment was provided.

## **L. Public Comment**

Dr. Douglas Hilblom, representing Prescription Solutions and the California Pharmacists Association (CPhA), provided comment on the guidelines established by the California Privacy and Security Advisory Board with regards to medication safety and the sharing of patient medical information. He encouraged the board to address this area at future meetings.

Steve Gray, representing Kaiser Permanente, encouraged the board to consider vendor owned inventory when considering 3PLs and Prescription Drug Discount Programs.

There was no additional public comment.

## **VI. Licensing Committee Report and Action**

President Schell provided that there has been no Licensing Committee Meeting held since the July 2009 Board Meeting.

### **A. Subcommittee to Evaluate Drug Distribution within Hospitals**

#### **1. Summary of the Meeting Held September 17, 2009**

Mr. Weisser provided that during the spring of 2008, the board identified 94 hospital pharmacies with recalled heparin still within the facilities, two to three months following the last recall. He stated that the board cited and fined the hospital pharmacies and pharmacists-in-charge of these pharmacies. Mr. Weisser indicated that because many of these hospitals and PICs have appealed the citations and fines, board members cannot discuss the specific parameters of any of these cases without recusing themselves from voting on the specific case in the future should they be appealed to the Office of Administrative Hearings.

Mr. Weisser provided that the recall system is not working. He stated that board staff worked closely with the California Department of Public Health and the California Society of Health-System Pharmacists to identify problems and we are hoping to develop California-specific solutions.

President Schell provided that he established a two-board member task force to work with these agencies on ways to improve recalls, and other changes needed to provide for improved drug distribution and control within a hospital. He stated that the first meeting of this subcommittee was March 2, 2009.

President Schell provided that the second meeting was held June 2, 2009, at University of California, San Francisco.

President Schell provided that the most recent meeting was held on September 17, 2009 in Sacramento. He stated that during this meeting presentations were given by Marjorie DePuy, Director, Industry Relations, HealthCare Distribution Management Association, Larry Hunley, Distribution Center Manager, McKesson Supply Solutions, Amy Gutierrez, PharmD, Director of Pharmacy Affairs, Los Angeles County Health Services and Elizabeth (Betty) Gregg, Manager, Recalls and Licensure, Cardinal Health. President Schell indicated each of the presenters provided information on the recall process from their perspective.

President Schell stated that also during the meeting, attendees discussed the draft best practices document and provided feedback. He provided the following summary of the main best practices in a recall process:

1. Pre-position the facility to receive early notice of recalls from multiple sources.
2. Identify if the facility has the product.
3. If so, quickly remove the product from all patient care areas.
4. Identify, assess, notify and treat patients who may have received the product.
5. Identify alternative products to maintain therapy.
6. Return the quarantined product.
7. Evaluate the process.

President Schell provided that attendees heard a presentation by Deputy Attorney General Joshua Room highlighting possible legislative and regulatory changes to improve drug distribution within a hospital. He stated that at the conclusion, attendees provided comments of the presentation and offered additional changes to be considered.

President Schell provided that the subcommittee will no longer be functioning in its current task force structure. He stated that the meetings were a tremendous success and provided a new avenue for reaching out to the public and the professional community.

No public comment was provided.

## 2. Draft Recall Procedures for Hospitals

President Schell referenced to the draft recall best practices for board member consideration. He stated that a finalized document will be presented during the next scheduled Licensing Committee Meeting, December 3, 2009 at LAX. President Schell advised that at the conclusion of this process, the best practices will be published on the board's Web site.

No public comment was provided.

3. Survey Results: Drug Distribution Within a Hospital

President Schell provided that during the June 2009 Subcommittee Meeting, a survey was distributed to elicit responses to several questions surrounding the control of drugs within a hospital.

President Schell provided an overview of the survey results.

No public comment was provided.

4. Discussion of the Board on Possible Future Activities of this Subcommittee

Mr. Weisser provided that all subcommittee meetings held were very outcome oriented and proved to be a valuable forum to take on such an important issue and ensure it was fully vetted. He advised that staff recommend that this separate subcommittee be dissolved and the matter referred back to the Licensing Committee for final approval.

No public comment was provided.

**B. Licensing Issues**

1. Emergency and Disaster Response Planning: Presentation on the H1N1 Emergency Response Activities in California by the California Department of Public Health (CDPH)

Mr. Weisser provided that when disasters strike California, people need emergency care, and those not injured in the event often are relocated from their homes without their medicines. He stated that in both cases, board licensees are called upon to aid these people in ways law may not specifically provide for. Mr. Weisser indicated that in the early to mid 2000s, the board sponsored legislation to ensure the public would not be deprived of necessary medicines when disasters occur and emergency response teams are making efforts to care for the public.

Mr. Weisser provided that by late 2006 (following Hurricane Katrina), the board developed an emergency response policy to aid pharmacies with knowledge about what the board expected pharmacies, pharmacists, wholesalers and other licensees to do in the event of a declared disaster. He stated that the emergency response plan boils down to once an emergency is declared, use sound judgment, but "take care of patients."

Mr. Weisser provided that over the course of the last year, the Licensing Committee has heard presentations and discussed disaster response. He stated

that most recently, the committee and attendees heard a presentation from Dr. Dana Grau, the Department of Public Health (CDPH) Emergency Response Unit, who oversaw California's H1N1 response earlier this year. Mr. Weisser indicated that Dr. Grau shared the department's response as well as deficiencies identified in the disaster response plan that need correction before the next declared disaster.

### **Presentation – Dr. Dana Grau – Department of Public Health**

Dr. Dana Grau, representing the Department of Public Health Emergency Response Unit (CDPH), provided an update on CDPH's response to the H1N1 emergency. He outlined CDPH's needs from pharmacies and pharmacists to respond to the emergency. Dr. Grau reviewed the needs of infants and young children that require a compounded version of Tamiflu and Relenza.

### **Public Comment**

Dr. Steve Gray, representing Kaiser Permanente, provided comment on hospital bed availability for those affected by H1N1 and the validity of the information being provided by the media about the vaccine. He discussed the importance of the vaccine and proper dissemination of accurate information.

Discussion continued regarding H1N1 and the vaccine.

2. Proposed Delegation to the Board President to Act 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

Mr. Weisser provided that during the October 2006 Board Meeting, the board voted to adopt a policy statement for pharmacies when providing emergency response. He indicated that a copy of this policy statement was published in the January 2007 issue of *The Script*.

Mr. Weisser provided that Business and Professions Code section 4062 provides the board with broad waiver authority and was recently amended in SB 819 (Chapter 308, Statutes of 2009) to allow for the use of a mobile pharmacy in the event of a declared emergency as specified. He stated that the board intends to use this authority when warranted.

## Board Discussion

Ms. Schieldge reviewed the board's options with respect to delegating authority collectively to the board or to an individual board member to waive statutory requirements to benefit public safety in response to a declared emergency or disaster. She recommended that the board limit this authority to situations wherein the board is unable to convene.

The board sought general clarification regarding its options and adherence to the Open Meetings Act. The board reached a consensus to allow any three members of the board to teleconference in the event that the board is unable to convene during a declared emergency.

Discussion continued with regards to both the authority of the board and of the Governor during a declared emergency.

## Public Comment

President Schell sought clarification regarding what would be achieved during the emergency meeting.

Mr. Room provided that the members attending the emergency meeting would establish and issue guidelines regarding the laws that will be waived during the emergency.

There was no additional board discussion or public comment.

**MOTION:** In the event that the board is not able to convene a public meeting on regular notice or pursuant to the emergency meeting provisions of the Open Meetings Act, any three members of the board may convene a meeting by teleconference, by electronic communication (e.g., e-mail), or by other means of communication to exercise the powers delegated to full board pursuant to Business and Professions Code section 4062.

M/S: Weisser/Swart

Approve: 6    Oppose: 0    Abstain: 1

3. Update: Psychometric Assessment of the PTCB and ExCPT Pharmacy Technician Exams

Mr. Weisser provided that during the April 2009 Board Meeting, the board voted to direct staff to take the necessary steps to secure a vendor to complete the necessary psychometric assessments of the Pharmacy Technician Certification Board (PTCB) and Exam for the Certification of Pharmacy Technicians (ExCPT). He stated that board staff initiated the process; however, because of an Executive Order signed by the Governor, staff were unable to proceed.

Mr. Weisser provided that the psychometric assessment of the examination is needed to ensure for compliance with Section 139 of the Business and Professions Code and is the first step to allowing the use of the ExCPT exam as a qualifying method for licensure as a pharmacy technician.

Mr. Weisser provided that board staff will resume this process and provide an update to the committee during its December 2009 meeting.

No public comment was provided.

4. Reporting and Accounting of Intern Hours for California Pharmacy School Students

Mr. Weisser provided that the Licensing Committee has discussed a major change to intern experience requirements established by the Accreditation Council for Pharmacy Education (ACPE) in the last few years. He stated 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.

Mr. Weisser provided that given the changes surrounding the intern hours requirements as well as the disparity in how the board accepts hours from various jurisdictions, board staff recommend that the intern hours requirements remain unchanged, but that the method by which staff confirm this information be contingent upon one of the following:

- a candidate's PharmD graduation from an ACPE accredited school of pharmacy OR
- licensure status in another state for one year OR
- 1500 hours of experience for foreign educated pharmacist that satisfies all other requirements for licensure.

## Public Comment

Dr. Steve Gray, representing Kaiser Permanente, sought clarification regarding the ACPE graduation requirement.

Ms. Herold provided that the board no longer receives license verification of intern hours from New York, Illinois, and Florida. She stated that a minimum of 1740 hours of intern experience is required in order to complete a PharmD degree at an ACPE accredited school of pharmacy. Ms. Herold indicated that the board will accept this standard as meeting the 1500 hours of intern experience requirement.

Dr. Gray expressed concern that new graduates are not adequately prepared.

There was no additional board discussion or public comment.

### 5. Impact of State Furloughs on Processing Timelines and Work Flow of the Board

Ms. Herold provided that in late June, the Governor issued an Executive Order imposing a third furlough day on each month on state employees. She stated that this order also closes state offices three Fridays each month through June 2010.

Ms. Herold provided that board and executive staff continue to evaluate the board's most mission-critical functions for the board's licensing unit staff. She stated that even with changes, processing times are extending well beyond the board's strategic objectives detailed in the strategic plan and may continue to grow. Ms. Herold indicated that the current processing times for pharmacy technician applications is about 90 days and is about 60 – 75 days for all other application types. She advised that while this is not where the board wants to be organizationally, it is reality for the near future.

Ms. Herold provided that to allow staff to focus on the most important functions of their jobs, processing applications and issuing licenses, executive staff twice previously authorized a temporary stop in responding to applicants calling on the status of a pending application. She stated that such a temporary stop allows staff to focus on reducing the backlog of new applications as well as complete a file inventory.

Ms. Herold encouraged all licensees to renew their licenses in a timely manner.

Ms. Herold stated that executive staff and managers continue to be available to address immediate or urgent applicant concerns.

President Schell recognized board staff for its efforts.



No public comment was provided.

#### 6. Competency Committee Report

##### (a) Pharmacist Exam Performance Statistics for April 2009 – October 2009 CPJE and NAPLEX Exam Administrations

Mr. Weisser referenced to the breakdown of the passing rates for the CPJE and NAPLEX exams contained within the board packet. He stated that the overall passing rate during the specified time frame for the CPJE is 78.3 and 97.8 for the NAPLEX.

No public comment was provided.

##### (b) Job Analysis for the CPJE to Be Undertaken at the End of 2009

Mr. Weisser provided that pursuant to Business and Professions Code section 139, the board is required to complete an occupational analysis periodically which serves as the basis for the examination. He indicated that in order to complete this analysis, the committee recently developed a job analysis with the board's contracted psychometric firm. Mr. Weisser stated that the information learned from this survey will determine if changes are necessary to the content outline of the CPJE.

Mr. Weisser provided that the board anticipates releasing this survey to a random sample of pharmacists before the end of year. He stated that pharmacists that complete the survey will be awarded three hours of continuing education credit.

No public comment was provided.

#### C. First Quarterly Report on Licensing Committee Goals for 2009/10

Mr. Weisser referenced to the first quarterly report on the Licensing Committee's goals contained within the board packet.

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

Dr. Doug Hillblom, representing Prescription Solutions, sought guidance from the board regarding participation in a distribution program for H1N1 therapy.

There was no additional public comment.

## **Recess for Day**

The board meeting was recessed at 3:06 p.m.

The board reconvened at 9:07 a.m. on October 22, 2009.

## **VII. Legislation and Regulation Committee Report**

*Report of the Committee Meeting Held October 21, 2009*

### **Part 1: Regulation Report and Action (Note: CCR as used below means California Code of Regulations)**

Mr. Lippe referred to the following regulations:

#### **A. Board Approved Regulations -- Adopted**

*Amendment of 16 CCR §1773 and Adoption of 16 CCR §1773.5 – Ethics Course for Pharmacists*

##### **Background**

*In April 2007, the board established a subcommittee to examine the development of an ethics course for pharmacists as an enforcement option as part of discipline. Based on the work of this subcommittee, the subcommittee recommended to the full the board that it vote to create a program similar to the program used by the Medical Board. This proposal would establish in regulation the minimum requirements for the ethics program. These minimum requirements are designed to better guide the board and licensees when they are finding a course and will ensure that the course will be of high quality. This proposal will provide licensees with the necessary information to assist in their rehabilitation.*

*During the October 2008 board meeting, the board held a regulation hearing on the proposed changes. The Office of Administrative Law approved the regulatory action on August 4, 2009, and the new regulations became effective on September 3, 2009.*

**B. Board Approved Regulations – Currently Undergoing Administrative Review**  
*Pharmacies that Compound Medication – Repeal of Title 16 CCR §§1716.1 and 1716.2, Amend and Adopt §§1751 through 1751.8, and Adopt §§1735 through 1735.8*

**Background**

*Current pharmacy law authorizes a pharmacist to compound drug products as well as compound injectable sterile drug products. As required in Business and Professions Code section 4127, the board adopted regulations to implement the provisions for pharmacies that compound sterile injectable products. There are no similar provisions in regulation to detail the requirements for pharmacies that complete general compounding. This regulation establishes guidelines to provide uniformity in compounding for California consumers.*

*Draft regulatory text was published at the end of August 2008, and a regulation hearing was held at the October 2008 Board Meeting. At the conclusion of the regulation hearing, the board voted to create a subcommittee of two board members to work with staff and fully consider all comments received both orally and in writing.*

*At its January 2009 Board Meeting, the board voted to pursue a 15-day comment period to exempt from some of the record keeping requirements detailed in Section 1735.3 those sterile products compounded on a one-time basis for administration within 2 hours, as specified. The modified text was noticed on February 26, 2009.*

*At the April 2009 Board Meeting, the board considered the comments received during the 45- and 15-day comment periods, along with a draft response to each. The board again considered modifications to proposed section 1735.3(a)(6) and subsequently voted to pursue a 2<sup>nd</sup> 15-day comment period to exempt from some of the record keeping requirements in proposed 1735.3(a)(6) those sterile products compounded on a one-time basis for administration within 24 hours, as specified. The 2<sup>nd</sup> 15-day comment period was noticed on May 4, 2009.*

*At the July 2009 Board Meeting the board considered the comments received during the 2<sup>nd</sup> 15-day comment period, as well as a draft response to each comment. The board then voted to adopt the regulation text as noticed on May 4, 2009, and to specify that the requirements would not go into effect for six months following approval by the Office of Administrative Law to allow for implementation. The board further moved that staff will exercise its enforcement discretion for an additional six months to allow for education and transition.*

*Staff compiled the final regulatory proposal, which is currently being reviewed by the department.*

### **C. Board Approved Regulations – Currently Awaiting Notice**

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

#### **Background**

*The adoption of Section 1785 of the California Code of Regulations would establish a self-assessment form for veterinary food-animal drug retailers and require the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form would also aid these licensees in complying with legal requirements of their operations and therefore increase public safety as a result of this compliance.*

*The draft form was reviewed and approved at the September 2007 Enforcement Committee Meeting. During the October 2007 Board Meeting, the board voted to approve the regulation for the 45-day comment period.*

*The Licensing Committee is completing a program review of the Veterinary Food-Animal Drug Retailer program. Board staff does not anticipate proceeding with this regulation change until the Licensing Committee completes its review of the Veterinary Food-Animal Drug Program for possible changes.*

2. Title 16 CCR §§1721 and 1723.1 – Dishonest Conduct During a Pharmacist's Licensure Examination Confidentiality

#### **Background**

*At the October 2007 Board Meeting, the board voted to approve proposed amendments to 16 CCR §1721 and §1723.1 to strengthen the penalty an applicant would incur for dishonest conduct during an examination, as well as further clarify the penalty an applicant would incur for conveying or exposing any part of a qualifying licensing examination.*

*This recommendation was generated from the board's Competency Committee, which is responsible for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists examination. According to the board's current exam psychometrician, the cost to generate a new test item is \$2,000/item. Compromised test items pose not only a financial loss to the board, but also inhibit the board's ability to test for minimum competency and, if an otherwise incompetent applicant passes the exam because the exam has been compromised, such a breach is a public safety issue.*

*This regulation will be noticed in the future.*

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

Background

*Business and Professions Code section 4127.1 requires a separate license to compound sterile injectable drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. Since the inception of this statute, the board has approved two such agencies.*

*The proposed regulation specifies the criteria the board will utilize to consider approval of those accrediting agency requests.*

*This proposed regulation is still awaiting notice.*

**D. Regulations Under Development**

1. Title 16 CCR §1780 – Update the USP Standards Reference Material

Background

*CCR §1780 sets minimum standards for drug wholesalers. Section 1780(b) references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. The USP Standards is updated and published annually. Consequently, this section requires an amendment to §1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards if determined appropriate.*

*Because of stated concerns about whether referencing the 2005 USP standards is 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.*

2. Title 16 CCR §1732.2 – Continuing Education for Competency Committee Members

Background

*At the October 2008 Board Meeting, the board voted to award up to six hours of continuing education (CE) credit annually to complete on-line review of examination questions if the committee member is not seeking reimbursement for their time.*

*Competency Committee members serve as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists. A committee member's term is generally about eight years.*

*The board also awards CE for:*

- *Attending one board meeting annually (6 hours of CE),*
- *Attending two committee meetings annually (2 hours of CE for each meeting, must be different committee meetings), and*
- *Completing the PSAM, which is administered by the National Association of Boards of Pharmacy (6 hours).*

*Board staff is drafting regulation language for consideration at a future Legislation and Regulation Committee meeting.*

**E. Proposed Regulations to Implement Recently Enrolled Legislation**

1. Proposed changes to Title 16 CCR Section 1749 to conform with provisions contained in AB 1071 (Emmerson) Pharmacy Fees

Background

*The board sponsored AB 1071, authored by Assembly Member Emmerson, to adjust application and renewal fees to ensure that the Board of Pharmacy has sufficient funds to fulfill all of its statutory obligations as a consumer protection agency. In most case, the measure established new minimum fees, and also capped future fees to increase no more than 30 percent.*

*AB 1071 was signed by the Governor on October 11, 2009, resulting in Chapter 270, Statutes of 2009. This mandate is effective January 1, 2010, which establishes these new fees.*

*At some point in the future, the board will need to amend its regulation requirements for fees so they are consistent with those in the new law. Those in the law take precedence over the fees in regulation if there is an inconsistency.*

2. Proposed adoption of provisions to implement provisions contained in AB 931 (Fletcher) Emergency Supplies

Background

*The Governor signed AB 931 on 10/11/09 to amend Health and Safety Code §1261.5 to increase the limit of oral dosage form and suppository dosage form drugs in a secure emergency pharmaceutical supplies container to 48 (from 24) in a health facility licensed under H&SC §1250. AB 931 places limitations on psychotherapeutic drugs, and also provides CDPH with authority to increase the number of those drugs in the e-kit, as specified. The measure is sponsored by the California Pharmacists Association. The board did not take a position on the bill.*

**Public Comment**

Steve Gray, representing Kaiser Permanente, sought clarification regarding the timeframe for the compound regulation.

Ms. Herold provided that the compound regulation is not yet at the Office of Administrative Law (OAL). She advised that a 120-day extension has been granted to allow for the department's review.

There was no additional public comment.

**Part 2. Legislative Report: Discussion and Action on Pending Legislation**

The board reviewed the following pieces of legislation:

**A. AB 931 (Fletcher, Chapter 491, Statutes of 2009) Emergency Supplies – Doses Stored in an Emergency Supplies Container**

Committee Recommendation: *To direct board staff to work on the provisions contained in AB 931.*

Mr. Lippe provided an overview on AB 931 and indicated that it greatly expands the number of drugs and doses of drugs in emergency kits for skilled nursing facilities.

## Board Discussion

Ms. Herold stated that board staff will generate some regulation requirements to ensure there is consistent accounting for the drugs in these kits. She stated that the draft language will be presented to the board at the January 2010 Board Meeting.

There was no additional board discussion. No public comment was provided.

**MOTION:** Direct board to staff to develop regulatory requirements for the emergency kits provided to skilled nursing facilities.

Approve: 8   Oppose: 0   Abstain: 0

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

*Committee Recommendation:* To direct staff to proceed with amending §4081 to specify a time period in which records shall be provided to the board when requested by an inspector or authorized representative of the board.

Mr. Lippe provided an overview on §4081.

## Board Discussion

The board discussed an amendment to replace “an inspector or authorized representative of the board” with “authorized representative.”

There was no additional board discussion. No public comment was provided.

**MOTION:** To approve the proposed amendment to the committee’s recommendation.

Approve: 8   Oppose: 0   Abstain: 0

**MOTION:** To adopt the committee’s recommendation as amended.

Approve: 8   Oppose: 0   Abstain: 0



## Final Language

### **§ 4081. Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory**

4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) When requested by an inspector or authorized representative of the board, the owner, corporate officers, or manager of any entity licensed by the board shall provide the board with records as requested within 72 hours of the request. The entity may request an extension of this timeframe for a period up to 14 days. Such a request must be made in writing and is subject to approval.

~~—(b)~~ (c) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.

~~—(c)~~ (d) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

~~(d) This section shall become operative on January 1, 2006.~~

**C. §4104 – Licensed Employee, Theft or Impairment: Pharmacy Procedures**

*Committee Recommendation: To amend §4101, subdivision (c) to require a pharmacy to provide the information specified in subparagraphs (1) through (6) within 14 days and to amend (c)(4) to include a provision that a pharmacy shall conduct an audit to determine the loss, if any, from the pharmacy, and that the audit results be provided to the board.*

Mr. Lippe reviewed the amendments to §4104.

No public comment was provided.

**MOTION:** To adopt the committee's recommendation.

Approve: 8   Oppose: 0   Abstain: 0

**Final Language**

**§ 4104. Licensed Employee, Theft or Impairment: Pharmacy Procedures**

4104. (a) Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

(b) Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.

(c) Every pharmacy shall report and provide to the board, within ~~30~~ 14 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy:

(1) Any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice.

(2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs.

(3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual. As part of this evidence, the pharmacy shall conduct an audit to determine the loss, if any, from the pharmacy. A certified copy of the audit and results shall be provided to the board.

(5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs.

(d) Anyone making a report authorized or required by this section shall have immunity from any liability, civil or criminal, that might otherwise arise from the making of the report. Any participant shall have the same immunity with respect to participation in any administrative or judicial proceeding resulting from the report.

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

*Committee Recommendation: To add a subsection to state that a nonresident pharmacy shall not permit a pharmacist whose license has been revoked by the board to manufacture, compound, furnish, sell, dispense, or initiate, the prescription of any dangerous drug or dangerous device, or provide any pharmacy-related service to any patient in California.*

Mr. Lippe provided an overview on §4112.

**Board Discussion**

Dr. Swart suggested that this requirement also be used in stipulations.

President Schell stated concern about the enforceability of this requirement and possible implementation issues.

Mr. Room provided some guidance on the possible implementation of this requirement.

**Public Comment**

Dr. Steve Gray, representing Kaiser Permanente, expressed concern with the provision and its implications. He encouraged the board to not move forward with this.

Rich Palombo, representing Medco Health, provided comment on the National Association of Boards of Pharmacy (NABP) clearinghouse.

Ms. Schieldge responded explaining some of the legal options to facilitate implementation of this issue. She stated that the board can provide licensure verification through the board's Web site as well as with a certification of licensure status.

Dr. Kajioka provided that it is the due diligence of the employer to verify that their employees are registered to service California. He discussed the importance of the board's ability to revoke a license.

Mr. Room offered a suggestion to amend the language to state "whose license has been revoked without subsequent reinstatement" and to add "or surrendered with disciplinary action pending."

Dr. Gray sought clarification on the frequency with which employers need to check on the license status of their employees.

Ms. Herold provided that license verification via the board's Web site is proof of licensure. She stated that license verifications can also be requested to the board for a minimal fee.

Discussion continued regarding license verification and the timeframe for which revocations are listed.

There was no additional board discussion or public comment.

**MOTION:** To adopt the committee's recommendation.

Approve: 6   Oppose: 2   Abstain: 0

### **Final Language**

#### **§ 4112. Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation**

**§ 4112.** (a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy.

(b) All nonresident pharmacies shall register with the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.

(d) A nonresident pharmacy shall not permit a pharmacist whose license has been revoked by the California State Board of Pharmacy to manufacture, compound, furnish, sell, dispense, initiate the prescription of any dangerous drug

or dangerous device, or provide any pharmacy-related service to any patient in California.

~~(d)~~ (e) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

~~(e)~~ (f) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

~~(f)~~ (g) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

~~(g)~~ (h) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state. The board shall not adopt any

regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.

~~(h)~~ (i) The registration fee shall be the fee specified in subdivision (a) of Section 4400.

~~(i)~~ (j) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.

~~(j)~~ (k) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

#### **E. §41 20 – Nonresident Pharmacy; Registration Required**

*Committee Recommendation: The committee discussed the proposed repeal of §4120, and tabled this item to allow further research and consideration of the provisions that may be duplicative of other Pharmacy Law provisions.*

Mr. Lippe provided that this section has been tabled by the committee.

No public comment was provided.

#### **F. §4200.1 – Retaking Examinations; Limits; Requirements**

*Committee Discussion: To add §4200.1 as proposed to re-implement the provision in Pharmacy Law.*

Mr. Lippe provided an overview on §4200.1. He stated that an amendment to remove the sunset date in this section was supported by the board but never made it into a 2009 bill. As such, the provision will sunset January 1, 2010.

## Board Discussion

Mr. Room clarified this provision is needed to maintain current requirements. He stated that the section will reauthorize a law that has been sunsetted.

Ms. Herold stated that the board did support this provision last year.

There was no additional board discussion. No public comment was provided.

**MOTION:** Adopt the committee's recommendation.

Approve: 8   Oppose: 0   Abstain: 0

## Final Language

### **§ 4200.1. Retaking Examinations; Limits; Requirements**

4200.1. (a) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination four times, and may take the California Practice Standards and Jurisprudence Examination for Pharmacists four times.

(b) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists four additional times each if he or she successfully completes, at minimum, 16 additional semester units of education in pharmacy as approved by the board.

(c) The applicant shall comply with the requirements of Section 4200 for each application for reexamination made pursuant to subdivision (b).

(d) An applicant may use the same coursework to satisfy the additional educational requirement for each examination under subdivision (b), if the coursework was completed within 12 months of the date of his or her application for reexamination.



(e) For purposes of this section, the board shall treat each failing score on the pharmacist licensure examination administered by the board prior to January 1, 2004, as a failing score on both the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists.

#### **G. §4301 – Unprofessional Conduct**

*Committee Recommendation: To amend §4301 (g), (q) and (t) as follows:*

- *(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts or furnishing false, misleading, or incomplete information to the board, or the failure to furnish information requested by the board or required by this chapter.*
- *(q) Engaging in any conduct that subverts or attempts to ~~subvert~~impede an investigation by the board.*
- *Strike subdivision (t) – the date the section becomes operative.*

Mr. Lippe provided an overview on §4301.

#### **Public Comment**

Dr. Steve Gray, representing Kaiser Permanente and the California Pharmacists Association (CPhA), questioned if “knowingly” applies to both scenarios in subdivision (g).

The board discussed providing clarification to this section by adding a new subdivision. Clarification was provided that the burden is always on the agency to specify what it is requesting. It was the consensus of the board to refer this matter back to the committee.

**MOTION:** To refer this section back to the committee.

M/S: Schell/Kajioka

Approve: 8    Oppose: 0    Abstain: 0

## **Final Language**

### **§ 4301. Obtaining License by Fraud, etc., Unprofessional Conduct: Incompetence or Gross Negligence, Furnishing False Information, etc.**

4301. The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

(a) Gross immorality.

(b) Incompetence.

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts or furnishing false.

misleading, or incomplete information to the board, or the failure to furnish information requested by the board or required by this chapter.

(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

(i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering, or offering to sell, furnish, give away, or administer, any controlled substance to an addict.

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.

(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions,

and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, Information, or indictment.

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program. The record of the compromise is conclusive evidence of unprofessional conduct.

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

(p) Actions or conduct that would have warranted denial of a license.

(q) Engaging in any conduct that subverts or attempts to ~~subvert~~ impede an investigation of the board.

(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

(s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to be considered in determining whether the furnishing of dangerous drugs is clearly excessive shall include, but not be limited to, the amount of dangerous drugs furnished to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities, the previous ordering pattern of the pharmacy, and the general patient population to whom the pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a tracking system that complies with the requirements of subdivision (b) of Section 4164 shall be considered in determining whether there has been a violation of this subdivision. This provision shall not be interpreted to require a wholesaler to obtain personal medical information or be authorized to permit a wholesaler to have access to personal medical information except as otherwise authorized by Section 56 and following of the Civil Code. For purposes of this section, "long-term care facility" shall have the same meaning given the term in Section 1418 of the Health and Safety Code.

#### **H. §4301.1 – Pharmacist License; Suspension; Felony Conviction**

*Committee Recommendation: The committee offered support for the proposal to add section 4301.1 and directed staff to work with counsel and others on language to bring back at a future committee meeting.*

Mr. Lippe provided that this section was tabled by the committee.

No public comment was provided.

## **I. First Quarterly Report on Legislation/Regulation Committee Goals for 2009/10**

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

## **J. Public Comment**

No public comment was provided.

## **IX. Communication and Public Education Committee Report and Action**

President Schell provided that there has been no meeting of the Communication and Public Education Committee during this quarter.

### **A. Discussion and Possible Action to Initiate Rulemaking to Adopt Proposed Section 1707.5 Relating to Patient-Centered Prescription Container Labels**

#### **Background**

*Senate Bill 472 (Chapter 470, Statutes of 2007) added Section 4076.5 to the Business and Professions Code, relating to development of patient-centered prescription drug labels. This statute requires the board to promulgate regulations for standardized, patient-centered, prescription drug labels on all prescription medication dispensed to patients in California by January 1, 2011. The board was also directed to hold special public forums statewide in order to seek input from the public on the issue of prescription labels. These forums and one-on-one surveys of consumers were conducted over a period of 17 months.*

*The timeline envisioned for this process was:*

*2008: conduct public hearings statewide*

*2009: develop regulations and adopt the requirements by the end of the year*

*2010: pharmacies implement requirements to be ready for 1/1/11 implementation*

*2011: requirements become effective and labels on prescription medicine are compliant*

*At the July and August 2009 Board Meetings, the board devoted time to development of the regulation requirements. In fact, the sole purpose of the August Board Meeting was to refine the regulation requirements.*

*At the October meeting, the board refined the regulation requirements and directed the release of the regulation language for the required 45 days of public comment. The board will hold a regulation hearing at the January 2010 Board Meeting, and if necessary, modify the language for 15 days of public comment,*

*and then adopt the regulation. This will allow pharmacies nearly 6- 9 months to implement the language, a bit less than the one year envisioned.*

*The board worked with a draft version of the language developed by the board during the August meeting.*

President Schell read a letter provided by Senate Bill 472 author Senator Ellen Corbett in support of the draft regulations.

## **Board Discussion**

Ms. Herold provided an overview of some of the issues involved with the regulation. Ms. Herold indicated that both draft versions of the regulation, the July 2009 "blue draft" and the August 2009 "pink draft," are generally consistent with the guidelines of the National Association of Boards of Pharmacy (NABP). She discussed where the US Pharmacopeia will be going with respect to the standardization. Ms. Herold highlighted the diversity of prescription labels already in use, some that are very patient centered.

Ms. Herold highlighted the timeline and encouraged the board to move the language at this meeting to initiate the rulemaking process.

Ms. Herold reviewed the research underway that is funded by the California Endowment to develop translations for the directions for use to aid California in developing these standards. She suggested that the board make these translations available for individual pharmacies to use at their own discretion.

## **Public Testimony**

Steven Rosati provided support for the "pink draft." He presented sample labels exemplifying the ability to reformat a label easily based on the requirements from the "pink draft." Mr. Rosati highlighted recommended changes and provided justification for these changes.

Beth Abbott, representing Health Access Foundation, encouraged the board to move forward with the regulatory process. She provided that it is essential for labels to be workable and readable in order to reduce medical errors. Ms. Abbott provided that the board has done a comprehensive job to solicit information from consumers and researchers. She stated that she is convinced that any remaining concerns brought forward by industry can be addressed through the rulemaking process.

Diane Madoshi stated that seniors need a strong voice and deserve consideration. She urged the board to accept the standards of the "pink draft." Ms. Madoshi shared a story regarding a personal experience of a person who did not understand how to take her medication.

Dr. Swart discussed directions for use including "take at bedtime" and "take in the evening."

Shirley Wheat sought clarification on pill box use that Ms. Madoshi provided during a previous meeting that contains a week's supply of various drugs a patient takes.

Ms. Madoshi responded that, when a pill box is used, the label is still relied upon.

Hene Kelly, representing the California Alliance for Retired Americans (CARA), provided an overview of the CARA organization and urged the board to support CARA's recommendations. She reviewed the current roll seniors play with regards to prescription drugs. Ms. Kelly explained her use of the pill box and highlighted how she uses the information on the prescription. She highlighted the problems with the current prescription bottle. Ms. Kelly spoke in support of the standardization of the directions for use as well as the font size and underscored the necessity of including the purpose or condition. She highlighted that the fastest growing population of seniors are those with English as a second language and underscored the need to translate labels in the dominant California languages. Ms. Kelly urged adoption of the regulation.

Alisha Tran, representing Asian Health Services, provided translation for Vilys Vuong. Ms. Vuong discussed her daily challenges with taking her medications and understanding the directions. She provided that she relies on her son-in-law's interpretations to explain the directions, but she explained that she often forgets his explanation. Ms. Vuong stated that she hopes directions will be printed in Vietnamese and underscored the value of translated directions.

Jin Young, representing Asian Health Services, shared stories regarding patients who could not understand their prescription labels. She emphasized the need for directions that are understandable.

Ms. Wheat provided comment on a patient's ability to understand the label and to understand how to take the medication. She provided that all patients are encouraged to speak to their physicians and pharmacists.

Ms. Young provided that patients who do not speak English cannot go back and check their label to verify the directions.

Dr. Swart indicated that he is concerned about providing a prescription with a label that is in a language that the pharmacist does not speak.

Dr. Castellblanch stated that the label is a vital piece of information.



Brett Kaufman, representing the pharmaceutical industry, stated that larger labels will impact container size, raise costs, and provide potential impact on the environment.

Mr. Lippe provided that many bottles may be thrown away as many people have indicated that they transfer their medications from the bottle to a pill box or other container.

Dr. Castellblanch highlighted the cost of human life with regards to people not understanding their prescription label.

Doreena Wong, representing the National Health Law Program, provided an overview of her organization. She stated that all of the organizations that have submitted letters are encouraging the board to initiate the rulemaking. Ms. Wong advised that the draft regulations are a good beginning point; but, would encourage the board to consider 12 languages consistent with Medi-Cal requirements. She provided an overview on the requirements in New York and highlighted a recent settlement agreement with Medco and the Office of Civil Rights which creates a language services program.

Ms. Wheat sought clarification of New York law and expressed concern that if the label only provides the translation, it will be difficult for the pharmacist to know if the provided information is correct.

Ms. Wong underscored the value of standardizing the directions for use.

Ms. Wheat asked how more complex directions would be translated. Ms. Wong recommended that the prescription label be provided in both languages if possible.

Ms. Wheat expressed concern regarding liability and the quality control of translated prescriptions.

Discussion continued regarding liability and the responsibility for securing translations.

Cynthia Downs underscored the need for consistency. She encouraged the board to consider the needs of seniors and their caretakers.

Missy Johnson, representing the California Retailers Association (CRA), provided that the proposed regulations provide operational challenges. She highlighted the efforts of the CRA members. Ms. Johnson provided suggested changes to the board's draft regulation ("white draft").

Mary Staples, representing the National Association of Chain Drug Stores (NACDS), provided that the "pink draft" is overly prescriptive. She stated that the

"white draft" establishes general criteria instead of a specific format to provide a uniform label.

Jim Gross, representing the California Pharmacists Association (CPhA), asked if the proposed changes will improve or exacerbate the problem with medication errors. He expressed confusion with how the proposed regulation will help the patient and expressed concern with the current construct. Mr. Gross stated support for the "white draft."

Dr. Castellblanch expressed concern that the "white draft" does not meet the directives of SB 472.

Ms. Wheat spoke in support of the amendment offered in subdivision (h) of the "white draft" and sought clarification on the changes offered in (a).

Ms. Staples responded that there are other ways to highlight the information other than just the font size.

Dr. Swart referenced Mr. Rosati's solution and asked for input regarding implementation.

Ms. Johnson expressed concern that the directions for use could be contrary to what the prescriber intends.

Don Gilbert, representing Rite Aid, expressed concern regarding translation and liability issues. He highlighted Rite Aid's efforts including a brochure as well as phone interpretation.

Al Carter, representing Walgreens, detailed that the intent of the legislation was to reduce medication errors. He stated that pharmacists need to be freed up to talk to patients. Mr. Carter provided that Walgreens offers on-site interpretative services and can also provide information in a large font at the request of the consumer.

Marty Martinez, representing the California Pan-Ethnic Health Network, provided that a lot of the concerns raised are all valid but have been vetted in other aspects of the health area. He strongly encouraged the board to move forward with the rulemaking.

The board discussed this issue with regards to the board's liability and translations. It was clarified that the board could bear some potential for liability.

Wendy Ho provided that the regulations are a good starting point; but, there is room for improvement. She underscored the value of translations. Ms. Ho stated that the process needs to be moved forward and encouraged the board to initiate the rulemaking process.

Dan Wills, representing Grandpa's Compounding Pharmacies, expressed concern regarding standardized directions for compounding drugs and the diversity in fonts for other languages. He spoke in support of Rite Aid's efforts to provide oral translation services.

Dr. Steve Gray, representing Kaiser Permanente, provided support for the concept of a patient centered label. He stated that Kaiser is willing to work with the board. Dr. Gray expressed concern with the requirements in subdivision (h).

Vanessa Cajina requested action by the board and recognized the efforts by industry to provide oral translation services.

There was no additional public testimony.

### **Board Discussion**

Ms. Herold advised the board of the regulatory process and strategically how the board should proceed. She summarized the challenges from the industry standpoint as well as from the consumer standpoint.

The board evaluated each subdivision of the "pink draft" while considering the public testimony and the proposed language within the submitted "white draft."

It was the consensus of the board to move ahead with subdivision (d) as drafted in the "pink draft."

It was the consensus of the board to move ahead with subdivision (e) as drafted in the "pink draft" and to change the deadline date to October 2011.

It was the consensus of the board to eliminate subdivision (g).

It was the consensus of the board to move ahead with subdivisions (b) and (c) as drafted in the "pink draft."

It was the consensus of the board to move ahead with subdivision (a) as drafted in the "pink draft" and to refine (a)(2) to combine the name of the drug and the strength of the drug.

The board discussed subdivision (h) with regards to available technology and whether translations are an option. It was the consensus of the board to move ahead with subdivision (h) from the "white draft" submitted by industry and to create a new subdivision (i) to direct the board to revisit the status of available technology in two years.

There was no additional board discussion.

**MOTION:** Initiate the rulemaking process with the proposed language developed by the board to Section 1707.5 relating to patient-centered prescription container labels.

M/S: Castellblanch/Hackworth

Approve: 6    Oppose: 0    Abstain: 1

### **Proposed Language**

**To Add Section 1707.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

#### **1707.5 Patient Centered-Labels on Medication Containers**

(a) Labels on drug containers dispensed to patients in California shall conform to the following format to ensure patient-centeredness.

(1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point, sans serif typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name, or the generic name and the name of the manufacturer.

(C) Directions for use

(D) Purpose or condition, if entered onto the prescription by the prescriber, or otherwise known to the pharmacy and its inclusion on the label is desired by the patient.

(2) For added emphasis, the label may also highlight in bold typeface or color, or use "white space" to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in Business and Professions Code section 4076 and other items shall be placed on the container in a manner so as to not interfere with emphasis of the primary elements specified in subdivision (a)(1), and may appear in any style and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

- (A) Take 1 tablet at bedtime
- (B) Take 2 tablets at bedtime
- (C) Take 3 tablets at bedtime
- (D) Take 1 tablet in the morning
- (E) Take 2 tablets in the morning
- (F) Take 3 tablets in the morning
- (G) Take 1 tablet in the morning, and Take 1 tablet at bedtime
- (H) Take 2 tablets in the morning, and Take 2 tablets at bedtime
- (I) Take 3 tablets in the morning, and Take 3 tablets at bedtime
- (J) Take 1 tablet in the morning, 1 tablet at noon, and 1 tablet in the evening
- (K) Take 2 tablets in the morning, 2 tablets at noon, and 2 tablets in the evening
- (L) Take 3 tablets in the morning, 3 tablets at noon, and 3 tablets in the evening
- (M) Take 1 tablet in the morning, 1 tablet at noon, 1 tablet in the evening, and 1 tablet at bedtime
- (N) Take 2 tablets in the morning, 2 tablets at noon, 2 tablets in the evening, and 2 tablets at bedtime
- (O) Take 3 tablets in the morning, 3 tablets at noon, 3 tablets in the evening, and 3 tablets at bedtime
- (P) Take 1 tablet as needed for pain. You should not take more than \_\_\_ tablets in one day
- (Q) Take 2 tablets as needed for pain. You should not take more than \_\_\_ tablets in one day

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) Beginning in October 2010, the board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(d) For patients who have limited English proficiency, upon request by the patient, the pharmacy shall provide an oral language translation of the prescription container label's information specified in subdivision (a)(1) in the language of the patient.

(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

Authority cited: Sections 4005 and 4076.5, Business and Professions Code.  
Reference: Sections 4005, 4076, and 4076.5, Business and Professions Code.

## **B. Update Report on *The Script***

President Schell provided that work on the next of *The Script* is nearly completed. He indicated that in order to save money, the board will be combining the July and January issues into one issue. President Schell stated that the issue will focus on new legislative requirements involving pharmacy law, interpretations of pharmacy law and the Integrated Waste Management Board's Model Guidelines for drug-take back programs.

President Schell provided that this is also the last issue that will be published and mailed to pharmacies and wholesalers. He stated that future issues will be e-version, released to licensees and the public electronically.

No public comment was provided.

## **C. Update on Public Outreach Activities**

President Schell referenced to the following public and licensee outreach activities performed during the first quarter of Fiscal Year 09/10:

- July 3, 2009 – Executive Officer Herold spoke at a Board of Directors Meeting of the California Society Of Health-Systems Pharmacists.
- July 25, 2009 – President Schell volunteered in "Standdown" an event for homeless veterans in San Diego and dispensed prescriptions and counseled patient's regarding their medications.
- July 31, 2009 – Executive Officer Herold made a presentation on patient-centered medication labels during a "Women in Government Conference" in San Diego. The group was comprised of female legislators representing the western United States.

- September 12, 2009 – Board President Ken Schell made a presentation to the Indian Pharmacist Association about board activities.
- September 13, 2009 – Board Inspector Judi Nurse made a presentation to the California Pharmacist Association's Long-Term Care members regarding the DEA and CURES compliance issues.
- September 21, 2009 – Executive Officer Herold made a presentation on California e-pedigree requirements to Logipharma, a group of drug manufacturers and distributors.
- September 23, 2009 – Executive Officer Herold made a presentation on California e-pedigree requirements to Specialty Pharma, an association of contract drug manufacturers.
- September 24, 2009 – Executive Officer Herold provided a law update to the Sacramento Valley Chapter of the California Society of Health Systems Pharmacists.
- October 1, 2009 – Executive Officer Herold provided an update about board activities to the Board of Directors of California Society of Health-System Pharmacists.
- October 2 and 3, 2009 – Board of Pharmacy staffed a booth at CSHP's Annual Meeting, Seminar in San Diego.
- October 2, 2009 – Executive Officer Herold provided a presentation on 2009 pharmacy legislation at the CSHP Annual Meeting.
- October 3, 2009 – Board President Schell provided a presentation on Board of Pharmacy activities at the CSHP Annual Meeting.

No public comment was provided.

#### **D. First Quarterly Report on Committee Goals for 2009/10**

President Schell referenced to the first quarterly report on the Communication and Public Education Committee's goals contained within the board packet.

#### **E. Public Comment**

No public comment was provided.

## **X. Organizational Development Committee Report and Action**

### **A. Budget Update/Report**

#### **1. Governor's Executive Order to Furlough State Employees**

Ms. Herold provided that the legislature and Governor debated necessary cuts and perhaps taxes to resolve the more than \$25 billion shortfall in the 2009-10 budget.

She stated that beginning February 2009 all board staff were furloughed two days per month. Ms. Herold indicated that in July 2009, the board's staff was furloughed one additional day each month, through June 2010. She added that the Governor also directed that state agencies close the first three Fridays per month.

Ms. Herold provided that a byproduct of the furloughs is an increase in our timelines to review applications, issue licenses, investigate complaints and discipline licenses. She stated that the key business processes will be left intact and the focus of our activities will remain doing the most important activities first. Ms. Herold advised licensees to seek a status inquiry check via email in the event an application is pending more than 90 days.

No public comment was provided.

#### **2. Final Budget Report for 2008/09**

President Schell referenced to the Final Budget Report for 2008/09 contained within the board packet. He stated that in 2008/09, the board collected over \$10 million in revenue, primarily from license fees and fines and had over \$9 million in expenditure.

No public comment was provided.

#### **3. Budget Report and Constraints for 2009/10**

President Schell provided that the new fiscal year started July 1, 2009. He stated that the board received a budget augmentation of \$650,000 this year to establish 6.5 new positions to review and investigate criminal convictions of board licensees – a unit necessary due to the exponential increase in the number of criminal conviction reports the board has received in recent years (from about 300 to nearly 3,000 annually). President Schell advised that the augmentation also includes enforcement expenses for anticipated added enforcement actions.



President Schell provided the following estimated budget figures (including a 15% reduction in operating expenses) for 2009-10:

- Revenue: \$8,729,225
- Expenditures: \$9,822,157

#### **Board Discussion**

Mr. Weisser sought clarification regarding the revenue figures.

Ms. Herold provided that the final budget report includes revenue collected for collected citation and fines and cost recovery.

There was no additional board discussion. No public comment was provided.

#### **4. Fund Condition Report**

President Schell 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	\$11,003,000	13.8 months in reserve (actual)
2009/10	\$10,160,000	11.2 months in reserve
2010/11	\$9,228,000	10.0 months in reserve
2011/12	\$8,056,000	8.6 months in reserve

President Schell provided that the fund conditions represented above include the new fees (at their statutory minimums) as included in AB 1071(Chapter 270, Statutes of 2009).

#### **Board Discussion**

Dr. Castellblanch asked how long the current fees have been in effect.

Ms. Herold provided an overview of the current fees and history of fee increases and the newly enacted fee bill that increased the top range for most fees.

There was no additional board discussion. No public comment was provided.

#### **5. Reimbursement to Board Members**

President Schell referenced to the expenses and per diem payments to board members contained within the board packet provided.

No public comment was provided.

## 6. Board Meeting Dates for 2010

President Schell provided that the board still plans to hold 4 board meetings per year.

President Schell provided the following future board meeting dates for 2010:

- January 20-21: Sacramento
- April 21-22: Loma Linda
- July 28-29: Sacramento
- October 20-21: San Diego

President Schell provided that the department will host its second Professionals Achieving Consumer Trust Summit on July 27, 2010 in Sacramento. He stated that this is a new date and location. President Schell advised that this summit will be similar to the November 2008 Summit held in Los Angeles, where the boards and bureaus of the department host joint meetings and attend communal meetings on items of interest and will focus on "Going Green," Licensee Manpower Issues and Enforcement Enhancements.

No public comment was provided.

## 7. BreEZe (I-Licensing) Progress

President Schell provided that the Department of Consumer Affairs has been working for a number of years to replace and/or enhance the legacy licensing 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 Schell indicated that the feasibility study report was approved by the Department of Finance several years ago, and the board is in the first tier of new agencies that may be able to offer this service in the future.

President Schell provided that the board is about 2 years away from implementing an I-Licensing according to current estimates and timelines. He stated that the department hopes to award the contract for the system this year and is looking for an interim solution to allow for credit card payments.

President Schell provided that this priority project for the board means additional delays before the board can achieve on-line renewals of licenses. He stated that the executive officer has been an executive sponsor of this project, and periodic meetings have just been resumed due to staff changes in the Office of Information Services.

No public comment was provided.

## **B. Recognition Program of Pharmacists Who Have Been Licensed 50 Years**

President Schell provided that since July 2005, the board has acknowledged 895 pharmacists with 50 or more years of licensure as pharmacists in California. Seventy-seven pharmacists reached this milestone between May and July 31, 2009. He stated that each was sent a certificate and invited to a future board meeting for public recognition.

No public comment was provided.

## **C. Personnel Update**

### **1. Board Member Changes**

Ms. Herold provided that there are currently nine board members, and four board member vacancies. She stated that the vacant positions are Governor appointments of one public member and three pharmacist members.

No public comment was provided.

### **2. Staff Changes**

Ms. Herold provided that currently all staff positions are filled. She stated that there will be one inspector vacancy in December. Ms. Herold provided that the open exam for the inspector vacancy will be posted on-line.

Ms. Herold provided that the December staff meeting has been cancelled as a cost cutting measure.

President Schell provided that once a year, the board evaluates its executive officer. He stated that this evaluation process has been initiated. President Schell indicated that there is a form for this that will be sent to each board member in several weeks. President Schell explained that each member will have the opportunity to provide comments regarding the performance of the executive officer within the last year, and send these to President Schell. He stated that a final evaluation form will be prepared, which will be provided to the executive officer in closed session at the next board meeting.

No public comment was provided.

#### **D. First Quarterly Report on the Committee's Goals for 2009/10**

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

No public comment was provided.

#### **E. Public Comment**

Steve Gray, representing Kaiser Permanente, provided comment on the Troy and Alana Pack Foundation. He recommended that the board address this effort at a future meeting.

There was no additional public comment.

#### **XI. Closed Session**

The board moved into closed session to deliberate on disciplinary matters pursuant to Government Code section 11126(c)(3).

The meeting was adjourned at 2:48 p.m.