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

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

DATE: January 28 - 29, 2009

LOCATION: Sheraton Hotel – Mission Valley
1433 Camino Del Rio South
San Diego, CA 92108

BOARD MEMBERS PRESENT:
Kenneth Schell, PharmD, President
D. Timothy Dazé, Esq., Public Member, Vice President
Stanley C. Weisser, RPh, Treasurer
Ryan Brooks, Public Member
James Burgard, Public Member
Robert Graul, RPh
Randy Kajioka, PharmD
Robert Swart, PharmD

BOARD MEMBERS NOT PRESENT:
Susan L. Ravnan, PharmD
Shirley Wheat, Public Member
Andrea Zinder, 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
Carolyn Klein, Legislation and Regulation Manager
Tessa Fraga, Staff Analyst

Call to Order

President Schell called the meeting to order at 9:05 a.m.

President Schell recognized new board members, Randy Kajioka PharmD and Ryan Brooks. He recognized former board member, Raffi Simonian. He also recognized all pharmacy students in attendance.

I. Approval of the Full Board Meeting Minutes of October 29 and 30, 2008:

MOTION: To approve the minutes of the October 29 and 30, 2008 Board Meeting.

M/S: SW/JB

Support: 7 Oppose: 0

II. Approval of the Full Board Meeting Minutes of November 20, 2008 of the Summit on E-Prescribing:

MOTION: To approve the minutes of the November 20, 2008 Board Meeting of the Summit on E-Prescribing.

M/S: TD/SW

Support: 7 Oppose: 0

III. Approval of the Board Meeting Minutes of November 20, 2008 of the Forum on Designing Patient-Centered Prescription Labels

President Schell referred to the draft meeting minutes of the forum on designing patient-centered prescription labels. President Schell reminded the board that a quorum of the board was not present during this forum and as such, the board can only vote to accept the board meeting minutes provided in the packet.

MOTION: To accept the minutes of the November 20, 2008 Board Meeting of the forum on designing patient-centered prescription labels.

M/S: JB/TD

Support: 6 Oppose: 0 Abstain: 1

IV. Enforcement Committee Report and Action

A. Presentation and Request from San Diego County for an Exemption to Distribute Prophylaxis Drugs to Emergency Response Staff Prior to a Declared Emergency

Robert Swart provided that, in 2007, the board received a request from San Diego County to

provide an unspecified number of up to 500,000 bottles of a 7-14 day dosing regiment of doxycycline or ciprofloxacin to first responders, that would be stored in their homes for their and their families' use, with the remainder being stored somewhere (unmentioned) else. The county was seeking an exemption from patient-specific labeling because it would be "difficult, if not impossible" to label these containers. Dr. Swart stated that this request was later withdrawn.

Dr. Swart indicated that, in September 2008, the board received a new request from San Diego County. He added that this is the proposal being submitted to the board for action at this meeting.

Dr. Swart provided that this plan calls for doxycycline 100mg #20 to be prescribed to approximately 100,000 first responders and critical access employees and their family members. A total of about 500,000 individuals are estimated to be covered under this plan. Each prescription will be written by the Public Health Officer (a licensed California prescriber) and transmitted to a pharmacy for dispensing. The pharmacy would label the container and dispense the medication.

Dr. Swart stated that San Diego County is seeking confirmation from the board that this model satisfies the requirements in pharmacy law.

Dr. Swart indicated that there are several problems with this proposal as submitted:

1. The Medical Board of California has informally advised the Board of Pharmacy's Executive Officer that a prescription written by a public health officer in this manner would not be a valid prescription because there would have been no prescriber-patient relationship established pursuant to an examination.
2. During a declared emergency, California law provides the board with broad waiver authority to ensure care of patients. However, unless there is a declared emergency, a pharmacy needs a valid prescription to provide prescription medicine to patients (with limited exceptions that would not be relevant in this proposal).
3. The board lacks the authority to waive requirements for the dispensing of drugs in such a manner – a statutory amendment to the Business and Professions Code would be needed.

Dr. Swart provided that San Diego's proposal is being offered as part of the pre-planning process for a public health disaster to ensure the more immediate availability of disaster response workers. However, as proposed, the board lacks the authority to approve it.

Dr. Swart stated that, very recently, San Diego has verbally advised the executive officer of a revised proposal that would seemingly solve the statutory problems associated with this request.

Presentation to the Board:

Jack Walsh (San Diego County EMS, Counter Bioterrism Division):

Mr. Walsh indicated that San Diego County is revising its proposal to request that the county's Public Health Officer provide a letter to first responder's physicians to allow for the dispensing of drugs. The personal health care providers (who do have a patient-prescriber relationship) could determine whether to write such a prescription, but if written, the responders could take the prescription to their own pharmacies. The county would pay for the drug prescribed by the responder's own health care provider.

Board Discussion:

Stan Weisser sought clarification on the number of people that would be impacted by this plan.

Mr. Walsh responded that 12,000 people would be impacted.

There was no additional board or public comment.

B. New Data Collection Vendor Secured for the Controlled Substance Utilization Review and Evaluation System (CURES), Effective January 1, 2009

Dr. Swart advised the board that in mid December 2008, the board was notified that effective January 1, 2009, the California Department of Justice would have a new data collection vendor for CURES, and that all California pharmacies were to submit data to this new vendor beginning January 1, 2009.

Dr. Swart highlighted that despite the very short notice to California pharmacies during the holiday season, the board is not aware that there have been monumental problems with the transition. Nevertheless, two board staff have been assisting callers and redirecting them to the California Department of Justice.

Executive Officer Herold asked the audience to share any input or problems with the new reporting system to CURES.

Public Comment:

Paul Guidices shared that, initially, he was not receiving transmittal confirmations. He provided that he is now receiving transmittal notifications; but, is not being notified about required corrections.

Steve Gray, representing Kaiser Permanente, stated that upon the initial switch to the new vendor, Kaiser received no information from the new vendor on either rejections or confirmations. Dr. Gray highlighted that Kaiser continues to receive rejections for all submissions that include the DEA number of resident prescribers currently in medical school. Dr. Gray informed the board that such prescribers are issued a DEA permit by their employer hospital. This type of DEA number presents a chronic problem with reporting data to CURES as their number does not fit in the requirement field.

Ms. Officer Herold indicated that she will convey these concerns to the Department of Justice.

There was no additional board or public comment.

C. Department of Consumer Affairs Professionals Achieving Consumer Trust (PACT) Policy Statement

Dr. Swart stated that the Department of Consumer Affairs sponsored its first Professionals Achieving Consumer Trust (PACT) Summit in November 2008. At this conference, departmental regulatory board members and staff joined with Schwarzenegger Administration officials, consumers, consumer advocates, professional associations and others to discuss topics that would advance the protection of the public. The Board of Pharmacy held two board meetings during this conference - one on e-prescribing, the other on designing patient-centered prescription container labels.

President Schell stated that as part of the board's participation in this summit, the department requested that all board presidents sign a Resolution stating the board's commitment to consumer protection and education. Dr. Schell stated that the document was a symbolic gesture to California consumers.

Ms. Herold advised the board that the department most likely will schedule additional summits next year.

There was no additional board or public comment.

MOTION: To approve the Pact Summit Resolution signed by President Schell.

M/S: JB/SW

Support: 7 Oppose: 0

D. Presentation by Jan Hirsch, PhD, UCSD, On Research Regarding Use of Automated Dispensing Machines in Community Pharmacies

Dr. Swart provided that in 2005 and 2006, the board discussed and eventually promulgated a regulation to allow automated dispensing machines in pharmacies to dispense refill medications -- if requested by the patient and approved by the pharmacist. This allowed the use of emerging technology. Several pharmacies had sought the board's authority to install such machines in their pharmacies to provide patients with after-hours access (as well as access during times when the pharmacy was open) to previously dispensed prescriptions. The machine was to be located near the physical area of the pharmacy.

As part of the implementation process, UCSD conducted a consumer satisfaction survey of how patients felt about use of these machines. While the results of the study were not available in time for adopting the regulation (which took effect in January 2007), UCSD continued the study. The study is now complete and will be published very shortly.

Presentation to the Board:

Jan Hirsch, PhD (UCSD):

Dr. Hirsch provided the board with the survey results and stated that the results will be published in Journal of American Pharmacists Association to be released in February 2009. Dr. Hirsch stated that the Automated Prescription Delivery Center is similar to an ATM with security features and stated that the survey was designed to compare use of this device to regular counter patients to pick up refill prescriptions. The survey assessed several items including the rates of counseling for refill prescriptions and convenience to the customer. Dr. Hirsch detailed the study methods and data collection including the age and gender of the customer as well as satisfaction of using device. Dr. Hirsch also highlighted the limitations of the study citing that the study only included two pharmacies for a limited amount of time and that the sample size was small. Dr. Hirsch shared conclusions from the study including that few patients asked to speak with a pharmacist and noted that, based on UCSD's study results, most consumers were willing to use the new technology and that there appears to be no notable barriers to access a pharmacist when such technology is employed.

Board Discussion:

Dr. Swart questioned if UCSD also worked with other pharmacies that used this technology.

Dr. Hirsch indicated that the study was limited to the two pharmacies only.

Ryan Brooks sought clarification on the proximity of the delivery unit to the pharmacy and was advised that the unit is nearby, as required by regulation.

Dr. Hirsch responded that the unit is located at the dispensing counter of the pharmacies.

Mr. Brooks requested the percentage of customers that requested consultation.

Dr. Hirsch responded that the percentage was notably low; however, the study only looked at refill prescriptions, consistent with the parameters for using the device.

President Schell inquired about the hours of operation of the delivery device.

Dr. Hirsch responded that the device was available only during the hours of operation.

Dr. Swart stated that based on his experience, 30% of use occurs when the pharmacy is closed and clarified that a pharmacist must be available during off hours.

Ms. Herold stated that, while the study was limited, it very closely followed the requirements within the regulation and highlighted that, post evaluation, there are no notable changes required in the regulation.

Robert Graul requested clarification on how a pharmacy would handle a prescription that was electronically transmitted, and was advised that regulation does not limit the use of the device to only refill prescriptions, but rather prescriptions that have been previously dispensed.

Public Comment:

Sara vonGal, representing Asteres Inc., notified the board that Asteres provides pharmacies with a survey to specifically conduct customer satisfaction. This survey yields a 75% – 80% response rate. Ms. vonGal stated that Longs and Safeway are currently using these delivery devices and that there are about 30 units being employed in California. Ms. vonGal also clarified that if a customer attempts to obtain a new prescription from the delivery device, a notice comes out advising the consumer to go to the counter to pick up the prescription and that it is the pharmacy's responsibility to contact a patient if the instructions are changed.

Mark Chew, representing the Orange County Health Care Agency, asked if a person who has picked up a prescription can use the 800 number to speak to a pharmacist.

Dr. Swart stated that use of the 800 number is not limited.

There was no additional board or public comment.

E. Report on the Meeting of December 9, 2008

1. Update on the Implementation of Model Programs for Drug Take Back from Patients (SB 966, Simitian, Chapter 542, Statutes of 2007)

Dr. Swart stated that Senate Bill 966 (Simitian, Chapter 542, Statutes of 2007) directed the California Integrated Waste Management Board (CIWMB) to develop the parameters for "model" drug take-back programs in pharmacies. These model programs are intended to provide consumers with the ability to dispose of unwanted prescription and over-the-counter drugs (but NOT controlled substances) without flushing them down the toilet or tossing them into the garbage. Under SB 966, these guidelines were required to be in place by December 2008.

Dr. Swart indicated that state and federal law regulates prescription medicine until it is dispensed to patients. It is not regulated again unless it is collected at consolidated points, at which point it becomes medical waste and must be handled and destroyed in specific, mandated ways.

Dr. Swart provided that pharmacies have, in some cases, agreed to take back unwanted drugs from patients. However, this acquisition by pharmacies is not authorized in law.

Dr. Swart stated that some drug manufactures (and the state of Maine, where there is a pilot program underway for seniors) provide mailers that patients can use to send

unwanted medicine to a predetermined location for destruction. This is the process preferred by the DEA for controlled drugs.

Dr. Swart provided that one of the greatest problems for the board with drug take-back programs is the potential for these drugs to be diverted to the streets. Dr. Swart explained that there is a serious prescription drug abuse problem in the US, and the uncontrolled aggregation of prescription medicine is an attractive enticement. In some cases, drugs collected in collection bins could re-enter the prescription drug supply if pharmacies or wholesalers (or others) sell these items back into the supply chain. Dr. Swart indicated that this has occurred in Washington, where a pharmacy operating a take-back program was selling returned drugs to patients as new medicine.

Dr. Swart stated that pharmacies are areas where health care is provided – concern has been expressed that it is difficult for this purpose to be combined with a recycling center, where high sanitation is not necessarily a priority.

Dr. Swart indicated that pharmacies also have expressed concern that they may be required to absorb the costs of paying for disposal of these returned drugs, for sorting out controlled drugs (which potentially would require a pharmacist's time) and for assuring the safe and periodic emptying of collection bins. Senate Bill 966 specifically prohibits pharmacies from charging for drug take back.

Ms. Herold provided an update on SB 966. She indicated that on November 13, 2008, CIWMB adopted the Model Guidelines without incorporating the additional changes listed in the board's November letter. She explained that the model program is not in regulation and does not have the effect of law. Ms. Herold indicated that the board will need to determine how it is going to enforce these provisions.

Ms. Herold stated that she met with CIWMB staff on January 22, 2009. She was informed that CIWMB is going to amend the guidelines. Ms. Herold is requesting approval to resubmit the comments to the CIWMB. This will ensure the board's concerns are on record.

There was no additional board or public comment.

MOTION: To authorize Executive Officer Herold to resubmit comments to the CIWMB.

M/S: RS/SW

Support: 7 Oppose: 0

2. <u>Sharps Take Back by Pharmacies</u>

Dr. Swart discussed the issue of disposal of used sharps.

Dr. Swart indicated that according to estimates by CIWMB, California patients use hundreds of millions of needles and syringes each year. This does not include lancets. This is a disposal issue and a public health and safety issue.

Dr. Swart stated that at the October 2008 Board Meeting, the board approved a policy statement that:

> "California law does not authorize pharmacies to accept the return of sharps when appropriately contained in an approved sharps container. The board reserves its enforcement discretion about whether to intervene with any pharmacy that takes back sharps containers inappropriately. However, until this matter is fully resolved, the board does not anticipate intervening in such practices. Nevertheless, this policy change as a result of a complaint or public safety issue."

Additionally, at the October 2008 Board Meeting, the board agreed to sponsor a statutory amendment to allow pharmacies to take back sharps. This proposal would add Business and Professions Code section 4146:

> A pharmacy may accept the return of needles and syringes from the public if contained in a sharps container as defined by Health and Safety Code section 117750.

Dr. Swart provided that a similar provision is contained in this year's SB 26 (Simitian).

Dr. Swart stated that during the Enforcement Committee Meeting, members of industry indicated that they are complying with local ordinances in conformance with sharps take back requirements. Longs, specifically, indicated that they are receiving not only returned needles, but also drugs. In addition, needles are being returned in unauthorized containers. While Longs Drugs has sharps containers available for sale, many consumers are not returning the used needles in sharps containers. San Luis Obispo (SLO) is providing Longs with containers to place the sharps units directly into the container. Consumers do put other items in the containers. SLO is also arranging for the disposal of the needles and is paying for it with a two-year grant. Marin County has a similar program and also pays for the disposal in Marin County, the county also pays for the sharps container.

Dr. Swart indicated that according to additional comments at the Enforcement Committee Meeting, patients appear resistant to purchasing mail back containers, which cost over $20. He added that there is a company that is promoting the ability of pharmacies to melt sharps units. To do this, a specific sharps container is used, that when returned by the customer, can be melted by the pharmacy. Dr. Swart stated that the cost of each unit is about $1,800 and the pharmacy would be left with the cost to implement.

Dr. Swart provided that the CPhA stated that CIWMB may not be aware of some of the hidden costs and all of the different laws that cover such disposal, and expressed willingness to work with the board and the other interested parties in finding solutions.

3. Future Activities to Support E-Prescribing Implementation

Dr. Swart provided that on November 20, 2008, the Board of Pharmacy hosted an e-prescribing forum in conjunction with the Department of Consumer Affairs' Professionals Achieving Consumer Trust Summit. The board hosted this forum to provide information about e-prescribing in hopes of fostering its implementation in California.

Dr. Swart explained that a current deterrent is that controlled substances cannot be e-prescribed. In mid-2008, the DEA sought comments on its proposal to allow e-prescribing of controlled substances. The board submitted comments, and while supporting e-prescribing of controlled substances noted that the DEA's proposed requirements made e-prescribing much more stringent than written orders.

Dr. Swart provided that Ms. Herold and the executive officer of the Medical Board met with the California HealthCare Foundation to discuss future activities to bring licensees together to implement e-prescribing.

Board Discussion:

Ms. Herold provided that the board, in conjunction with the Medical Board, is planning to hold 3-4 regional meetings to discuss the issue of e-prescribing. She explained that hospital based providers are working with pharmacies in northern California where the pharmacies are faxing refill authorizations instead of e-prescribing. Pharmacies currently get charged every time they send information via the e-prescribing system. Resolutions for this, and other issues, will be sought at these meetings. The Medical Board will offer CE to physicians to participate in these forums. Ms. Herold suggested that the board also offer CE credit to pharmacists who participate at these meetings.

Tim Dazé questioned whether the board needs to approve the CE concept for participation.

Ms. Herold responded that board approval is not needed at this point in the process.

There was no additional board or public comment.

4. Fingerprinting Initiative of the Department of Consumer Affairs for Health-Related Boards

Dr. Swart provided that for a number of years the board has fingerprinted all applicants to secure criminal background information before issuing a license. This is not true of all sister boards.

Dr. Swart indicated that since the fall, Department Director Carrie Lopez has been advocating a department-wide initiative to ensure that health board licensees are fingerprinted. One of the specific requirements detailed by the director is that all health boards within the department implement a plan for securing fingerprints from all licensees regardless of when they were licensed.

Dr. Swart stated that when researching the possible impact to board operations to implement such a change, staff learned that the board was fingerprinting pharmacist applicants as early as September 1949, and estimates that approximately 150 pharmacists licensed before this date still hold active licensees, but were not fingerprint cleared with the Department of Justice. He indicated that the board has been researching criminal backgrounds of applicants longer than any other board in the department.

Dr. Swart also discussed the creation of a Criminal Conviction Unit. The board receives approximately 3,000 arrest notifications a year. The creation of this unit will ensure the timely review and investigation of such notifications and allow the board to pursue administrative action as necessary in the interest of public protection. The projected costs for this unit is approximately $640,000 annually, and this budget augmentation has been added to the Governor's Budget for 2009-10, reflecting the Administration's interest in securing such timely review as a public protection initiative. Dr. Swart stated that the board hopes to initiate this unit in several months, and fund the staffing until July 2009 from redirections from other board programs.

Board Discussion:

President Schell discussed how conviction information could be obtained. He provided that suggestions have recommended that the board obtain this information on renewal forms.

Kristy Schieldge, DCA Staff Counsel, provided that the board has authorized the executive officer to pursue legislation to add a question on applicant and licensee forms about convictions and disciplinary actions. She added that the department is recommending that the board pursue regulation to allow for collection. Ms. Schieldge recommended that the board authorize staff to draft language for board consideration.

Steve Gray, representing Kaiser Permanente, clarified that a conviction question is currently on the renewal application for pharmacy technicians.

Ms. Herold responded that the question was just recently added to the form.

Dr. Gray provided that there is concern whether this question will create delays in the renewal process. He also indicated that there is a lot of confusion on what constitutes a conviction or discipline. Dr. Gray suggested that these issues be researched and addressed.

Ms. Herold provided that clarification and additional information will be provided in *The Script*. She added that the language on the renewal form was developed by DCA and is consistent with all healing arts boards.

Melvin Hamm, representing Eli Lilly USA, indicated that the question is a very common question for other states.

There was no additional board or public comment.

MOTION: To authorize staff to draft language to bring back to the Legislation/Regulation Committee to initiate a rulemaking to place the conviction question and discipline question on the renewal forms.

M/S: BG/SW

Support: 7 Oppose: 0

5. Citation and Fine Program Overview 2007-2008

Dr. Swart provided that during the Enforcement Committee meeting, Supervising Inspector Bob Ratcliff provided an overview of the citations and fines issued by the board during fiscal years 2006-07 and 2007-08. He indicated that this presentation was requested by President Schell and CPhA, following the board's specific presentation on citations and fines that focused on prescription errors that was presented at the July 2008 Board Meeting.

Dr. Swart indicated that following the presentation, the committee heard discussion on whether citation and fines should be issued, whether this was appropriate for a first offense, and the role of the board as a consumer protection agency. He added that at the end of the discussion, CPhA emphasized its desire for compliance inspections by the board, to ensure pharmacies and pharmacists are compliant with California's requirements, and strongly pressed the need for these inspections at least once every three years.

6. DEA Policy on Correcting Schedule II Prescriptions

Dr. Swart provided that in October 2008, the board received clarification from the Drug Enforcement Administration on the Final Rule entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72 FR 64921) as it relates to the changes that can be made by a pharmacist.

Dr. Swart stated that the preamble to the final rule is in conflict with information posted on the DEA's website regarding changes a pharmacist may make to a Schedule II prescription after oral consultation with the prescriber.

Dr. Swart stated that in light of this confusion, the DEA is instructing pharmacists to adhere to state regulations or policy until this matter is resolved through a future rulemaking.

Dr. Swart indicated that California law does not specifically indicate what changes a pharmacist can make to a Schedule II prescription. He added that current law provides that both the date and signature of the physician must be in the prescriber's handwriting. California Code of Regulations Section 1761 (a) allows for a pharmacist to contact a prescriber for oral clarification on a prescription that is ambiguous, erroneous,

irregular, uncertain or contains an omission, unless that omission is the prescriber's signature or date.

Dr. Swart stated that an article on this topic will be published in the next issue of *The Script.*

Public Comment:

Steve Gray, representing Kaiser Permanente, stated that the board materials imply that the board's policy will allow for these changes. He added that the Schedule II prescriptions only account for 1.67% of total prescriptions filled, most of which are used for pain. Dr. Gray emphasized that vulnerable patients are greatly impacted by this issue. He also provided information regarding complaints from pharmacists that HMO's are invalidating a CA prescription payment by deeming that it was unauthorized.

Dr. Swart highlighted that the rules can change when the DEA acts.

Randy Kajioka sought clarification on regulations regarding verbal confirmations and Schedule II prescriptions.

Joshua Room, Deputy Attorney General, provided clarification that if an error is present, the pharmacist can correct it by clarifying it with the prescriber.

There was no additional board or public comment.

7. Theft of Dangerous Drugs from the Pharmaceutical Supply Chain

Dr. Swart provided that, at the Enforcement Committee Meeting, discussion included that California Pharmacy Law requires that all deliveries of dangerous drugs or devices may only be received by and signed for by a pharmacist or designated representative. He indicated that the law specifies that delivery of such products to a hospital's central receiving area must be subsequently delivered to the hospital pharmacy within one working day, and the pharmacist on duty must immediately inventory the products. (Business and Professions Code Section 4059.5(a) and (c)).

Dr. Swart stated that board staff received correspondence from Kaiser Permanent requesting the board's assistance in communicating the delivery requirements for dangerous drugs or devices to pharmacies. He provided that according to information received from Kaiser, despite numerous attempts to address this issue with common carriers like FedEx and UPS, deliveries are still made to unauthorized locations.

Dr. Swart indicated that the board does not regulate common carriers, nor is there any requirement in pharmacy law requiring such licensure to handle dangerous drugs or devices. He added that board licensees are responsible for ensuring the appropriate delivery, receipt and handling of such products.

Dr. Swart provided that in July 2008, the board included an article in *The Script*, which highlighted the problem of drug diversion from common carriers and stated that the

board, as well as the DEA, holds licensees/registrants accountable for failing to take actions to prevent, discover, and report in-transit thefts as required by law. He added that this article highlighted that as a result of these thefts, dangerous drugs are sold on the street, on the Internet, or reintroduced into the medication supply chain by being sold to pharmacies and wholesalers.

Dr. Swart provided that everyone is in agreement that a problem exists with this issue. He indicated that the board does not regulate common carriers. He added that the Enforcement Committee has suggested that this is a contractual issue and wholesalers should address this as such.

8. Summary of the Enforcement Committee Meeting held December 9, 2008

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

F. Second Quarterly Report on Enforcement Committee Goals for 2008/09

Dr. Swart stated that the second quarterly report on enforcement committee goals is contained within the board packet provided.

G. Enforcement Statistics 2008/09

Dr. Swart stated that the board's enforcement statistics for 2008/09 are contained within the board packet provided.

H. Public Comment

Raffi Simonian, representing UCSD Medical Center, discussed the implementation process and procedures of the CURES program. He also discussed an organization that is now looking at the data in general as opposed to on a case-by-case basis. Dr. Simonian suggested that the Enforcement Committee may benefit from CURES data mining. He also provided that meetings are scheduled monthly at the DOJ office in San Diego.

Dr. Swart suggested that CURES provide a presentation at a future Enforcement Committee Meeting.

Ms. Herold responded that this is an option at the board's next Enforcement Committee Meeting in southern California.

Lynn Rolston, representing CPhA, commented that the Enforcement Committee has dealt with some difficult issues. She thanked the board and the committee for their continued vigilance.

There was no additional board or public comment.

V. Communication and Public Education Committee Report and Action:

A. Discussion Regarding Action to Implement SB 472, Patient-Centered Medication Container Labels

President Schell provided an overview of the SB 472 Meeting held on January 27, 2009.

President Schell provided the time envisioned for the SB 472 process:

- 2008: conduct public hearings statewide – six meetings were envisioned
- 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

President Schell indicated that the board is currently on schedule with this timeline. He provided that by the April Board Meeting, the general requirements for the labels should be in draft form. He stated that a regulation should be ready by July for board action; if not, a special board meeting may need to be convened in advance of the October Board Meeting.

President Schell discussed issues regarding patient safety including the label being the first step to providing consumers with additional safety in taking their medicine. He stressed that the label is just one part in patient safety.

President Schell provided that the next SB 472 meeting is scheduled for March 12, 2009.

Dr. Swart suggested that the board bring in additional public participation.

President Schell indicated that the meeting will be held in the evening in Sacramento to try and better engage the public.

Ms. Herold underscored that the board is using the surveys to also reach consumers as well as a radio survey. She indicated that the results reinforce the research that is already out there.

There was no additional board or public comment.

B. Update and Discussion Regarding the Consumer Fact Sheet Series with California Schools of Pharmacy Interns

President Schell provided that the board initiated a proposal to integrate pharmacy students into public outreach activities. Initially the project was initiated with UCSF and nine fact sheets were developed. However, about two years ago (when UCSF could no longer devote the resources needed for the program without a board subsidy) the board decided to offer the opportunity to all California schools of pharmacy to have their students develop the one-page fact sheets.

President Schell indicated that the board will attend the CPhA Outlook Meeting in February 2009 in order to move forward with this project.

President Schell provided that board staff strongly believes that this program offers beneficial and appropriate opportunity to interns to develop public health materials.

C. Development of New Consumer Brochures by the Board

President Schell provided that two new consumer fact sheets have been developed since the October Board Meeting. He stated that staff is developing a new brochure on medication errors in collaboration with the department's Public Affairs Office. President Schell indicated that this brochure should be in print before the next board meeting.

D. Update on *The Script*

President Schell provided that the next issue of *The Script* is scheduled for publication late this month or perhaps in February 2009. The issue will focus primarily on new laws and regulations enacted in 2008. There will also be a segment dealing with medication errors, and summaries of several errors the board investigated.

President Schell stated that, as a result of the Governor's Executive Order in August, for several months the board lost its newsletter editor, Retired Annuitant Hope Tamraz. He added that Ms. Tamraz resumed work on the newsletter in November, once the board could resume using retired annuitants.

President Schell provided that the board is mailing a letter to all pharmacists advising them about Senate Concurrent Resolution 19, that provides that health care providers must not participate in torture and must report suspected torture. A newsletter article will also provide this information.

E. Update on Public Outreach Activities

President Schell highlighted the public and licensee outreach activities performed during the second quarter of Fiscal Year 08/09:

- Board President Schell spoke at the Indian Pharmacists Association Annual Meeting on October 25.
- Supervising Inspector Ratcliff provided a presentation to the Sacramento Valley Society of Health System Pharmacists on November 6.
- Executive Officer Herold provided information about new pedigree requirements to a national audience of supply chain members attending a GHX meeting on November 14.
- Executive Officer Herold provided information about new pedigree requirements to NABP's Symposium on Counterfeit Drugs on December 4.

- Executive Officer Herold provided information about new pedigree requirements to a Center for Business Intelligence Conference on December 9.

F. Second Quarterly Report on Communication and Public Education Committee Goals for 2008/09

President Schell stated that the second quarterly report on communication and public education committee goals for 2008/09 are contained within the board packet provided.

G. Public Comment

No public comment was provided.

VI. 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, as will be done today for several pharmacists.

Robert Swart recognized William Ratzlaff. Mr. Ratzlaff graduated from USC in 1949. He currently lives in Santa Rosa and is working at the Sonoma Developmental Center. Mr. Ratzlaff thanked the board for the opportunity to be honored. Mr. Ratzlaff was honored with a pin.

Tim Dazé recognized Harry Pfeifer. Mr. Pfeifer was licensed in 1959. He worked for Longs Drugs for 32 years as a full-time pharmacist and for 16 years as a part-time pharmacist. He is currently working 2 days a week. Mr. Pfeifer was honored with a pin.

VII. Organizational Development Committee Report and Action

Mr. Dazé provided that the Organizational Committee met via teleconference on January 8, 2009. Mr. Dazé indicated that a summary of this meeting was provided in the context of the report contained within the board packet provided.

A. Governor's Executive Order to Furlough State Employees and Close the Board's Office Twice Monthly on Current Business Days

Mr. Dazé provided that in accordance with the Governor's Executive Order, board staff will be furloughed two days per month. He indicated that staff is working diligently to provide consumer protection to the public.

Mr. Dazé provided that the board will notify applicants, licensees and the public with notices in *The Script,* telephone messages, and on the board's Web site.

B. Presentation to the Board of the 2008 Audit Report of Board Fees and Board Action

Mr. Dazé provided that the board is solely self-funded from the fees it collects from its applicants and licensees.

Mr. Dazé stated that at every board meeting for at least the last four years, the board has discussed that it is nearing the time when it will need to seek a statutory increase in its fees that were last set in statute in the mid-1980s.

Mr. Dazé indicated that monitoring the fund condition report prepared by the Department of Consumer Affairs has been integral to measuring the fiscal condition of the board and is done at every board meeting. He added that despite increasing workload and a substantial salary increase granted 18 months ago to the board's pharmacist inspectors (to enable recruitment of quality applicants), the board has waited to seek an increase in any of its fees until absolutely necessary.

Mr. Dazé provided that last January (2008), principally to help finance the salary increase to inspectors ($576,000), the board promulgated regulations to increase all fees to the statutory maximum. Projections for the board's budget indicate a serious problem in 2010/11 and a deficit in 2011/12.

Mr. Dazé explained that in 2008 the board commissioned an independent audit of the board's fees. This audit was undertaken as part of the background for any fee increase, to ensure that fees are set at the appropriate levels with respect to the expenses of providing services. Mr. Dazé added that this audit involved a cost allocation of all duties to ensure that fees are appropriately allocated to the time and cost required to provide the service. Mr. Dazé provided that the final audit report was submitted at the end of December 2009.

Presentation to the board:

Lynda McCallum (Sjoberg Evashenk Consulting):

Ms. McCallum provided that the Sjoberg Evashenk Consulting Firm was commissioned to conduct an independent audit of the board's fee structure, considering the following objectives:

- Performing an analysis of the board's fee structure to determine if fee levels are appropriate for the recovery of the actual cost of conducting its programs;
- Assessing and revealing any levels of subsidy, surplus, or cross subsidies existing between licensure groups, such as individuals and facilities;
- Assessing activity and workload data for each staff person to determine an hourly cost or cost per unit for the various board activities and services.

Ms. McCallum stated that an expenditure-allocation analysis was performed to determine the cost of the services by the board to compare against the fees charged for providing those services. While cost allocation results do not necessarily set the ideal price point to charge for providing and being reimbursed for the services, the information is one key consideration in identifying consumption of resources and establishing reasonable justification for ultimate fees for those services. She provided that other key considerations involve workload changes, economic volatility, and client climate.

Ms. McCallum indicated that based on the cost allocation process that was employed to arrive at the unit cost for each of the fees charged by the board, an estimate was determined for the board's future fee revenue and reserve position. As a result, analysis reveals that the board's current fee structure is insufficient to maintain the legislatively mandated 12-month reserve requirement (beginning in Fiscal Year 2008-2009) and the board's position will continue to deteriorate until it eventually exhausts all reserves. Ms. McCallum explained that four scenarios to adjust the board's fee structure have been created to improve the board's reserve position and to assist in the board's decision-making process.

Assistant Executive Officer Anne Sodergren reviewed licensee growth over the last five years and current license and renewal fees established in 1987 by Business and Professions Code 4400. She provided comparable fees from various boards within the department.

Ms. McCallum reviewed the following four scenarios:

1. Utilizing increases to fees that are currently subsidized
2. Utilizing full cost recovery of the unit cost of each fee category
3. Utilizing a low "across the board" 15 percent increase for fee categories
4. Utilizing a high "across the board" 20 percent increase for fee categories

Board Discussion:

Mr. Brooks questioned if the real cost for each individual operation was assessed.

Ms. McCallum responded that the unit costs were identified for each of the license fees.

Mr. Brooks questioned if the audit included an analysis of efficiencies to identify ways to streamline processes and avoid increasing fees.

Ms. McCallum responded that this area was analyzed including high-level process flows and redundancies.

Mr. Brooks sought clarification on the cost saving measures assessed.

Ms. McCallum provided that a job analysis was conducted for each position.

Mr. Brooks stressed the importance of avoiding fee increases whenever possible.

Ms. Herold referenced revenue and expenditure comparisons for 2007-2008, noting that current fees vary from the unit cost. She added that a licensee's access to staff and staff efficiency have been greatly impacted by the 20% cut in staff positions in 2001-02. Ms. Herold welcomed suggestions to improve efficiency.

Mr. Brooks sought clarification on any options for technology that have been explored to increase efficiency.

Ms. Herold provided that I-licensing is the best option for future technological implementations. She explained that it will require several more years before the board can secure a vendor and the necessary funding to implement the I-licensing program.

Mr. Brooks questioned if an analysis of I-licensing in other states has been conducted.

Ms. Herold discussed I-licensing as a whole and the current status and process of the system within DCA and the board.

Mr. Weisser sought clarification on whether scenario four was being recommended.

Ms. McCallum indicated that a recommendation is not being provided.

Mr. Brooks stated that all fees should be cost-neutral and that one fee should not subsidize another fee.

Ms. McCallum explained that each proposal assists to "bridge the gap" between costs and fees, but at different lengths of time.

Discussion continued regarding the need to ensure fee increases are justified.

Ms. Schieldge provided that regulations require justification when seeking to increase fees.

Ms. McCallum reiterated that the four scenarios have been created to assist the board with data to consider in its decision-making process and to improve its reserve position.

Dr. Swart noted that the largest increase for subsidized fees was for technicians. He suggested subsidizing technician fees as they have a significantly lower income level.

Public Comment:

Billy Hughes, representing Loma Linda University, provided that the study is a retrospective and static model. He questioned if the study consisted of any prospective analysis.

Ms. McCallum responded that they relied on the board's projections and data in regards to future workload.

Joe Grasela, representing University Compounding Pharmacy, provided that the dispensing physician is not included in the report. He suggested that dispensing physicians be charged a fee as a source of revenue for the board.

Lynn Rolston, representing CPhA, questioned if the data is reflective of all functions of the board with no change.

Ms. McCallum responded that the data reflects the projections of future workload provided by the board.

Ms. Rolston suggested that information regarding projections for future workload be considered.

Ms. Herold provided that cost recovery for inspector time (for formal disciplinary cases) is no longer accurate and is increasing. She indicated that if mandatory inspections occur in the future, inspector staff will need to increase. Ms. Herold stated that revenue projections tend to be conservative.

There was no additional board or public comment.

C. Possible Recommendation to Sponsor Legislation to Increase All Board Licensing Fees

Mr. Dazé provided that the board will need to seek a statutory increase in fees to take effect, possibly sometime in 2010. While the timing is bad given the economic conditions of the state, several other regulatory boards in the Department of Consumer Affairs also will be seeking statutory increases in the Legislature this year.

Mr. Dazé indicated that one component the board will institute immediately is for purposes of cost recovery, specifically the hourly reimbursement cost for Board of Pharmacy inspectors' investigation time. The board currently calculates cost recovery for board inspector time at $65 per hour. Based on the results of the fee audit this will be increased to the auditor's recommended level of $102 per hour. This increase will be retroactive to July 2007 when the inspectors' salaries were increased by $2,000 per month.

Board Discussion:

Mr. Dazé questioned whether a cost of living increase could be added to the fee structure defined in Business and Professions Code section 4400.

Mr. Room responded that legislation would allow for this. He indicated that, typically, a range is placed to allow for the ability to increase fees as needed for cost of living increases.

Ms. Schieldge reviewed the process for submitting fee increase regulation packets to the Department of Finance and the Office of Administrative Law. She provided that the process requires a range in the statute and a regulation specifying the fee for each

license category. Ms. Schieldge indicated that the regulation must include an audit's recommendation as evidence to factually demonstrate and support the necessity for the fee increase.

Dr. Swart suggested that the board not wait until April to act on this issue and that it should consider the timeline imposed by the department.

Ms. Herold reviewed the legislative deadline for introducing new bills. She indicated that the board should consider an additional board meeting to act on this issue to ensure that the bill meets this year's deadline. Ms. Herold emphasized the importance of the subsidy issue.

Ms. Schieldge sought clarification regarding the range requirement for legislation.

Mr. Brooks suggested that the Attorney General draft the bill. He suggested that changes to the bill can be made at a later date.

Ms. Herold indicated that a vote would be required today.

Mr. Dazé provided that, if the board feels it has enough information, he is comfortable with taking action at this meeting.

Discussion continued regarding a possible range and fee increase.

Mr. Room suggested that the board make a motion that will be sufficient to remedy the board's fund condition. He recommended that the board decide on specifics, including the issue of subsidizing, at a later date between now and the deadline.

There was no additional board or public comment.

MOTION: To increase recovery fees from $65 to the auditor's recommended level of $102 per hour, effective July 2007 when the inspector's salaries were increased by $2,000 per month.

M/S: SW/RS

Support: 6 Oppose: 0 Abstain: 1

MOTION: To increase licensing fees at an amount that will be sufficient to remedy board's fund condition and fulfill fiduciary requirements for next 5 years.

M/S: RB/SW

Support: 6 Oppose: 0 Abstain: 1

D. Report of the Meeting of January 8, 2009

1. Budget Update/Report

a. Budget for 2008/09

Mr. Dazé provided the following estimated budget figures from DCA's estimates.

- Revenue: $8,396,000
- Expenditures: $9,800,000

Mr. Dazé stated that the new fiscal year started July 1, 2008, without a state budget being in place until mid September. He indicated that the enacted budget contained a $1 million loan from the board's fund to the state's General Fund. Mr. Dazé provided that this loan will be repaid to the board in the future, in advance of any need for the board to increase fees because of a deficit in the board's fund.

Mr. Weisser sought clarification on the condition of the $1 million loan.

Ms. Herold responded that when in a deficit situation, the $1 million would be paid back under the terms of the loan.

Discussion continued regarding the budget.

b. Fund Condition Report

Mr. Dazé 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:

2007/08	$10,833,000	13.3 months in reserve (actual)
2008/09	$8,479,000	9.6 months in reserve
2009/10	$6,109,000	6.8 months in reserve
2010/11	$3,410,000	3.7 months in reserve ($1 million repayment will likely occur this year)

c. Board Member Reimbursement

Mr. Dazé provided that expenses and per diem payments to board members are reported to the board and are provided in the board packet.

d. Ethics Course for Board Members Due

Mr. Dazé provided that most board members were required to take the two-hour ethics course required by California law before the end of 2008. He indicated that this course must be taken every two years and most members were due to repeat it before the end of 2008.

e. Sexual Harassment Prevention Training Due

Mr. Dazé provided that most board members are required to take a two-hour sexual harassment prevention training course required by the California law. He added that this course also must be taken every two years.

2. I-Licensing Progress

Mr. Dazé provided that the I-Licensing project will offer online application and renewal of licenses.

Mr. Dazé stated that the board spent $50,000 in 2006/07 on programming specifications needed for its programs. He indicated that in the next three years, the board will spend $342,000 as its share of costs to implement this system department-wide.

Mr. Dazé explained that the board is about 2 years away from implementing I-Licensing according to current estimates and timelines. He provided that the department hopes to award the contract for the system this year.

3. Recognition Program of Pharmacists Who Have Been Licensed for 50 Years

Mr. Dazé provided that the board will continue its program to recognize pharmacists who have been licensed for 50 years.

4. Personnel Update

Mr. Dazé indicated the following staff changes:

- Enforcement Manager Karen Cates will retire from state service at the end of this month after more than 22 years with the board. The board's staff will celebrate this achievement with a retirement party. Ms. Cates has been a strong contributor to the board's operations over the years, and was manager of the board's Enforcement Program and acting assistant executive officer for 18 months.
- Carolyn Klein has been hired as the board's legislative and regulation manager. She also will manage the central services staff of the board including budget, contracts, and outreach activities. Ms. Klein has come from the Department of Public Health, where she was a manager.
- Tina Thomas has shifted into an enforcement analyst position doing drug audits and undercover buys off the Internet.
- Tessa Fraga has been hired as the new administrative analyst. She will provide support to board members and the executive office, and will work overseeing the Pharmacists Recovery Program.
- Pamela Martinez, an enforcement technician, has retired from state service.
- Michelle Gallagher has transferred into Ms. Martinez' prior position.
- Bridgette McFarland, who has processed examination applications for pharmacists for one year is leaving the board at the end of the month.

- Maria Arriaga and Raymond Flores are the board's new receptionists. The prior receptionists have transferred to other positions with the board. Juanita Balinski is now the budget analyst for the board, and Jessica Liu is now a board cashier.
- Amber Crosby, prior board cashier, is now the board's examination analyst (replacing Debbie Anderson who was promoted to the Licensing Unit manager).
- Helen Meeks Lawson has been hired to perform administrative case tracking and mail votes processing, replacing Veronica Hagen.

Mr. Dazé stated that the board has also moved to establish and recruit to fill 6.5 positions for a new unit to review background checks involving conviction and arrest information on applicants and licensees. He indicated that the positions will be filled in the next few months on a temporary basis while permanent authority to establish these positions was recently added to the Governor's 2009-10 budget, at an annual expense of $638,000 to the board. Mr. Dazé explained that these positions are needed to allow the board to thoroughly research and take action against licensees and applicants with criminal backgrounds. He added that this is part of the department's initiative to improve the ability of healing arts boards to take action against health care licensees with serious criminal convictions.

Mr. Dazé also provided an update on staff training and development. He provided that Supervising Inspector Janice Dang will attend the winter management academy training provided by the Department of Consumer Affairs. This course is a six-day intensive session in developing future leaders.

Mr. Dazé indicated that all board staff attended a staff meeting on December 10. The meeting was hosted by The Communications Team (now called the Totally Cool Team), which is a group of six staff-elected employees who plan these meetings and coordinate team-building activities. He added that all staff attended a two-hour presentation provided by DCA's Training Office on the traits of Baby Boomers, Gen Xers and Gen Ys.

Mr. Dazé stated that on December 11, board inspectors met with pharmaceutical consultants of the Department of Public Health regarding joint heparin inspections of California health care facilities completed in spring 2008 as well as other items of mutual interest.

E. Second Quarterly Report on the Committee's Goals for 2008/09

Mr. Dazé provided that the second quarterly report on the Organizational Development Committee's goals was provided.

F. Public Comment

Carrie Lopez, Director of the Department of Consumer Affairs, provided an update on the department. She discussed the issue of finger printing and indicated that the department is now requiring finger printing for licensure. Ms. Lopez expressed that the department is committed to ensuring consumer protection. She thanked the board for its

participation at the November 2008 PACT Summit and noted that future collaborative efforts will be scheduled. Ms. Lopez welcomed new board members and supported their role as a regulator. She announced that the next summit will be held in early 2010.

Dr. Schell provided that the board has signed the PACT document.

Ms. Lopez provided that the document is symbolic and represents the group's mission as a whole.

Dr. Schell discussed some additional organizational issues. He provided that the board needs to consider rescheduling the next two board meetings due to scheduling conflicts.

Dr. Schell provided that the April Board Meeting will now be held on April 30 and May 1, 2009 in Sacramento.

Dr. Schell provided that the July Board Meeting will now be held on July 15 and 16, 2009 in Los Angeles.

There was no additional board or public comment.

VIII. Legislation and Regulation Committee Report and Action

Report of the Legislation and Regulation Committee Meeting of January 7, 2009

A. Regulati on Report and Action (Note: CCR as used below means California Code of Regulations)

1. Regulations Adopted by Board – Action Required
   Action to Amend Title 16 CCR Section 1760 – Disciplinary Guidelines

Mr. Graul provided that at the April 2008 Board Meeting, the board voted to adopt a regulation change to amend Title 16 CCR §1760 – Disciplinary Guidelines. He indicated that during discussion at this Board Meeting, counsel recommended that the board add several responses to comments submitted during the written comment period. Mr. Graul stated that staff has received these comments from our counsel and the compiled rulemaking was submitted to the department on September 12, 2008. He added that the Department has 30 days to complete its review of the rulemaking and then it will be forwarded to the Office of Administrative Law for final review.

Mr. Graul stated that while the department did approve this regulation, State and Consumer Services Agency are concerned about the optional language relating to automatic revocation when a probationer fails to submit cost recovery as mandated. He indicated that as a result, it is being brought back to the board for further consideration.

Mr. Graul explained that to allow the board to continue to pursue the regulation change and obtain agency approval that will be required to move forward with the regulation, the board will need to either withdraw the rulemaking and begin over, or seek a 15-day

notice removing this specific term. He indicated that either action will require a vote from the full board.

MOTION: To direct staff to take all steps necessary to complete the rulemaking process, including preparing modified text for an additional 15-day comment period, which includes the following amendments: strike the "option language" from the "cost recovery" provisions relating to automatic revocation when a probationer fails to submit cost recovery as mandated. This proposed change would be incorporated by reference in the proposed amendments to the Board's Disciplinary Guidelines. If after the 15-day public comment period, no adverse comments are received, authorize the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the amendment to Section 1760 of the proposed regulations with the modified text.

M/S: JB/TD

Support: 6 Oppose: 0 Abstain: 1

2. Action to Repeal 16 CCR Sections 1716.1 and 1716.2, Adopt Sections 1735-1735.8 and Amend Sections 1751-1751.8 Regarding Requirements for Pharmacy Compounding and Sterile Injectable Compounding

Mr. Graul provided that, currently, pharmacy law provides the authority for a pharmacist to compound drug products as well as compound sterile injectable 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. He indicated that there are no similar provisions in regulation to detail the requirements for pharmacies that complete general compounding. This proposal would establish guidelines to provide uniformity in compounding for California consumers.

Mr. Graul stated that the 45-day comment period began in September 2008 and a regulation hearing was held at the October 2008 Board Meeting. He indicated that 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.

The Subcommittee's recommendation is to amend § 1735.3 as proposed in the rule making to include the following:

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

Public comment:

Elaine Levy sought clarification on the exemption.

President Schell clarified the difference between the time to initiate therapy and the time to complete therapy.

Steve Gray, representing Kaiser Permanente, sought clarification regarding the "supplier" and the manufacturer.

Mr. Room responded that the supplier is the source of where a product is obtained. He added that the supplier name can be provided if the manufacture information is not available.

Discussion continued regarding the supplier vs. the manufacturer.

There was no additional board or public comment.

MOTION: Direct staff to take all steps necessary to complete the rulemaking process, including preparing modified text for an additional 15-day comment period, which includes the following amendment: add an exemption to section 1735.3(a)(6) for sterile products compounded on a one-time basis for administration within two hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code. If after the 15-day public comment period, no adverse comments are received, authorize the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the following changes with the modified text: repeal sections 1716.1, 1716.2, 1751.01, 1751.02; add sections 1735, 1735.1, 1735.2, 1735.3, 1735.4, 1735.5, 1735.6, 1735.7, 1735.8; and amend sections 1751, 1751.1, 1751.2, 1751.3, 1751.4, 1751.5, 1751.6, 1751.7, and 1751.8 of Division 17 of Title 16 of the California Code of Regulations.

M/S: TD/SW

Support: 6 Oppose: 0 Abstain:1

3. <u>Regulations Previously Adopted by the Board – No Action Required</u>

a. Amend 16 CCR Section 1773 and Add Section 1773.5 -- Establishment of an Ethics Course as an Optional Enforcement Component for Discipline

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.

The board determined the requirements as necessary, based on testimony received during the October 2007 Board Meeting. During the meeting, the board received testimony from the Institute for Medical Quality (IMQ), the course provider for the Medical Board's ethics course. The board determined that a minimum of 14 direct contact hours is appropriate to allow for case presentations, group discussion and experiential exercises and role-playing to ensure sufficient time to discuss and evaluate situations. In addition, based on the recommendation of IMQ, the board's proposal also incorporates an additional 8 hours of time to allow the pharmacist to complete self-reflection on the decisions made that led to the violations and ultimate referral to the program and post-classroom instruction for up to one year. This self-reflection includes completing questions as part of a background assessment. The two post-course longitudinal studies ensure that the pharmacist has successfully internalized the necessary changes to prevent future violations resulting from unethical behavior.

During the October 2008 board meeting, the board held a regulation hearing on the proposed changes. At the conclusion, the board directed staff to take all steps necessary to complete the rulemaking process, including preparing modified text for an additional 15-day comment period, which includes the following amendments: change the word "medicine" to "pharmacy" at proposed §1773.5(a)(5)(B). If after the 15-day public comment period, no adverse comments are received, authorize the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt amendments to §1773 as filed and adopt §1773.5 of the proposed regulations with this modified text.

Mr. Graul stated that the15-day comment period is over and no additional comments were received. He indicated that board staff will begin compiling the rulemaking and will submit it to the department during the first quarter of 2009.

b. Amend Title 16 CCR Section 1715 – Self-Assessment Forms for Community and Inpatient Pharmacies

Mr. Graul noted that at the October 2008 board meeting, the board voted to pursue a Section 100 change to update self-assessment forms required by 16 CCR § 1715 for community and inpatient pharmacies.

These regulations require a pharmacist-in-charge to conduct a self-assessment by July 1 of each odd-numbered year, using either form 17M-13 or 17M-14. Because of changes in pharmacy law since the last revisions date (10/07), changes were made to the self-assessment forms to correct misstated references, correct typographical errors, incorporate appropriate subsection references, make formatting changes and to reflect changes in law since the last form revision. The changes met the criteria of a "Section 100" change in that they were "changes without regulatory effect" – those which do not materially alter any requirement, right, responsibility, condition, prescription or other regulatory element.

c. Amend Title 16 CCR Section 1784 – Self-Assessment Form for Wholesalers

Mr. Graul provided that at the October 2008 Board meeting, the board voted to pursue section 100 changes to update the form. He indicated that board staff will be pursuing the section 100 changes the first quarter of 2009 to ensure approval in advance of the July 1, 2009 completion date.

The self-assessment form (17M-26), which is incorporated by reference in the regulation, is a compilation of relevant laws. A Section 100 regulation change is necessary to update the self-assessment form to reflect changes in pharmacy law since the last form revision date (rev 12/14/06). There are several types of changes being made: to correct previously misstated references; to correct typographical errors; to incorporate appropriate subsection references; to reflect changes in law since the last form revision; and to make formatting changes.

4. Board Approved Regulations – Awaiting Notice

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

Mr. Graul provided that the Licensing Committee is completing a program review of the Veterinary Food-Animal Drug Retailer program. He indicated that 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.

b. Title 16 CCR Section 1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Mr. Graul provided that Business and Professions Code section 4127.1 requires a separate license to compound sterile injectable drug products. He explained that 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.

Mr. Graul indicated that this proposed regulation would specify the criteria the board uses to evaluate these agencies.

c. Title 16 CCR Sections 1721 and 1723.1 – Dishonest Conduct During a Pharmacist's Licensure Examination/Confidentiality

Mr. Graul provided that at the October 2007 Board Meeting, the board voted to approve proposed amendments to Title 16 CCR §§1721 and 1723.1 that would 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 the licensing examination.

Mr. Graul indicated that this recommendation was generated from the board's Competency Committee, which is responsible for the development of the CPJE examination. He stated that according to the board's current exam psychometrician, the cost to generate a new test item is $2,000/item. Mr. Graul added that 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.

Board Discussion:

President Schell sought clarification on the cost per item for exam questions. He asked if we would charge $2,000 for any item compromised on the exam.

Mr. Graul responded that this charge would not be incurred.

There was no additional board or public comment.

5. Regulations Under Development

a. Title 16 CCR section 1780 – Update the USP Standards Reference Material

Mr. Graul provided that Title 16 CCR §1780 sets minimum standards for drug wholesalers. Section 1780(b) references the 1990 edition of the United States Pharmacopeia (USP) Standards for temperature and humidity. He added that the USP Standards are updated and published annually. Mr. Graul indicated that this section requires an amendment to CCR §1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards if determined appropriate.

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

Mr. Graul provided that a subcommittee will be working with board staff and industry to address potential concerns. He indicated that volunteers to work with the subcommittee were requested at the January 2009 Legislation and Regulation Committee Meeting. Kaiser, California Society of Health-Systems Pharmacist and Western Medical Center Santa Monica will have representatives on the subcommittee. Ms. Herold will also contact HDMA for volunteers.

b. Title 16 CCR section 1732.2 – Continuing Education for Competency Committee Members

Mr. Graul provided that at the October 2008 Board Meeting, the board voted to award to Competency Committee members up to six hours of continuing education (CE) credit annually to complete on-line review of examination questions should the committee member not seek reimbursement from the board for their time associated with this function.

Mr. Graul explained that Competency Committee members serve as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). He added that a committee member's term is generally about eight years.

Mr. Graul indicated that board staff will be drafting regulation language for board consideration.

Public Comment:

Joe Grasela, representing University Compounding Pharmacy, stated that there is one major error with the pharmacy rules and laws. He indicated that physicians can compound in their office and are not required to follow the compounding regulation. Mr. Grasela stated that these requirements should be applied to all physician offices where compounding occurs to ensure public protection. He shared that mini pharmacies are beginning to be established in physician offices.

Mr. Graul provided that this issue will be referred back to the next Legislation and Regulation Committee Meeting.

Dieter Steinmetz, representing Coast Compounding Pharmacy, reiterated the comments provided by Mr. Grasela. He stated that the board needs to look at all avenues where compounding occurs and prescriptions are dispensed.

There was no additional board or public comment.

B. Legislative Report

1. Legislation Sponsored by the Board of Pharmacy

a. Reintroduction of 2008 Omnibus Provisions Contained in SB 1779 (2008)

Ms. Sodergren provided that an omnibus provision is a non-controversial change in pharmacy law.

Ms. Sodergren stated that at the October 2008 Board Meeting, the board voted to pursue all of the omnibus provisions approved for sponsorship in 2008. She added that many of these provisions were included in SB 1779 (Senate Business and Professions Committee) which was vetoed by the Governor.

Mr. Graul provided that the 2008 omnibus provisions were categorized into four types of changes:

1. Use of mobile pharmacies.
2. Changes resulting in a comprehensive legal review by board staff and counsel on the legal requirements surrounding the Pharmacist-in-Charge and Designated Representative-in-Charge.
3. General omnibus provisions.

4. Omnibus provisions resulting from the recodification of Business and Professions Code section 4052.

b. Omnibus Provisions for 2009

Mr. Graul provided that at the October 2008 Board Meeting, the board voted to pursue several new omnibus provisions, as well as previously approved omnibus provisions, that were not incorporated in SB 1779 (2008).

Mr. Graul provided that these provisions were available in the board packet.

Public Comment:

John Cronin sought clarification on Section 4013 – Subscriber Alert. He asked how this section will affect a pharmacy that does not have an e-mail address.

Ms. Herold responded that pharmacies should have an e-mail address as they enable the board to get in contact and provide vital information to licensees in a timely manner.

Dr. Cronin expressed concern regarding the use of e-mail as the form of communication. He stated that many pharmacies do not check their e-mail on a regular basis.

Ms. Herold provided that e-mail is a cost effective and efficient way to communicate with licensees.

Discussion continued regarding the use of e-mail and other methods of communication to notify licensees.

Dr. Gray questioned if their will be an opportunity to add to the bill as it moves through the legislature.

Ms. Herold responded that the committee advised that no amendments will be allowed after the bill leaves the house of origin. She indicated that the deadline for any amendments to the omnibus bill is June 10, 2009. Ms. Herold clarified that there will be one additional opportunity for comment at the April board meeting.

There was no additional board or public comment.

MOTION: To approve the omnibus provisions for 2009.

MS: RS/TD

Support: 6 Oppose: 0 Abstain: 1

c. Immunization Proposal – Amendment to Business and Professions Code 4052 and Adoption of 4052.8

Mr. Graul provided that at the October 2008 Board Meeting, the board voted to pursue a statutory change to allow a pharmacist to initiate and administer immunizations pursuant to the published recommendations of the Advisory Committee on Immunization Practices (ACIP).

Mr. Graul stated that beginning in November 2007, board staff worked with stakeholders to address question as well as to elicit support for this proposal for sponsorship in 2008. He provided that in April 2008, after consideration it was decided not to move the proposal last year due to a lack of staff and other legislative priorities.

Mr. Graul indicated that board staff is contacting potential authors for this proposal and will resume stakeholder meetings in February 2009 to solidify a broad base of support for this proposal.

d. Elements of a Prescription Label – Amendment to Business and Professions Code section 4076

Dr. Graul provided that at the October 2008 Board Meeting, the board voted to pursue a statutory change to replace the "condition" for which a prescription is prescribed, with the "purpose" for which the medicine is prescribed. He indicated that this change will clarify a pharmacist's authorization within Business and Professions Code section 4076(a)(10) and allow a pharmacist to place the "purpose" of the medication on the label that is affixed to every prescription container dispensed to a patient, if requested by the patient. Mr. Graul stated that this proposal is consistent with the results of the board's prescription label survey where approximately 19% of all respondents requested the purpose of the medicine be included on the label.

2. Legislative Proposal Regarding Return of Medicine to Reverse Distributors

Mr. Graul provided that for several years, the board has been involved in the issue of take-back drugs, where patients can return unwanted medicine (both OTC and prescription) to pharmacies for disposal instead of tossing them in the garbage or flushing them down the toilet.

Mr. Graul provided that the board is working with the California Integrated Waste Management Board along with several other state agencies and the California Department of Public Health on model programs to take back drugs. He stated that model program guidelines were put in place December 1, 2008, as required by SB 966 (Simitian, Chapter 542, Statutes of 2007). Mr. Graul added that CIWMB may make several amendments to these guidelines, possibly in February 2009. He indicated that no amendments to the guidelines are currently available.

Mr. Graul explained that there appears to be some confusion over when a licensed integrated waste hauler (licensed by the California Department of Public Health) and a

licensed reverse distributor (licensed by the Board of Pharmacy) may pick up unsaleable medicine from a licensed or non-licensed facility.

Mr. Graul provided that pharmacies can return unwanted drugs in a variety of ways, as identified below.

- To the wholesaler from which it purchased the drugs. This provision was created as part of the pedigree provisions to prevent a pharmacy from acting as a wholesaler.
- To a reverse distributor (a licensed wholesaler) if the drugs are unsaleable.
- To an integrated waste hauler (for disposal) and for all drugs taken back by the pharmacy from patients.

Mr. Graul stated that based on discussion during the committee meeting, board staff will survey some drug manufacturers to identify how they currently determine the quantity as specified in B&PC § 4081(b).

Mr. Graul reviewed the committee's recommendation to add the proposal.

Public Comment:

Cookie Quandt, representing Longs Drug Stores, suggested that clarification be provided in the case of a recall where the drug is coming back from the patient.

Steve Gray, representing Kaiser Permanente, indicated that the language does not support a Class I recall at the consumer level.

There was no additional board or public comment.

MOTION: To recommend the addition of this proposal to amplify regulatory structure of reverse distributors to the board's legislative calendar for 2009 including amendment to Business and Professions Code sections 4040.5, 4043 and 4081.

Support: 6 Oppose: 0 Abstain: 1

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

a. AB 67 (Nava) – Pharmacy Patient Protection Act of 2008

Mr. Graul indicated that this bill will not be pursued.

b. SB 26 (Simitian) – Home-Generated Pharmaceutical Waste

Mr. Graul indicated that there is no change with this bill.

Public Comment

Joe Grasela, representing University Compounding Pharmacy, discussed the advances of e-prescribing. He suggested that the board consider a law that requires electronic prescribing. Mr. Grasela stated that the implementation of e-prescribing will result in a reduction in medication errors and help to save lives.

There was no additional board or public comment.

IX. Licensing Committee Report and Action

A. Report of the Licensing Committee Meeting Held December 17, 2009

1. Emergency and Disaster Response Planning -- Emergency Pharmaceutical Assistance Program

Stanley Weisser provided an overview of the request by San Diego County and the Emergency Pharmaceutical Assistance Program as presented by Dana Graul.

Mr. Weisser provided that the California Department of Public Health recently shared with the board information about a federal government program intended to assist persons affected by disasters, who do not have any type of prescription drug coverage, to obtain necessary medication without charge from a local pharmacy while providing pharmacies with a method to recoup their expenses in providing medicine.

Mr. Weisser stated that according to the California Department of Public Health, "This program could go a long way toward helping fill the identified in previous disasters where people without health insurance had to rely on community pharmacy to essentially give away medications and medical supplies. This program could also help manufacturers appropriately donate drugs without adding to the chaos."

2. Formation of Subcommittee to Evaluate Drug Distribution Within Hospitals

Mr. Weisser provided that, in late spring, the board identified 94 hospital pharmacies with recalled heparin still within the facilities, two to three months after the last recall. He indicated that the board has cited and fined the hospital pharmacies and pharmacists-in-charge of these pharmacies. However, 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 stated that the recall system is not working, and staff is pursuing identification of problems with the recall system with the California Department of Public Health, the California Society of Health-System Pharmacists, The California Hospital Association and the FDA. He indicated that the board is hoping to develop California-specific solutions.

Mr. Weisser provided that President Schell 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.

Mr. Weisser indicated that this topic bridges both enforcement issues and licensing issues, but may result in legislative changes identified that involve licensing issues, and therefore this task force was moved to the Licensing Committee.

Public Comment:

Steve Gray, representing Kaiser Permanente, sought clarification on the California Department of Public Health's Taskforce and any legislative changes.

Ms. Herold provided a summary of the board's approach to this issue and the role of DPH. She indicated that the timeline is most likely to pursue legislation in 2010.

There was no additional board or public comment.

3. Update on the Coalition on Shortages of Allied Health Professionals — A Workgroup to Assess Shortages of Pharmacists in Hospitals

Mr. Weisser provided that The California Hospital Association established a coalition whose mission is to create and lead a statewide coordinated effort to develop and implement strategic solutions to the shortage of non-nursing allied health professionals. This coalition is comprised of workforce committees, an advisory council and four workgroups. He added that board executive staff was invited to participate on the pharmacy services workgroup. Mr. Weisser stated that the focus is on pharmacists and pharmacy technicians in the hospital setting.

Mr. Weisser provided that this workgroup, comprised of staff and members of the California Hospital Association (CHA), the California Society of Health-Systems Pharmacists, a representative from academia, representatives from various hospitals and health systems as well as board staff, has met on at least three occasions. He added that based on the results of this workgroup as well as two others, it is the hope that the coalition will develop and implement solutions to eliminate barriers, foster collaboration among CHA member hospitals and health systems, promote a long-term vision for the allied health workforce in California and develop links with workforce partners and stakeholders.

Mr. Weisser provided that during the first meeting, barriers to the profession for both pharmacists and pharmacy technicians were identified, however further discussion resulted in the group concluding that there is not a shortage of pharmacy technicians; rather it is a shortage of qualified pharmacy technicians. Subsequent meetings continue to further define the barriers as well as a ranking of the top barriers. Some of the barriers identified for pharmacists included a limited number of student slots for individuals looking to enter the profession, the pharmacist examination and reciprocity, losing potential candidates to other healthcare professions, e.g., medical school, and

untested new schools of pharmacy. Mr. Weisser stated that the most recent meeting focused on a draft issue statement.

Mr. Weisser indicated that board statistics show that 2061 applicants took the board's examination between June 1, 2007 and July 31, 2008; 890 of those applicants were graduates of California Schools of Pharmacy.

4. Number of Intern Hours That Can Be Earned Outside a Licensed Pharmacy

Mr. Weisser provided that, under current law, an intern must possess 1,500 hours of intern experience under the supervision of a pharmacist before he or she can be made eligible to take the pharmacist licensure examinations.

Mr. Weisser stated that board regulations specify that a minimum of 900 hours of pharmacy experience must be earned under the supervision of a pharmacist in a pharmacy. He indicated that the remaining 600 hours can be granted for experience under the supervision of a pharmacist substantially related to the practice of pharmacy, but not specifically within a pharmacy. Mr. Weisser provided that California pharmacy students typically earn the 600 "discretionary" hours for school-required experiential training (clinical clerkship).

Mr. Weisser indicated that the committee discussed this topic at the June 2008 Licensing Committee Meeting. He added that at that time the committee's recommendation was to table any action at this time to alter the intern hours' requirement. Mr. Weisser stated that after the July 2008 Board Meeting, it was referred back to the Licensing Committee to further explore the issue.

Mr. Weisser provided that during the December 2008 Licensing Committee Meeting, members of the committee again discussed where any changes should me made to alter the intern hours' requirement. He added that the committee considered public comment both in support and opposed to this proposal. Mr. Weisser stated that the committee did not take action on this item.

5. Task Force to Evaluate Pharmacy Technician Qualifications

Mr. Weisser provided that, during the last legislative cycle, the California Society of Health-System Pharmacists (CSHP) sponsored legislation to increase the requirements for an individual to become licensed in California as a pharmacy technician. He indicated that this bill was pulled due to concerns expressed by key pharmacy stakeholders, with the intent of pursuing legislation again in 2009.

Mr. Weisser stated that during the Licensing Committee Meeting, the committee was advised that CSHP during the most recent stakeholder meeting discussed a redraft of the proposal and, more specifically, the ratio requirement for the community pharmacy setting, as well as potentially limiting the proposal to hospital based or inpatient pharmacy technicians only.

Mr. Weisser indicated that during the NABP Annual meeting, a resolution was passed to establish a task force on standardized pharmacy technician education and training. This task force will assess and recommend revisions, if necessary, to language in *the Model State Pharmacy Act and Model Rules of National Association of Boards of Pharmacy.*

6. Florida Rule Change Regarding the NAPLEX Examination

Mr. Weisser provided that the committee was advised that the Florida Board of Pharmacy recently amended its law which had required license transfer applications (by endorsement) to have passed the North American Pharmacist Licensure Examination (NAPLEX) within 12 years.

Mr. Weisser explained that applicants for licensure in Florida must meet all other Florida endorsement criteria before they can become eligible for licensure in that state.

Public Comment:

Steve Gray, representing Kaiser Permanente, stated that this rule change augments the shortage of pharmacists in Florida. He described the pharmacist shortage nationwide and detailed the shortages within hospitals. Dr. Gray spoke about the "Snow Bird Pharmacist", pharmacists that migrate to the south during the winter to address the increase in the senior population. He stressed that the shortage will get worst before it improves.

There was no additional board or public comment.

7. Competency Committee Report

Mr. Weisser provided that each Competency Committee workgroup is scheduled to meet early in 2009 and will focus on examination development and item writing. He indicated that later on this year the committee will begin to develop a job survey to be used to complete an occupational analysis with the board's contracted psychometric firm. Mr. Weisser stated 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.

Mr. Weisser discussed the four time failure report. He provided that Business and Professions Code (B&PC) section 4200.1 establishes a requirement in law that an applicant who fails either the California Practice Standards and Jurisprudence Examination for Pharmacists (CJPE) or the North American Pharmacist Licensure Examination (NAPLEX) four times, must complete 16 units of pharmacy education prior to being eligible to take either examination again. Mr. Weisser stated that the board was required to collect specified data from January 1, 2004 through July 1, 2008 and submit a report to the legislature detailing findings.

Mr. Weisser indicated that the report was sent to the legislature and that board staff will seek legislation to repeal the sunset date in B&PC section 4200.1.

X. Public Comment for I tems Not on the Agenda – Agenda Items for Future Meetings

No public comment was provided.

XI. Recess for Day

The board meeting was recessed at 4:19 p.m.

The board reconvened at 8:18 a.m. on January 29, 2009.

XII. Petition for Reduction of Penalty

Administrative law judge, Mary Agnes Matyszewski, conducted a hearing to consider petition for reduction of penalty for:

- Karen Hartson

XIII. Closed Session

The board went into closed session pursuant to Government Code §11126(c)(1) to discuss and evaluate the administration of the pharmacist licensure examination.

The board went into closed session pursuant to Government Code §11126(c)(3) to deliberate on disciplinary matters and the petition for reduction of penalty.

The meeting was adjourned at 11:00 a.m.