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

DATE: **April 18, 2007 – April 19, 2007**

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

BOARD MEMBERS PRESENT:
William Powers, Public Member, and President
Kenneth H. Schell, Pharm. D., Vice President
Ruth M. Conroy, Pharm. D., Treasurer
D. Timothy Dazé, Esq., Public Member
Stanley W. Goldenberg, R. Ph.
Clarence K Hiura, Pharm. D.
Henry Hough, Public Member
Susan L. Ravnan, Pharm. D.
Robert E. Swart, Pharm. D.
Robert Graul, Pharm. D.

BOARD MEMBER ABSENT:
Andrea Zinder, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Karen Cates, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi 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
Gloria Schultz, Administrative Assistant

CALL TO ORDER

President Powers called the public board meeting to order on April 18, 2007 at 9:00 a.m.

GENERAL ANNOUNCEMENTS

All board staff was introduced, which is a tradition for our Sacramento Public Board Meetings.

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

1. Discussion and Action on the Board's Public Forums on Medicare Prescription Drug Plans

Chairperson Schell noted two meeting summaries provided in the packet:

- February 1, 2007 Public Forum on Medicare Prescription Drug Plans (San Diego)
- March 30, 2007 Public Forum on Medicare Prescription Drug Plans (Los Angeles)

Also provided in the packet was a document prepared by the Center for Medicare Advocacy, Inc., a consumer advocacy organization. The document was entitled "Medicare Part D After Year One: A Review Of Problems, And Recommendations For Change," dated January 16, 2007. The document discussed remaining problems with the Medicare Prescription Drug Program.

Dr. Schell stated that discussion at both forums centered around several issues including prior authorization requirements that can delay patient drug therapy for as long as three to five days before a medicine is authorized, and "coverage" issues. He summarized the board's involvement in addressing these and other issues.

The board hosted a forum on the Medicare drug benefit, which was created with the Medicare Modernization Act (MMA), on February 1, 2007, during the second day of the board meeting. Although the board allocated 2.5 hours for this discussion, it was insufficient time for all those present to speak. As a result, the board scheduled a second forum, which was held on March 30, 2007 in Los Angeles.

Since 2006 when the prescription drug benefit was established under the MMA, there have been problems for some patients getting their medicine. The board, as a consumer protection agency,

has fostered discussion among patient advocates, stakeholders, and policymakers, to resolve problems and to benefit patients.

The program is working better than when initially implemented in January 2006, but problems remain that prevent patients from getting necessary care timely, causing higher health care costs, delayed therapy, and impaired health. Over the six meetings the board has convened on this issue since January 2006, the board has facilitated discussions that have aided some patients. However, there are still problems that can and should be corrected. Some of the issues that have been 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 for before a medicine is authorized (which may not be the one initially prescribed)
2) Poor "coverage" information for billing
3) Co-payment problems in skilled nursing facilities, where patients are told to make co-payments
4) Plans change formularies, creating coverage problems
5) Multiple formularies and physician prescribing that does not correspond to a formulary
6) Poor continuity of care when a patient is discharged from an acute hospital on "non-covered" drugs, impacting the patient's drug therapy and health
7) Poor understanding of IV product/coverage/billing by plans (and therefore determining such services are "not covered" with the resultant care problems for patients, or continued hospitalization until the coverage is secured)
8) Poor "timely" response by plans to the pharmacy when the law requires in a skilled nursing facility a 1-hour or 4-hour delivery of medication under Title XXII
9) Requirements that physicians must do prior authorizations (not allowing the pharmacist to do this, which further delays therapy for patients, and redirects pharmacies to additional phone calls, away from other care functions)
10) Drugs on plan formularies that are "not geriatric friendly" per federal and state regulations and guidelines

Dr. Schell emphasized that as a consumer protection agency, the board's role is to aid patients in getting their prescribed medicine timely. He asked if there was a recommendation that the board could take at this time.

Mr. Goldenberg asked if the public consumer agency that spoke at the forum on March 30th was here to share information with the board.

Executive Officer Herold stated that David Lipschutz, from California Health Advocates, gave a presentation at the March 30th forum with respect to Medicare Part D problems. A copy of his presentation was in the packet, and it outlines those problems. Ms. Herold said that Mr. Lipschutz was invited to give the presentation to the full board, but he was unable to attend today; he had hoped to send an alternate. Ms. Herold was unable to confirm someone.

President Powers said it was his recollection that, at a minimum, the board would send a letter to the delegation urging them to look at the issues raised, particularly dual eligibles.

Mr. Goldenberg said he was in full agreement with sending a letter, but also suggested that the board develop a roundtable to have all stakeholders meeting with the board, and to set timelines and goals we could all agree on to help protect the public. If the goals and timelines are not met, it will go back to the board. He stated that his experience on the subcommittee shows a waning of resolve by the parties in resolving these problems. The plans say they're working on the problems, but providers are left with these unresolved problems. Mr. Goldenberg stressed that we can move faster in California to protect consumers. He wants a more definitive role, with a list of goals and agreed-upon timelines, to be sure that seniors of California get the protection they should.

MOTION: That the Board of Pharmacy sends a letter to the congressional delegation encapsulating the current issues surrounding Medicare Part D.

M/S: POWERS/GOLDENBERG

SUPPORT: 9 OPPOSE: 0

Dr. Schell asked that the board entertain Mr. Goldenberg's motion that the Medicare Part D Subcommittee be adjusted so it becomes a taskforce or roundtable discussion whose goals have a timeframe to accomplish certain objectives to protect the seniors of California.

Mr. Powers stated that it sounds like an expansion of the current activity the board is engaged in now, but making it more specific. He said Ms. Herold should invite the California delegation to participate as well.

Mr. Goldenberg stated that his concern is that the subcommittee has not been taken seriously enough, either by stakeholders or by possibly even by CMS. The providers are coming to the table sharing their concerns, and seniors have been coming to the meetings explaining the difficulty they have been experiencing. We're at a time now when providers will come to the decisions as to whether they will provide care or not provide care, especially for dual eligibles with multiple conditions.

Mr. Goldenberg emphasized that he wants accountability that the plans will do specified things by a certain date. We want to do this in advance of having consumers come to the board stating that they did not get the treatment they needed because of these problems.

Mr. Dazé stated that there should be a timeline for the taskforce to meet goals.

Mr. Powers stated that Congress is moving on some of these issues. The Senate passed a law requiring CMS to negotiate with pharmaceutical firms and the House passed one earlier. This legislation addresses the cost of pharmaceuticals. So there is some movement, but Congress hasn't focused fully on a variety of other issues. Congress may not understand the problems that providers and seniors are having.

Mr. Dazé emphasized that the taskforce should not wait for Congress to act, and that's why a timeline is important.

Dr. Schell asked if there was any further discussion from the board or any comments from the public in attendance. There were no comments.

MOTION: That a roundtable meet periodically with timelines for goals and changes for action, and to include in it what steps the board will take if the goals and timelines are not met, and to include the California delegation.

M/S: GOLDENBERG/SWART

SUPPORT: 9 OPPOSE: 0

2. Report and Action of Items Discussion at the Communication and Public Education Committee Meeting of April 3, 2007

Chairperson Schell stated that the Communication and Public Education Committee met on April 3, 2007. Minutes from that meeting were provided in the board packet.

- **Update of the Committee's Strategic Plan for 2007-08**

Dr. Schell stated that at this Board Meeting, each of the board's strategic committees will provide a report to the board on the need to amend the committee's respective strategic plan for relevance and currency.

Staff has identified two recommendations to amend the strategic plan of the Communication and Public Education Committee, but because there were only two committee members present at the April 3, 2007 Meeting, no formal recommendation for action to the board was made. Dr. Schell said the recommendation was as follows:

Approve the committee's strategic plan for 2007-08 by adding two activities to Objective 4.1 "Develop a minimum of 10 communication venues to the public by June 30, 2011"; specifically, to add:

Evaluate the practice of pill splitting as a consumer protection issue

Evaluate the SCR 49 Medication Errors Report for implementation

Dr. Charles Phillips approached the board. He stated he believed the board operated under Roberts Rules of Order as other state agencies do. He said that if anyone has a major personal interest, that they would not chair a particular topic.

Mr. Spencer curtailed Dr. Phillips' comments, advising that public comments were not applicable at this time. He emphasized that Dr. Phillips should hold his comments until called, and that the board was not addressing the issue of pill splitting yet. He clarified that the board was only considering the amendment of the committee's strategic plan, and that Dr. Phillips would have an opportunity to share his comments later.

Dr. Schell asked if there was any discussion by the board. There was none.

MOTION: That the board approve the committee's strategic plan for 2007-08 by adding two activities to Objective 4.1 "Develop a minimum of 10 communication venues to the public by June 30, 2011"; specifically, to add:

6. Evaluate the practice of pill splitting as a consumer protection issue
7. Evaluate the SCR 49 Medication Errors Report for implementation

M/S: GOLDENBERG/CONROY

SUPPORT: 9 OPPOSE: 0

- **Discussion on Pill Splitting by Patients**

Dr. Schell stated that he received communication, external to sources on the board, questioning his objectivity in leading board discussion on the subject of pill splitting. He voluntarily recused himself. He said he had been a pharmacist for 25 years, and had practiced the highest ethical and moral standards. He said that he had been prejudged his whole life, and thought he would get used to it, but he hasn't.

Mr. Powers thanked Dr. Schell for his statement. Dr. Schell left the room for the rest of the discussion on pill splitting.

Mr. Powers said that this is the fourth session where the issue had come before the board. Apparently, the issue came before the board several years ago, but the board took no action at that time.

Mr. Powers summarized the issue of pill splitting for the benefit of those present.

At the January 2007 Board Meeting, the board heard a discussion on pill splitting. The presentation was initiated by Charles Phillips, MD, an emergency room physician, who indicated he was concerned with the practice of pill splitting and the resultant crumbled residue of drug product in the bottom of pill containers. He stated the practice of pill splitting is a problem because pills do not split evenly, and patients get uneven doses of medicine. He has asked the board to initiate steps to prohibit pill splitting.

Comments from others in the audience at the January 2007 Board Meeting disagreed with Dr. Phillips' concerns with pill splitting. As a result, the subject was directed for a more lengthy discussion at both the Legislation and Regulation Committee and the Communication and Public Education Committee.

At the April 3, 2007 Communication and Public Education Committee, Dr. Phillips appeared and provided additional information about pill splitting. The minutes of this meeting detail some of his presentation.

Dr. Phillips stated that because he thought that perhaps the board may not take instant action to prohibit pill splitting, he had developed an "informed consent" sheet that could be provided to patients warning them about the dangers.

There were no comments from individuals present in support of pill splitting. However, as there were only two committee members present at this meeting, no action was voted upon to recommend to the board. However, Dr. Schell suggested that the board:

1) Develop a document about the myths and facts involving pill splitting, providing information to the public so they can make informed decisions

2) Look at the clinical impact of pill splitting to see if harm is done to patients, and whether patients remain stable (based on clinical outcomes)

The Legislation and Regulation Committee Meeting, held on April 3, 2007, had a shorter presentation by Dr. Phillips due to time constraints, and did not recommend action items to the board either.

Mr. Powers stated that at issue for the board today is that, in addition to perhaps preparing consumer information on pill splitting, is there other action that the board is interested in pursuing?

- Is there sufficient evidence of harm to the public in the literature to take other steps aimed at curtailing or prohibiting pill splitting?
- Can the board or the California Legislature mandate that manufacturers produce pills at costs that do not result in pill splitting?
- Are there patients who would go without drug therapy if they could not split pills?

- Should consumers have the right to decline to split pills?
- Should patients who are physically unable to split pills be required to split pills?

A number of articles on pill splitting were provided in the board packet.

Mr. Powers stated that for him, pill splitting is one of the most critical issues the board has faced in the recent period. He has taken a lot of time to read the material provided and to determine a position in his own mind about who is affected, and what the role of the board is. Mr. Powers said he would wait until he heard the presentations before he gives his feelings on the issue. He emphasized that it is an important issue, one that the board should hear more on. It has more than one side, and it's not an easy one for the board to come to grips with.

Mr. Powers stated that Dr. Phillips deserved a vote of tenaciousness to bring the issue to the board. He opened the floor for a discussion on the issue, and said he would ask the board to look at a follow-up position.

Dr. Phillips approached the board, and stated that he presented new information each time he addressed the board. He said he wanted to invite Dr. Schell back to the table because as the chairman of the Contra Costa County Hospital, he did not leave the table; he just had another person chair a particular topic when necessary. He had hoped the Dr. Schell would be a participant, and made additional references to Roberts Rules of Order.

Mr. Spencer stated that Dr. Schell's recusal was a non-issue, and that Dr. Phillips should proceed on the issue at hand.

Dr. Phillips invited the board to send any investigator to the front line to see "garbage" in bottles full of fragments varying in size. The biggest fragments could be 30% above dose, down to 40% below dose.

Dr. Phillips made several comments including the Consumer Reports articles that "leaned on their medical editor." Consumer Reports stated that if you split one pill and take half and then the remaining half at the next dose, you would receive the proper dosage. Dr. Phillips stressed that with pill splitting of all pills at once, patients take the larger pieces first, and work their way down to dust. He thanked the board for hearing his concerns.

Mr. Powers invited Dr. Phillips to stay in the event there were questions.

Mr. Hough stated that he understood the arguments about pill splitting, but he's trying to understand what the quantitative advantages for manufacturers and providers like Kaiser for doing it. He wanted to know how the practice would give an advantage to people in the supply chain.

Dr. Phillips responded that basically, there was no particular advantage to a pharmaceutical company. In 1992, they made different dosage levels of some pills available at the same cost –

flat pricing. The VA and Kaiser are also able to purchase different dosages for the same price. So if you split a pill, your cost goes down.

Dr. Hiura stated that as a practicing pharmacist, a prescriber who writes a prescription with instructions to "take a half tablet," he is obligated to fill the prescription that way. He wanted to know why physicians write prescriptions saying take a half tablet. He asked Dr. Phillips if he had contacted the CMA or AMA or the Medical Board about this practice.

Dr. Phillips responded that pharmacists are never obligated to do anything considered unsafe. He said that he wrote a normal prescription and it came to him to split the pills by the system. He said that the issue isn't doctors imposing the practice. It's an unsafe practice, and he will also be going to the Medical Board. He is not asking to outlaw all pill splitting; just the massive pill splitting, particularly splitting pills over a couple days.

Mr. Graul stated that he was at the San Diego board meeting on January 31, and it appears that the action the board just took today to add pill splitting to the strategic plan for this year and next year addressed what Dr. Phillips was asking for.

Dr. Phillips responded that it was not enough to put the issue into a long-term topic of public education. If the board finds the practice unsafe to do in massive style, they can step up the issues now. He further stated that 1,000,000 pills are split every day.

Dr. Goldenberg stated that pharmaceutical manufacturers are driven by profit and that we have an access problem for consumers. If we saddle a pharmacy by saying split this one and don't split this one, he's not sure what this will accomplish in safety issues. He would like to see a more balanced presentation to the board about financial impact, how best to protect the public, as opposed to "no pill splitting."

Dr. Goldenberg said that some pills could cost $2, $3 or $4 per pill for new drugs, and for others $10, $15, $20, or $100 per dose when you get into bio-engineered drugs. The board needs to review pill splitting in a methodical fashion, not just as a long-term goal. It affects seniors and patients in general. The board would be very clear if they found a pharmacy splitting drugs purely for profit, for example, Coumadin. He wants the board to treat this as an important topic, and maybe get schools of pharmacy input.

Dr. Ravnan stated that she agreed with Mr. Goldenberg, and she wants to see a more balanced approach. She wants to know what "massive" pill splitting means. She suggested development of guidelines from the board about whether a pill is safe to split.

Dr. Phillips stated that if the pills are split, particularly by seniors, and dosage was off by 40% either way, how would you educate someone about that? There is risk to disease for pill splits for hypertension and high cholesterol drugs. When his patient asks to split a pill, he gives the patient information, including the risks. He said that when he gives the patient the information,

he says the patients usually says they won't split. He's said he's not against choice, but a piece of paper giving patients information may not be fair to patients.

Dr. Hiura stated that he's a senior citizen. He knows it's an economic issue, and that some seniors have a difficult time cutting these pills in half. Dr. Hiura further stated that he gives free pill splitters to patients, and a lot of them don't work too well. He stressed that pharmacy is a precise practice – 5 milligrams one way or another makes a big difference.

Dr. Swart stated that the board needs to develop language about informed consent. We need to be clear in education that patients can opt out and get a regular tablet without splitting, and that patients should talk to their insurance company.

Mr. Room suggested that the board divide the discussion into two areas – public education and informed consent. He also asked whether the board wants to mandate, prohibit, or curtail the actual practice of pill splitting.

Mr. Powers asked Dr. Phillips what specifically he is asking the board to do.

Dr. Phillips responded that he wants two things. He wants the board to connect activity to the research that one must split a pill and take the halves in consecutive administration. He also wants the board to send an investigator to go to an emergency room to see bottles of pills. He would like the board to disallow the practice of splitting pills.

Dr. Conroy said she wants to see an advisory to pharmacists on the issue. She said that she cuts her dad's medicine all the time, cutting 14 pills at once, and never heard she should match a split dose as day one and day two. So a regular advisory to pharmacists should be first.

Dr. Conroy also noted that the "overrides" on the pharmacy computer is a roadblock. Patients with dexterity problems and vision problems should not be asked to split pills. She suggested maybe working the Department of Insurance for on an advisory to insurance companies.

Mr. Goldenberg stated that the focus needs to be on the payors. Over time, payors have influenced physicians, for example, to write a prescription for 90 days with multiples refills, or 30 days, and so on. Payors will make sure physicians get the message, patients get the message, pharmacists get the message. Mr. Goldenberg emphasized that he doesn't think the board is the appropriate place to drive change.

Mr. Powers asked if for additional comments from the audience.

Maggie Dee thanked the board for allowing public testimony on the matter. She described herself as a disabled person, and said she hosts a radio program specifically dealing with disability and senior issues.

Ms. Dee stated that she normally travels with an attendant. If she needs to split pills and an attendant isn't there, it's a problem. She said she's appealing to everyone to consider people with palsy, Parkinson's, or severe spasms. Her hands sometimes close, and she can't use a splitter. And she does not always have neighbors to assist.

Ms. Dee said she said she has a cognitive disability, and can't always remember day one and day two, or even what she had for breakfast sometimes. She can't see tiny pills and scores on pills. When she's reaching into a bottle, she can't tell which fragment is halved. When she has a bottle with 30 pills, what happens when there are 31 days in the month. She said it's not rocket science – it's a serious danger for those required to split pills.

Ms. Dee said she worked for a daily newspaper writing two columns. She said the board talks about consumers and a taskforce – she has to spend 5 dollars a day on drugs and pill splitting affects health. She said she honestly believes she's in danger. She said Dr. Phillips has been at this issue for six years, and she asked how many people have already been endangered in 6 years. She said that life-sustaining drugs can become life threatening with pill splitting. She said she appreciated the chairman's concerns.

Mr. Powers thanked Ms. Dee. He asked if there were additional comments from the public.

Paris Pachay approached the board. He said that he wanted to reiterate two things that Dr. Phillips spoke about. He said he has a pacemaker and a defibulator. He said that he had a bad reaction to a medication and went into the hospital, which quadrupled the amount of medication he takes. He stated he was able to split them himself and it seemed to work. But if he were unable to split pills, it would be a problem.

Mr. Pachay said he was trying to get another problem addressed, one dealing with Acutrim, because children are taking this over-the-counter medication like cough syrup. Mr. Pachay stated that no child under 16 should be able to purchase these over-the-counter drugs because they are so harmful, like cigarettes or alcohol.

Mr. Powers suggested that USCF create a fact sheet for students and parents on this issue. He also suggested that it could be legislated, like the sale of drugs that are used to produce methamphetamine. He recommended that Mr. Pachay talk to his legislator.

Mr. Goldenberg asked if Mr. Pachay knew whether the dosage that he was taking was commercially available without splitting.

Mr. Pachay responded that no. He said that before Medicare coverage, he could not afford the medicine, but now he can get it for about $4 per pill.

Steve Gray, from Kaiser Permanente, said he spoke on the issue of pill splitting at previous board meetings. He said it is a conundrum – we know there are a lot people not getting medical care they need because of cost of medical care, and also manufacturers are pricing different strengths

of medicine at the same price. The cost of distribution and marketing a tablet is the major cost. Thus, they can price and sell different dosages at same price. Also, there are a lot of citizens who cannot afford prescription drug benefits, and it's a big problem in California. Affordability of health care, and in this case, affordability of medications is a big issue. Kaiser's tablet splitting program is just one way to reduce costs. Decisions about tablet splitting are made with input from scientists and physicians and pharmacists.

Dr. Gray stated that Kaiser believes there must be exceptions for patients and for pharmacists to make those exceptions. In other words, if a patient is identified or "self-identifies" as someone who should not pill split, then an exception is made. He said that Kaiser repeatedly does education on this, but he can't guarantee that with six million patients, physicians, and pharmacists, the right decision is made very time. He said that special new pharmacist orientation is highlighted with pill splitting. They need to make health care and coverage more affordable – if less people are taking their meds, then more patients are harmed, and it's very careful balancing.

Dr. Gray stated that he does not want the board to adopt any one-way black and white rules because decisions need to be made by physicians. He does not know of a single payer that doesn't allow exceptions. He said that maybe prior authorization process is necessary and a decision can be made instantaneously. He stressed that it is a valuable program saving tens of millions of dollars. Tablet splitting programs make sense, and it would be irresponsible to not pill split because of medications are priced so high. He said he agrees with the patients here that exceptions must be able to be made, not just for seniors, because there are different categories of ability. He wants to remind people that tablet splitting helps seniors under Part D in the doughnut hole.

Dr. Swart asked if he is on a tablet splitting medication, how difficult is it to get the full tablet.

Dr. Gray responded that he would just have to mention it, and that is their policy. He also stated that that is very rare because the vast majority of patients accept these programs, and that if you state you don't want to split pills, you won't have to.

Mr. Goldenberg stated that one situation is a 40 year old opting out, and another is a 40 year old being fully informed to make that decision. A patient may need help to make that decision and asked if the pharmacist is able to make the decision.

Dr. Gray stated that Kaiser has an integrated care program and operates their own pharmacies, so the pharmacist can make the decision. He is aware, though, that other pharmacies have to learn about different payors and their rules; they need a prior authorization process.

Mr. Powers asked if it was Dr. Gray's position that in Kaiser, anyone with a physical or cognitive problem does not have to split pills.

Dr. Gray responded that if a patient self-identifies that he or she doesn't want to split pills, he or she doesn't have to split pills. He acknowledged that they may miss someone occasionally.

Dr. Ravnan asked to make one comment. She said she agreed with Dr. Gray that this is a balance, and there are certain chronic disease states where our blood pressure and cholesterol vary in our bodies. A slight difference will not make a big difference.

Ms. Dee said that she left Kaiser because she was told that if she didn't like how Kaiser practiced, she should rethink whether she wants to be a Kaiser patient.

Mr. Powers said that the board has devoted significant time to this issue. The problem is a health care system that's dysfunctional and based on money. Mr. Powers further stated that he is asking the board's legal counsel what we can do with the recommendations we received on this. There are unanswered questions and we don't operate in a vacuum. If we mandate something, it results in cost to others. At the same time, the issue may have significant physical problems for patients asked to split.

Mr. Powers stated that we must continue this discussion, and somewhere along the line, the board can take action. Our health care system is so fragmented that we're not sure the best way to move. We need a healthcare system that doesn't force people into this situation.

- **Update on the Development of Consumer Fact Sheet Series with UCSF's Center for Consumer Self Care**

Dr. Schell summarized the activities of this collaborative effort with the UCSF Center for Consumer Self Care, to integrate pharmacy students into public outreach activities. The project involves UCSF pharmacy students developing one-page fact sheets on diverse health care topics for public education.

Nine fact sheets were developed in the first year of the project, and recently translated by the board into Spanish, Vietnamese and Chinese. The board has been distributing these fact sheets at community health fairs, and they are available on the board's Web site.

The committee is working on eight additional fact sheets including falls, consumer reporting of adverse drug events, driving while taking medicines, tips for parents, and allergies to medicines. Dr. Schell stated that interns from other schools of pharmacy expressed interest in developing fact sheets for this project, and will be added to the project.

- **Update on Activities of the California Health Communication Partnership**

Dr. Schell stated that there have been three major campaigns initiated by the partnership since the formation of the group three years ago. The last major campaigns have focused on cancer

screening, which aimed at educating the public about the need for and importance of breast cancer or prostrate cancer screening. Outside funding from a private foundation enabled the use of a vendor that specializes in distributing prewritten consumer columns for small and typically weekly newspapers. There were also public service announcements intended for airing on radio. This greatly expands the exposure and reach of the campaign.

There has not been a meeting of the partnership in recent months, but the Center for Consumer Self Care reaffirmed its support for developing additional outreach campaigns in the future, and hopes to find a means to finance them.

- **Update on *The Script***

Dr. Schell advised that the next issue of *The Script* is being developed for publication for July 2007. It will focus on new regulations and implementation issues in Pharmacy Law.

Mr. Graul commented that the information in *The* Script has been very helpful to pharmacists and their practice.

- **New Board Web Page Under Development**

Dr. Schell stated that the Governor's Office recently developed requirements for a new look to state government's Web pages. So the board will redesign its Web page to conform to the new look for state agency Web pages. The deadline for conversion to the new format is November 2007. Staff has begun work on the new format, and should meet the November deadline.

- **Development of New Consumer Brochures**

Dr. Schell advised that Consumer Outreach Analyst Karen Abbe has initiated work on the development of new public education materials, as well as revising existing materials. Proposed text for the board's "overview" brochure and "complaint" brochure are being reviewed by the Department of Consumer Affairs.

- **Update on Public Outreach Activities**

Dr. Schell advised that board staff have recently conducted six presentations to professional association meetings, and staffed information booths at two public outreach events. He added that future presentations are planned, and that the board places an emphasis on these requests for public and licensee education.

3. Discussion and Action on the SCR 49 Medication Errors Report

Mr. Powers chaired this portion of the meeting.

Mr. Powers advised that on March 6, 2007, the Medication Errors Panel, brought together by SCR 49, released its report entitled "Prescription for Improving Patient Safety: Addressing Medication Errors." A copy of the report was included in the meeting materials, along with the executive summary and an article from The Sacramento Bee.

Former Board Member Sandra Bauer introduced the report. She said she recently served on the panel convened regarding medication errors.

Ms. Bauer emphasized that most errors are made by consumers and that intervention by pharmacists is a very effective way to reduce those errors. In the community pharmacy setting, the three general types of errors and their order of occurrence are consumer self-administration (50 percent), prescribing errors (39 percent) and dispensing errors (11 percent). She also encouraged mandatory reporting of errors to the board, and that errors should not be cited and fined. She said that the panel hadn't come up with all the answers, but she asked the board to develop strategies to address each type of medication error.

Mr. Goldenberg said that it should be obvious to the board that the big numbers are with consumers themselves. He suggested promoting health care through properly counseling patients about their disease states. He further stated that if the board will take the time to hear the recommendations given, it will enable consumers of California to benefit from the knowledge of the whole cadre of pharmacies. The rewards would be enormous. Mr. Goldenberg emphasized that he wants the leadership of the board to focus on this subject, and apply some of our resources to change.

Dr. Ravnan clarified that she was not representing the board while serving on the SCR 49 Panel. She added that prescription labels are not very clear, particularly about warnings. Dr. Ravnan recommended, that from a consumer standpoint, the labels should be made more consumer friendly.

Mr. Powers stated that several aspects, including labeling, are being addressed in proposed legislation in California. We're looking forward to helping consumers and participating in bringing about standardized labeling for consumers. He thanked Ms. Bauer for her comments.

4. Third Quarterly Report on Committee Goals for 2006-07

Mr. Powers advised that a copy of the Communication and Public Education Committee's updated goals for 2006-07 were provided in the materials packet. He asked if there were any questions or comments regarding the document.

LICENSING COMMITTEE REPORT

1. **Report and Action of Items Discussed at the Licensing Committee Meeting of March 7, 2007**

   Chairperson Conroy noted that minutes of the March Licensing Committee Meeting were provided in the meeting materials.

- **Update of the Committee's Strategic Plan for 2007-08**

  During the March 7, 2007 meeting, the committee reviewed the Licensing Committee's strategic plan but recommended no changes. Upon compilation of the minutes, staff recommended two additions to the strategic plan for this committee so that the strategic plan tracks and reports major activities.

  MOTION: Amend and approve the committee's strategic plan for 2007-08 by adding two activities:

  1. Participate with California's schools of pharmacy in reviewing basic level experiences required of intern pharmacists, in accordance with new ACPE standards.
  2. Implement new test administration requirements for the CPJE.

  M/S: POWERS/GRAUL

  SUPPORT: 9 OPPOSE: 0

- **Request by Pacific University of Oregon to Receive Board Recognition for Purposes of Issuing California Intern Licenses**

  Chairperson Conroy stated that the Pacific University School of Pharmacy has requested board recognition under 16 CCR section 1719 so that its students can receive California intern license. She added that the school is currently in precandidate status. According to ACPE, the school is proceeding toward eligibility to candidate accreditation status.

MOTION: LICENSING COMMITTEE: Recommend board approval of Pacific University School of Pharmacy for purposes of issuing CA intern pharmacist licenses to its students.

SUPPORT: 9 OPPOSE: 0

- **Request to Accept the Certification Examination of the Commission for Certification in Geriatric Pharmacy for Continuing Education Credit for Pharmacists**

Chairperson Conroy welcomed Lance O. Hoxie, Executive Director of the Commission for Certification in Geriatric Pharmacy, who informed the board about their geriatric certification examination.

Mr. Hoxie stated that the commission is requesting that the California board recognize the geriatric certification exam for purposes of continuing education. Currently, there are four states that recognize the Commission for Certification for Geriatric Pharmacy (CCGP's) certification examination for continuing education credits: Washington, Indiana, Ohio, and West Virginia.

There are approximately 1300 certified geriatric pharmacist in the United States, Canada, and Australia. It is an international association, but the concentration is nationally, domestically, and on the North American Continent. The 1300 certified pharmacists represent a 30% increase since the end of 2004.

Mr. Hoxie stated while the new Medicare Part D program is still in its infancy, there is evidence that CCGP certification is becoming at least one criterion for selecting pharmacist participation on pharmacy and therapeutics committees and networks of providers used by pharmacy benefit managers and prescription drug plans to provide drug benefit services.

Mr. Hoxie stated that the dilemma is that there are no particular criteria established by the federal government to provide care for the elderly. Literally, any pharmacist could provide services without having to demonstrate the qualifications to do so. He believes that CCGP certification is tangible evidence that a board certified geriatric pharmacist is uniquely qualified to provide pharmacy care to the frail and elderly.

Board Member Goldenberg asked if there were any guidelines on the number of hours required for continuing education or what other states have done.

He wanted to know how long it took an individual to typically take the test.

Mr. Hoxie stated that to become certified, the individual must pass a 3-hour, 150 multiple-choice question examination covering three major areas:

1. Patient Specific
2. Population Specific Activities
3. Disease Specific Issues

A firm specializing in such processes has psychometrically validated the exam, and information is available from www.ccgp.org.

Pharmacists need to be licensed for at least two years to meet the entrance eligibility requirements. There is a 75-85% pass rate on the exams.

Mr. Hoxie stated that all four states recognize three contact hours. He added that CCGP's certification is a five-year certification. In order to re-certify, the pharmacists must reexamine. If the pharmacist does not pass the exam, he or she does not get re-certified.

Mr. Hoxie requested that the board recognize CCGP's certification examination for continuing education and to allow it to be taken at least once every 5 years for purposes of CE.

Board Member Schell asked for the process that the organization uses to develop and validate the exam and how to maintain the integrity of the exam over time.

Mr. Hoxie explained the process as follows:

1. Start by doing a practice analysis
2. Weigh the development or contents of those responses and develop a content outline for construction of the exam.
3. Then use an exam development committee, made up of certified geriatric pharmacists, write questions and answers for the exam under the guidance of Applied Measurement Professionals (AMP)

Twice a year CCGP meets with the exam development committee where they send items into a test bank before they enter it into an exam bank. The exam committee evaluates the results. The exam is now administered on a computer. The psychometric procedures that CCGP uses are the same as the boards in developing the CPJE.

Board Member Graul asked if specific educational or CE requirements were needed in order to take the exam for the first time. And once certified, would there be continuing educational requirements?

Mr. Hoxie answered yes to both questions and explained that the CCGP doesn't require that someone go through a geriatric pharmacy curriculum in pharmacy school or undertakes a postgraduate geriatric pharmacy residency. They do suggest taking a self-assessment exam, which is based on the same content map as CCGP's real exam based on 150 questions. The exam is scored by CCGP and the results are not shared with anyone.

Board Member Ravnan stated that she felt CCGP's content outline was very extensive as to what pharmacists needed to know to become certified. Some might not see CCGP's CE units as an incentive and instead do it just to get their certification. The amount of time spent studying would be far greater than the amount of CE's awarded. She asked Mr. Hoxie if there were any other incentives that may be better.

Mr. Room informed the board that if they chose to grant CE, there was a couple of ways to do so. They could award CE for:

1. Taking the exam whether or not one passes the exam
2. Becoming certified

Mr. Room asked if the participants of the exam have documentation of having taken the exam separate from documentation of actually becoming certified.

Mr. Hoxie answered yes. Exam results are reported in five skill set areas. Participants are informed on where they earned points on the exam. A formal notification is sent notifying candidates of their scores, and certificates are sent to those who passed.

The CCGP will advise and release if a person is certified, when he or she became certified, and when he or she needs to be re-certified.

Mr. Room asked why the CCGP does not go through the normal procedures of becoming an ACPE provider as opposed to coming directly to the board.

Mr. Hoxie responded that the ACPE is solely focused on primary and continuing education. ACPE does not recognize certification programs; however, they do participate and support them.

Mr. Hoxie stated that CCGP was the only organization that divides this type of certification. Other certification bodies look at disease states for other areas of care such as nutritional care or pharmacology.

Mr. Hoxie stated that CCGP is not a governmental agency; seven of the thirteen commissioners are elected by certified geriatric pharmacists.

Chairperson Conroy stated that if the board recognizes the CE, that it might help raise the stature and visibility of the exam and the certification process. The Licensing Committee did not have a recommendation on this proposal, as Mr. Hoxie did not appear before the committee in advance of this meeting.

Board Member Schell and Board Member Ravnan stated that the board should consider recognizing the program, but not for merely for continuing education.

Board Member Goldenberg felt by supporting this program, it would enable pharmacists to provide a higher level of education and knowledge to the public. This might stimulate development of other professional programs.

Board Member Swart stated that the CE hours awarded should be limited to the maximum of amount it takes to take the exam.

Mr. Hoxie replied that as a point of information, currently the four states that recognize the CCPG award three contact hours based on three hours of taking the exam.

Ms. Herold stated that in terms to awarding CE credit, a few years ago the board recognized NABP's PSAM exam for 6 hour of CE credit.

MOTION: Grant 3 continuing education units to those individuals who successfully pass the CCPG exam.

M/S: GOLDENBERG/HOUGH

SUPPORT: 8 OPPOSE: 1

- **Proposed Regulation Requirements for Pharmacies that Compound Medication – Amendments to 16 California Code of Regulations Sections 1716.1 and 1716.2 and the Adoption of Sections 1735-1735.8**

Chairperson Conroy reviewed the board packet stating that at the January 2007 Board Meeting, the board moved to regulation hearing proposed regulations for pharmacies that compound medication, providing patient protections when they receive medication compounded by a pharmacy. These regulations were developed during 2004 while the board was convening its Work Group on Compounding with stakeholders and other regulatory agencies.

At the March 2007 meeting, there was much discussion and public input. They committee feels that more work are needed on the proposed language before it is released for public comment. Before the next meeting of the Licensing Committee in June, staff will work on refining a new draft based on all the input from the public. Chairperson Conroy requested that written comments be submitted to Ms. Herold.

- **Proposals for Possible Future Legislation**

(1) Renaming of the "Multistate Pharmacy Jurisprudence Exam for California" to More Accurately Reflect Examination Content

Chairperson Conroy stated that the Licensing Committee recommends that a more reflective name for the examination is in order. Staff recommends that the board retain the acronym CPJE for the new name, thus the proposal is to change the name of the examination from the California Pharmacist Jurisprudence Examination to the California Pharmacist-Patient Communication and Jurisprudence Examination.

Ms. Herold stated that during the committee meeting, staff promised to bring some alternative proposals for particular name options for the CPJE to this meeting. The reason for the name-change is because people misunderstand what the California Pharmacist Jurisprudence Exam is all about. The law requires that the board test California consultation skills, California pharmacy law and patient specific, situation specific pharmacy experiences that are allowed in California that are not tested on the NAPLEX. So it is a little broader than a jurisprudence exam. Particularly, educators have been complaining that the students who take the exam are very surprised to learn that the exam does not just test law.

Ms. Herold further stated that to maintain the CPJE acronym, the committee is taking a little liberty with the words.

Chairperson Conroy informed the board of three alternative names for CPJE:

1. The California Pharmacist-Patient Communication and Jurisprudence Examination.
2. The California Practice Standards and Jurisprudence Examination for Pharmacists.
3. The Contemporary Practice Standards and Jurisprudence Examination for California Pharmacists.

Chairperson Conroy asked board if anyone had comments or preferences to any of the three alternative names recommended for CPJE.
The majority of the board preferred "The California Practice Standards and Jurisprudence Examination for Pharmacist." The board first voted on the committee's recommendation for a name change.

MOTION: LICENSING COMMITTEE: 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 for Pharmacist.

M/S: SCHELL/GOLDENBERG

SUPPORT: 9 OPPOSE: 0

(2) Establishment of State Protocols for Immunizations by Pharmacists

At the March 7, 2007 Licensing Committee, Jeff Goad, PharmD, a professor at USC, provided information to the committee about a proposal to establish a statewide protocol under which pharmacists could administer immunizations if using the CDC's National Protocol for Vaccinations.

Dr. Goad stated that in 44 states, pharmacists could administer immunizations. In California, pharmacists can administer immunizations under a protocol with a physician. However, some physicians are reluctant to accept the liability for this action, even though the practice has wide support. Dr. Goad distributed information about pharmacy immunization protocols for a number of vaccines.

Under the proposal, which is parallel to the state emergency contraception protocol under which pharmacists can provide emergency contraception, a pharmacist could provide immunizations if following the state protocol.

Chairperson Conroy asked if there were any comments or questions, none were made.

MOTION: LICENSING COMMITTEE: That the board approve the establishment of a state protocol under which pharmacist can provide immunizations. Amend Section 4062 (a)(9) to allow pharmacists to administer immunizations pursuant to the National Protocol for Vaccinations.

SUPPORT: 9 OPPOSE: 0

- **Update of Emergency Preparedness for California Pharmacy**

Chairperson Conroy reviewed the board packet for informational purposes only stating that one of the Governor's key initiatives is emergency preparedness. The board had an important role in this because the provision of pharmaceuticals, and who will provide them, will certainly be an important component in any emergency response.

At the October Board Meeting, the board amended and approved a general policy statement that outlines its expectations for how disaster response in California may proceed. This policy statement is on the board's Web site and was published in the January 2007 *The Script*.

For seven days in late February and early March, the state hosted a conference for state agencies to compile materials for disaster preparedness. California is the first state to actively plan for a

surge when a surge. Several inspectors from the board and Committee Chair Conroy attended part of this training.

- February 27th – March 1st: Surge Response
- March 5th – 6th: Standards and Liability
- March 8th – 9th: Reimbursement

The board recognizes disaster preparedness and emergency response as key board initiatives. The goal is to assure that licensees and the public have better knowledge of what the board will require, and licensees will be comfortable volunteering to participate in emergency response and obtain training before a disaster occurs.

The California Department of Health Services (CDHS) has contracted with PriceWaterhouseCoopers, an international consulting firm, in an aggressive six-month project to address this challenge. The goal of this project is to develop the following:

1. A standards and guidelines manual – that addresses the existing statutes and regulations that currently govern the standards of care, and identifies those that may be flexed or waived during a declared emergency.
2. Operational tools – that will guide healthcare planners in the adoption and implementation of new temporary standards.
3. A training curriculum – to support the planning and preparation for optimal surge response.

During the operational aspects, 1500 issues were identified and ranged from man concepts, logistical operations, field operations, management personnel acquisitions, support organizations, and inventory requirements.

There will to two additional days of meetings in May.

Board Member Goldenberg commented that he was recently an observer at the UCLA campus for an emergency response exercise. The profile of the exercise was; a dirty bomb explodes in a healthcare facility, while terrorists attack the healthcare facility during an 8.0 earthquake, and missiles shoot down helicopters that came in to transfer patients, within a four-hour period. The first thing that came in mind was that we are in a state of war. Secondly, can this ever happen simultaneously.

Ms. Herold added that there are a number of additional planning events going on simultaneously at the state government level.

She attended a daylong meeting coordinated through the Governor's Office that included very high-ranking cabinet officials, including Agency Secretary Marin. The board was recognized for having its disaster response policy.

Board Member Goldenberg stated that Southern California designated every Fire Department to be on-call in the event of an emergency. If you do not know where to go, go to a Fire Department.

Chairperson Conroy stated she attended a surge response meeting on March 1. The general consensus was that there would be a shortage of pharmacists in an emergency situation. Basically, it was about how to get around pharmacist, who else can distribute drugs, medications, and provide group counseling. So, it is very important for all the pharmacy groups to be vocal, participate, and show the knowledge and importance of pharmacists being involved.

Board Member Powers introduced Nicole Rice, Deputy Director for Strategic Planning for the Department of Consumer Affairs who was in attendance at the meeting.

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

Chair Conroy stated this exam has to be reviewed before it can be implemented. Currently, there is no PhD level staff available in the department to do the review.

Board Member Goldenberg, if a person wanted to become a pharmacy technician, could he or she just take and pass the exam to become a pharmacy technician.

Chair Conroy answered yes.

Board Member Goldenberg asked if there were any educational requirements.

Ms. Herold replied that a High School diploma, GED, and fingerprints are required in order to be able to be licensed as a technician.

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

Chair Conroy stated that a number of meetings have been held to create a list of competencies that intern pharmacists should attain by the end of their basic level of intern training.

Board Member Ravnan stated from the board's standpoint, we are be done as there has been consensus of what the basic competencies are for early experience. However, the board has not seen the final report yet. She stated that the next parts of the meetings are faculty development to be able to develop, administer and continue a testing process.

- **Competency Committee Report – Including Announcement of a New Test Administration Company for the CPJE**

  Ms. Herold stated that the Board of Pharmacy has been using Thompson Prometric to administer the CPJE. This contract expires June 1, 2007.

  A new testing firm has been selected, Psychological Services, Inc. or PSI. As soon as the board found out there was going to be a new vendor, the board contacted all pharmacy schools in California. The schools were notified that if students graduated before June 1, 2007, the board would make every effort to qualify them so they could take the CPJE before June 1.

2. Licensing Statistics

Licensing statistics for the first nine months of the fiscal year were provided to the board in the meeting materials.

3. Third Quarterly Report on Committee Goals for 2006-07

The committee's strategic plan update for the third quarter of 2006/07 was provided to the board in the meeting materials.

LEGISLATION AND REGULATION COMMITTEE

1. BOARD ACTION ON REGULATIONS

Acting Chairperson Dr. Schell discussed the Notice to Consumers pending regulation, which was noticed on February 23, 2007. The Comment period was over April 9, 2007. This regulation was noticed without a hearing.

Proposed Amendment to 16 CCR 1707.2 – Notice to Consumers

California Code of Regulations section 1707.2 currently requires every pharmacy to prominently post a "Notice to Consumers" poster as authorized by Business and Professions Code section 4122 or to print the same information on the back of a receipt. 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 is required.

Dr. Schell stated that to date the board has received three comments with regard to the proposal. Based on these comments, staff recommended that the board withdraw this rulemaking, revise the language to address the concerns contained in the comments and file a new notice with revised language.

Dr. Schell referenced the revised language in the board's supplemental packet.

MOTION: Withdraw the initially noticed language and move the revised proposed language to amend 16 CCR 1707.2 – Notice to Consumers and request that board staff notice the new language.

M/S: POWERS/DAZÉ

SUPPORT: 9 OPPOSE: 0

Deputy Attorney General Room stated that the proposed motion would allow the board to move forward with a new 45-day comment period to allow for additional comments.

Dr. Ravnan requested clarification about some of the proposed language and whether the revised language addressed the concerns included in the comments received. Specifically, the obligation the pharmacy has to ensure the timely filling of the prescription in the event a pharmacist declines to fill a prescription for ethical or moral reasons.

Board staff indicated that the language was revised to more accurately reflect the requirements of the statute and should address the written comments received. Staff continued that the previous language noticed stated that the pharmacy was required to refer consumers to another pharmacy should the pharmacist decline to fill a prescription. The language detailing that requirement was changed to indicate that the pharmacy is responsible to assist the consumer to obtain the prescription.

Dr. Conroy requested clarification as to whether the revised language would require a second poster because there were comments that the enabling statute did not require a second poster. Dr. Conroy continued that it is the intent to require a second poster, as the first poster is already full with information.

Executive Officer Herold responded that the current poster is already difficult to read because of all the information contained within the poster. The additional language would more than double the information that must be contained on the poster. Ms. Herold continued that the enabling statute does not prohibit the board from developing and requiring a second poster, however agreed to only require a single poster if the board can incorporate the additional language into the existing poster without compromising the intent of the poster.

Deputy Attorney General Room stated that the board's counsels are in agreement that the board has the discretion to decide that a single poster is impractical.

2. APPROVED REGULATIONS

Dr. Schell reported that the Office of Administrative Law recently approved two board rulemaking files. Both will be reported in the July *The Script*.

- **Repeal of 16 CCR 1717.2 Notice of Electronic Prescription Files**

The repeal of Section 1717.2 of the California Code of Regulations removes a barrier that prevents pharmacists in some circumstances from having full knowledge of all prescription drugs a patient is taking. This section was developed in the early 1980s when pharmacies were beginning to use computers; the repeal of this section will result in better patient care without compromising patient medical record privacy, which is granted by other stronger laws. This regulation change was effective March 26, 2007.

Dr. Schell stated that a copy of the exact language is contained in the meeting materials.

- **Adoption of 16 CCR 1784 – Self-Assessment of a Wholesaler by a Designated Representative-in-Charge**

The adoption of Section 1784 of the California Code of Regulations establishes a self-assessment form and process for wholesalers with the requirement that the designated representative-in-charge complete this form to ensure compliance with pharmacy law. This form will also aid wholesalers in complying with legal requirements of wholesaler operations and therefore increase public safety as a result of this compliance. This regulation will take effect in April 25, 2007.

Dr. Schell stated that a copy of the exact language is contained in the meeting materials.

3. PENDING REGULATIONS

a. Board Adopted Regulations – Pending Administrative Review

Wholesalers have been notified about this equation in a mailing sent earlier in April.

Dr. Schell reported that at the January 2007 Board Meeting, the board voted to adopt two pending regulation changes.

(1) Proposed Amendment to 16 CCR 1706.2 – Abandonment of Application Files

Dr. Schell provided some background on this proposal stating that in 1997, the board established the provisions of 1706.2 to define when an application for a pharmacy, manufacturer, supplier, clinic, medical device retailer, or warehouse of a medical device retailer, had been abandoned. In 2005, the board updated this regulation to add non-resident pharmacy and sterile injectable compounding pharmacy to the regulation and to delete the terms "manufacturer," "supplier," "medical device retailer," and "warehouse of a medical device retailer." This proposed regulation change would update the regulation to add veterinary food-animal drug retailer, hypodermic needle and syringes, pharmacist interns and designated representatives to the regulation. This rulemaking was submitted to the Department of Consumer Affairs on February 16, 2007 and is still in review.

(2) Proposed Amendment to 16 CCR 1775.4 – Reschedule of an Office Conference to Contest a Citation

Dr. Schell summarized the proposed amendment to 16 CCR 1775.4, including that the Board of Pharmacy proposed to amend Section 1775.4 of Division 17 of Title 16 of the California Code of Regulations. The purpose of amending the regulation is to limit the number of times a person or entity can reschedule an informal office conference. This proposal would afford a person or entity the right to request that the informal office conference be rescheduled one time. This rulemaking was submitted to the Department on February 16, 2007.

Dr. Schell stated that the DCA Legal Office has advised the board that this regulation is not necessary, as the board already has the latitude to limit the number of office conferences through board policy. As such this rulemaking will be withdrawn.

b. Board Approved Regulations Awaiting Notice

(1) Section 100 Changes

Dr. Schell discussed board-approved regulations currently awaiting notice.

Dr. Schell summarized pending Section 100 changes. A Section 100 change is used when a regulation requires changes that are technical rather than substantive, for example to update references when statutory law has changed.

- **Proposed Amendment to 16 CCR 1709.1 – Replace the term "Exemptee-in-Charge" with "Designated Representative-in-Charge"**

  In 2004 Senate Bill 1307 (Chapter 857, statutes of 2004) replaced the term "exemptee-in-charge" with "designated representative-in-charge" in pharmacy law, effective January 1, 2006. This section requires an amendment to ensure the consistency with the Business and Professions Code.

- **Proposed Amendment to 16 CCR 1780 – Update the USP Standards Reference Material**

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

  Steve Gray, Kaiser Permanente, commented that before simply changing the reference to 2005, the board needs to carefully examine the changes in the USP volume.

- **Proposed Amendment to 16 CCR 1780.1 and 1781 – Replace the term "Exemptee" with "Designated Representative"**

  In 2004 Senate Bill 1307 (Chapter 857, statutes of 2004) replaced the term "exemptee" with "designated representative" in pharmacy law, effective January 1, 2006. This change would update this section.

- **Proposed Repeal of 16 CCR 1786 – Return of Exemption Certificates**

  This section is outdated and needs to be repealed. The provision requires a wholesaler to immediately return a certificate of exemption to the board if an exemptee leaves the employment of a wholesaler. This regulation is based on prior Pharmacy Law, which linked an exemptee license (designated representative) to a specific licensed wholesaler location.

- **Proposed Amendment to 16 CCR 1715 – Self Assessment Forms**

  This pharmacy self-assessment forms are incorporated by reference in this section. A Section 100 regulation change is necessary to update the self-assessment form to reflect changes in pharmacy law since the form's last revision date (2005).

This form is currently undergoing revisions by staff to ensure all changes in pharmacy law are reflected.

- **Proposed Amendment to 16 CCR 1793.8 – Pharmacy Technicians in Hospitals**

  This section currently references Business and Professions Code section 4052; however, because of recodification of this section included in Assembly Bill 2408 (Chapter 777, Statutes of 2006) this reference requires correction.

2. **Proposed Addition to CCR 1785 – Self Assessment of a Veterinary Food-Animal Drug Retailer**

   Dr. Schell discussed a proposal to adopt section 1785 of the California Code of Regulations which would establish a self-assessment form and process 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.

   Dr. Schell reported that staff is currently developing this form. It will be reviewed at a future enforcement committee meeting and board meeting prior to the initiation of the formal rulemaking process.

3. **Proposed Amendment to 16 CCR 1760 – Disciplinary Guidelines**

   Dr. Schell reviewed the proposed amendment to 16 CCR 1760 – Disciplinary Guidelines stating that 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.

   Dr. Schell reported that staff has additional recommendations for changes that will be presented to the board at the June 2007 Enforcement Committee. Based on the recommendations from the committee, the Disciplinary Guidelines may be ready for board approval at the July 2007 Board Meeting.

c. **Board Approved Regulation Awaiting Conformance with California Building Standards Rulemaking Process**

   At the April 2006 Board Meeting, the 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 injectable solutions. In

April 2006 the Building Standards Commission advised the board that there is a new process to submit items into the California Building Code. Staff will pursue these changes in the new format this year to secure adoption of these standards into the building code.

d. Board Approved Regulations – Proposed Language to be Developed

1) Process and Criteria to Approve Accreditation Agencies for Pharmacies

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 approved 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 will be developed in concert with staff counsel and will be presented at a future Legislation and Regulation Committee meeting.

Legislation

SB 966 (Simitian) Pharmaceutical Drug Disposal

Dr. Schell stated that existing law is silent on how consumers should dispose of unused medications. This bill makes findings and declarations related to the presence of drugs in streams and the negative effects on fish and other aquatic species, discusses the potential impact on human health, and establishes a program by which the public may return unused medications.

Dr. Schell reported that the White House Web site contains information about how consumers can flush their unused medications down the toilet. Dr. Schell suggested that this could be an opportunity for the board to notice the Federal Government that they have some questionable information on the Web site.

Board Member Dazé stated concern about the current language in the bill and that in its current form; a 7-11 could accept unused medications. He suggested that the board offer an amendment to limit the scope of this legislation to accept only prescription drugs.

Mr. Goldenberg asked how positions are recommended to the board coming before the full board.

Executive Officer Herold responded that on some legislation board, for staff to make recommendations to the Legislation and Regulation Committee during the committee meeting.

During the discussion at the committee meeting, the committee can choose to make a recommendation on any bill to the full board.

Discussion included questions about what happens to the drugs once they are returned to the retailer.

Ms. Herold suggested that there is currently no good answers about how a consumer should dispose of unused medications. The board has received a number of press calls about this topic as well. Some pharmacies advise consumers to flush such medicines. Ms. Herold suggested that the board might want to discuss what a voluntary drug take back program would look like. This model could be offered to the author's office as amendments to the bill. This would perhaps allow the board to direct the control mechanisms at the pharmacy and would provide a consumer with the opportunity to do the right thing.

Mr. Goldenberg suggested that perhaps a taskforce should be established to come up with recommendations. He reiterated that wholesalers have a mechanism in place to dispose of unused medications. He suggested that the board act quickly to resolve this problem.

President Powers stated that this is a national problem and suggested that it should be resolved at the national level through the Congress.

Ms. Herold stated that there is a national policy addressing the disposal of unused medications, but it is designed to prevent drug diversion, not to address environmental issues.

Board Member Graul stated that examples of two hospice patients whose families had huge amounts of unused medications to dispose of. Hospice took back the unused morphine, but left everything else with the family. It is a DEA issue with respect to controlled drugs.

Mr. Dazé agreed that this is a national issue, but suggested that the board can come up with a good regulation to deal with the disposal of unused medications in conjunction with the stakeholders.

Supervising Inspector Ratcliff stated that this problem is not limited to pharmacy, but is also an issue for waste management. He suggested a partnership with waste management companies; pharmacy and manufacturers might be able to come up with a workable solution.

Mr. Powers suggested to the board needs to respond quickly as this legislation is moving because of committee deadlines.

Dr. Gray representing Kaiser Permanente stated that this is a huge problem because of the overlapping of jurisdictions including the Department of Health, EPA, DEA, Department of Agriculture, state departments, county health and sewage departments, as well as all city departments. Dr. Gray suggested that because of all this overlap, the language must include a

directing statement that regardless of any law, this is how the disposal of unused medicines is going to be handled.

Dr. Gray continued that according to the Department of Health Services, the pharmacy must obtain a waste hauler's permit prior to taking back medicines and that reverse distributors do not want to take back dispensed unused medicines because a manifest of each item must be completed. DEA prohibits any licensee from taking back any controlled substances that have previously been dispensed to a consumer. The end result of this review included a recommendation that the local county waste management company should dispose of unused medicines in a lined landfill or take them to community centers that are responsible for disposing of items such as paint. However this is again problematic for the DEA as the local county waste companies are not authorized to handle such products.

Dr. Gray outlined other problems with the legislation, including possible product contamination as well as an unfair burden on some retailers who would be responsible for disposing of medicine obtained from another retailer.

Kathy Lynch representing the California Pharmacists Association stated that CPhA participated in a stakeholders meeting but has not heard back from the author's office yet on the results of the meeting. Ms. Lynch stated that CPhA did not have a formal oppose position on the bill, but could after the committee meeting scheduled for the following week because of concerns about this being an unfunded mandate, potential problems with liability associated with taking back unused medicines, as well as the procedure for disposing of the medicines once returned to the pharmacy.

Bryce Docherty representing the California Society of Health Systems Pharmacists stated that CSHP agrees with the problems detailed by the CPhA. CSHP requested that the bill be amended to make it a voluntary program.

President Powers suggested that the board should attend the committee hearing and testify that the board has concerns about the bill but is working with the author's office to explore possible alternatives.

Dr. Schell suggested that the board could take a watch position on this bill.

Dr. Gray offered that the board could take an "oppose unless amended" position and offer the amendment to include the creation of a panel to look into drug disposal and take back programs.

Mr. Dazé suggested that the board could take an "oppose unless amended" position and offer amendments to make the program voluntary as well as to allow the participating pharmacies to charge a disposal fee.

Ms. Herold confirmed her understanding of the board's concerns with this legislation and offered to speak with the author's office.

MOTION: The board will take no position on the bill with the understanding that the Executive Officer will contact the author's office to address board concerns.

M/S: HIURA/CONROY

SUPPORT: 8 OPPOSE: 0

Dr. Schell suggested that four proposals be reviewed together:

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.

Board staff indicated that this proposal has become a 2-year bill. As such the board did not discuss this proposal any further.

AB 1276 (Karnette) Pharmacies: Prescription Containers: Labels

Board staff stated that this proposal was recently amended. This proposal would require a prescription label to include the intended use of the medication, if noted on the prescription by the prescriber.

SB 472 (Corbett) Prescription Drugs: Labeling Requirements

Board staff stated that this proposal was recently amended to establish a panel to develop recommendations for a standardized prescription label that the board will then need to have adopted by the board. Board staff identified some of the concerns with the language in its current form, including the timetable included in the language.

AB 1399 (Richardson) Pharmacies: Prescription Labels

Board staff summarized this proposal, which would require a pharmacy to provide a prescription label that is readable by an assistive technology device if requested. Board staff also highlighted some concerns with this proposal.

Dr. Schell indicated that the committee did not develop a recommended position on any of these proposals.

Dr. Graul sought clarification on the intent of SB 472 and indicated that he was not opposed to the idea. Dr. Graul also stated that he does not have a problem with AB 1276 as long as the physician does indicate in a clear fashion the intended purpose of the medicine being prescribed. Dr. Graul is concerned about the unfunded mandate associated with AB 1399.

Dr. Ravnan stated that there are two different issues with SB 1399: the pharmacist needs to know the intended use of the medication to properly counsel the patient but is concerned that there is no option to allow the physician to notify the pharmacist of the intended use, without requiring the pharmacist to include the information on the prescription label.

Board Member Swart stated that he has a concern with SB 472 in that the label is becoming so prescriptive that there could be unintended consequences such as the label size becoming too large to fit on a prescription vial. Dr. Swart also expressed concern about potential language barriers.

President Powers stated that a number of these proposals are a direct result of the Medication Errors Panel Task Force Report and while there may be problems with the proposals, the board needs to be concerned with medication errors and what it can do to reduce the number of medication errors that occur. Mr. Powers suggested that at a minimum the board should support the efforts of a task force established in SB 472.

Deputy Attorney General Room highlighted a technical flaw with AB 1276. Specifically, the citation and fine provisions for a practitioner who fails to comply with this proposal is included in the 4000 series of the Business and Professions Code. As such it implies that the board will be responsible for assessing administrative fines against practitioners despite the fact that the board really has no jurisdiction over these prescribers.

Executive Officer Herold stated that the board would need to seek an amendment to fix that problem.

The California Pharmacists Association has submitted a letter to all four authors of the labeling bills requesting that they all work together to look at the label comprehensively as opposed to four unfunded mandates. CPhA has some concerns with SB 472 including the number of panel members as well as the timeframe. CPhA has an oppose position on AB 1399.

The California Society of Health System Pharmacists has taken a watch position on all four bills. Several of these proposals seem to speak to health care literacy. CSHP has shared some language with the author's office of SB 472 requesting that health care literacy be considered by a stakeholder taskforce, similar to the work of SCR 49 taskforce.

The California Retailers Association (CRA) has a neutral position on AB 1275 and is working with the author's office on SB 472. CRA has asked the author's office on a number of occasions to include the board at stakeholder meetings. CRA has not taken a formal position on this bill.

CRA has an oppose position on AB 1399 after failed attempts to get clarification about the technology devices to be used and how the requirements would be funded.

Kaiser has a neutral position on AB 1276. Kaiser did participate in the stakeholders meeting on SB 472 and supports the idea of a panel to develop the standardized prescription label. Kaiser has concern that the board would be required to adopt all of the recommendations of the panel as well as the timeframes for implementation detailed in the current version of the bill.

MOTION: That the Board of Pharmacy Support SB 472 if. The amendments would be to require the board to consider the recommendations of the panel, not mandate that the board adopt all recommendations of the panel. In addition, create a new timeline for both the creation of the panel and the implementation.

M/S: POWERS/CONROY

SUPPORT: 8 OPPOSE: 0

MOTION: Watch AB 1276

M/S: POWERS/HOUGH

SUPPORT: 8 OPPOSE: 0

MOTION: Watch AB 1399

M/S: POWERS/HOUGH

SUPPORT: 8 OPPOSE: 0

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

Dr. Schell provided a brief summary of the proposal, which 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 or for an arrest where a final disposition has not occurred within one year.

Deputy Attorney General Room described sections 1203.4 and 1203.4a of the Penal Code. Mr. Room clarified that a dismissal pursuant to these Penal Codes does not provide or require evidence of rehabilitation, nor does it require findings of the court. Rather these codes require mandatory dismissal if a person satisfies the conditions of probation. In the case of a misdemeanor conviction relating to 1203.4a, this could happen in as little as one year. In addition, 1203.4a does not expunge the matter for all instances, such as law enforcement positions or for purposes of professional licensing.

Supervising Inspector Nurse indicated that controlled substances arrests would qualify for such a dismissal under Penal Code sections 1203.4 and 1203.4a.

Mr. Room reminded the board that it must still prove that a crime is substantially related to the duties of the license being sought. This proposal would in some respects reduce the ability of the board to take action against persons that have been convicted.

Nicole Rice from the Department of Consumer Affairs indicated that the DCA has an oppose position on this bill.

MOTION: Oppose AB 1025 (Bass)

M/S: GRAUL/CONROY

SUPPORT: 8 OPPOSE: 0

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

This proposal would allow for the use of General Fund money to purchase needles for the need exchange programs. The committee's recommendation on this bill was Watch.

President Powers stated that the board has a history of supporting such proposals.

MOTION: Committee Recommendation: Watch AB 110 (Laird)

SUPPORT: 3 OPPOSE: 6

The motion failed. A second motion was made to support AB 110.

MOTION: Support AB 110 (Laird)

M/S: GOLDENBERG/POWERS

SUPPORT: 7 OPPOSE: 2

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

This proposal would prevent all health care practitioners from including a "gag clause" in settling a civil action.

Mr. Room provided some legislative history stating that a similar proposal was passed last year and then vetoed by the Governor.

MOTION: Legislation and Regulation Committee: Support AB 249 (Eng)

SUPPORT: 8 OPPOSE: 0

AB 501 (Swanson) Pharmaceutical Devices: Hypodermic Needle and Syringe Disposal

This proposal would require every pharmaceutical company whose product requires the use of a prefilled syringe, prefilled pen needle or other prefilled injection device to provide a method for California patients to dispose of the device.

MOTION: Legislation and Regulation Committee: Support AB 501 (Swanson)

SUPPORT: 8 OPPOSE: 0

AB 543 (Plescia) Ambulatory Surgical Centers: Licensure

This proposal would standardize the licensing requirements for ambulatory surgical centers.

Bryce Docherty spoke on behalf of the sponsor and reiterated the intent of the legislation to include the expansion of the board's ability to issue a clinic license to ambulatory surgical center that are not currently licensed by the DHS but are Medicare Certified or accredited by an approved agency.

Ms. Herold indicated that this bill would allow clinics that are not otherwise licensed and inspected by the DHS to obtain a clinic license from the board. As such, the board will perform annual inspections of the sites that qualify for a license under the provisions in this bill.

MOTION: Legislation and Regulation Committee: Support AB 543 (Plescia) Ambulatory Surgical Centers

SUPPORT: 8 OPPOSE: 0

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

Dr. Schell provided an overview of this proposal, which would require all state agencies to answer public telephone lines within 10 rings.

MOTION: Legislation and Regulation Committee: Neutral on AB 865 (Davis)

SUPPORT: 8 OPPOSE: 0

AB 1587 (De La Torre) Personal Information: Pharmacy

Dr. Schell provided an overview of the proposal, which would make exemptions to the definition of marketing materials, and allow a pharmacy to provide information to consumers that are currently prohibited under the definition of marketing materials. Dr. Schell stated that the committee did not take a position on this bill during its meeting.

Board staff stated that this proposal further defines materials that would be exempted from the definition of marketing materials to allow pharmacies to provide drug information that may currently be prohibited from distribution under the current definition.

Mr. Room stated that this would allow additional information to be included in patient packet inserts and make additional information permissible to be distributed to patients.

Board staff clarified that the conditions under which the exemption would apply include:

- The communication does not involve the sale or transfer of individually identifiable patient information
- The communication assists the pharmacist or pharmacy personnel in the transmittal of useful information regarding a prescription drug dispensed to the patient
- The content of the communication provides information about the dispensed drug, another treatment or therapy for a disease or health condition for which the drug is

dispensed or a drug dispensed within the last three years, general information about a health condition for which the patient's disease may put the patient at risk, or general information about a health condition for which the patient may be at risk given the age or gender of the patient

- The pharmacist is available upon request of the patient to answer questions regarding the communication
- If the communication is paid for, the communication must also include, among other things, the source of the sponsorship in typeface no smaller than 14-point type
- The communication contains instruction in typeface no smaller than 14-point font, describing how the patient can opt out of the portion of the communication that is an advertisement paid for

Mr. Room provided some history, indicating that last year a presentation was given to the board by a group concerned that certain fact sheets prepared by certain associations or manufacturers for the purpose of patient education would be disallowed by the current version of the law.

Dr. Gray, representing Kaiser Permanente stated that these exemptions only apply to face-to-face interaction with a patient. These exemptions would not apply to information being mailed to patients.

President Powers suggested that the board should not take a position on this bill. Tim Dazé agreed.

MOTION: Committee Recommendation: No position on AB 1587 (De La Torre)

SUPPORT: 8 OPPOSE: 0

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

Dr. Schell provided an overview of the proposal which 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. The committee did not establish a position on this proposal during its meeting.

Ms. Herold indicated that the board anticipates a fiscal impact of approximately $24,000 in one time costs to cover programming and implementation.

Mr. Goldenberg suggested that the board oppose this bill.

Board staff informed the board that there is currently a scholarship fund for pharmacists, which allows for a voluntary $25 contribution at the time of renewal. No scholarship money has been

distributed from this fund, and there needs to be at least $200,000 in the fund and only $35,000 has been contributed to date. The next issue of *The Script* will describe this fund.

Mr. Goldenberg stated that he agreed with the intent of the proposal, but did not have enough information about how many scholarships would be awarded.

MOTION: Oppose SB 615

M/S: GOLDENBERG/HIURA

SUPPORT: 8 OPPOSE: 0

Bryce Docherty, representing CSHP stated that their organization felt that the benefit of the bill would outweigh the negative consequences, which for pharmacy technicians would be about $5 a year. As such CSHP took a support position on this bill.

MOTION: Recall the previous vote of the board which took an oppose position on the bill.

M/S: POWERS/HOUGH

SUPPORT: 5 OPPOSE: 3

The motion was passed and the discussion was reopened for discussion.

President Powers indicated that to the degree this proposal could help pharmacy technicians, the board should reconsider its previous oppose position.

Board Member Hough asked if there is a shortage of pharmacy technicians.

Board staff indicated that according to the author's office, there is a shortage in rural areas, and this proposal will help to draw people to become pharmacy technicians in these underserved areas.

Mr. Goldenberg asked what percentage of licensees or applicants this fund would be able to assist and expressed concern that the money could potentially just remain in the fund without being used.

Bryce Docherty stated that the proposal creates the program and the special fund to administer the program. The overhead to run the program also comes out of the special fund.

Mr. Goldenberg stated his concern that this fund would be used to cover the overhead for the program rather than assist pharmacy technicians.

Mr. Docherty indicated that there is a federal definition for underserved areas, including rural as well as high-density urban areas that are medically underserved with a shortage of pharmacists and pharmacy technicians. CSHP weighed the potential benefits and considered the increased role a pharmacy technician plays in a hospital pharmacy. This expanded role allows pharmacists to better utilize their education and expertise.

Board Member Dazé agreed with Mr. Goldenberg's concerns and stated that he did not have enough information to support the proposal.

President Powers again suggested that the board should not oppose the bill.

Board Member Graul asked if the proposed $10.00 incurred with this proposal would be in addition to the proposed fee increase that the board is also considering with proposed amendments to CCR 1749.

Board staff indicated that pharmacy technician fees would not be raised with the proposed regulation change as they are already at the statutory maximum.

A second vote was taken to oppose the bill.

President Goldenberg made a motion to have the board reconsider this position upon receipt of additional information, which would better clarify the actual benefit, including the net amount of money that would be available to pharmacy technicians.

MOTION: Oppose SB 615. The board will reconsider this position upon receipt of additional information, which would better clarify the actual benefit, including the new amount of money that would be available to pharmacy technicians

M/S: GOLDENBERG/HOUGH

SUPPORT: 5 OPPOSE: 3

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. The proposal requires that such nurse practitioners would be required to have additional education as well as 6 months of

special training. The intent of this proposal is to remove the requirement for a nurse practitioner to perform certain functions under the protocol of a physician.

Dr. Ravnan expressed concern about this proposal and stated that physicians have four years of training on how to prescribe medications. Requiring six months of additional training by a nurse practitioner will put an additional burden on the pharmacist to detect and catch medication errors.

MOTION: Watch SB 809

M/S: GRAUL/DAZÉ

SUPPORT: 8 OPPOSE: 0

SB 963 (Ridley-Thomas) Regulatory Boards: Termination

This proposal would remove the Department of Consumer Affairs as the automatic successor in the event a board is "sunsetted" and allow the Joint Committee on Sunset Review to reconstitute the board.

Ms. Herold stated that the Sunset Review Process itself is being reviewed and may change. Ms. Herold also clarified that under current law, should the board be sunsetted, the duties of the board would be placed under the Department of Consumer Affairs.

MOTION: Watch SB 963

M/S: POWERS/DAZÉ

SUPPORT: 8 OPPOSE: 0

SB 993 (Calderon) 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.

Board staff notified the board that the sponsor of this legislation intends to amend the proposal, however, did not provide staff with the specific amendments.

Mr. Docherty notified the board that CSHP has a strong oppose on this proposal and is also in opposition to SB 822. The CSHP opposes this bill because of the potential medication errors

that could result from psychologists prescribing medications, as they do not have sufficient training and knowledge to perform this function. The CSHP is also concerned that the psychologist does not have sufficient training to analyze possible drug interactions a patient might experience with other prescription and nonprescription medications being taken.

MOTION: Oppose SB 993

M/S: HIURA/HOUGH

SUPPORT: 8 OPPOSE: 0

Dr. Schell indicated that the remainder of the legislation provided was for information only and would not be discussed by the board and indicated that the meeting summary from the last Legislation and Regulation Committee Meeting is provided.

SB 606 (Scott) Pharmaceutical Information: Clinical Trial Data

This bill would require drug companies to provide consumers with clinical trial data.

President Powers spoke in support of this proposal.

Staff clarified the requirements of this proposal to include the posting requirements for the information, as well as the types of information that must be provided and the timeframes provided within the proposal.

MOTION: Support SB 606

M/S: POWERS/GRAUL

SUPPORT: 8 OPPOSE: 0

ENFORCEMENT COMMITTEE REPORT

President Powers asked Chairperson Goldenberg to present the report for the Enforcement Committee and the meeting held March 21, 2007.

1. **Report and Action of items Discussed at the Enforcement Committee and Workgroup on E-Pedigree Meeting of March 21, 2007**

- **Proposal to Develop an Ethics Course for Pharmacists Disciplined by the Board**

  At the January 2007 Board Meeting, the board voted to form an exploratory subcommittee to examine the development of an ethics course for pharmacists as an enforcement option as part of discipline. The subcommittee was directed to report back to the board at the October Board Meeting.

  Since the January Board Meeting, President Powers appointed Dr. Ravnan and Dr. Swart to this subcommittee; however, there has been no meeting yet of this group.

  Chairperson Goldenberg stated that the subcommittee will provide a report at the October Board Meeting.

- **Update of the Committee's Strategic Plan for 2007-08**

  Chairperson Goldenberg stated that the committee viewed its strategic plan for relevance and currency, and made two recommendations to keep the plan current with committee activities:

  1. Evaluate establishment of an ethics course as an enforcement option.
  2. Participate in emerging issues at the national level affecting the health of Californians regarding their prescription medicine.

  MOTION: ENFORCEMENT COMMITTEE: Amend and approve the committee's strategic plan for 2007-08 by adding these two activities to objective 1.5 "institute policy review of 25 emerging enforcement issues by June 30, 2011."

  SUPPORT: 9 OPPOSE: 0

- **Letter of Concern to CMS regarding the Federal Deficit Reduction Act's Use of Average Manufacturers' Price as the Reimbursement Base of Medications for Medicaid**

  Chairperson Goldenberg stated that following the last board meeting and in conference with the board's action, a letter was written to CMS about the lack of pharmacy access that could result if reimbursement is made based on average manufacturer's price. A copy of the letter was included in the board packet.

  President Powers asked the board if there were any response for patients.

  Executive Officer Herold stated that she understood that CMS had received 10,000 responses.

Board Member Schell informed the board that 49 senators also spoke up against making this type of change.

- **Report of the Workgroup on E-Pedigree and Summary of the March 8, 2007 EPCglobal Meeting with Board Representatives**

  Chairperson Goldenberg informed the board that there have been two meetings with EPCglobal since the last board meeting. He expressed the encouraging atmosphere he felt at one of the meetings he attended. He stated that people in the room are committed to this project, moving forward, and hitting the some of the board's timelines. Clarification is being asked for timelines not being met. President Powers and Chairperson Goldenberg emphasized the 2009 date repeatedly to stakeholders.

  Chairperson Goldenberg further stated that he truly believes that California and possibly the nation will be a safer place once in place. He thanked and congratulated all stakeholders for their participation and ongoing dialogue.

  Ron Bone, TriChair, EPCglobal Healthcare & Life Sciences Industry Action Group, gave a presentation on the status of EPCglobal as standards development for e-pedigree.

  Executive Officer Herold stated that the EPCglobal presentation will be posted on the Board of Pharmacy Web site following the meeting.

2. Report on Enforcement Actions

The board received a copy of all enforcement actions taken since July 1, 2006.

3. Third Quarterly Status Report on Committee Goals for 2006/07

The board received a copy of the third quarterly status report.

ORGANIZATIONAL DEVELOPMENT COMMITTEE

1. Report and Action of Items Discussed at the Organizational Development Meeting of April 9, 2007

- **Proposed Regulation Change to Increase Fees Effective January 1, 2008**

Ms. Herold stated that for several years, the board has been carefully watching its fund condition to assure that the board maintains a prudent reserve. A report of the board's fund condition has been made at each board meeting for a number of years.

Part of the reason for careful monitoring of the board's fund condition is that for a number of years, the board has spent more than it has collected in revenue. This has been possible because the board has had a reserve in its fund that could be used to fund expenses that exceed revenue collection.

Additionally, the board was owed $6 million from a loan made to the state's General Fund in 2001. This year (2006-07), the state will repay all money borrowed from the board in 2001 to offset the state's fiscal crisis.

Moreover, in July 2007, the board hopes to begin paying its inspectors a $2,000 monthly recruitment and retention differential above their normal salary. The aggregate of this expense will be $576,000.

However, when the $576,000 funding for the differential is added to the authorized spending for 2007-08, it triggers the need to increase fees about six months sooner that the board would have otherwise needed to take effect Jan 1, 2008.

Ms. Herold stated that in the state's 2007/08 budget hearings, the board would get three new positions lost in 2001. However, the board was told to re-direct money in order to get the three new positions because the board's fund could not support any additional expenditures annually.

Anne Sodergren, legislative liaison, stated that the biggest change in fees was the $100 from statutory minimum to the maximum for sterile compounding. The fee schedule increase will be as followed:

	Current Fee	*Proposed Fee*
1. Issuance of pharmacy license	$340.00	$400.00
2. Annual renewal of pharmacy license	$175.00	$250.00
3. Penalty for failure to renew pharmacy license timely	$ 87.50	$125.00
4. Issuance of a temporary license	$175.00	$250.00
5. Issuance of a pharmacy technician license	$ 50.00	$ 50.00
6. Failure to renew pharmacy technician license timely	$ 25.00	$ 25.00
7. Pharmacist application and examination fee	$155.00	$185.00
8. Fee for regarding a pharmacist examination	$ 75.00	$ 75.00
9. Issuance of an original pharmacist license	$115.00	$150.00
10. Biennial renewal of pharmacist's license	$115.00	$150.00

11. Failure to renew biennial pharmacist's license timely	$ 57.50	$ 75.00
12. Issuance or renewal of a wholesaler's license	$550.00	$600.00
13. Failure to renew wholesaler's license timely	$150.00	$150.00
14. Issuance or renewal of a hypodermic license	$ 90.00	$125.00
15. Failure to renew hypodermic license timely	$ 45.00	$ 62.00
16. Issuance or renewal of a license as an out-of-state distributor/non resident wholesaler	$550.00	$600.00
17. Failure to renew out-of-state non resident distributor license timely	$150.00	$150.00
18. Intern pharmacist license	$ 65.00	$ 75.00
19. Fee for transfer of intern hours or verification of licensure to another state	$ 10.00	$ 25.00
20. Fee for the re-issuance of any permit, license, or renewal thereof, which must be reissued because of change in the information, other than name change	$ 60.00	$100.00
21. Evaluation of continuing education courses for accreditation (each hour of accreditation requested)	$ 40.00	$ 40.00
22. Issuance of a clinic license	$340.00	$400.00
23. Annual renew of clinic license	$175.00	$250.00
24. Failure to renew clinic license timely	$ 87.50	$125.00

In the board packet were several projections of board revenue at current and statutory maximum fees. If raised to the maximum level, $1.4 million more in annual revenue will be collected. The board is not able to increase fees higher that the statutory maximum without the Legislature approving the increase via legislation. For ongoing operations, the board will need to seek a fee increase in 2008 increase to become effective in 2009 or 2010.

MOTION: ORGANIZATIONAL DEVELOPMENT COMMITTEE: Move to regulation hearing for the July Board Meeting amendments to 16 CCR section 1749 to increase fees to the statutory limits effective January 1, 2008.

SUPPORT: 9 OPPOSE: 0

- **Update of the Committee's Strategic Plan for 2007-08**

Ms. Herold stated that during segments of committee hearings, the board has requested modifications of various committees' strategic plans and would like for the board to approve the strategic plan with the amendments that were done throughout the whole meeting.

There are no committee changes for the Organizational Development Committee's strategic plan.

At the April Organizational Development Committee, the committee reviewed its strategic plan and has no recommendations to change to the plan for 2007-08.

MOTION: ORGANIZATIONAL DEVELOPMENT COMMITTEE: Approve of the board's Strategic Plan for 2007-08.

SUPPORT: 9 OPPOSE: 0

- **Recognition of Pharmacists who Have Been Licensed 50 Years**

Since July 2005, the board has acknowledged 616 pharmacists who have been licensed 50 years as pharmacists.

- **Board Meeting Dates for 2008**

Chairperson Goldenberg noted that the board meeting dates for 2008 have been set. The proposed meeting dates for the rest of 2007-2008.

2007

- July 24, 25 – Los Angeles
- October 24 and 25 – San Francisco/Bay Area (CSHP's Seminar is October 18-21 in Palm Springs)

2008

- January 23 and 24 – San Diego (CPhA's Outlook is February 7-10 in Sacramento)
- April 23 and 24 – Sacramento (NABP's Annual Meeting is May 17-20 in Baltimore)
- July 23 and 24 – Orange County/Los Angeles
- October 29 and 30 – San Francisco (CSHP's Seminar is October 12-19 in Anaheim)

- **Development of Parameters for Board Recognition of Notable California Pharmacists**

Chairperson Goldenberg stated that the committee is now moving ahead with a trial program to recognize preceptors who have contributed significantly to the training and development of new pharmacists. An article will be printed in the next *The Script*, encouraging those who have a

preceptor who has made a significant difference in training interns, including a number of interns, over a period of time, to nominate the preceptor for board recognition.

The committee will review the nominations and consider whether any or all warrant recognition. Three letters of recommendation will be required.

- **Personnel Update and Training Report**

Chairperson Goldenberg noted that a full Personnel Update was provided in the board meeting materials. The board has all Sacramento-based positions filled – there are no vacancies except for the assistant executive officer position, which is undergoing a reclassification request.

The board also has four inspector and one supervising inspector positions vacant. Development of new civil service hiring lists is underway (this requires a civil service examination) so a list of eligible pharmacists is available from which the board can hire the most qualified. The board was able to recruit for this classification with a statement that a $2,000 monthly recruitment and retention differential was pending approval. The result was an enormous increase in the number of applications – more than 60 for the inspector classification.

Meanwhile, the board is continuing to work to secure the $2,000 differential for all inspectors. The budget proposal to authorize this expenditure is undergoing review by the Senate in the Governor's budget for 2007/08.

- **Budget Report**

A full budget report was provided in the board-meeting packet. An overview is provided below.

Current Year's Budget 2006/07

- Revenue projected: $9,569,203

  Revenue for this year has estimated to be comprised of $5,791,000 in fees and $157,000 in interest on money in the board's contingency fund.

  This year the board is currently projected to receive the final repayment of $3 million from the 2001 loan of $6 million from the board's fund to the state's General Fund during California's budget crisis. There is also an additional $233,000 in interest that will be paid linked to the loan.

  Final revenue for the year also includes additional amounts for cost recovery and citations and fines. During the three quarters of this fiscal year, the board collected $298,427 in citations and fines and $89,776 in cost recovery.

- Expenditures Projected: $8,522,000

Final actual expenditures for the year will be available in August.

Future Budget 2007/08

The Governor's Budget that was released on January 10, 2007 for 2007-08 contains two augments to the board's budget:

- $576,000 increase for a recruitment and retention differential for board inspectors
- Restoration of 3 positions (licensing expediter, enforcement analyst, receptionist); the positions are being restored without an increase in the board's expenditure authority. This means that the board will have to find funding for the positions within its budget. The Department of Finance would not approve an increase in funding for these positions because the board lacks sufficient money in its fund to sustain an increase in expenditures in the future (again, why the board needs to increase fees).

Fund Condition

The fund condition at the end of the next few years if maximum fees are put in place 1/1/08 is estimated as:

	Amount	*Months in Reserve*
2005/06 (actual)	7,285,000	10.3
2006/07	8,077,000	10.3
2007/08	5,448,000	6.8
2008/09	3,297,000	4.1
2009/10	907,000	1.1
2010/11	1,695,000	-2.0

I-Licensing Update

In the board meeting packet was an update on the I-Licensing project that will offer online application and renewal of licenses. 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 is projected to spend $50,000 this 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.

On January 8, 2007, the board transitioned all its pending applications to the department's applicant tracking system. This is a streamlined "platform" upon which transition to the new

I-Licensing system will be made simpler. The board did the transition only because it will aid in implementing
I-Licensing.

Delays in securing vendors and new staff overseeing the project at the Department of Consumer Affairs has probably delayed the project six to nine months, so the board is about 2+ years away from implementing I-Licensing.

Reimbursement to Board Members

The board's quarterly report on reimbursement to board members was provided in the packet.

- **CURES Feasibility Study Report**

The board packet also contained an update on the CURES Feasibility Study, which the board is required to propose with a vendor if money is donated to the board specifically for this purpose.

Specifically, 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 Department of Justice is moving to amend section 11165.5 to require the FSR to evaluate the "near real time access" instead of the currently required "real time access." According to the DOJ and the sponsor of this provision. This section of the Health and Safety Code was intended to create a web-based access system for pharmacists and prescribers to access reported CURES date more timely than the current system which requires a request to the DOJ staff. On-line, real-time access to data was never intended to be part of the FSR (although the current Health and Safety Code is in conflict with this interpretation, this amendment is needed.)

The Board of Pharmacy has no access to the Department of Justices computer systems, nor should we be in the position to be doing a feasibility study report about what it would take to allow them to do this.

Multiple agency committees have been created (Board of Pharmacy, DCA, DOJ, Medical Board, staff and several other individuals) to develop the parameters for the vendor solicitation and to review the proposals that are submitted.

2. Third Quarterly Report on the Committee's Goals for 2006/07

The board meeting packet contained the third quarterly update of the committee's strategic plan.

3. **Approval of Full Board Minutes (January 31 - February 1, 2007 and April 18-19, 2007)**

Ms. Herold informed the board that January board meeting minutes are not yet ready and will be brought to the next board meeting for approval.

ELECTION OF OFFICERS

President

MOTION: Elect William Powers as president of the Board of Pharmacy.

M/S: GOLDENBERG/HIURA

SUPPORT: 9 OPPOSE: 0

Vice President

MOTION: Elect Ruth M. Conroy as vice president of the Board of Pharmacy.

M/S: SCHELL/HOUGH

SUPPORT: 9 OPPOSE: 0

Treasurer

MOTION: Elect D. Timothy Dazé as treasurer of the Board of Pharmacy.

M/S: SCHELL/GRAUL

SUPPORT: 9 OPPOSE: 0

NEW BUSINESS/AGENDA ITEMS FOR FUTURE MEETINGS

There were no additional items mentioned.

RECESS

There being no further business, President Powers recessed the board meeting at 6:03 p.m.

Thursday, April 29, 2007

PETITIONS

- *Petition for Reinstatements*
  Hoda Soliman
  Chu Vu
  Hoichi Cheung
  Dewane McConnell

- *Early Termination and Reduction of Penalty*
  Robert Garlick
  Faramarz (Fred) Ganjian

CLOSED SESSION

The board moved into closed session pursuant to Government Code section 11126(c)(3) to deliberate upon disciplinary cases and petitions for reinstatement, early termination of probation and reduction of penalty.