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

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

DATE: July 24-25, 2007

LOCATION: Embassy Suites Hotel
Los Angeles International Airport - SOUTH
1440 E. Imperial Avenue
El Segundo, CA 90245

BOARD MEMBERS PRESENT:
William Powers, Public Member, President
Ruth M. Conroy, PharmD
Kenneth H. Schell, PharmD, Vice President
D. Timothy Dazé, Esq., Public Member
Stanley Goldenberg, RPh
Clarence Hiura, PharmD
Henry Hough, Public Member
Susan L. Ravnan, PharmD
Robert Swart, PharmD
Robert Graul, RPh
Andrea Zinder, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Karen Cates, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judith Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Joshua Room, Deputy Attorney General
Spencer Walker, DCA Staff Counsel
Anne Sodergren, Legislation and Regulation Manager
Karen Abbe, Public and Licensee Education Analyst

Tuesday, July 24, 2007

CALL TO ORDER

President Powers called the public board meeting to order on July 24, 2007 at 9:15 a.m.

I. Committee Reports and Action

A. Enforcement Committee

Chairperson Goldenberg announced that at the June enforcement meeting, disciplinary guidelines were presented. He explained that review of the guidelines occurs approximately every 5-10 years, and it's an important topic. Mr. Goldenberg asked all board members to review the comprehensive guidelines, which will be discussed at next enforcement meeting. Action will be taken at the October Board Meeting.

- Workgroup on E-Pedigree

  Bob Celeste, EPCglobal North America, gave a presentation to the board, which included graphic displays of the overview of standards development for E-pedigree. (A copy of the PowerPoint presentation is attached at the back of these minutes.)

  Mr. Celeste provided an update on six items concentrated on for the health care industry. He said it is important to note that there has been progress in all six areas:

  - Pedigree Messaging Standard
  - Item Level Tagging
  - Serialization
  - Supply Chain Integrity
  - Track & Trace
  - Tag Data Standard

  Mr. Celeste also provided information regarding the Industry Adoption Task Force and its mission, objectives, and timeline. He also spoke about Receipt of Partial Shipments and other topics such as:

  - Unit Dose Serialization
  - Receipt of Partial Shipments
  - Drop Shipments
  - Signature and Certification Inbound
  - Resale of Returned Product
  - Intra-Company Transfers
  - Voided Pedigrees
  - Inference

Mr. Celeste also spoke about EPCglobal's communication activities, including planned Web seminars on the Pedigree Messaging Standard, Supply Chain Integrity, and EPCIS. There will also be hospital forums held every other month, to aid hospitals in preparing for California's requirements.

Mr. Goldenberg added that the industry and the stakeholders, including hospitals, have really come together. He stressed that EPCglobal needs input from all stakeholders so that the industry will embrace these steps. He encouraged stakeholders to contact Bob Celeste and congratulated EPCglobal on its accomplishments.

Mr. Celeste stated that the standard is complete. Refined versions will go forward, but the standards are complete and ratified. Three companies are now certified – Axway, rfXcel, and SupplyScape.

Executive Officer Virginia Herold responded that the current law requires a 2009 implementation date, but gives flexibility to push the date back to 2011.

Mr. Goldenberg stated that the board material in the packet includes several articles referring to counterfeit drugs. The problem is alive and well, especially internationally, and he doesn't want to see that to happen in this country.

Mr. Hough asked Mr. Celeste what he meant by "scale up" when referring to industry responsibilities and systems integration.

Mr. Celeste responded that, for example, RFID tagging would be implemented in a test environment, and the production line would be tested later.

Mr. Goldenberg referred to the board packet materials, which included presentations from Walgreens, PhRMA, and others. He stressed that the increasing volume of prescriptions per day per pharmacist is really a challenge, so "scale up" is a challenge in and of itself.

Deputy Attorney General Room asked whether the National Drug Code (NDC) would be embedded in the standards.

Mr. Celeste responded that the serial number must be unique among all of the products.

Mr. Room said he was reassured that there will be a placeholder for the NDC.

Mr. Swart noted that according to Mr. Celeste's presentation, for supply chain integrity, 62 weeks until industry adoption is not enough time for industry, then all the way to end user, to have the technology ready by January 1, 2009.

- Use of Average Manufacturers' Price (AMP) as the Reimbursement Base of Medications for Medicare and Medicaid Patients

Mr. Goldenberg stated that CMS is going forward with the use of AMP as the reimbursement base for medications for Medicare and Medicaid patients.

Ms. Herold stated that she knows that this is a very serious concern for pharmacy providers, and CPhA and other groups are working with the Legislature and the Department of Health on this issue.

John Cronin, representing the California Pharmacists Association, provided an update on AMP. He said that the final rule dealt with the issues of PBMs, rebates on third party plans, and Medicare Part D plans, but kept mail order pharmacies as a retail class of trade.

Dr. Cronin stated that the fiscal impact report for pharmacies revealed that these changes in the law would have an impact on only 1% of their revenue. That 1% of revenue translates to a 35% reduction in profit. He further stated that even though odd things in the initially proposed rule were cleaned up, the final rule will still have same impact. There is interest in Congress to address the remaining problems in the rule, which will go into effect October 1, 2007. A bill supported by NCPA should be introduced, which will change the reimbursement formula. It is a more appropriate way to fix the problems, but the bill may not go forward or ultimately be signed by the President.

Mr. Powers asked if access for low-income people and seniors is still expected to be affected.

Dr. Cronin responded, "yes," and added that another group of people, those infected with HIV, would be detrimentally affected. AMP will affect high cost drugs. He suggested that the board's "next step" may not be at the federal level, but instead, within the state, to make the seriousness of the situation regarding dispensing fees evident to the Department of Health Services.

Mr. Room stated that the regulations are final. The comment period is still open, but the rule is final, and it will go into effect October 1, 2007.

Mr. Graul stated that as a community pharmacy owner, his store doesn't dispense many Medi-Cal prescriptions, but he can see that the proposed cuts are devastating. Pharmacies doing a lot of Medi-Cal business will go out of business. Mr. Graul added that he doesn't see another entity moving in to help those patients, and he asked whether a follow-up letter to CMS would help.

Dr. Cronin responded that a follow-up letter would probably not help. As CMS stated repeatedly, pharmacists may be able to buy generic drugs at or below limits, but even if their costs of goods are covered 100%, that's only half the cost of dispensing the drugs.

Mr. Dazé asked about conversing with the Speaker of the House.

Dr. Cronin responded that he is not aware of any efforts to meet with the Speaker of the House; however, an answer to the problem lies in Congress. There must be a statutory change.

Mr. Powers recommended that the board send a copy of the board's letter to CMS to our congressional delegation.

MOTION: That the Board of Pharmacy send a copy of its letter to CMS to our congressional delegation.

M/S: DAZÉ/HOUGH

SUPPORT: 10 OPPOSE: 0

- Requirements of the Center for Medicare and Medicaid Services to Use Security Prescription Pads for Prescriptions

  Mr. Goldenberg stated that, pursuant to new federal law, security prescription pads must be used for all Medicare and Medicaid prescriptions as of October 1, 2007. In California, security prescription forms are currently required only for controlled drugs.

  Ms. Herold stated that the board is working with CMS and the Department of Health Services and CMS has been looking at California's security forms. CMS' requirements should not be more stringent than those of California. By mid-August the federal requirements will be released. Medi-Cal prescriptions can be given orally, electronically or on security forms.

  Ms. Herold stated that currently there are 10 states with security forms. She added that using the board's subscriber alert, the board will continue to get information out to people, in the event there is subsequent legislation. "Wait for guidance document" is all that the board has heard from CMS. They are not apparently ready to discuss future requirements.

- Status Update: Proposed Modified Disciplinary Guidelines for the Board of Pharmacy

  Ms. Herold stated that, as requested by Chairperson Goldenberg, she will send the proposed guidelines to board members after this meeting so a thorough discussion can take place at the October meeting.

- 2007 Self Assessment Process for Community and Inpatient Hospital Pharmacies

  Ms. Herold stated that the 2007 form is updated and current, and self-assessment should be done using the new versions of the forms. Staff is currently seeking a section 100 rulemaking filing to require the new forms.

- Meeting Summary

A copy of the meeting summary of the Enforcement Committee and Workgroup on E-Pedigree Meeting held June 20, 2007 was provided in the materials packet.

- Presentation by the Nevada Board of Pharmacy on the Nevada Electronic Pedigree Program

Mr. Goldenberg called on the Nevada State Board of Pharmacy, which attended the meeting to provide information about their new pedigree requirements.

Louis Ling, General Counsel, and Larry Pinson, Executive Secretary, represented the Nevada State Board of Pharmacy. Their PowerPoint presentation was entitled "Nevada's Electronic Pedigree Program, Brilliant or Just Nuts."

Dr. Pinson stated that counterfeit drugs are alive and well in California. Bad wholesalers are where the challenge is, and that is the basis of their presentation. Dr. Pinson said he opened his own pharmacy in 1979, and quickly learned about "secondary source wholesalers." He stressed that secondary source wholesalers can be unscrupulous. They are not legitimate, but try to carry themselves off as mom and pop business people.

Dr. Pinson shared facts regarding a case they tried against two Las Vegas wholesalers. An AIDS patient bought Serostim from a CVS Pharmacy in California. The patient took the medicine, but it didn't feel right, so he took the medicine back to the pharmacy. The pharmacist advised the patient to contact the FDA who later confirmed the drugs were counterfeit based on the lot number. The medicine was identified as a relabeled product, not Serostim. An extensive investigation eventually revealed that a group in Miami was the source of various secondary transactions. A sting was set up, and those individuals were caught. Mr. Pinson said he presided over the hearing, which was full of disruptions and unnecessary motions. He said we need to protect the public from the unscrupulous actions of secondary wholesalers and diverters.

Mr. Ling stated that we need drug pedigrees. California, Nevada, and the FDA wouldn't need pedigrees if there weren't bad and unethical wholesalers out there. It's a very small segment of wholesalers that are driving these efforts. Nevada has been working on electronic pedigree and trying to catch bad wholesalers. Nevada applauds California and the federal government for trying to get RFID and full track and trace implemented, and patients will be a lot safer when we get there.

Mr. Ling added that around two years ago, Nevada had a January 2007 deadline for full track and trace, but they were way off in meeting that deadline, so they came up with an interim approach. Their approach will work from the opposite end that California is currently working on. He said that California's system is wonderful and may eventually work, but since 1991, Nevada has been requiring wholesalers to provide hard copy (hand-written) pedigrees. Instead of providing the information by hand, wholesalers have been providing it electronically. Nevada asked wholesalers to provide the documents in electronic format in January 2007, and has since been receiving Excel files. The Excel files are clunky, but the 5-6 months of data collected so far has enabled them to spot trends and show that the secondary source market is still alive and well.

Mr. Ling also noted that Nevada is building a Web center with two portals. Nevada wants other states to start contributing to the database, and to have access to what's in the database as well. States can conduct ready-made searches, and develop their own searches. States can press a button and get the data they want, whether they're providing data or not. This will occur at no cost, they hope. There will be a wholesaler portal, which will be user-friendly. There will be manual entry for those who cannot transmit information to the database otherwise. Nevada will be notifying a wholesaler, as well as the applicable state, when data transmitted meets the standards. The system is under construction, and they look forward to showing California how the tools work.

One of the key reports that will be available in the system will be a pedigree report. The report will generate dates and other key information showing where a drug has been and when.

Mr. Ling stressed that bad secondary source wholesaling is a national problem, and trying cases where drugs cross many state lines makes enforcement and disciplinary actions difficult. Without interstate tracking, it is very difficult for investigations to be completed. Nevada's new system will help eliminate voluminous paper handling when conducting these investigations. Mr. Ling asked California to consider reporting to Nevada's centralized database. They have found it is not onerous to wholesalers, and that it has become part of their routine now. Reporting to the system has not been causing wholesalers any trouble.

Mr. Ling added that if we all share the database and intelligence, it would be hard for counterfeiters to continue their illegal activities. As a sister state to Nevada, he asked that the California board consider asking California wholesalers to dump information into the database.

Dr. Schell asked how Nevada validates the information that the wholesalers provide for the database.

Mr. Ling responded that they do nothing to validate the information provided electronically, which is the same as the paper system. If wholesalers are lying on paper, they'll lie on the database too. With the database, though, Nevada has the ability to track things better, like prices.

Mr. Dazé asked whether they crosscheck the information, or flag something out of the ordinary.

Mr. Ling stated that the system will track things, and each state can write business rules helpful to their state. For example, it can track the "3-bounce" rule. It can also check various connections and lot splitting.

Dr. Swart asked whether that meant maximum participation, like 75 sent and 75 actually received.

Mr. Ling responded, yes. He added that Nevada's pedigrees start with the first wholesaler after the manufacturer.

Supervising Inspector Ratcliff asked how many total wholesalers are in Nevada.

Mr. Ling responded that there around 500, but actually less than 100 in the state. The number of secondary wholesalers has gone down from 50 to just one or two. He said that bad wholesalers are leaving Nevada and California to go to states without regulations. For example, Dade County, Florida, currently has 1,200 secondary wholesalers.

Dr. Ratcliff asked whether Nevada requires non-resident wholesalers to report in to the system.

Mr. Ling responded, yes.

Mr. Goldenberg asked if there were any further comments or questions. There were none. He thanked Mr. Ling and Mr. Pinson for their presentation.

- Presentation on the Pharmacists Recovery Program by Program Contractor Maximus

Don Fensterman provided an overview of the Pharmacists Recovery Program (PRP). Mr. Fensterman is the Program Director for the PRP. He works for Maximus, the board's contract provider for this program. There are 75 pharmacists in the program. He said that chemical dependency affects pharmacists like anyone else.

Mr. Fensterman said that he sees a progression of how dependency can begin. For example, a pharmacist may take one Vicodin from a bottle when he is 25 years old, and become a heavy drinker later in his career. Mr. Fensterman stressed that honorable people can become chemically dependent.

Mr. Fensterman stated that the intent of the PRP is to identify and rehabilitate pharmacists whose competency may be impaired, so that the public is not endangered. Maximus became the statewide vendor in July 1, 2003, and the program's goals include access to appropriate intervention and early detection.

Each program participant is assigned a clinical case manager (CCM), who oversees the participant's compliance and ongoing development of their recovery contract. Thus far, there have been 230 pharmacists who have successfully completed the program. The program includes intense monitoring of participants and reassessments of participants. The CCMs look at a participant's scope and pattern of use, including the age of first use. They ask the pharmacist whether he or she diverted medications from a pharmacy, because this type of information will affect the recovery plan.

Mr. Fensterman added that living arrangements (home environment) and employment history (multiple sites of access) have an affect on recovery as well. Entry into the program begins with a telephonic intake of a participant. Thereafter, the CCM arranges for a face-to-face meeting to conduct an in-person assessment. This often results in additional critical information affecting

the recovery contract. Treatment options are discussed with the participant, and a "recovery contract" is created within 10 days of coming into the program. The recovery contract outlines the expectations of the participant.

Each case is individual, and safeguards are built into each recovery contract. For example, access to controlled substances may be prohibited for one participant, but not another. Supervision may be required for one participant, but not another. Random body fluid monitoring is required for all participants.

Mr. Fensterman stated that peer support groups are helpful due to the extensive knowledge of pharmacists, and peers hold other pharmacists more accountable in a peer group. These groups are a compliment to regular 12-step meetings in the community. Maximus tailors the entry agreement for each participant. For example, if a pharmacist has been sober for six months, there is no need for that participant to have in-patient care.

Maximus also tracks trends in compliance. Mr. Fensterman said that he works with Anne Sodergren and Joan Coyne at the board, both of whom he commended. He said that the board emphasizes public protection, as well as giving pharmacists a chance to recover, but that public protection is paramount. Every participant is evaluated quarterly by the Pharmacist Review Committee (PRC), which determines acceptance into the program, return to work, and the rehabilitation plan. The PRC also determines "termination" from the program, which can be either successful or unsuccessful termination.

The recovery contract contains extensive requirements and requires abstinence from drugs and alcohol.

Dr. Swart asked what percentage of participants are successful in the program.

Mr. Fensterman responded that the average is about 40-45% that successfully complete the program. It takes three to five years, with a four-year average, but California Pharmacy Board participants are in the program about 5 years. Other state boards may allow less time in the program, but the board is philosophically more stringent, placing public protection first. The board progresses people only when they should progress.

Mr. Room added that there are three ways to get into the PRP, two from the board, but pharmacists can also self-refer on a confidential basis. Participants that self-refer are not evaluated by the PRC, unless the pharmacist becomes non-compliant.

Mr. Goldenberg stated that he wanted to address the students in attendance. He said that one of the greatest challenges for board members is to make decisions about pharmacists. He asked the students to work with their colleagues and friends and when they see someone headed for a bad outcome, don't just stand there and look blindly, help them understand that this is a slippery slope. He stressed to the students that they have a long career ahead of them, and they will help not only their colleagues and friends, but themselves as well.

Mr. Hough asked what percentage of "successful" participants fall back into problems.

Mr. Fensterman stated that the only way they find out is if the participants readmit into program, and he believes that number is quite low. He added that it would be beneficial to extend surveys to participants beyond 6 months after discharge; surveys one year or two years after discharge would be helpful.

Dr. Schell asked about the completion rate for Maximus, compared to other programs.

Mr. Fensterman responded that for diversion programs, he can't quote a number, but he knows it's good. He added that for folks terminated as noncompliant or "public risk," in a way, they're not a failure because the program offered multiple opportunities for rehabilitation.

Mr. Fensterman stated that the program is only for pharmacists and interns. Most of the cost is borne by the pharmacist. The board also contributes as well.

Mr. Goldenberg thanked Mr. Fensterman for his presentation.

- Report on Enforcement Actions

  Mr. Goldenberg stated that the Report on Enforcement Actions was included in the meeting materials packet.

- Fourth Quarterly Status Report on Committee Goals for 2006/07

  Mr. Goldenberg stated that the Fourth Quarterly Status Report on Committee Goals for 2006/07 was included in the meeting materials packet.

Public Comment

Mr. Goldenberg asked if there were any public comments regarding the Enforcement Committee.

David Breslow, Pharm D. with United Pharmacist Network (UPNI), thanked Mr. Goldenberg for recommending that they attend the meeting. He stated that UPNI wants to reach out as a conduit and liaison to community independent pharmacies, and their services include clinical representation and third party contract advisors. As new issues emerge, UPNI can act as a conduit to get information out to pharmacies. He said that UPNI's compliance program was based on the board's 2007 self-assessment form. Among other goals, they are trying to prepare community pharmacies for the inspection process.

Mr. Goldenberg thanked UPNI for attending, and added that we all share a common goal. He asked whether there were any additional question or comments from the public. There were none.

B. Organizational Development Committee

- Statistical Review of the Board of Pharmacy Workload: 2001-2007

  Dr. Conroy stated that a Statistical Review of the board's workload from 2001-2007 was included in the meeting materials in Attachment 1.

  The packet contains graphic displays of licensing workload, staffing, and complaints received and closed over the last six years. [The board continues to have more licensees, and renew more licenses each year. The board gets more requests for individual licenses than site licenses each year.]

  Ms. Herold stated that the number of complaints have remained relatively constant. The board has generally received the same number of complaints, and also closes approximately the same number of complaints each year.

- Recognition of Pharmacists who Have Been Licensed 50 Years

  Dr. Conroy noted that 674 pharmacists with 50 or more years of licensure had been recognized by the board. There were 58 pharmacists reaching this milestone between May and August 2007, and each was sent a certificate and invited to a future board meeting for public recognition.

  Dr. Conroy introduced Eugene Elkin, and presented him with a BOP pin recognizing 50 years of licensure as a pharmacist. Mr. Elkin spoke a few words about his career.

  Mr. Goldenberg introduced Emil S. Marcarian, and presented him with a 50-year BOP pin. Mr. Marcarian thanked the board.

  Dr. Hiura introduced James Hoppe, and presented him with a 50-year BOP pin. Mr. Hoppe stated that it's been a wonderful 55 years as a pharmacist.

  Dr. Ravnan introduced Milton Bardovi, and presented him with a 50-year BOP pin. Mr. Bardovi said 50 years went by very fast. He said he chose to work in chain stores and it was much less pressure working for a chain than for an independent. Mr. Bardovi advised the students in attendance to have integrity and do a good job.

  Dr. Swart introduced Joseph Hirt, and presented him with a 50-year BOP pin. Mr. Hirt said he started his career in a rural part of Virginia, then moved to California to a hospital pharmacy. He worked in manufacturing and research, making products not commercially available at the time. Mr. Hirt said he was most proud of how he was able to influence people who had drifted to the shadows of drug abuse, and was able to turn them around with praise, and by doing the right thing.

Mr. Dazé introduced Ronald Marantz, and presented him with a 50-year BOP pin. Mr. Marantz stated that after he graduated from college and began his career, a woman came in to the store and said, "A punk like you? A doctor?" He said he always remembered that, and he learned to have a lot of patience with the public. Mr. Marantz thanked the board for inviting him to the meeting to be honored for his service.

- Board Member Committee Roster

  Dr. Conroy stated that the 2007/08 Board Member Committee Roster was provided in the meeting materials for information only. The roster reflects President Powers' appointments to board committees for the next year.

- Personnel Update and Training Report

  Ms. Herold stated that there are four inspector vacancies and one supervising inspector vacancy. There is over a 20 percent vacancy rate that soon should be fixed.

  A letter was sent to each inspector exam applicant indicating that the $2,000 monthly retention and recruitment differential looked likely. However, there was around a 50 percent no-show rate of the 70 plus applicants, though some applicants rescheduled their interviews. Two board supervising inspectors sat on the interview panel.

  The supervising inspector exam interviews should occur in August.

  Employment interviews for inspector and supervising inspectors are planned for September.

  Ms. Herold further stated that there are two office vacancies where job offers have been conveyed. The three new positions in the board's 2007-08 budget will be filled as one receptionist, one licensing unit technician, and one office technician for enforcement.

  The board submitted a reclassification request to the Department late in June to reclassify the Assistant Executive Officer's position to a more appropriate level commensurate with the duties. The Department indicated that the review process would take approximately three months. The proposal must be approved by the DCA, Department of Personnel Administration, and voted on by the State Personnel Board.

  Ms. Herold reminded all board members to take the required Sexual Harassment Prevention Training. Some classes are offered on-line. She will send a list of course providers to all board members.

  Ms. Herold noted that DCA Director Carrie Lopez is holding an executive retreat from July 31 through August 2, 2007. The retreat is for Executive Officers and will focus on team building exercises and strategic planning for the future five years, based on demographic

projections. Unfortunately, Ms. Herold cannot attend because the Competency Committee is holding its annual planning meeting in San Diego during that time. She completed a worksheet about board operations and strategic planning processes that will be used during the retreat.

- Budget Update and Report

Ms. Herold stated that the board wouldn't have final budget figures until August. She advised that the meeting materials contained the projected dollar figures as follows:

(1) Prior Year's Budget 2006/07

- Revenue Projected: $9,747,988
- Expenditures Projected: $8,522,000

(2) Current Year's Budget 2007/08

- Revenue Projected: $6,044,000 (assumes fee increase 1/1/08)
- Expenditures Projected: $9,389,000 (includes budget change proposals)

(3) Board Fund Condition

A fund condition report prepared by DCA stated that if the board increases fees to the statutory maximum on January 1, 2008 and begins the inspector recruitment and retention differential, the board will have the following fund conditions at the end of the identified fiscal years shown in Attachment 3:

- 2006/07 $ 8,077,000 10.3 months in reserve
- 2007/08 $ 4,732,000 5.9 months in reserve
- 2008/09 $ 2,552,000 3.1 months in reserve
- 2009/10 $ 134,000 0.2 months in reserve
- 2010/11 $(2,483,000) -3.0 months in reserve

The estimates are built upon a conservative estimate of revenue, and revenue does not include cost recovery or cite and fine revenue that we collect during the year. The board will need to seek a statutory increase in fees to take effect about January 2010, or as late as July 2010.

(4) Cashiering Update

Ms. Herold advised that DCA has hired a consultant team to review how the department's cashiering unit operates. The evaluation will look at all processes, all training, the classification of staff used, and improvements needed.

The problems with cashiering affect other boards and bureaus as well, not just the Board of Pharmacy.

The cashiering unit has been understaffed and under-performing for several years, to the point where there is now a renewal crisis. It is taking three weeks or more for checks to be cashed, and if there is any correction to be made as part of the renewal, it can be six or eight weeks or even longer before the information is provided to the board for resolution. In the interim, the status of the renewal is in suspense, even though the check may have been cashed. The licensee then must mail overnight a second check to the board so the board itself can renew the license. Then when the duplicate fee appears, the board refunds the extra fee. This is extremely labor-intensive on the board's part (telephone calls, e-mails, mail handling, cashiering, refunding).

Other significant cashiering irregularities have surfaced too, such as uncashed checks delivered to the board three months after first being received in the cashiering unit.

Ms. Herold stated that DCA's cashiering unit has recently been augmented by five temporary staff, borrowed from another agency. The unit is working to eliminate some of the backlog, cashiering renewals more timely, and sending the batch work to agencies on a more regular basis.

(5) I-Licensing Update

The department's I-Licensing project will offer online application and renewal of licenses (a much needed relief from mail-in renewals). A feasibility study report has been approved by the Department of Finance, and the board is in the first tier of new agencies that may be able to offer this service in the future.

The board spent $50,000 during the last fiscal year on programming specifications needed for its programs. In the next two years, the board will spend $143,000 (2007-08) and $199,000 (2008/09) as its share of costs to implement this system department-wide.

Delays in securing vendors and new staff overseeing the project at DCA have probably delayed the project six to nine months, so it is approximately two years before implementation of I-Licensing at the board.

- CURES Feasibility Study Report as Required by Health and Safety Code 11165.5

Dr. Conroy noted that California Health and Safety Code Section 11165.5 requires the board to contract for a feasibility study report to evaluate the feasibility of real time reporting and access to data on prescriptions submitted to CURES. The law requires the board to work with the Department of Justice and the Medical Board to contract with a vendor to develop the feasibility study report, using money voluntarily contributed to the board specifically for this purpose.

Since November 2006, there has been a small group working to develop the proposed scope of work needed for the feasibility study report.

Ms. Herold advised that she has been working with DCA's Divisions of Administration and Information Technology and the Department of Justice to assure the board's interests are represented. The Department of Justice was going to sponsor a legislative amendment to modify the definition of "real time" in Section 11165.5, but that amendment has been dropped by that agency.

- Meeting Summary of Organization Development Committee Meeting of July 17, 2007

  Dr. Conroy advised that the board packet contained the Meeting Summary of the Organizational Development Committee Meeting held on July 17, 2007. The following items, among others, were discussed by Organizational Committee on July 17, 2007:

  (1) Board Recognition of Notable California-Licensed Pharmacists
  (2) Strategic Plan 2007-08
  (3) Monthly Report to the Director
  (4) NABP Annual Meeting
  (5) NAPB Salary Survey
  (6) Department of Personnel Administration Salary Survey

- Fourth Quarterly Report on the Committee's Goals for 2006/07

  Dr. Conroy noted that the Fourth Quarterly Report on the Organizational Committee's Goals for 2006/07 was provided in the meeting materials.

- Approval of Full Board Minutes (January 31, 2007 and February 1, 2007)

  Dr. Conroy asked if there were any corrections to the board minutes of January 31, 2007 and February 1, 2007.

  MOTION: Approve the board minutes of January 31, 2007 and February 1, 2007.

  M/S: ZINDER/HOUGH

  SUPPORT: 10 OPPOSE: 0

- Approval of Full Board Minutes (April 18 and 19, 2007)

  Dr. Conroy asked if there were any corrections to the board minutes of April 18 and 19, 2007.

Dr. Ravnan stated that the minutes did not reflect the correct name of the California Practice Standards and Jurisprudence Examination for Pharmacists. She said it had to do with Pages 20-24, and was in the Omnibus Bill.

Mr. Room added that a motion was made by the Licensing Committee, then the motion was withdrawn, then another motion was made.

Ms. Herold said the minutes would be corrected to reflect the motion that the board took action on.

MOTION: Approve the board minutes of April 18 and 19, 2007, with two corrections. The first correction will reflect that a motion was made regarding the California Practice Standards and Jurisprudence Examination for Pharmacists in the Omnibus Bill, the motion was withdrawn, and then another motion was made and the board took action on the subsequent motion. The subsequent motion that the board took action on was to pursue amendment of sections 4200-4200.3 of the California Business and Professions Code regarding the statutory reference to what the board calls the California Pharmacist Jurisprudence Examination (CPJE) to more accurately reflect the statutorily established breath of the exam to the: California Practice Standards and Jurisprudence Examination for Pharmacists. The second correction will reflect that Robert Graul was in attendance.

M/S: GRAUL/DAZÉ

SUPPORT: 10 OPPOSE: 0

Public Comment

Dr. Conroy asked if there were any comments from the public regarding the Organizational Development Committee. There were none.

Dr. Conroy introduced Antonette Sorrick, Deputy Director of Board Relations, representing DCA's Executive Office.

C. Licensing Committee

- Proposed Regulation Requirements for Pharmacies that Compound Medication – Amendments to 16 CCR sections 1716.1, 1716.2 and 1751.3 and Adoption of Sections 1735-1735.8

Dr. Conroy stated that since January, the board has been refining regulation requirements for pharmacies that compound medication. Initially developed during the meetings of the Work Group on Compounding held throughout 2004, refinements to the regulations have been made at the March and May 2007 Licensing Committee Meetings.

At the Licensing Committee Meeting held on May 30, 2007 in Los Angeles, the committee worked through the regulations, section by section. Comments submitted in writing or made during this review session were considered. Following the meeting, Mr. Room, Mr. Ratcliff, Ms. Nurse, and Ms. Herold worked through the sections and the comments. Attachment 1 of the board packet contains the amended regulations for board consideration.

The regulation requirements provide a balance of consumer protection with the need for pharmacies to compound medication for patients, either pursuant to a prescription or based upon the need for future furnishing. Records, labeling, and quality assurance are needed for any product a pharmacy compounds, even if the pharmacy does it only rarely. The level of record keeping and quality assurance required as specified in these regulations does depend on the frequency and volume of medicine compounded. The pharmacy that rarely compounds medicine or does so to a limited extent may provide much of the record keeping on the prescription document itself. When larger volumes of medicine are compounded, the board expects more record keeping and higher quality assurance.

Some of the comments made at the May Licensing Committee Meeting included beyond use vs. expiration dates, a definition of unit dose containers, why require downloading of certificates, what is a master formula, must compounding occur in a pharmacy, use of the term compounded preparation vs. compounded drug product. There were also comments expressing concern that any requirements on pharmacies that compound would be overly burdensome and prevent pharmacies from compounding.

Dr. Conroy said in order to move the draft language to formal public notice, the board will need a motion and a second.

Mr. Room advised that the comments made during the May 30th meeting are reflected in the current draft.

Dan Wills of Grandpa's Compounding Pharmacy stated that CPhA asked him to officially represent them. He asked about Section 1731 and the word "quality." He wanted to know if it applied to harmful decomposed material, or something already partially oxidized.

Mr. Room responded that the language in the final draft included all the federal and state manufacturing codes.

Mr. Wills stated that in the absence of not knowing what it means, what if pharmacists do a Vitamin B6 compound, which can decompose, but it would not harm a patient. Also, on industry standards, "beyond use" is the phrase used to mean expiration date.

Mr. Spencer responded that "quality" means the absence of "harmful."

Mr. Room added that in Section 1735.2(h), "expiration date" is "beyond use," so we merged the terminologies.

Dr. Conroy asked if there was any further comment.

John Cronin stated that he was representing CPhA on this topic. He recommended that the board schedule a hearing on the matter.

Dr. Cronin also commented on the issue of compounding. He stated that compounding is defined "by or under the license of a pharmacy" and he asked the board to think about whom that would affect. Tablet splitting could also come under this language. He recommend that the definition be adjusted to accommodate other activities that are in the interest of public health and welfare, but don't fit specifically within this definition.

Dr. Cronin stressed that Section 1735.2(h) needs adjustment, and the other areas need some technical adjustment. He encouraged the board not to ignore other comments already given.

Ms. Herold stated that the board could choose to adopt the regulation without a hearing. If someone requests a hearing, the board is required to hold one.

MOTION: That the board approve the June 29, 2007 version of the Proposed Regulation Requirements for Pharmacies that Compound, and forward the language to notice for a 45-day public comment period.

M/S: DAZÉ/HIURA

SUPPORT: 10 OPPOSE: 0

- Legislative Proposal: Establishment of State Protocols for Pharmacists to Administer Immunizations

Dr. Conroy provided a brief overview of a statutory proposal to allow pharmacists to administer immunizations pursuant to a protocol established by the CDC. She asked if there was any comment.

Dr. Swart asked if "travel vaccination" could be added to the language.

Mr. Room responded that there is a list of protocols developed by the CDC.

Dr. Ravnan asked if the board wants to know what all the immunizations are because they are not listed in the legislative proposal.

Ms. Herold stated that the regulatory language would be brought to the next Legislation and Regulation Committee meeting.

Dr. Schell clarified that he was speaking in support of the motion. He advised that he had viewed the CDC Web site and saw the protocols, and believed that they would be helpful to the public.

Jeff Goad, PharmD, approached the board, and said that he can answer some technical questions on the issue. He stated that 11 vaccinations are under the adult and adolescent immunization table, which are the core vaccination series. Only the vaccinations for which they've protocols have been developed are listed.

Dr. Conroy stated that protocols are for a routine vaccination schedule.

Dr. Goad stated that the table is growing to accommodate items in the future, like yellow fever or HPV.

Mr. Goldenberg said that he recently went to a travel vaccination clinic, and the pharmacist giving the vaccinations couldn't get paid because she must be under the guidance of a physician. This modification would help people like her.

Dr. Goad responded that he runs a travel medicine clinic. The yellow fever vaccination has federal guidelines, and a physician must be in charge.

Dr. Conroy asked if there were any other public comments.

Dr. Radcliff asked Dr. Goad about small pox and anthrax.

Dr. Goad stated that those vaccines are not commercially available, but he's talking with the state public health department for emergencies. There are no ACIP [Advisory Committee on Immunization Practices] statements that are "active" because they are not commercially available vaccines.

MOTION: Adopt the Proposed State Protocols for Pharmacists to Administer Immunizations by seeking an amendment to Business and Professions Code section 4052.

(a) Notwithstanding any other provision of law, a pharmacist may:
(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.
(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.
(4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1.
(5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2.
(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.
(7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.
(8) Furnish emergency contraception drug therapy as authorized by Section 4052.3.
(9) Administer immunizations pursuant to a protocol with a prescriber or pursuant to the recommendations of the Advisory Committee on Immunization Practices (ACIP) of the federal Centers for Disease Control and Prevention.

(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.
(c) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.
(d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

M/S: SCHELL/GRAUL

SUPPORT: 10 OPPOSE: 0

- California Schools of Pharmacy Proposal to Identify and Agree on the Professional Competencies that Should be Achieved by the End of Basic Internship Experiences

Dr. Conroy stated that this information was provided in the meeting materials for information only.

From January through April 2007, the board participated in a joint project of California's pharmacy schools to develop and assess the competencies that pharmacy students should achieve by the end of the introductory pharmacy experience of 300 hours. This is part of changes to intern experience objectives made by the Accreditation Council for Pharmacy Education, which accredits US schools of pharmacy. Dr. Ravnan, Ms. Herold, and Ms. Sodergren attended three work sessions held for this purpose since the beginning of the year.

Attachment 3 of the board packet contained the proposed competencies developed by the workgroup. This phase of the project is now over.

The next phase of the project will be done by the pharmacy schools and will involve developing an exam to assess student achievement of the basic competencies. The first meeting to do this was held in mid-June, and additional work sessions will be needed to complete this portion of the project. The workgroup hopes to complete the process in time for incorporation during the 2007-08 academic year.

Dr. Ravnan stated that the board sat in on initial meetings to reach experience competencies. From there, the schools of pharmacy would break off and develop exams. She stated that UCSF would like the board to adopt these competencies.

Dr. Schell said that he read through the proposed competencies, but was not prepared to make comments. He asked whether the Licensing Committee would do the focus work and bring it back to the board, as it is the duty of the committee. Dr. Schell said that he does want the board to have an official opinion on it.

Ms. Herold asked whether there would be a modified timeline for implementation of the examination component for academic year 2007.

Dr. Ravnan responded that this date had been pushed back from the original date.

Dr. Conroy advised that the matter would be sent back to the Licensing Committee for recommendation and report.

- Update of Emergency Preparedness for California Pharmacy

  Dr. Conroy stated that this information was provided in the meeting materials for information only.

  1. Surge Response Planning

     In late February, the state began working with PriceWaterhouseCoopers to develop a response plan for the surge response following a serious emergency event or emergency events. The goal is to prepare state agencies for an effective and less chaotic surge response. The need for pharmacists during emergency surge was minimized, however, repeated clarification from board staff about what the meaning of waiving requirements means have helped to reshape disaster planning with respect to needing pharmacists.

     Dr. Conroy noted that Inspector Orlandella and other inspectors participated in the meetings to develop surge response planning.

     The Licensing Committee reviewed a preliminary report of the "Development of Standards and Guidelines for Healthcare During Emergencies, Supplies, Pharmaceuticals and Equipment" during the meeting. A copy of this draft is included in the board packet.

Ms. Herold added that the report is still in draft form, and is going through review in the Governor's Office. The framework for the plan is contained in the packet.

An update was also provided in the packet that on July 11, 2007, the Center for Medicare and Medicaid Services established an Emergency Prescription Assistance Program (EPAP) that will use "the existing supply chain infrastructure as the distribution mechanism for future emergency response." The announcement from CMS states:

> In the event of disaster of national significance, the Federal Emergency Management Administration (FEMA) will identify individuals or groups of individuals who may be eligible for the (EPAP) and that information will be communicated to pharmacies through Argus. Upon activation of the EPAP system, disaster victims may present at any network pharmacy to fill a prescription written for a covered medication to treat an acute condition, to replace maintenance drugs that the individual may have lost in the emergency or to obtain certain covered DME. Pharmacies will be required to check for existing coverage at the point of sale prior to billing the EPAP. If the disaster victim does not have private third party prescription drug coverage or other federal or state prescription drug coverage (e.g., Medicaid) they will be eligible for EPAP coverage.

2. NABP Recommendations for Disaster Response

   Dr. Conroy noted that the NABP came out with 11 recommendations, and our board has already accomplished or is working on many of these items.

   The Licensing Committee reviewed information published in the May 2007 NABP Newsletter on guidelines for boards to use in preparing for disaster response during the May 30th meeting. The committee also reviewed other NABP-prepared materials including the "Emergency and Disaster Preparedness and Response: Roles of Federal, State and Local Governments."

   Pharmacists need to become trained in disaster response so that the public health can be better served with respect to appropriate drug therapy during disasters.

   The July *The Script* contains another article on disaster preparedness and the need for pharmacists to preregister for training for disaster response so they can be "first responders."

   Dr. Conroy noted that staff have also served on a panel to select the vendor to do the preregistration of health care responders (ESAR-VHPs).

3. County of San Diego's Request for Dispensing Doxycycline or Ciprofloxacin

   Dr. Conroy stated that San Diego County requested board approval to provide an unspecified number of up to 500,000 bottles of a 7-14 day dosing regimen 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 sought an exemption from patient specific labeling because "it would be difficult, if not impossible" to label these containers.

At the meeting there was discussion that while the board could exempt such labeling after an emergency had been declared, the board has no authority to exempt labeling requirements in advance of a disaster unless the board promulgates a regulation or obtained statutory authority to authorize this.

At least one county has provided labeled medication to first responders.

- Update on the Request to Add the Exam for the Certification of Pharmacy Technicians as a Qualifying Method for Pharmacy Technician Registration

  Dr. Conroy advised that solicitation had begun for an independent contractor to review materials for the ExCPT and PTCB exams to assure both are job related.

  Ms. Herold added that she is still working on it along with Mr. Spencer, Ms. Cates, and a Department of General Services attorney.

  The board hopes to develop a process by which the two exam vendors would pay for the evaluation of the respective exams, and the assessment reports would be provided to the board.

- Mobile Community Clinics and Licensing by the Board of Pharmacy

  Dr. Conroy noted that part of the Department of Health Services (DHS) is now the Department of Public Health (DPH). The DPH licenses certain types of health care clinics. A DPH clinic may operate using the drug stock of its medical director, using the individual drug supplies of each of its practitioners or using a board issued clinic license. Apparently the DPH will issue a unique license number for mobile community clinics.

  The Licensing Committee held a discussion at the request of Paul Drogichen, PharmD, Director of Pharmaceutical Services, in which he requested that the Board of Pharmacy alter it licensing requirements to issue clinic permits to mobile clinics, and not just to the brick and mortar administrative offices from which the mobile clinics operate.

  Dr. Drogichen stated he was concerned with the differing licensing policies of the board and the DPH. Board staff explained that the board only issues a permit to a clinic at a brick and mortar location. Such a location can have multiple mobile clinics, but the main location, typically the main and administrative office, is what actually holds the board's license. There should be no problem with a mobile clinic having the benefits of a board license so long as a brick and mortar address is used as the licensed location.

  No additional action is planned.

- Competency Committee Report – Including the New Test Administration Company for the CPJE

  Dr. Conroy stated that on June 1, 2007 the board began using the new test administrator for the CPJE. The transition has not been wholly smooth, and there are issues the board is working to resolve with the new vendor and the Department of Consumer Affairs (which is the board's intermediary to the vendor). Staff hopes that the transition to the new vendor will be invisible to candidates.

  Ms. Herold added that 170 people have taken the exam since June 1, 2007. The board is currently doing a quality control assessment of the CPJE. The department has a detailed list of requirements for this vendor, which must be met. The exam is given in state and out of state. The cost to take the exam under the new vendor is $33. Ms. Herold stated that there have been administration issues with the new vendor that she has taken to the department's Chief deputy Director for resolution.

  Dr. Conroy thanked board staff because they cleared 400 new exam applicants to take the exam under the prior test administrator (whose contract ended May 31).

  Ms. Herold added that that reflected most of the 2007 graduating class with the exception of one school, whose candidates graduated in mid-May.

  Dr. Conroy asked if there were any public comments on the issue.

  Larry Drexler, a preceptor coordinator for Target who works in recruiting, said that 170 people are waiting for results until 400-plus exams are done.

  Dr. Drexler asked what the normal time frame would be for applicants to take the exam.

  Ms. Herold responded that the complete application is normally processed in 3-4 weeks.

  Dr. Drexler asked what the timeframes would be to receive exam results, after 400 people have taken the exam.

  Ms. Herold responded that scores are released every 14 days, and sometimes as often as every 7 days.

  Rachelle Mashburn, a recent graduate from USC, stated that her concern and the concern of her classmates is that they could not take the exam with the old vendor and are having to wait for their scores.

  Ms. Herold stated that USC was the school that did not graduate students in time to take the exam prior to June 1. She added that June through September is peak season for taking the exam, and there are a lot of applicants from out of state who took the exam after June 1. The

results could be released within a couple weeks or a month. The board must wait until the QA evaluation is complete.

- Meeting Summary of the May 30, 2007 Meeting

  Dr. Conroy stated that the Meeting Summary of May 30, 2007 Licensing Committee Meeting was provided in the board packet.

- Licensing Statistics

  Dr. Conroy stated that licensing statistics describing the Licensing Unit's processing activities throughout Fiscal Year (06/07) were contained in the board packet.

- Fourth Quarterly Report on Committee Goals for 2006/07

  Dr. Conroy noted that the Fourth Quarterly Report on the Licensing Committee Goals for 2006/07 was contained in the board packet.

Public Comment

Dr. Conroy asked if there were any additional comments regarding the Licensing Committee. There were none.

D. COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Dr. Schell stated that the report of the Communication and Public Education Committee Meeting held June 27, 2007 was provided in the board packet, and the minutes from that meeting were provided in Attachment A.

- Discussion and Action on the Board's Public Forum on Medicare Prescription Drug Plans

  Dr. Schell advised that no action was taken on this item, but there was discussion by the committee. At the April 2007 Board Meeting, the board decided to move forward with a public forum and invite the California congressional delegation to participate.

  Dr. Schell responded that the meetings have not been scheduled, but will be scheduled.

  Mr. Powers added that a letter has been mailed to Congressman Stark, Chairman of the Ways and Means Committee. Congressman Stark has been looking to makes changes in the program.

  As a consumer protection agency, the board's role is to aid patients in getting their prescribed medicine timely. The board hopes to schedule this meeting with the California delegation later this summer.

Steve Gray commented that he is frustrated with this issue and has spent time in DC talking to legislators. For patients and for plans, you can make a choice January 31st about a prescription drug plan and be eligible on February 1st. If the patient has already given up other coverage and the new coverage is not there, that's a tragedy. Dr. Gray stressed that the board discuss the issue with the California delegation.

Although generally the belief is that the program is working better than when initially implemented in January 2006, there remain problems that prevent patients from getting necessary care timely, with an impact on higher health care costs, delayed therapy and impaired health.

Over the six meetings the board has convened in this area since January 2006, the board has facilitated discussions that have aided some patients. However, those who have heard the discussions believe there are still problems that can and should be corrected. Some of the issues brought to the board's attention are:

1. Prior authorization requirements that delay patient drug therapy – if the pharmacy doesn't provide the medicine before knowing whether it will be reimbursed, patients may wait 3-5 days or longer before a medicine is authorized (which may not be the medicine initially prescribed).
2. Unacceptable sales tactics used by insurance agents selling Medicare plans, for example, resulting in dual eligibles being targeted and selling private fee-for-service plans that their physicians will not accept.
3. Patients who are enrolled in a plan but coverage in the plan has not yet been activated are unable to obtain their medicine.
4. The Part D benefit is too complex to enable true comparison shopping by consumers of the 55 competing plans in California. The number of plans and lack of standardization of benefits make it difficult to select plans that work for a patient, much less select the best plan for an individual patient.

A meeting with the California delegation is hoped for later this summer or in the fall.

- Projects Under Development by the Committee

(1) Consumer Fact Sheet Series with UCSF's Center for Consumer Self Care

Dr. Schell advised that the meeting packet contained information on this project for information only. The board has been working with UCSF's Center for Consumer Self Care to have interns develop fact sheets for consumer, though only nine fact sheets have actually been completed since the project was initiated. The project has not progressed as quickly or as expansively as the board had hoped.

Dr. Schell and Ms. Herold plan to meet with Dr. Soller and his students in August to see if the project can be revived. In the meanwhile, we are contacting other schools of pharmacy in California to see if they are interested in establishing such a program on their campuses. The board is willing to coordinate this project on its own if the Center for Consumer Self Care is unable to continue to commit to the project.

Dr. Schell advised that a list of fact sheet topics were provided in the board packet, under Attachment 1. From that list, the Committee identified six priority subjects for future fact sheets:

- Counterfeit medicine
- Immunizations
- Direct to consumer drug marketing
- Buying drugs off the Internet (revision to existing brochure)
- Cold medication for your children under the age of two
- Pediatrics and over-the-counter products

Dr. Schell said that looking at the full list of topics, we can't do them all at once. From the six priority subjects, he said the committee welcomed input. He said that the committee can prioritize them, but input is welcomed.

Mr. Graul stated that the last two on the list relate to direct patient care, as opposed to the first four topics.

Dr. Schell responded that the general theme is to enhance consumer awareness. We are trying to make the public aware of issues, like immunizations. Direct-to-consumer drug marketing is not as critical. Buying drugs off the internet is pretty relevant, though. The board wants to give solid info to consumers. He believes the last two items are valuable to consumers as well.

Mr. Graul stated that the topic of immunization topic is very important. He said that patients ask whether it's too late to get an immunization. They have questions about timeframes and availability of immunizations.

Dr. Schell stated that we should get a fact sheet out in the fall about vaccinations reflecting specific timepoints. It should address vaccinations for seniors, kids going back to school, and also college students.

Mr. Dazé said that he reviewed the list of fact sheet topics from top to bottom and back, and no topic was more important than another. He said the biggest problem is that we don't have enough schools to assist us to plough through these topics.

Dr. Schell responded that only a couple of individuals have contacted the board, so we will have to proceed with something in-house. Thus, the committee prioritized the full

list of topics to the six provided. With our current resources, we can't proceed on all the topics at once. Dr. Schell agreed with Mr. Dazé that no one topic is more important than any other.

Dr. Swart suggested that the committee reach out to some of the companies who have already developed materials on these subjects. For example, information regarding children's medication has already been developed.

Dr. Schell responded that the genesis of this project was to involve students in the development process, and to utilize the talent in the schools, but based on the comments made today, we will make some priorities.

Dr. Ravnan added that she contacted two schools, and received no positive response. She said that they are overwhelmed and participation in this project cannot be a priority.

Dr. Schell added that he received a lukewarm response, maybe because school is out. He said he will continue to press for involvement from other schools.

Dr. Gray commented that it is not clear to him whether the board is only looking at schools of pharmacy in drafting these articles and fact sheets. He asked whether the board would consider the Pharmacy Foundation of California and other not-for-profit groups, who can pursue grants and hire faculty. Dr. Gray added that he serves on two boards, and will broach the topic with those boards. They may have particularly interest in the direct-to-consumer topic.

Sam Shimomura, from Western University, said that he would be happy to make some contacts to see if their students are interested.

(2) Pill Splitting by Patients

Dr. Schell stated that the committee developed a consumer fact sheet on the subject of pill splitting and sent it out to key members for comments.

Board staff also developed an article for *The Script*, which provided relevant information for pharmacists. The board has also developed a section on the web site containing pro, con, and other information on the subject of pill splitting.

The board has emphasized that patients should not be required to pill split. It was a key issue that people should have a choice. The board did not take a stance as to whether pill splitting is "safe" or not safe or to evaluate that piece of the puzzle.

Additional information regarding the subject of pill splitting was provided in the Report of the Communication and Public Education Committee Meeting of June 27, 2007.

(3) Update Report on *The Script*

Dr. Schell said that the July 2007 issue of *The Script* was sent to the printer early in July for publication and mailing to pharmacies and wholesalers. A copy is available on the board's Web site as well. The California Pharmacy Foundation will again mail the newsletter to pharmacists in California, for which the board is grateful.

John Cronin asked about Pages 14 and 15 in the July 2007 issue of *The Script* relating to the repackaging of drugs from long term care facilities.

Mr. Goldenberg responded that it is in the Department of Social Services regulations. He said he would pursue specific cites on their interpretive guidelines of assisted living facilities in Title 22.

(4) New Board Web Site Under Development

Dr. Schell noted that in early 2007, the Governor's Office released new requirements for state government Web pages. The board is redesigning its Web site again to conform to the new look for state agencies. The deadline for conversion to the new format is November 2007; the board's Web site will be ready.

Additionally, board staff will develop a section of its Web site into a resource on preventing medication errors. The board has been actively involved in a number of activities aimed at reducing errors, including the quality assurance program requirements mandating pharmacies to evaluate every prescription error. The Web site will include prescription error data identified by the board through investigations of consumer complaints. It will also include information from other sources, such as way to prevent errors and frequently confused drug names. It will have links to Web sites and other materials as well.

(5) Development of New Consumer Brochures

Dr. Schell stated that draft brochures were provided in the board packet under Attachment 3:

- Board of Pharmacy Informational Brochures – Ms. Abbe revised two brochures about the board. One is an overview of the board, and the other is information about filing a complaint with the board.
- Prescription Drug Discount Program for Medicare Recipients – The board has revised the "Prescription Drug Discount Program for Medicare Recipients" brochure that was developed in response to SB 393 (Speier, Chapter 946, Statutes of 1999). This state program allows Medicare recipients to obtain medications at the Medical price if the patients pay out of pocket for the medication.

Dr. Cronin stated that on the text for the Medicare Drug Discount program brochure, there is an error. The statute says specifically that it does not apply to a drug that is covered by insurance. There is a question in the text for the brochure, "If I already have coverage, will the program affect me?" and another question and bullet point that refer to patients who have a deductible and are in the donut hole. In those cases, the patient just happens to have a 100% co-payment.

Mr. Powers said it doesn't make sense to have a 100% co-payment.

Dr. Cronin responded that it's an issue of coverage. There are Part D drugs, but at a certain tier, the patient's co-payment is 100%.

Dr. Swart clarified that it still is covered because it's a contract price, instead of a cash price.

Dr. Cronin said he's talking about AMP, and this is one more factor that affects whether pharmacies can participate. He said he just thinks there is a lot of misunderstanding about SB 393. He was involved in the legislation.

Mr. Powers responded that the board would get some clarification on that.

Dr. Schell stated that Ms. Abbe will also be drafting information fact sheets for applicants. This is vital information for applicants as to what they need to do to get ready for exam. While information about applying for the CPJE or a California intern pharmacist license is on the board's Web site, some applicant do not read it or retain it.

Dr. Schell asked whether there were any further comments from the public on development of new consumer brochures. There were none.

- Update on Public Outreach Activities

  Dr. Schell advised that Attachment 4 of the board packet contained an update on the board's public outreach activities. The board has attended several events this quarter.

- Meeting Summary of the Meeting of June 27, 2007

  Attachment A of the packet contained the Meeting Summary of the Communication and Public Education Committee Meeting of June 27, 2007.

- Fourth Quarterly Report on Committee Goals for 2006/07

  Dr. Schell advised that the Communication and Public Education Committee's Fourth Quarterly Report on Committee Goals for 2006/07 was provided in the board packet.

Public Comment

Dr. Schell asked if there were any additional comments from the public regarding Communication and Public Education.

Dr. Gray suggested that the board consider public outreach to educate pharmacists on addiction to gambling. He said that several other licensing organizations have such a program. California has many gambling opportunities including casinos, on-line, and Indian gaming, which could lead to bad behavior including drug abuse. Dr. Gray further stated that our profession is unaware of programs to help them with their gambling addiction. We may not have considered this a problem years ago, but now the gambling addictions have increased among our pharmacists and employees.

E. Legislation and Regulation Committee

Dr. Schell stated that he would not go into details on each informational item, though some items will be pulled for discussion.

Part 1: Regulation Report and Action

1. Board Action on Regulations – Board Action Required

a. Proposed Amendment of 16 CCR 1707.2 – Notice to Consumers

Dr. Schell gave a brief background on this section relating to a patient's right to obtain a prescription, and advised that the previous rulemaking was withdrawn.

CCR 1707.2 currently requires every pharmacy to prominently post a "Notice to Consumers" poster as authorized by Business and Professions Code Section 4122. Assembly Bill 2583 (Chapter 487, Statutes of 2006) amended Sections 733 and 4122 of the Business and Professions Code to require the board to amend the "Notice to Consumers" to include a statement that describes a patient's right to obtain medication from a pharmacy even if a pharmacist has ethical, moral or religious grounds against dispensing a particular drug, in which case protocols for getting the medication are required.

This is the second rulemaking the board is pursuing to ensure compliance with AB 2583. The previous rulemaking was withdrawn from the Office of Administrative Law after the April 2007 Board Meeting. The revised Notice, exact language and Initial Statement of Reasons was provided in attachment E-1.

MOTION: Adopt the Proposed Amendment of 16 CCR 1707.2 – Notice to Consumers.

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:
(1) upon request; or
(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:
(A) whenever the prescription drug has not previously been dispensed to a patient; or
(B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.

(2) When the patient or agent is not present (including but not limited to a prescription drug that was shipped by mail) a pharmacy shall ensure that the patient receives written notice:
(A) of his or her right to request consultation; and
(B) a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

(3) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.

(c) When oral consultation is provided, it shall include at least the following:
(1) directions for use and storage and the importance of compliance with directions; and
(2) precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

(d) Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:
(1) the name and description of the medication;
(2) the route of administration, dosage form, dosage, and duration of drug therapy
(3) any special directions for use and storage;
(4) precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;
(5) prescription refill information;
(6) therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;
(7) action to be taken in the event of a missed dose.

(e) Notwithstanding the requirements set forth in subsection (a) and (b), a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation.

(f) In every pharmacy subject to the provisions of Business and Professions Code Section 4122, there shall be prominently posted in a place conspicuous to and readable by prescription drug consumers the following notice:

"NOTICE TO CONSUMERS"

At your request, this pharmacy will provide its current retail price of any prescription without obligation. You may request price information in person or by telephone.

Ask your pharmacist if a lower-cost generic drug is available to fill your prescription.

Prescription prices for the same drug vary from pharmacy to pharmacy. One reason for differences in price is differences in services provided.

Before taking any prescription medicine, talk to your pharmacist; be sure you know:

What is the name of the medicine and what does it do?
How and when do I take it – and for how long? What if I miss a dose?
What are the possible side effects and what should I do if they occur?
Will the new medicine work safely with other medicines and herbal supplements I am taking?
What foods, drinks or activities should I avoid while taking this medicine?

Ask your pharmacist if you have additional questions.

(g) In addition to the "NOTICE TO CONSUMERS" referred to in subdivision (f), every pharmacy subject to the provisions of Business and Professions Code §4122 shall prominently post in a place conspicuous to and readable by prescription drug consumers the following notice:

Know your rights under California law concerning medicine and devices prescribed to you.

You have the right to receive medicine and devices legally prescribed to you, unless:
1. The medicine or device is not in stock in the pharmacy,
2. The pharmacist, based upon his or her professional judgment determines providing the item:

- is against the law,
- could cause a harmful drug interaction, or
- could have a harmful effect on your health

This pharmacist may decline to fill your prescription for ethical, moral or religious reasons, but the pharmacy is required to help you get the prescription filled at this or another nearby pharmacy timely.

The pharmacy may decline to provide the medicine or device if it is not covered by your insurance or if you are unable to pay for the item or any copayment you owe.

If the pharmacy is unable to fill your prescription, you are entitled to have the prescription returned to you or transferred to another nearby pharmacy. Ask about our procedure to help you get an item that we don't have in stock.

Any questions? Ask the pharmacist!

Authority cited: Sections 4005 and 4122 Business and Professions Code. Reference: Sections 733, 4005 and 4122 Business and Professions Code.

M/S: CONROY/GRAUL

SUPPORT: 10 OPPOSE: 0

b. Proposed Amendment of 16 CCR 1749 – Fee Schedule

16 CCR 1749 details the application and renewal fees of licensees as set forth in Business and Professions Code. At the April 2007 Board Meeting, the board voted to approve a recommendation from the board's Organization Development Committee to increase all board fees to their statutory maximum amounts.

This proposal will raise board fees to their statutory maximum as provided for in referenced Business and Professions Code sections. This proposal is necessary to ensure sufficient resources to maintain current board operations.

Anne Sodergren stated that some modifications were made to the regulatory language, so there must be a new 15-day notice to the proposed regulation.

Dr. Schell asked the board to move to adopt the regulations after the 15-day notice has passed. He asked the board to look at Subdivision (i).

Ms. Sodergren provided information regarding a couple of changes to the language, including $62.50 as the actual dollar amount in "numbers" and the general statement removing Section 122.

MOTION: Adopt proposed regulation 16 CCR 1749 after the 15-day notice has passed. Return to the board if negative comments are received.

M/S: GRAUL/ZINDER

SUPPORT: 10 OPPOSE: 0

2. Regulations Approved by the Office of Administrative Law – For Information Only

Amendments to 16 CCR 1706.2 – Abandonment of Application Files

Dr. Schell advised that this regulation adds several board licensure programs into existing provisions regarding when an applicant has abandoned an application. The effective date of this

amended regulation was June 22, 2007. He asked if there were any comments from the board or the public. There were none.

3. Regulations Submitted to the Administration for Approval

a. Section 100 Technical Changes

Dr. Schell asked Ms. Sodergren to give the students in attendance an explanation of Section 100 changes.

Ms. Sodergren stated that Section 100 changes are without regulatory effect because they merely conform to statutory changes already in effect or they remove outdated regulations.

Dr. Schell stated that a copy of the exact language for each of the following proposed amendments was provided in Attachment E-3 of the board packet.

(1) Proposed Amendment to 16 CCR § 1709.1 – Replace the Term "Exemptee-in-Charge" with "Designated Representative-in-Charge"

(2) Proposed Amendment to 16 CCR § 1780.1 and 1781 – Replace the term "Exemptee" with "Designated Representative"

(3) Proposed Repeal of 16 CCR § 1786 – Return of Exemption Certificate

(4) Proposed Amendment to 16 CCR § 1715 – Self Assessment of a Pharmacy by the Pharmacist-in-Charge to Update for Changes in Pharmacy Law

(5) Proposed Amendment to 16 CCR §1793.8 to Update Regulation Reference to Recodified Business and Professions Code § 4052

(6) Proposed Amendment to 16 CCR § 1707 Waiver Requirements for Off-Site Storage of Records

(7) Proposed Amendment to 16 CCR § 1787 Authorization to Distribute Dialysis Drugs and Devices

(8) Proposed Amendment to 16 CCR § 1790 Assembling and Packaging

(9) Proposed Amendment to 16 CCR § 1719 Pharmacy Practice

Dr. Schell asked if there were any comments regarding the Section 100 changes. There were none.

b. Addition to the California Building Code – 24 CCR 490A.3 and 505.12.2 Related to Compounding Parenteral Solutions: Technical Changes to the Building Code Relating to Pharmacies

April 2006 Board Meeting, board voted to amend language in the California Building Code, Title 24, California Code of Regulations, Section 490A.3 and 505.12 with respect to the building standards for pharmacies that compound parenteral solutions. Thereafter, the Building Standards Commission advised the board of a new process to submit items into the California Building Code. These changes were submitted to the Buildings Standards Commission in compliance with their rulemaking procedures. The board anticipated adoption of these regulations by the end of July 2007.

4. Board-Approved – Awaiting Public Notice – For Information Only

a. Proposal to Require the Self Assessment of a Veterinary Food Animal Drug Retailer Premises, Addition of 16 CCR § 1785

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

Staff is currently developing this form. It is anticipated that the draft form will be reviewed at the September 2007 Enforcement Committee meeting and could be forwarded to the board for consideration at the October 2007 Board Meeting.

Dr. Schell asked if there were any questions or comments on this proposed regulation. There were none.

b. Proposed Amendment to 16 CCR § 1760 – Disciplinary Guidelines

Dr. Schell advised that this item was provided for information only. This rulemaking will allow the board to use the revised 2007 edition of this publication when deciding on appropriate disciplinary action to take for violations of Pharmacy Law. Staff has suggested a number of amendments to the Disciplinary Guidelines that were last revised in 2001. Upon Completion, this rulemaking will allow the board to use the revised 2007 edition of this publication when deciding on appropriate disciplinary action to take for violations of Pharmacy Law.

Staff made recommendations for changes that were presented to the board at the June 2007 Enforcement Committee. Based on comments received during the Enforcement Committee

Hearing, the Disciplinary Guidelines will remain with the Enforcement Committee for discussion at the September 2007 Meeting and will be forwarded to the board for consideration at the October 2007 Board Meeting.

c. Section 100 Change: Update 16 CCR § 1780 – USP Standards Reference Material CCR

Ms. Herold noted that Dr. Schell offered to chair a mini-task force on this endeavor. They will be looking at the United States Pharmacopeia Standards (USP Standards) to be sure they update the 2005 version of the publication, not the 1990 version. Mr. Dazé, Dr. Schell, and Dr. Gray will be on the task force.

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

Dr. Schell asked if there were any comments or questions from the public regarding this item. There were none.

5. Board Approved – Proposed Language to be Approved – Board Action Required

Proposed Regulation on the Process and Criteria to Approve Accreditation Agencies for Pharmacies that Compound Sterile Injectable Drug Products

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

This proposed regulation would specify the criteria the board uses to evaluate these agencies.

Language was considered at the July 2007 Legislation and Regulation Committee meeting. The committee is forwarding the provided language to the full board for consideration and approval. Upon approval by the board, staff will prepare the regulation for initiation of the rulemaking process.

Dr. Schell asked if there were any questions or comments on this item from the board or the public. There were none.

MOTION: Release for public comment the proposed regulatory language for California Code of Regulations Section 1751.8.

(a) Agencies seeking to become approved accrediting agencies for pharmacies that compound sterile injectable drugs pursuant to Business and Professions Code section 4127.1, shall provide evidence satisfactory to the board that:
  (1) The accrediting agency performs site inspections and re-accreditation reviews of each accredited pharmacy at least every three years.
  (2) The standards for granting accreditation and scoring guidelines for those standards reflect California law and sound professional practice as established by nationally recognized professional or standard-setting organizations.
  (3) The surveyors who perform site inspections possess qualifications necessary to evaluate the professional practices subject to accreditation.
  (4) The accrediting agency is recognized by at least one California healthcare payors (e.g., HMOs, PPOs, PBGH, CalPERS).
  (5) The accrediting agency is able to accredit California and non-resident pharmacies.

(b) An agency seeking recognition from the board to become an approved accrediting agency must submit a comparison of the agency's sterile compounding standards with each of the components of this article and other California law regarding sterile injectable compounding. The applicant agency's request will not be processed unless the comparison demonstrates the agency's standards are in compliance with California Pharmacy Law.

(c) The board shall consider the length of time the agency has been operating as an accrediting agency.

(d) The board shall be able to obtain access to an approved accrediting agency's report on individual pharmacies.

(e) On an annual basis, no later than July 1 of each year, an approved accrediting agency will submit a report to the board listing all board- licensed facilities that have been accredited during the past 12 months.

(f) The board may conduct unannounced inspections of accredited sites to determine if the licensed facility is in compliance with California law and good professional practice.

(g) This approval shall be good for a period of three years. Three months before the end of the approval period, an approved accrediting agency must submit a reapplication to the board for continued recognition as an approved accrediting agency. The Board of Pharmacy shall take action on a completed application at a scheduled board meeting.

M/S: GRAUL/ZINDER

SUPPORT: 10 OPPOSE: 0

Public Comment

Dr. Schell asked if there were any additional questions or comments regarding proposed regulations. There were none.

Part 2: Legislation Report and Action

6. Board-Sponsored Legislation – For Information Only

Omnibus Provisions Contained in SB 1048

Dr. Schell provided a summary of the Omnibus Provisions Contained in SB 1048.

The board's provisions were only recently incorporated into SB 1048, a committee bill containing omnibus provisions for several boards within the DCA.

(1) CURES Reporting – Dispense Schedule IV Drug to Emergency Room Patients – Amend Business and Professions Code § 4068

Revise section to include Schedule IV controlled substances to the CURES reporting requirements for hospitals.

(2) Authorize Board Inspectors to Embargo Misbranded Drugs – Amend Business and Professions Code § 4084

To allow board inspectors to embargo a prescription drug when the inspector has probable cause that it is misbranded.

(3) Correct "Exemptee-in-Charge" Reference to "Designated Representative-in-Charge – Amend Business and Professions Code § 4101

Amend Business and Profession Code § 4101 to change the term "exemptee" to designated representative."

(4) Establish a Temporary License Fee for Wholesalers – Amend Business and Professions Code §§ 4160(f) and 4161(k)

Revise section to specify temporary license fee of $550. Current law does not specify the temporary fee.

Ms. Herold stated that the fee would be $550, and she asked if it would be the board's preference to raise this fee to $600.

Members of the board responded, yes.

MOTION: Amend the proposed regulatory language for Business and Professions Code Section 4160(f) and 4161(k) to reflect the temporary licensee fee as $600.

M/S: GRAUL/ZINDER

SUPPORT: 10 OPPOSE: 0

(5) Extend Bonding Requirements for Wholesalers – Amend Business and Professions Code §§ 4162 and 4162.5

Extend bonding requirements for wholesalers from 2011 to 2015 to match the extension given to implement the e-pedigree requirements, restoring provisions in SB 1476 chaptered out by SB 1475.

(6) Amend Name of CPJE to Reflect Exam Requirements Specified in the Business and Professions Code – Amend §§ 4200, 4200.1 and 4200.2

Changes in the name of the exam to more accurately reflect the requirements described in Business and Professions Code Section 4200.2. The new name will be the "California Practice Standards and Jurisprudence Examination for Pharmacists" (CPJE).

(7) Authorize the Board to Extend an Intern Pharmacist License – Amend Business and Professions Code § 4208

Revise requirements for intern licenses to allow the board discretion to extend the duration of an intern license.

(8) Authorize Citation and Fine Authority for Repositories for Redistribution of Unused Medication (as authorized by SB 798, Chapter 444, Statutes of 2005) – Amend Business and Professions Code §§ 4314 – 4315

Allow the board to cite and fine licensees for violations of Health and Safety Code Sections 150200-150206 which authorize a county to establish by local ordinance, a repository and distribution program for specified unused medications from skilled nursing homes to medically indigent patients served by government-owned pharmacies.

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

a. Active Bills with Positions Taken by the Board

Dr. Schell advised that the meeting materials contain copies of bills impacting the practice of pharmacy or the board's jurisdiction. These bills were reviewed at the July 5, 2007 Legislation and Regulation Committee meeting. He noted that bill analyses and copies of letters of support and opposition were included in the packet.

(1) AB 110 (Laird) Drug Paraphernalia: Clean Needle and Syringe Exchange Projects

Dr. Schell stated that this proposal would allow for the use of General Fund money to purchase needles for NEP programs. The board's current position is support.

Megan Ralston introduced herself as the Drug Policy Access Coordinator for the Drug Policy Alliance. She said she spoke in support of the board and their support of this measure. SB 1159, also known as the Disease Prevention Project, was implemented in Los Angeles. Currently, there are 177 pharmacies are involved in the project. The bulk of the pharmacies involved are chain stores, but her group is working with independents to have them become involved as well.

Dr. Schell asked if there were any further comments about AB 110. There were none.

(2) AB 249 (Eng) Licensees: Healing Arts: Settlement Agreements

Dr. stated that this proposal would prevent all health care practitioners from including a "gag clause" in the settlement of a civil action. The board's current position is support. He asked whether there were any questions or comments from the board or the public on this item. There were none.

(3) AB 543 (Plescia) Ambulatory Surgical Centers: Licensure

Dr. Schell stated that this proposal would standardize the licensing requirements for ambulatory surgical centers. The board's current position is support. He asked whether there were any questions or comments from the board or the public on this item. There were none.

(4) AB 1025 (Bass) Professions and Vocations: Denial of Licensure

Dr. Schell stated that this proposal would prohibit the board from denying an application for licensure or pursuing administrative action against a licensee for a conviction that has been set aside under certain circumstances. The board's current position is oppose. He asked whether there were any comments or questions on this item. There were none.

(5) AB 1587 (De La Torre) Personal Information: Pharmacy

Dr. Schell stated that the bill was heavily amended, and now relates to recall elections for the City of Lynwood. As such, neither a copy of the bill nor a bill analysis was provided in the meeting materials.

(6) SB 472 (Corbett) Prescription Drugs: Labeling Requirements

Dr. Schell advised that this proposal would mandate that the board develop and adopt a patient-centered standardized prescription label. The board's current position is support.

Ms. Herold stated that she was not recommending a change of position, but advised that this proposal will result in a major workload impact requiring a new prescription label.

Dr. Gray added that there is significant confusion in the labeling requirement, but some of the questions may have been resolved. There is a difference between the board "developing standards" and the board "developing a standardized label." He said examples of that would be an exact layout or color requirements or design features.

Mr. Room responded that the bill, as written, is option B, a standardized label, with all of the pertinent information on the label.

Ms. Herold added that Target, who spent money developing a consumer-friendly label format, may not be able to continue to use that format.

Dr. Gray said that Target was innovative, and is to be commended for what they have done. He emphasized that if a standardized label is imposed, it will inhibit innovation. He said he was not sure what the sponsor of the bill had in mind, but he would recommend standards instead.

Mr. Dazé that there a problem, and he believes that consumers would prefer a standardized label.

Mr. Room responded that there's something in between standards and a standardized label. Every label does not have to be exactly alike, without limiting or restricting retailers.

Mr. Hough stated that he agreed with Dr. Gray and Mr. Room, but it gets into matters of policy and philosophy. He said it's important to look at this because we don't want to get into the effects or micromanaging. Mr. Hough stressed that he is adamantly opposed to a standardized label with the same font size. He said that people who have made this country so great should have an opportunity to innovate.

Dr. Gray said that under current law, there is no distinction between ambulatory or out-patient, or IV bag labels or bubble packs for long term care. He wants to be sure there is enough latitude for the pharmacies for different patient care environments. Dr. Gray said he hoped there is latitude, but that is not his understanding from the sponsors of the bill.

Ms. Herold responded that different sponsors give different versions of the intent of this legislation. They know that the board will blend options dealing with issues that affect the pharmacy side. She said that the board must recognize that this will be a huge effort and complex. However, board inspectors should not be put in a position to measure pica size print on a label, for example. Another example would be the size or type of printing on eye drop containers and inhalers may be different than on a bottle.

Ms. Zinder asked whether the bill was written so that the standard would have to be done in a year.

Ms. Herold responded that implementation date is January 1, 2011 which should give industry a year to gear up. She added that there is a group that will issue a report on leading edge research in labeling.

Dr. Schell asked about the interpretation of the statute.

Mr. Room responded that, absent regulations, the courts will determine. The canons of construction are that you look at the legislative intent. The Office of Administrative Law (OAL) will determine whether our regulatory language is consistent with the statute, but typically, the regulation is used to define or clarify the statute. If OAL says the regulations are consistent, then the prevailing interpretation would be our regulations.

Dr. Schell asked whether there were additional comments or questions regarding this item.

Joseph Warren introduced himself as an attorney, and stated that all this is set forth in Business and Profession Code Section 4076. He asked whether the purpose of this legislation is so that a consumer can look at a label and know what the drug is.

Ms. Herold clarified that we are not amending Section 4076. The same information should be on your label today, but this will put the "consumer information" in a place most prominent on the label, so that the patient knows what's in the container.

Regarding Target's innovative prescription drug containers, Ms. Herold said that when the bill was first introduced, she spoke with the corporate office at Target. Her concern was that the bill would outlaw what Target had done with their label. Target noted that there are some states that have different labeling requirements.

Larry Drexler, Target Pharmacy, said that they have modified the print on the bottles to increase font size, and added color-coded rings on the necks of bottles to identify what is contained in the bottles. As to liquids, they have a syringe to remove more precise dose, which is a patented product of Target's. Mr. Drexler added that he has also seen a patient-friendly label from CVS. So he said he was not just speaking on behalf of Target; he was speaking on behalf of other retailers.

Mr. Powers stated that a number of public hearings will be held and there will be plenty of opportunities for input.

Ms. Herold stated that Target's label is wonderful and serves as a model. It is a very high standard.

(7) SB 606 (Scott) Pharmaceutical Information: Clinical Trial Data

Dr. Schell stated that this proposal would require a pharmaceutical company that sells, delivers, offers for sale, or gives away pharmaceutical drugs within the state to make publicly available the results of every completed clinical trial, except a phase I trial or bioequivalence study, for that drug and an explanation of noncompletion for any clinical trial, except a phase I trial, that the company initiates or sponsors the initiation of, but does not complete.

Dr. Schell said that the board's current position is support. He asked if there was any change in the board's position. There was none.

(8) SB 615 (Oropeza) Pharmacy Technicians: Scholarship and Loan Repayment Program

Dr. Schell stated that this proposal would establish a scholarship and loan repayment program for pharmacy technicians and require all pharmacy technicians as well as pharmacies to contribute $10 at the time of renewal. He said the board's current position is support.

Ms. Zinder asked whether this will increase the license renewal fees.

Ms. Herold responded yes, but the board doesn't receive the increase. It would be a surcharge.

Antonette Sorrick stated that DCA has an oppose position on this bill. She read aloud from correspondence from DCA to the author's office. Ms. Sorrick added that the department is concerned that this bill would create a financial burden to persons in a profession that is not highly paid.

Dr. Schell asked whether $5 a year would be a burden.

Ms. Sorrick responded that the Department does not feel it is right.

Dr. Cronin added that he was not speaking for CPhA, but their position on the bill is oppose. He believes the BOP should oppose the bill. Dr. Cronin said that the fees were just raised to the statutory maximums for licensing fees. He said the board shouldn't do this unless there's a really good reason to do it, and if you look at the shortages in medical care in a certain area, that has nothing to do with technicians.

Ms. Sorrick added that a health education fund already exists.

Dr. Cronin asked what would happen if no one applied for the scholarships.

Ms. Zinder asked that reconsideration should be given to pharmacy technicians because there are not highly compensated. She said she supports having pharmacists contribute, but it would be a burden for technicians.

Ms. Sorrick added that there is a loan repayment fund for medical professions and dentists, but not pharmacy technicians.

Jack Clayton introduced himself as a pharmacy technician in Bakersfield. He said he doesn't really want to repay someone else's loan.

Ms. Zinder added that she would support a voluntary program. She has a concern about pharmacy technicians that do not work full time.

Mr. Graul added that he would like contributions to be voluntary. He would support a motion, if contributions were voluntary.

Ms. Herold asked whether the board's position would be "oppose unless amended."

Ms. Sodergren clarified that there is a voluntary program for pharmacists, and there are not sufficient funds to have a program. So if there is a voluntary program for technicians, the board should consider whether a voluntary fund for technicians would result in sufficient funds. Ms. Sodergren added that other boards have had this type of mandatory contribution.

Dr. Sam Shimomura, Western University, added that there are administrative costs to decide who receives the scholarships. He asked who would be making the decisions. He also said that he serves on a scholarship board, and it takes a lot of time.

Ms. Sodergren added that the Health Professionals Education Fund, another entity, will administer the funds.

Dr. Swart said he was concerned that helping only 36 students would not warrant the cost of the program.

Dr. Schell asked whether the board wished to the change the board's position on the table to "oppose unless amended" to make it voluntary.

MOTION: Amend the board's position on SB 615 (Oropeza) Pharmacy Technicians to oppose unless amended to reflect that it will be a voluntary program.

M/S: ZINDER/HOUGH

SUPPORT: 10 OPPOSE: 0

(9) SB 963 (Ridley-Thomas) Regulatory Boards: Operations

Dr. Schell stated that this proposal would replace the sunset review process currently defined and create the Office of Consumer Advocate within the DCA. Among other thing, the Office of Consumer Advocate would be responsible for oversight of board operations to ensure compliance with the board's public protection mandate. Dr. Schell advised that the board does not currently have a position on this bill.

Ms. Herold stated that this bill will be going to interim hearing, so she suggested that the board not take a position on this two-year bill at this time.

Ms. Sodergren stated that the board should consider taking a look at the position because it would replace the sunset process. She added that the legislation, as currently amended, will hold the board under continual review under the Office of The Consumer Advocate (within DCA). That could result in some duplication of the board's efforts. For example, review of regulations would have to go through the Office of The Consumer Advocate. Ms. Sodergren added the board doesn't have to take a position now, but she wants the board to be aware of its provisions.

Mr. Goldenberg stated that sunset review takes a significant amount of time. Without the sunset review, the board could refocus on other activities. He asked Ms. Sodergren whether there would be continuous oversight through the department's oversight.

Ms. Sodergren responded that the bill would create the Office of Consumer Advocate, and would create a number of reporting requirements. The impact may not be great on our board because we are so proactive with our goals and missions. There would be other restrictions as well, like not being able to choose the board's Executive Officer, and corrective measures would be suggested by the new advocate.

Mr. Room stated that it would create a clearinghouse of reporting information on an ongoing basis, instead of on a periodic basis.

Ms. Herold responded that it also creates an unusual entity. The concern is that the sunset review process was established in the 1990s by legislators who have now been termed out. This proposed solution will leave the public protected, but will allow the Legislature to step out of the process, partly.

Ms. Sorrick added that DCA has a position of oppose. We need to be sure about some parts of the legislation regarding disciplinary actions, to be sure that the board is protecting the public. It would take away some of the autonomy of the board's decisions.

Mr. Powers stated that he wants to be sure that the board's concerns are heard.

Dr. Swart suggested that the board wait to take a formal position until additional information is provided.

Dr. Gray asked whether other boards have stated their position(s) on the bill.

Ms. Herold responded not to her knowledge. She added that the information from Ms. Sorrick was the first information that she had on the department's position on the bill.

(10)SB 966 (Simitian) Pharmaceutical Drug Disposal

Dr. Schell stated that this proposal would require retailers as defined to accept, then dispose of, returned unused medications. The board's current position on the bill is oppose.

Ms. Herold said that she has asked to meet with Senator Simitian, who is planning to make amendments to the bill. Senator Simitian will ask the Department of Waste Management to look at pharmacies (chain stores) to develop standards, but the board will have no direct authority over the regulations.

Ms. Herold stated that while this bill offers a much-needed solution for patients to dispose of medication, in its current form everything will go into bins, and this will be a public safety issue as well as a source of drug diversion. As such, there are many reasons to oppose this bill. She added that Senator Simitian wants people who create a pollution problem to take care of the pollution problem they create. The BNE opposes the bill.

Dr. Conroy stated that this relates to large pharmacies and to large supermarkets without a pharmacy anywhere around.

Mr. Goldenberg asked whether an oppose letter can be sent from the board.

Mr. Powers responded that a letter was sent and in our conversations we laid out the board's concerns.

Mr. Graul added that he had personal experience with disposal of bags of medications after two family members had died.

Mr. Powers emphasized that the public must have a legitimate and reasonable way to dispose of medicine.

Mr. Graul said that paint and pesticide can be taken to the county centers on certain days, so dropping off unused medicine at a pharmacy is totally inappropriate.

Ms. Herold added that there will be discussions with the Department of Hazardous Waste and other key agencies.

Dr. Schell noted that there will be no change in the board's position at this time.

b. Other Active Bills of Interest Impacting Board

Dr. Schell advised that these bills are for information only, as they may be of interest to the board or pharmaceutical industry, but may not directly impact the practice of pharmacy or the board's jurisdiction.

(1) AB 14 (Laird) Discrimination: Civil Rights Act of 2007

(2) AB 64 (Berg) Uniform Emergency Volunteer Health Practitioners Act

(3) AB 106 (Berg) Immunizations

(4) AB 329 (Nakanishi) Chronic Diseases: Telemedicine

c. Inactive Bills with Positions Taken by Board:

(1) AB 501 (Swanson) Pharmaceutical Devices

This proposal would require a pharmaceutical manufacturer who product is administered for home use through a prefilled syringe, prefilled pen needle, or other prefilled injection device to provide each person who uses the product with a container for the safe disposal of the used sharps from the syringe, pen needle, or other injection device. It would require the container to have a sticker with a specified warning and a toll-free telephone number that identifies safe disposal methods of the container.

(2) AB 851 (Brownley) Prescription Drugs: Informational Insert

This proposal would require the inclusion of a large font informational insert with all prescription medications that could adversely interact with alcohol and/or other prescribed or over-the-counter medications.

(3) AB 865 (Davis) State Agencies: Live Customer Service Agents

This proposal would require all state agencies to answer public telephone lines within 10 rings.

(4) AB 1276 (Karnette) Pharmacies: Prescription Containers: Labels

This proposal would require the prescription label to include the intended use for the medication if noted on the prescription by the prescriber.

(5) AB 1399 (Richardson) Pharmacies: Prescription Labels

This proposal would require a pharmacy to provide a prescription label that is readable by an assistive technology device if requested.

(6) AB 1436 (Hernandez) Nurse Practitioner: Scope of Practice

The bill would provide that a nurse practitioner is authorized to perform comprehensive health care services for which he or she is educationally prepared and competent to perform and to admit and discharge patients from health facilities in collaboration, as defined, with specified healing arts practitioners.

(7) SB 809 (Ashburn) Nurse Practitioners

This proposal would expand the scope of practice for nurse practitioners to include, among other things, the independent prescribing and dispensing of medications.

(8) SB 993 (Aanestad) Psychologists: Scope of Practice: Prescribing Drugs

This proposal would expand the scope of practice for psychologists to include prescribing medications for specially trained and certified psychologists.

Public Comment

Dr. Schell asked if there were any further comments or questions from the public in attendance. There were none.

8. Meeting Summary of the July 5, 2007 Legislation and Regulation Committee Meeting

The Meeting Summary of the July 5, 2007 Legislation and Regulation Committee Meeting was provided in the board packet.

9. Fourth Quarterly Report on Committee Goals for 2006/2007

The Fourth Quarterly Report on the Legislation and Regulation Committee Goals for 2006/07 was provided in the board packet.

II. New Business/Agenda Items for Future Meetings

No new business or agenda items for future meeting were suggested.

ADJOURNMENT

There being no further business, President Powers adjourned the meeting at 5:19 p.m.

Wednesday, July 25, 2007

III. Closed Session

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

IV. Petitions

a. Reinstatements

William Argentino
Michael Flores
Toan Phuoc Huynh

b. Early Termination

Tommy Kien Huynh

V. Closed Session

At the close of the hearings, the board moved into closed session pursuant to Government Code Section 11126(c)(3) to deliberate on the requests for reinstatements and early termination of probation.

ADJOURNMENT

There being no further business, President Powers adjourned the session at 3:30 p.m.