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

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

DATE: **January 31, 2007 – February 1, 2007**

LOCATION: **Skaggs School of Pharmacy and Pharmaceutical Sciences**
Education Center Rooms 2 and 3, Osler Lane
University of California, San Diego Campus
La Jolla, CA

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.
Andrea Zinder, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Karen Cates, Assistant Executive Officer
Robert Ratcliff, 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

CLOSED SESSION

The board went into closed session on January 31, 2007 at 8:00 a.m. pursuant to Government Code section 11126(a) to discuss the appointment of the executive officer.

CALL TO ORDER

President Powers called the public board meeting to order on January 31, 2007 at 9:00 a.m.

REPORT AND ACTION FROM CLOSED SESSION

President Powers announced that during the morning closed session, the board selected Virginia Herold as executive officer. He further stated that Ms. Herold had been serving as interim executive officer since July 2006. President Powers then performed the induction of Ms. Herold, reading aloud from the proclamation. Ms. Herold affirmed that she would faithfully serve the board as executive officer.

Ms. Herold acknowledged board staff that was present. She thanked staff for their public service and commitment to the important work of the board.

INTRODUCTIONS

President Powers welcomed members of the public, and acknowledged two former board presidents in attendance, John Jones and Raffi Simonian.

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Chairperson Schell advised that he reordered the agenda items in this segment to ensure adequate time for public comments and board discussion regarding pill splitting.

- **Subcommittee on Medicare Drug Benefit Plans**

Chairperson Schell referred to the Meeting Summary of the Subcommittee on Medicare Drug Benefit Plans held on November 30, 2006. The Meeting Summary was provided as part of the board meeting materials, Attachment 1 in the packet.

A variety of testimony was provided prior to and during the Subcommittee held on November 30th. The testimony demonstrated that although many patients are now benefiting from Medicare Part D

plans, there is still a group of patients who are frustrated with obtaining benefits. Patient advocate groups are also frustrated in trying to obtain medicine and coverage for many these patients.

The board responded to the information provided by scheduling a Public Forum on Medicare Part D Plans scheduled for February 1, 2007 from 9:00 - 11:00 a.m. Chairperson Schell announced that the Forum would be held in the same location as the public board meeting, in the Education Center of the UCSD Skaggs School of Pharmacy. The goal of the Public Forum will be to bring stakeholders and policymakers together for problem resolution to benefit patients.

- **Discussion Regarding Pill Splitting by Patients**

Chairperson Schell stated that during the Subcommittee on Medicare Drug Benefit Plans held on November 30, 2006, the committee was asked to consider the safety of pill splitting by patients. Board member Stan Goldenberg serves as Chairperson of the Subcommittee.

Charles Phillips, M.D., an emergency room physician, attended the Subcommittee on Medicare Drug Benefits Plans Meeting held on November 30th, and stated that he was concerned about the practice of pill splitting. Subcommittee Chairperson Goldenberg asked Dr. Phillips to provide information on this topic at a future board meeting.

Chairperson Schell called on Dr. Phillips to make his presentation on the subject of pill splitting.

Dr. Phillips introduced himself as an emergency room physician, currently practicing in Corcoran, California. He stated that he regularly fine tunes proper dosage medication for patients, teaches medication administration, and is experienced in titrating medication.

Dr. Phillips presented a bottle containing cholesterol medication, as a visual display. The bottle contained fragmentation and crumbled residue of drug product at the bottom of the container. Dr. Phillips stated that the crumbled residue was a result of pill splitting. He stated that he has not seen any books on the subject of pill splitting or pill fragmentation, yet the practice is commonplace.

Dr. Phillips stated that he wrote a prescription for himself for a 20-milligram dosage of medicine, and later presented that prescription to a Kaiser pharmacy to fill. The prescription that was filled and provided to him, however, contained a 40-milligram dosage. The medication was provided to him from the Kaiser pharmacy, along with a pill splitter. Dr. Phillips stated that he did not write the prescription that way. He expected 20-milligram dosage medication. He stated that the explanation given at the Kaiser pharmacy window was that it is their policy to provide the higher dosage pill to the patient, along with a pill-splitter.

Dr. Phillips stated that the policy to pill-split is carried out throughout Kaiser pharmacies, VA, and some Medi-Cal units. He stated the policy is carried out for fear of retaliation, peer reviews, and pressure to save costs and increase profits, and that physicians are afraid to speak out. He questioned whether it is ethical to ask patients to pill-halve when there is a standard pill in the lower

dose, particularly for patients who are physically incapable of performing an accurate pill split. He provided an example of a patient by the name of Nick Feldman, who has cerebral palsy. Mr. Feldman can move only his head, not his arms or legs. Yet he has been asked to pill-split, which he is incapable of doing. When Mr. Feldman's attendant is unavailable to perform a pill-split, he cannot take the proper dosage when needed, and that results in muscle pain and other problems.

Dr. Phillips stated that physicians are programmed with pocket inserts that encourage the practice of writing prescriptions to include pill splitting by patients. He stated that even when a prescription for a lower dosage is presented to a pharmacy, the pharmacy technician or pharmacist hits a button resulting in a higher dose medication, along with instructions to the patient that the pills must be split. He said there is no physician orientation book for Kaiser physicians on this policy. He stated that the prescriptions he has written have probably resulted in at least 100 occurrences of pill splitting by patients, as a result of how the pharmacies filled the prescriptions that he wrote.

Dr. Phillips asked Kaiser (in Oakland) for any research they have to support their policy of asking patients to split pills. He stated that no research was provided from Kaiser as a result of his request, but they stated that the VA started the practice, and Kaiser adopted it. Dr. Phillips stated that Kaiser enjoys a budget savings as a result of the practice, and the VA experiences around $40,000,000 in cost savings with the practice of pill splitting. Dr. Phillips referred to a VA study of 442 reports of pill splitting, which resulted in 38 adverse medical events that were not therapeutic to patients. According to the survey, not all pills were split evenly. Inconsistent dosages resulted in medications causing higher reactions one day and lower reactions on other days, including bouncing cholesterol and blood pressure. He also referred to a study of 752 reports of pill splitting that showed 41% of the split pills deviated by more than the accepted weight standard.

Dr. Phillips recommended that the board take a stand on pill splitting and pill fragmentation. He stated that if the board is silent on this issue, it enables the problem. He considers the policy of asking seniors to pill-split is a form of patient abuse. Dr. Phillips referred to a case against Kaiser where the judge said he hadn't heard a lot of noise from regulatory bodies on the subject.

Chairperson Schell opened the floor for questions or comments from the board and the public.

Mr. Goldenberg asked if any state's board had passed an informed consent rule regarding pill splitting.

Dr. Phillips stated that Kentucky's board came close, but only provided a general resolution on the subject of informed consent. He further stated that he has complained separately to California's Medical Board.

Dr. Hiura asked why physicians write these prescriptions when they are aware of the problems, especially when some manufacturers sell 10 milligrams for the same price as 20 milligrams or 40 milligrams.

Dr. Phillips responded that he does not write prescriptions that way, unless the patient specifically states that they cannot afford the medication and they must choose between the medication and food. In that case, Dr. Phillips will write the prescription and inform the patient as to the risks.

Mr. Hough stated that he agreed with Dr. Phillips' concerns, and believed that the issue relates directly to the cost of health care. Mr. Hough stated that patients should be able to have prescriptions filled as their physicians has prescribed, and not be asked to pill split. He also does not want financial decisions of bureaucracies driving medical decisions of doctors.

Mr. Goldenberg stated that the studies have merit, and we should carefully consider how to approach the issue of pill splitting and informed consent.

Chairperson Schell asked if there were any other public comments. Various comments were provided including reference to data from a study at Florida's College of Cardiology showing a safety efficacy window that was not affected by varying weights of split tablets.

Steven Gray, from Kaiser Permanente, provided a copy of an on-line article about pill splitting from Consumer Reports. Dr. Gray stated that although Consumer Reports is not a scientific magazine, they base their recommendations on science. The article listed medications that can be safely split. Dr. Gray stated that physicians and scientists must make decisions on which medications are safe to split, and learn as we go, reversing decisions based on data as applicable. He said that pill splitting devices should be provided free of charge to patients to effectuate pill splitting which he said would be better than using a paring knife.

Dr. Gray further stated that pill splitting is performed nationally and internationally. The practice is encouraged by medical group committees. He stated that the program is voluntary. Dr. Gray said that informed consent would have four types of mandates:

1. on patient
2. on physician
3. on pharmacist
4. on pharmacy

President Powers asked what happens if a patient tells their doctor they do not want to split a pill.

Dr. Gray responded that they'll get the dose they need in a non-split form. But he couldn't guarantee that that practice would be followed by every physician. And he couldn't guarantee that every patient would split a pill, even if asked to do so.

Mr. Dazé commented that there appears to be an educational process in a 3-person chain: patient, doctor, and pharmacist. Mr. Dazé asked if each patient should be informed that they do not have to accept a split pill prescription.

Dr. Gray responded that a doctor should inform their patient that they do not have to accept a split pill prescription. The patient has the right to request the proper dosage.

Anthony Morielli introduced himself as someone who works for the VA, but was not representing the VA. He's a pharmacist and researcher in this area. He stated that he believes the facts about pill fragmentation are being distorted. There are differences in clinical effects, and that 15% variation up or down in any individual dose is acceptable according to the USP. Dr. Morielli took scored tablets approved by FDA for splitting and matched them to unscored lower doses – he said results show same variation – 2% did not meet standard, but none exceed 17% of variation range. Dr. Morielli advocated health care system cost savings, but did agree that safeguards should be in place. Pill splitting has its benefits, and has limited clinical adverse events. At the VA, no one is mandated to split pills. In their computer system, medication will show as a pill-split dose, so the doctor gives the patient counseling along with a pill splitter. Most patients go along with the program. Dr. Morielli asked that the board recommend that doctors apply good science, and give patients options and informed consent.

John Jones introduced himself, stating he was from United Health Care and had 30 years practice in tablet splitting. He didn't recall any negatives with pill splitting, except for discarding some split pills. He provided a handout from United Health Care that indicates that pill splitting is a voluntary program. He further stated that he is on the IOM panel to review the VA drug management system. He suggested a public education program for patients to know when it's appropriate and when it's not appropriate. For example, mental acuity of a patient could affect whether the patient could perform a pill split with accuracy. Cost savings are important to vets, as well as avoiding the Medicare Part D donut hole. Out of pocket costs are reduced by pill splitting. Mr. Jones asked the board to preserve the pill splitting tool.

John Cronin introduced himself as a private pharmacist and attorney in San Diego. He said that a point not raised is that this practice is driven by dollars. The issue belongs in public education. He further stated that Consumer Report articles end up in broadcasts, even on UCSF student fact sheets. Pill splitting can be safe, but the problem is that many consumers start wanting to split everything, including odd-shaped tablets like Lipitor. Dr. Cronin asked the board to keep the matter of informed consent in the Public Education Committee.

President Powers said he has tried splitting a soft small pill that falls apart when he tries to split it. He said there is evidence of problems with pill splitting, and that he will refer the matter to both committees (Public Ed and Enforcement) for further recommendation.

- **Proposed Amendments to Modify the "NOTICE TO CONSUMERS" pursuant to AB 2583 (Nation, Chapter 487, Statutes of 2006)**

Assembly Bill 2583 (Nation) was signed by the Governor and became Chapter 487, Statutes of 2006. The statute requires the board to add to the Notice to Consumers a statement that describes a patient's right to obtain medication from a pharmacy:

1. even if a pharmacist has ethical, moral or religious grounds against dispensing a particular drug, in which case protocols for getting the patient the medication is required.
2. unless based upon the pharmacist's professional training and judgment that dispensing a drug is contrary to law or the drug would cause a harmful drug interaction or otherwise adversely affect the patient's medical condition.
3. unless the medication is out of stock or not available from the pharmacy.
4. unless the patient cannot pay for the medication or pay any required co-payment.

Chairperson Schell referred to Attachment 3 in the board meeting materials, which includes "Version B," the language for the new Notice to Consumers. Version B reflects the language approved in the Communication and Public Education Committee held on January 8, 2007.

Executive Officer Herold clarified that the board voted at the October Board Meeting to create the second Notice to Consumers poster, instead of adding additional language to the current Notice to Consumers poster. To be clear, both posters will be required to be displayed in pharmacies. As an alternative, pharmacies may print the same information from the second poster on a written receipt (Business and Professions Code Section 4122).

Chairperson Schell also referred to a handout containing proposed regulatory language adding subdivision (g) to the California Code of Regulations, Division 17, Title 16, Article 2, §1707.2. The information that must be displayed on the second Notice to Consumers poster must be promulgated in a regulation. The handout reflected language from the poster, converted to text.

Ms. Herold provided a mock-up poster created by the board's graphic designer, Victor Perez. The mock-up contained language from the first Notice to Consumers poster. The actual poster size would be larger than shown in the 8½" x 11" format. Both Notice to Consumers posters should be printed in a similar graphic format, once the regulation for the second poster has been formally adopted and approved by the Office of Administrative Law. The poster mock-up with a yellow margin and black ink reflected feedback from the Communication and Public Education Committee.

The timeline to develop the new Notice to Consumers poster, which will take approximately one year, is:

January 8, 2007:	Communication and Public Education Committee makes suggested changes to the required second Notice to Consumers poster
January 31, 2007:	(January Board Meeting): Board reviews, modifies and sets for regulation notice the proposed language
February 15, 2007:	Staff releases the proposed amendments to Section 1707.2 for the required 45 days of public comment
April 18, 2007:	(April Board Meeting): Board adopts final language as a regulation
June 1, 2007:	Board submits rulemaking file to the Department of Consumer Affairs for review
August 1, 2007:	Board submits rulemaking to the Office of Administrative Law for review

October 1, 2007:	OAL approves rulemaking file Board initiates printing of new Notice to Consumers posters (English) Board has regulation language translated into additional languages
November 1, 2007:	Regulation takes effect
December 1, 2007:	Board distributes printed Notice to Consumers posters (English) to California pharmacies Board obtains translated versions and makes them available on our Web site for downloading

Mr. Goldenberg asked about the five points shown in the mock-up of the current Notice to Consumers Poster, and whether those points need to be covered during consultation with a patient.

Dr. Swart clarified that those points reflect basic information that should be provided during a patient consultation, in addition to other patient consulting requirements.

A discussion ensued as to the board's expectation of licensees for patient consulting requirements. Ms. Herold stated that the purpose of the Notice to Consumers poster is to help patients understand how to optimize their medication. Mr. Goldenberg added that the poster is also designed to help licensees understand what is expected of them during patient consultations.

Chairperson Schell asked if there were any comments from the public. No comments were made.

A recommendation was made to accept the proposed regulatory language provided in the handout. Mr. Room clarified that no motion was necessary because the Communication and Public Education Committee made its recommendation to initiate the process of promulgating the regulation.

MOTION: Communication and Public Education Committee: Move to Regulation Hearing Modifications to 16 CCR Section 1707.2, Notice to Consumers.

SUPPORT: 9 Oppose: 0

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

Collaboration between the board and UCSF's Center for Consumer Self Care began in July 2004 with the intention of including pharmacy students in public outreach activities and developing consumer fact sheets. The board later agreed to co-sponsor a joint Web site with the Center for Consumer Self Care to house the approximately 35 fact sheets that would be developed.

The following nine fact sheets have been completed since the beginning of this project, and have been translated into Spanish, Vietnamese and Chinese:

1. Generic Drugs – High Quality, Low Cost
2. Lower Your Drug Costs
3. Is Your Medicine in the News?
4. Did You Know? Good Oral Health Means Good Overall Health
5. Have You Ever Missed a Dose of Medication?
6. What's the Deal with Double Dosing? Too Much Acetaminophen, That's What!
7. Don't Flush Your Medication Down the Toilet!
8. Thinking of Herbals?
9. Diabetes – Engage Your Health Care Team

Currently under review and editing are at the four additional fact sheets:

1. An aspirin a day? …maybe…check it out!
2. Uncommon Sense for the Common Cold
3. Put the Chill on Myths about Colds and Flu
4. Medication Errors – Mistakes happen…Protect yourself!

One of the original objectives of the fact sheet series was to develop new educational materials for issues emerging in health care for which there was no (or little) written consumer information available. Since that time, public outreach material from the FDA and other entities has been identified that duplicates some of the topics shown on the list of facts sheets to be developed.

The committee will reassess the current fact sheet series to ensure that the project does not languish, and that meaningful information is provided to consumers and licensees per the board's strategic plan.

Chairperson Schell introduced the board's new Public and Licensee Education Analyst, Karen Abbe, and stated that one of her duties will be to develop new public outreach material.

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

The board is a founding member of the California Health Communication Partnership. This group is spearheaded by UCSF's Center for Consumer Self Care to improve the health of Californians by developing and promoting consumer health education programs and activities developed by the members in an integrated fashion.

There have been three major campaigns since the formation of the group approximately three years ago. The last campaign ended in fall 2006, and was the second year of the cancer screening campaign, which aimed at educating the public about the need for and importance of breast cancer and prostrate cancer screening.

A video display of CPhA's "Priceless" was shown during the Communication and Public Education Committee Meeting held on January 8, 2007. The video was shown as an example of public education that can demonstrate the value of pharmacists' care. The video's theme was that priceless moments are added to people's lives as a result of pharmaceuticals and the intervention and knowledge of pharmacists.

There has not been a meeting of the partnership since September 2006. At that meeting, the partnership intended development of future outreach efforts for generic medicine and diabetes and aspirin. Also under consideration was the development of public education campaigns about pharmacist-to-patient consultation since many consumers are not aware of this requirement and how this can benefit their health. The committee also suggested that some form of outreach to educate other health care providers about a pharmacist's requirement to consult would benefit both providers and patients.

- **Update Report on *The Script***

Chairperson Schell stated that the January 2007 issue of *The Script* was published and mailed to pharmacies and wholesalers in January. A copy is also posted on the board's Web site. The focus of this issue is on new pharmacy law and regulations. The board's graphic designer, Victor Perez, designed this issue.

The Pharmacy Foundation of California is seeking sponsorship to mail this newsletter to all California-licensed pharmacists.

The next issue of the newsletter is being developed for publication for July 2007. It will focus on new regulations and implementation issues in Pharmacy Law.

- **Development of New Consumer Brochures**

Chairperson Schell stated that Public and Licensee Education Analyst Karen Abbe started with the board on December 1st. The restoration of her position returns one of two related positions lost during hiring freezes in 2001. The main focus of her position will be to develop consumer and licensee educational materials. (Retired Annuitant Hope Tamraz will continue to work on *The Script*.)

a. Consumer and Licensee Materials

- Board of Pharmacy Information Brochure
  The board lacks an adequate descriptive brochure about its mandate, jurisdiction, licensees and complaint handling processes. Two brochures are under development – one an "overview" brochure, and the other reflecting the board's complaint handling process.

- Prescription Drug Discount Program for Medicare Recipients
  The board will revise its "Prescription Drug Discount Program for Medicare Recipients" brochure that was developed in response to SB 393 (Speier, Chapter 946, Statutes of 1999). This state program allows Medicare recipients to obtain medications at the Medi-Cal price if the patients pay out of pocket for the medication. The revised brochure will mesh with the Medicare Part D Plan benefits that became available to beneficiaries in 2006.
- Information Fact Sheets for Applicants
  The board has a great wealth of information contained in its instructions for the pharmacist exam. However, some applicants do not read this information or perhaps do not retain it. Separate fact sheets will be developed on information about applying for the CPJE or a California intern pharmacist license specifically for pharmacists licensed in other states. Another fact sheet will include information regarding how foreign graduates can qualify for a pharmacist license in California.

b. Information on Preventing Prescription Errors

Staff will develop a section of the board's Web site into a resource on preventing medication errors. The board has been actively involved in a number of activities aimed at reducing errors, including the quality assurance program requirements mandating pharmacies to evaluate every prescription error. The Web site will include data such as that presented at the July 2006 Board Meeting on prescription error data identified by the board through investigations of consumer complaints. It will also include information from other sources, such as ways to prevent errors and frequently confused drug names. It will have links to Web site and other material as well.

- **Update on Public Outreach Activities**

Chairperson Schell stated since the last board meeting, board staff provided four continuing education presentations, made three presentations at conferences or association meetings, and staffed a booth at an Ask A Pharmacist event.

- **Second Quarterly Report on Committee Goals for 2006/07**

Chairperson Schell stated that the updated Communication and Public Education Committee Strategic Plan provided in the meeting materials packet. Several tasks have been completed towards the committee's goal.

LICENSING COMMITTEE REPORT

Chairperson Ruth Conroy provided a report of the September 20, 2006 Meeting. She noted that minutes of this Licensing Committee Meeting are provided in **Attachment A** of the board meeting packet.

- **California Schools of Pharmacy Project to Identify and Test on the Professional Competencies that Should be Achieved by the End of Basic Intern Experience**

Chairperson Conroy stated that the board was recently advised about a review of the intern experience component of pharmacy education that is being initiated by California's schools of pharmacy. This group will examine both the required and elective components of ACPE approved intern experience at both the basic (IPPE) and advanced (APPE) levels. The project will be called the California Pharmacy IPPE/OSCE Initiative (OSCE is the acronym for objective structured clinical examination). The goal is to develop an assessment exam to assess intern experience at the basic level. There is currently no assessment method used in California for any intern experience; California law requires only the completion of 1,500 hours of intern experience that complies with ACPE requirements (basic and advanced).

The California pharmacy schools are collaborating in this initiative to determine the competencies that students should achieve by the end of their introductory pharmacy practice experiences (IPPEs) and before starting their advanced pharmacy practice experiences (APPEs). This initiative is in response to new ACPE accreditation standards that spell out how much time students must spend in IPPEs and APPEs rather than what they should learn (outcomes).

One motivating concern of the group is that laws requiring a specific duration of experience (i.e., 1,500 intern experience hours) -- but without specifying the components to be gained from the experience -- are not beneficial.

The goals of the initiative are to:

1. Reach consensus on the basic foundational competencies that all pharmacy students in California should master during basic intern experiences.
2. Train faculty members from each pharmacy school in California how to develop and administer an OSCE-based assessment.
3. Develop a validated and standardized OSCE-based examination to assess achievement of the basic competencies.
4. Develop a mechanism to assure replenishment of the OSCEs and exam security in the future.
5. Petition ACPE to accept an OSCE-based assessment for basic experience as evidence of compliance with specific ACPE standards.

The timeline aims for incorporation of the standards during academic year 2007-08.

Chairperson Conroy stated that President Powers has appointed Board Member Susan Ravnan as the board's representative to this group.

Dr. Ravnan stated that the students enjoy the experience portion, however, if it is not quality experience, students might be discouraged because they would not benefit from it. She further stated that in the long run that it would be good, yet extremely time consuming.

MOTION: Licensing Committee: The Board of Pharmacy support and participate in this project.

SUPPORT: 9 OPPOSE: 0

- **Request from California Pharmacy School Intern Pharmacists to Increase the Number of Intern Hours That Can Be Earned Outside a Pharmacy from 600 to 1,000 Hours**

Under current law, an intern must earn 1,500 hours of intern experience. California law requires that a minimum of 900 hours of experience be earned in a pharmacy, under the supervision of a pharmacist. The remaining 600 hours of intern experience can be obtained outside a pharmacy, but this experience must still be done under the supervision of a pharmacist and be substantially related to the practice of pharmacy. California pharmacy students typically earn these 600 hours for school-required experience training during the fourth year (clinical clerkship).

Chairperson Conroy stated that at the March 2006 Licensing Committee Meeting, students from various California pharmacy schools requested that the board amend its regulations to allow up to 400 hours more (for a total of 1,000 hours) of intern experience that can be earned under the supervision of a pharmacist, but outside a pharmacy. At the March meeting, students were asked to compile information and return to the committee. The December 2006 Licensing Committee Meeting was the next opportunity for the students to return.

The students have been invited to this Board Meeting for additional discussion, but apparently were not able to appear.

According to the pharmacy students, opportunities for pharmacists have expanded beyond the traditional areas of community and hospital practice settings. Many students would like the opportunity to gain experience in the pharmaceutical industry, managed care, regulatory affairs and association management, but are unable to do so because they cannot earn intern hours for this experience. As part of the pharmacy school curriculum, students complete various rotations in their first and fourth years in both community and hospital pharmacy. In the fourth year, pharmacy experience is more clinical.

The students believe that even if the board were to change the ratio of intern hours as they propose, a large percentage of students would still earn the majority of their intern hours in a pharmacy. However, this new ratio would allow those students who show proficiency in pharmacy settings to be able to expand their experience in other areas.

The committee allowed considerable discussion during the meeting. Various options were discussed including a possible addition of 400 hours to the intern experience requirement (to total 1,900 hours) to permit such additional experience.

However, discussion also included the need for students to thoroughly understand the workings of a pharmacy, and why such experience is so important to a pharmacist's future as a supervisor of pharmacy functions and personnel.

The committee concluded that without a solid understanding of and actual experience in pharmacies, pharmacists will lack critical knowledge about pharmacy operations and practices because sufficient core experience in a pharmacy is lacking.

Chairperson Conroy stated that committee concluded that it is premature to move forward with the students' proposal at this time. Instead the committee decided to wait for the results of the IPPE/OSCE Project being launched this month by California's pharmacy schools that will establish a competency exam to assess basic pharmacy intern skills before recommending any changes in the ratio of intern hours.

- **Proposed Regulations 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 stated that the committee reviewed proposed regulation language that would establish parameters for pharmacies that compound medication for patients. This language was developed in 2004 as a work product following completion of the board's Workgroup on Compounding. Legislative proposals were also developed as another work product of this workgroup, but the legislation containing these provisions was dropped during the final stages of the 2006 legislative session due to opposition that could not be resolved.

The Workgroup on Compounding was formed to evaluate whether a distinction could be made between compounding by a pharmacy and manufacturing operations that are performed by a drug manufacturer. However, the group was unable to develop standards to distinguish when a pharmacy has crossed from compounding into manufacturing, and thus would be subject to licensure as a manufacturer. Instead, a legislative proposal and draft regulations were developed to establish standards for pharmacies that compound medication, leaving to the Department of Health Services or the FDA the determination of when a pharmacy is manufacturing.

Chairperson Conroy stated that the Licensing Committee now recommends that the board move forward with the regulation language that was developed in 2004 for pharmacies that compound. These requirements will establish standards for pharmacies that do compound, providing patient protection when they receive medication that has been compounded by a pharmacy. The proposed regulation changes are provided in Attachment 3, in the board packet.

What is missing from the regulations and the regulatory scheme that was initially envisioned by the board in 2004 is the authority for one pharmacy to compound medication for another pharmacy. This practice is currently allowed by Business and Professions Code section 4123 only for parenteral products.

During the Licensing Committee Meeting, various stakeholders made recommendations for slight modifications to the regulations. The individuals were asked to submit the comments in writing so that the language can be finalized. These comments have not yet been submitted to the board.

Modifications to the regulation can be made at the March 7, 2007 Licensing Committee Meeting and final language shared with the board at the April Board Meeting for final review and approval before being released for public comment.

Dennis Ming, Board of Pharmacy Inspector, encouraged the Board to move this proposed regulation forward. He asked the board to consider a deadline, leaning towards the end of February 2007. This would allow stakeholders to submit their comments and give staff time to collate information so that it could be presented to the Licensing Committee to work with, rather than postpone this three-year continuing process.

MOTION: Licensing Committee: The board moves to public notice this regulation package following consideration of amendments from stakeholders at a future meeting.

SUPPORT: 9 OPPOSE: 0

- **Emergency Preparedness for California Pharmacy**

Chairperson Conroy stated that one of the Governor's key initiatives is emergency preparedness. The board has 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 2006 Board Meeting, the board approved a general policy statement that outlines its expectations for how disaster response involving the Board of Pharmacy's jurisdiction could proceed. A copy of the final policy statement was published in the January 2007 issue of *The Script,* and is on the board's Web site.

Over the coming months, the board will work with the Department of Health Services to establish procedures for emergency response. 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.

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

  In September, the Licensing Committee initiated discussion about a new pharmacy technician examination, the Exam for the Certification of Pharmacy Technicians (ExCPT). This exam has been developed by the Institute for the Certification of Pharmacy Technicians.

  This examination is accepted by Connecticut, New Jersey, Minnesota, Oregon and Virginia as a qualifying route for registration for pharmacy technicians. According to material provided by the institute, the exam is a computer-based exam, which is administered in 700 locations nationwide. The National Community Pharmacists Association and the National Association of Chain Drug stores support use of the exam.

  At the October 2006 Board Meeting, the board directed staff to initiate a review of the ExCPT, and whether the examination is job related and has been validated as required by California Business and Professions Code section 139.

  To use the ExCPT exam as a qualifying method for pharmacy technician licensure, either a statutory or regulation amendment needs to be adopted. The board should not act to implement this exam until this review is completed.

  Within the Department of Consumer Affairs is the Office of Examination Resources. This office provides examination and psychometric services to professional and vocational licensing boards in the department. At the current time, this office is undergoing recruitment for a chief. Until such time as a new chief is hired, the board probably should not initiate a review of the ExCPT examination using this office.

  Alternatively, the board could direct what organization the ICPT could submit its exam to for independent evaluation. This is a process suggested by the American Society of Health System Pharmacists (which is also an owner of the Pharmacy Technician Certification Board Examination).

  Chairperson Conroy stated that the committee recommend no action on this agenda item, pending the hiring of a psychometric expert by the Department of Consumer Affairs.

- **National Provider Identifier**

  Chairperson Conroy stated that one component of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) required that the Health and Human Services Agency adopt a unique health identifier for health care providers. On January 23, 2004, the government published the final rule creating the National Provider Identifier (NPI) as the identifier.

All HIPAA-covered providers, whether they are individuals or companies, must obtain an NPI for use in HIPAA covered, HIPAA standard transactions (e.g., NCPDP for retail prescription drugs). This means that pharmacists and pharmacies will need to obtain an NPI. Once issued, a provider's NPI will not change, even if a pharmacist's job or pharmacy location changes. Information about the NPI is provided in the Board Meeting materials in Attachment 6.

- **Competency Committee Report:**

Chairperson Conroy asked Ms. Herold to provide the report.

Ms. Herold stated that the Office of Examination Resources (OER) within the Department of Consumer Affairs is seeking a new contract with a vendor to provide computer based testing through a Request for Proposal (RFP) process. The board uses this contract to administer the CPJE. The current contract expires June 1, 2007.

Ms. Herold state that total of 1,633 applicants took the CPJE in fiscal year 2005/06. Of the 1,633 applicants, 325 failed the CPJE while 1308 passed the CPJE. The pass rate for the CPJE in fiscal year 2005/06 is 80 percent.

RECOGNITION OF PHARMACISTS

The Board recognized Dr. Mel Baron, former Assistant Dean at the University of Southern California for his service as a pharmacist for 53 years. Dr. Baron thanked the board and presented the board members with honorary USC pharmacist pins.

Chairperson Goldenberg thanked Dr. Baron for all his efforts and contributions as a pharmacist and pharmacist educator.

LEGISLATION AND REGULATION COMMITTEE

Board Action on Regulations

- **Proposed Amendment to 16 CCR 1775.4 – Reschedule of an Office Conference to Contest a Citation**

Chairperson Zinder advised the board that there were rulemaking documents provided in the board packet.

She stated that the board proposes to amend Section 1775.4 of Division 17 of Title 16 of the California Code of Regulations. The purpose for amending the regulation is to limit the number of

times a person or entity can reschedule an informal office conference. Currently there is no provision to allow for a person or entity to reschedule the informal office conference once scheduled. This proposal would afford a person or entity the right to request that the informal office conference be rescheduled one time, which was a provision in the prior regulation, inadvertently deleted when the regulations were amended several years ago.

The regulation was noticed on December 22, 2006. The comment period is over February 5, 2007, however staff counsel advised that the board may take action on this pending regulation at the January Board Meeting, even though the 45-day period has not run, as long as a motion is made to adopt the regulations as noticed, absent any negative comments or recommendations for substantive changes.

MOTION: Legislation and Regulations Committee: Adopt Proposed Amendment to 16 CCR 1775.4 - Reschedule of an Office Conference to Contest a Citation and delegate to staff to compile the rulemaking file. If negative comments are received before the close of the comment period, staff is to return the regulation to the board for consideration at the April 2007 Board Meeting.

SUPPORT: 9 OPPOSE: 0

Specific Language

Amend Section 1775.4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

CCR 1775.4 (a) Any person or entity served with a citation may contest the citation by appealing to the board in writing within 30 days of the issuance of the citation. Appeals shall be conducted pursuant to the adjudication provisions of the Administrative Procedure Act. (Government Code Section 11500 et seq.)
(b) In addition to requesting a hearing, as provided for in subdivision (a), the person or entity cited may, within 14 calendar days after service of a citation, submit a written request for an informal office conference, The person or entity cited may contest any or all aspects of the citation. The informal office conference will be conducted by the executive officer or his/her designee within 30 calendars days of receiving the request. Persons or entities may reschedule an informal office conference once by submitting a written request at least 2 days in advance of the scheduled office conference.
(c) The executive officer or his/her designee shall hold an informal office conference upon request as provided for in subdivision (b) with the person or entity cited and their legal counsel or authorized representative if they desire representation at the informal office conference. At the conclusion of the informal office conference, the executive

officer or his/her designee may affirm, modify or dismiss the citation, including any administrative fine levied or order of abatement issued. The executive officer or his/her designee shall state in writing the reasons for their action and serve or send by certified mail, a copy of their findings and decision to the person or entity cited within 14 calendar days from the date of the informal office conference. This decision shall be deemed to be a final order with regard to the citation issued, including the administrative fine levied and/or an order of abatement.
(d) The person or entity cited does not waive their request for a hearing to contest a citation by requesting an informal office conference after which the citation is affirmed by the executive officer or his/her designee. If the citation is dismissed after the informal office conference, the request for a hearing on the matter of the citation shall be deemed withdrawn. If the citation, including any administrative fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. If a hearing is requested for the subsequent citation, it shall be requested within 30 days of the issuance of the subsequent citation.

Note: Authority cited: Sections 129.5, 148 and 4005, Business and Professions Code. Reference: Sections 125.9, 148, 684, 4067, 4127.4 and Business and Professions Code and Section 56.36 of the Civil Code.

- **Proposed Amendment to 16 CCR 1706.2 – Abandonment of Application Files**

Chairperson Zinder referred to the rulemaking documents provided in the board packet and provided a brief history.

She stated 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, 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.

The regulation was noticed on December 22, 2006. The comment period is over February 5, 2007, however staff counsel advised that the board may take action on this pending regulation at the January Board Meeting, even though the 45-day period has not run, as long as a motion is made to adopt the regulations as noticed and absent any negative comments or recommendations for substantive changes.

Dr. Schell requested clarification on the procedures when an application is abandoned.

Staff responded that the records are retained in compliance with the board's records retention schedule, and then confidentially destructed.

MOTION: Legislation and Regulation Committee: Adopt Proposed Amendment to 16 CCR 1706.2 – Abandonment of Application Files and delegate to staff to compile the rulemaking file. If negative comments are received before the close of the comment period, staff is to return the regulation to the board for consideration at the April 2007 Board Meeting.

SUPPORT: 9 OPPOSE: 0

Specific Language

Amend Section 1706.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

CCR 1706.2. (a) An applicant for a license to conduct a pharmacy, non-resident pharmacy, sterile injectable compounding pharmacy, wholesaler, out-of-state distributor, or clinic, veterinary food-animal drug retailer, or to sell hypodermic needle and syringes who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his, her or its file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements in effect at the time of reapplication.
(b) An applicant for a pharmacy technician license or a designated representative license who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.
(c) An applicant who fails to pay the fee for licensure as a pharmacist required by subdivision (f) of section 1749 of this Division within 12 months after being notified by the board of his or her eligibility be deemed to have abandoned the application and must file a new application and be in compliance with the requirements in effect at the time of reapplication.
(d) An applicant to take the pharmacist licensure examinations who fails to take the examinations within 12 months of being deemed eligible, shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements in effect at the time of reapplication.
(e) An applicant for a pharmacist intern license who fails to complete all application requirements within one year after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4029, 4030, 4037, 4042, 4043, 4053, 4110, 4112, 4115, 4120, 4127.1, 4141, 4160, 4161, 4180, 4190, 4200, 4201, 4202, 4203, 4204, ~~and~~ 4205, and 4208, Business and Professions Code.

- **Section 100 Changes**

At the January 8, 2007 Legislation and Regulation Committee Meeting, board staff presented two additional Section 100 changes for and board approval.

1. Amend CCR 1715 - Self Assessment Forms
   A section 100 regulation change is needed to update the self-assessment form to reflect changes in pharmacy law since the forms last revision date.

2. Amend CCR 1793.8 – Pharmacy Technicians in Hospitals
   This section currently references Business and Professions Code section 4052; however, because this section was recodified by Assembly Bill 2408 (Chapter 777, Statutes 2006), this reference section requires correction.

   There were no questions or comments from the board or the public specific to these proposed Section 100 changes.

MOTION: Legislation and Regulation Committee: Approve the amendments to CCR 1715 – Self Assessment Forms and CCR 1793.8 – Pharmacy Technicians in Hospitals

SUPPORT: 9 OPPOSE: 0

- **Proposed Addition of CCR 1785 – Self Assessment Form for Veterinary Food Animal Drug Retailer**

At the January 8, 2007 Legislation and Regulation Committee Meeting, board staff recommended the adoption of section 1785 of the California Code of Regulations to establish a self-assessment form for veterinary food-animal drug retailers and require the designated representative in charge to complete this form to ensure compliance with pharmacy and wholesaler law. This self assessment would also aid these licensees in complying with legal requirements of their operations and therefore increase public safety as a result of this compliance.

Public comment included clarification of this requirement, how frequency this form must be completed and by whom.

Board staff responded that this proposal is similar to the requirement for pharmacies and the recently adopted self-assessment requirement for wholesalers. In general, a designated representative-in-charge would be required to complete the self-assessment form every two years.

There were no additional questions or comments from the board or the public.

MOTION: Legislation and Regulation Committee: Approve the addition of 16 CCR 1785 – Self Assessment of a Veterinary Food-Animal Drug Retailer.

SUPPORT: 9 OPPOSE: 0

- **Approved Regulations**

Board members were advised of two regulations recently approved by the Office of Administrative Law.

(1.) Repeal of CCR 1717(e) and the addition of CCR 1713 – Prescription Drop Boxes and Automated Self-Use Delivery Device for Refill Prescriptions

Section 1717 of the California Code of Regulation was repealed and Section 1713 of the California Code of Regulations was added to Title 16 to allow pharmacy patients the ability to use a vending-like machine located near the pharmacy to obtain their refill medications if they choose to do so. This regulation allows the use of a prescription drop-off boxes outside the pharmacy as a means to leave a prescription for a pharmacy to fill later. These changes became effective January 26, 2007.

(2.) Amend 16 CCR 1793.7 and add 16 CCR 1798.8 – Pharmacy Technician Checking Pharmacy Technicians in an Acute Care Hospital Setting.

Section 1793.7 was amended and Section 1798.8 of the California Code of Regulations was added to define the conditions under which a specially trained pharmacy technician may check the work of another pharmacy technician in an acute care pharmacy setting. This regulation took effect on January 5, 2007.

There were no comments by the board or public about the recently approved regulations.

- **Pending Regulations**

The board was advised about the status of pending regulations.

(1.) Repeal of 16 CCR 1717.2 – Notice of Electronic Prescription Files

The repeal of Section 1717.2 of the California Code of Regulations would remove a barrier that prevents pharmacists in some circumstances from having full knowledge of all prescription drugs a patient is taking. The repeal of this section will result in better patient care without compromising patient medical record privacy.

The board voted to adopt this regulation at the October 2006 Board Meeting. This rulemaking was filed with the Office of Administrative Law on January 9, 2007.

(2.) Adoption of 16 CCR 1784 – Self-Assessment form of a Wholesaler by a Designated Representative-in-Charge

The adoption of Section 1784 of the California Code of Regulations would establish a self-assessment form for wholesalers and the requirement that the designated representative-in-charge complete the 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.

The board voted to adopt this pending regulation at the October 2006 board meeting. This rulemaking was submitted to the Department of Consumer Affairs on December 28, 2006.

- **Section 100 Changes awaiting completion**

Staff reviewed the previously approved Section 100 changes, which are changes without any regulatory effect. The changes make regulations congruent with statutory changes.
The board has previously approved all of these proposals.

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 is updated and published annually. Consequently, this

section requires an amendment to amend Section 1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards.

(1.) 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 section requires an amendment to ensure the consistency with the Business and Professions Code.

(2.) Proposed Repeal of 16 CCR 1786 – Return of Exemption Certificates
This section is outdated and needs to be repealed. The provision requires a supplier 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.

- **Rulemaking Awaiting Notice**

Proposed Amendment to 16 CCR 1760 – Disciplinary Guidelines

In addition to the Section 100 changes listed above, several meetings ago, the board approved amendment to 16 CCR 1760 – Disciplinary Guidelines.

This rulemaking will allow the board to use the revised 2007 edition of this publication when deciding on appropriate disciplinary action to take for violations of Pharmacy Law. Staff has additional recommendations for changes that will be presented to the board at the April 2007 Board Meeting.

- **Board Approved Regulations Awaiting Conformance with California Building Standards Rulemaking Process**

Board members were provided a brief overview of the status of the changes required to the California Building Standards.

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 parenteral solutions. Last summer, 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.

- **Board Approved Regulations – Proposed Language to be Developed**

Board members were advised about the status of board approved regulations requiring language to be developed to proceed with the rulemaking process.

(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 the next Legislation and Regulation Committee meeting.

(2.) Notice to Consumers, Proposed Amendment to 1707.2

Chairperson Zinder stated that in conformance with AB 2583 (Chapter 487, Statutes of 2006), the board is required to revise the Notice to Consumers poster that is provided to each pharmacy as required in Business and Professions Code section 4122 and defined in 16 CCR 1707.2. This proposal was acted upon earlier at this Board Meeting.

(3.) Proposed Amendment to 16 CCR 1707.3

Currently this regulation requires a drug utilization review on a new prescription. The recommendation proposed would require this review on all prescriptions. It would not require consultation on all prescriptions.

The committee had generally supported this proposal but recommends a discussion at the January 2007 Board Meeting.

Mr. Goldenberg questioned how board inspectors would know that a pharmacist did complete the drug utilization review.

Board staff responded that board inspectors observe pharmacists as part of the inspection process.

Mr. Room also stated that there are electronic fingerprints that someone could look at to confirm that this check did occur.

Board Member Goldenberg expressed his support for the recommendation, but asked how the board would know that it is being done.

Board President Powers asked how the board currently enforces this requirement on new prescriptions and indicated that this also needs to be looked into.

Board Member Schell also expressed support for this proposal and indicated that he does not feel the board should be prescriptive with specifying how a pharmacist is going to do this. The intent is that it gets done, but the board should not be telling the pharmacist how to do it because of the various types of software used.

Mr. Room indicated that it is unclear if the law currently requires this although it is a standard of practice. It is clearly already a requirement on a prescription where consultation is required. The law currently links the drug utilization review to any prescription where consultation is required. This proposal would require the drug utilization review to occur regardless of whether consultation is required.

Board Member Goldenberg indicated the drug utilization review could only be completed based on patient information on file with the dispensing pharmacy because there is no central databank for all patient information.

Board Member Goldenberg reiterated that a pharmacy should be able to document how it is complying with the drug utilization review.

Board Member Dazé offered a proposed revision to the draft language to include a notation that the pharmacist must review the information on file at the dispensing pharmacy. The way that it is written now, someone could argue that the drug utilization review was not complete because the patient went to several different pharmacies to have prescriptions filled. Without this revision, a pharmacist could be placed in a position of being sued for malpractice unless the board limits the scope of the drug utilization review to a specific location.

Chairperson Zinder responded that the limitation is inferred. Pharmacists are only required to review and consider the information that is available.

Board Member Swart responded that typically a patient completes a drug information sheet where they list all of the medications they are taking. Patients are asked to indicate if there have been any changes in the medications they are taking. The industry has a mechanism to obtain this information. The software used by many pharmacies completes the drug utilization review for the pharmacist.

Board Member Goldenberg questioned what will happen if a patient declines to fill out the form.

Board Member Dazé questioned if the language should be revised to require that the DUR be documented.

Board Member Swart indicated that any DUR completed will be either a pharmacist's initials or some type of scan to confirm that it has been completed.

Board Member Ravnan also expressed support for the concept but expressed concern that the board may be requiring a pharmacist to confirm information that has already been confirmed when the medication was initially dispensed and/or refilled, assuming that the DUR was done correctly the first time.

Executive Officer Herold responded that in the case that was the origin for this clarification a cash-paying patient received a refill way too early. No pharmacist reviewed the patient profile and the patient took all the drugs at once and died.

Executive Officer Herold stated that as a consumer she expects her pharmacist to look at her profile, which is part of the reason people go to a pharmacy as opposed to buying the drugs off the Internet. It is a professional service.

Board Member Goldenberg asked if the overrides are as a result of the software used by the pharmacy, or part of the patient's insurance coming back and saying they will not pay for the refill.

Board Member Swart indicated that the override requirement is a function of the software used in his experience, but that he could not speak to all of the various software programs used by the profession.

Board Member Goldenberg proposed that perhaps the solution to this problem would be to require all software used by pharmacies to require a pharmacist override.

Public comment included whether the board can mandate that the software have a built-in DUR.

Dr. Cronin stated that independent pharmacies have the same kind of software programs and similar records.

Dr. Cronin stated that this proposal will require a lot of discussion because of the economic impact this will have. Dr. Cronin also pointed out that the proposed language requires a pharmacist to complete the DUR, not a computer program. Dr. Cronin stated that he does not know if that requirement is economically feasible and does not know how the board would enforce this.

Dr. Cronin suggested that the board consider all of the possible consequences of this proposal before moving forward with it.

Supervising Inspector Ratcliff asked what to do about a patient that is non-compliant with their meds by not taking them.

Board Member Swart stated that a pharmacist should not have to sign off if there is no drug interaction.

John Jones commented that consumers are not loyal to one particular pharmacy as people may think and that it may be a bit much to saddle a pharmacist with the proposed requirement. Dr. Jones also pointed out that with e-prescribing rules, the physician could request that the pharmacist notify the physician if the prescription is not filled. This would put the responsibility to follow up with the patient back on the prescriber.

Board Member Hough stated that consumers are responsible for taking their medications.

The board asked the committee to continue to reexamine and discuss this issue.

Board Action on Legislation

Board staff reported that to date, no legislation has been introduced that directly impacts pharmacy practice.

- **Omnibus Provisions**

Chairperson Zinder indicated that the committee recommends that all of the following provisions should be omnibus provisions sponsored by the board for 2007.

(1.) Sections 4162 and 4162.5
Extend bonding requirements for wholesalers from 2011 to 2015 to match the extension given to implement the e-pedigree requirements, restoring provisions in SB 1476 inadvertently chaptered out by SB 1475.

(2.) Sections 4314 and 4315
Allow the board to cite and fine licensees for violations of Health and Safety Code sections 150200-150206 which authorize a county to establish by local ordinance, a repository and distribution program for specified unused medications from skilled nursing homes to medically indigent patients served by government-owned pharmacies.

(3.) Section 4084
To allow board inspectors to embargo a prescription drug when the inspector has probable cause that it is misbranded.
(4.) Sections 4160(f) – 4161(k)
Revise these sections to specify a temporary license fee for wholesalers of $550. Current law does not specify the specific temporary fee.
(5.) Section 4208
Revise requirements for intern licenses to allow the board the discretion to extend the duration of an intern license.

Board staff stated that they anticipate the Business, Professions and Economic Development Committee will author the 2007 omnibus bill of the Department of Consumer Affairs.

Board members requested clarification on suggested revisions to Business and Professions Code section 4208.

Staff clarified that currently there is no provision in pharmacy law to allow for the extension of an intern license. Absent a provision, there are certain cases when an individual is unable to complete the intern hours required by law to become eligible for the pharmacist licensure examination. Without this statutory change, such individuals could not become eligible to become licensed as a pharmacist.

Board Member Ravnan asked if these extension requests would be something the board would vote on.

Executive Officer Herold responded that it would be delegated to board staff to determine.

MOTION: Legislation and Regulation Committee: Approve each of the proposed omnibus provisions for board sponsorship in 2007.

SUPPORT: 9 OPPOSE: 0

Board Member Goldenberg asked if the board has ever pursued a common clearinghouse to store all patient information.

Executive Officer Herold indicated that such a clearinghouse would most likely violate patient confidentiality. It is anticipated that a lot of people would opt out of the system.

Dr. Cronin asked what a violation of the skilled nursing facility repository would look like.

Executive Officer Herold responded that the board is uncertain at this point. However without the specified cite and fine provisions, the board would lack the ability to pursue this type of action.

Dr. Cronin stated that a violation could occur in which the county, the nursing facility and the pharmacy were all at fault for a violation, but only the pharmacy would be issued a citation and fine. Dr. Cronin requested that the board review this proposal a little closer to determine what a violation of this section would look like.

Executive Officer Herold responded that only the pharmacy is within the board's jurisdiction. The board does not know how the Department of Health Services would enforce this provision for skilled nursing facilities.

Executive Officer Herold also stated that if the procedure is going to be authorized, there must be an enforcement procedure. Absent the citation and fine ability, the board would have to pursue administrative action against a licensee for such a violation.

- **Proposed changes to AB 2986 (Chapter 286, Statutes of 2006)**

Chairperson Zinder provided a summary of the issue and proposal. Last year AB 2986 changed the reporting requirement for CURES, expanded reporting to include Schedule IV controlled substances and added elements that must be entered into CURES (e.g., the patient phone number and number of refills). Specifically, reports of dispensed schedule II, III, and IV drugs now must be submitted weekly to Atlantic Associates.

However, staff is also recommending a specific amendment to mandate a January 1, 2008, "drop dead date" for aggressive enforcement, as well as a requirement for prescribers to use of the new security prescription forms that contain the new data fields also by January 1, 2008 (essentially by making the current security forms obsolete).

Executive Officer Herold stated that the intent of this proposal is to sponsor a bill that would establish new effective dates for the implementation of AB 2986. In general, the board encourages compliance with the expanded CURES requirements, which now includes collecting each patient's phone number. Unfortunately, this new legislation did not allow for any transition. As such, all security prescription forms are technically void as of January 1, 2007, as the forms no longer contain all of the required elements.

Mr. Room stated that this legislation was sponsored by the DOJ rather than the board. He stated that the DOJ recognized problems with the bill and that immediate implementation would be difficult and that there was an agreement to have a waiting period before enforcing these new requirements. The goal of the proposal before the board is to ensure everyone knows when the requirements will be enforced, rather than just having an understanding. This proposal would also clean up some of the requirements that are in place that were authored by people not as

familiar with pharmacy law and operations as this board. This proposal will make it more practical for physicians and pharmacists to comply.

Executive Officer Herold indicated that the revised date could be a negotiating point. The federal government wants compliance with the provisions in AB 2986 as soon as possible and the DOJ is pursuing grant money, but must be in compliance with the CURES reporting. The DOJ is moving forward with a contract amendment to allow for the weekly submissions of CURES data.

Mr. Room indicated also that this bill will need to go through the law enforcement committee and that stakeholders in law enforcement may not be agreeable to a longer implementation date.

Executive Officer Herold reinforced the fact that AB 2986 did not provide for a transition period. This places the pharmacist and pharmacy in a difficult position as it is unclear if they should deny filling a prescription that does not include all of the new required elements on the prescription form.

Executive Officer Herold stated that the hope is to have everyone work together to maintain support for the CURES program.

President Powers asked if this was going to be an urgency bill.

Executive Officer Herold indicated that it is not the intent to pursue this as an urgency bill, unless otherwise requested by the board.

Dr. Cronin stated that there are a lot of mixed messages being discussed about the implementation of AB 2986. Pharmacists are unclear what they are currently required to comply with.

Executive Officer Herold agreed with Dr. Cronin and reiterated that the board is doing the best it can to advise licensees how to comply and when.

President Powers indicated that we should be giving a single message to licensees.

Executive Officer Herold stated that there was an article in the newsletter about this issue.

MOTION: Legislation and Regulation Committee: Approve modifications to new CURES Requirements Enacted by AB 2986.

SUPPORT: 9 OPPOSE: 0

- **General Announcement**

Chairperson Powers introduced Palmer Taylor, Dean of the School of Pharmacy and Vice Chancellor of Health Sciences at UCSD, and David Adler, Vice Associate Dean of the School of Pharmacy.

Dr. Taylor welcomed everyone and gave a brief description about the Skaggs School of Pharmacy.

Chairperson Powers thanked Dr. Taylor and Dr. Adler.

ENFORCEMENT COMMITTEE REPORT

Chairperson Powers stated that a summary of the Enforcement Committee and Workgroup on E-Pedigree Meeting held December 12, 2006 is provided in the Board Packet materials.

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

Chairperson Powers introduced former executive officer of the Board of Pharmacy, Lorie Rice who provided a full report at the NABP, Enforcement, and Board meeting pertaining to establishing an ethics course for pharmacists.

Lorie Rice, Associate Dean, External Relations, of the UCSF School of Pharmacy provided a presentation on her experiences in developing an ethics course for physicians at the NABP District Meeting in October. Ms. Rice did this in her role as a public board member of the Medical Board of California, following the Medical Board's determination that exiting ethics courses available for physicians are inadequate for ethical violations.

Ms. Rice is willing to assist the board in developing a specialized course for pharmacists, similar to that developed for physicians.

According to Ms. Rice, if the board were to develop a course, some of the issues the board would need to address would include:

(1) Who would be part of the task force to develop the components?
(2) What type of cases would be referred?
(3) What criteria would be needed to assess rehabilitation, redemption and contrition? Is there a willingness to change on the part of the licensee?

(4) How to build skills involving empathy, to ensure there is an opportunity to focus about the impact of the licensee's action on society and how it impacted patients?
(5) Follow up for each licensee is needed in 6 –12 months after course completion.

The Medical Board's course is set up for a maximum of 12 individuals, and during her presentation before the Enforcement Committee, Ms. Rice indicated it would seem feasible to have physicians and pharmacists in the same class. According to the Medical Board regulations, the class must be at least 22 hours.

According to Ms. Rice, there are two different types of violations that everyone is familiar with:

- The Standard of Care Violation where a practioner makes a mistake. With standard of Care violations, you figure what was the cause of the mistake and try to find a way for there to be some remediation for that mistake. Perhaps it will mean the person needs some continuing education or possibly having a license revoked because it came to the conclusion the violation was so serious or being placed on probation. There is a very recognized form of remediation for standard of care violation.

- The Ethics Violations, which include molestation of a patient, drug diversion or Medi-Cal/Medicare fraud.

Ms. Rice noted that the Medical Board had in its penalty guidelines the provision of referring persons to ethics courses. The standard ethics course was usually like the type taken in college where one learns the techniques of making decisions and weighing the risks from benefits.

The following components of the program are very essential:

1. Course has an established minimum length of 22 hours
2. All faculty within the program need to have California professional licenses
3. Someone within the program must do a background assessment to familiarize the provider and instructors with factors that led to the referral to the class
4. An assessment to determine participants' knowledge
5. An assessment of the participants' expectations toward the program and purpose for their own personal need to change
6. The concept that if at any point if participants do not participate at a level required with the program that they would have to be referred back to the board to take any further action

Ms. Rice further stated that they want an ethics program that speaks to those specific violations and be able to help access a person's ability to be rehabilitated or remediated and brought back to practice if this is the decision of the program of the board.

MOTION: That the Enforcement Committee look at options for development of an ethics course as enforcement option. The committee is to report its recommendations at the October Board Meeting.

M/S: GOLDENBERG/POWERS

SUPPORT: 9 OPPOSE: 0

- **Proposed 90-Day Rule for Prescriptions for Schedule II Controlled Substances**

Chairperson Powers stated that the board sent a letter supporting a proposed shift in DEA policy to allow prescribers to prescribe up to a 90-day supply of Schedule II controlled substances during a single office visit. This would allow prescribers to provide patients with three 30-day prescriptions at once, writing "do not fill" until a specified date on the additional prescriptions so that patients do not have to return simply to obtain a new prescription.

A copy of the board's letter to the DEA was provided in the Meeting Materials.

- **Report of the Workgroup on E-Pedigree:**

Chairperson Powers introduced Mike Rose with Johnson & Johnson who provided a presentation on e-pedigree, prepared by EPCglobal.

Mr. Rose provided a brief summary on EPCglobal's progress (as reported at the December meeting).

This summary is:

1. Pedigree management use cases: objective: define all supply chain use cases, processes and information needs for use in creating pedigree messaging standards.
   Status: complete
2. Pedigree messaging standards: objective: define a standard format for the pedigree-messaging standard that meets all federal and state requirements.
   Status: all standards work completed, prototype event was successful, technical review passed, intellectual property review completed in January.
3. Item level tagging: objective: define requirements for tagging pharmaceuticals at the item level; this includes requirements for manufacturing lines, distribution environments, transportation and retail environments.
   Status: requirements complete. A high frequency technical work was formed to define the standard. High frequency and ultra high frequency pilots are underway to provide uniform

air interface protocol at the item level. The high frequency standard is expected to completed in the 3rd quarter of 2007

4. Serialization: objective: define requirements to be encoded on the electronic tag.
   Status: requirements completed. Two identifiers were identified for use, global trade item number (GTIN) and serialized shipping container number (SSCC)). The newly formed serialization group will address all remaining issues.
5. Decommissioning: objective: define requirements for decommissioning tags as they leave the supply chain.
   Status: work to begin in January 2007, timeline is 6 months
6. Track and Trace: objective: define supply chain use cases, processes and information needs for sharing EPC-related data for forward and reverse logistics.
   Status: forward and reverse logistics processes and data exchanges completed, additional use cases to be addressed for 3rd party logistics and repackagers, product recall, data sharing strategy and guidelines are being developed.

In early January 2007, EPCglobal did announce finalization of the standard for electronic messaging. A copy of this presentation is provided as an attachment to the Enforcement Committee Meeting minutes of December 12, 2006 (AmerisourceBergen's presentation). This is a major milestone for the implementation of electronic pedigree requirements. The new pedigree standard being developed will support item level serialization, electronic signatures, RFID using non-line of sight identification of pallets, cases or items, and inference.

EPCglobal's next steps will be to work through scenarios with the Board of Pharmacy, host a workshop for regulators from states with electronic pedigrees, and work with the formed industry adoption workgroup on serialization and time tagging issues. There will also be a regional summit for hospital issues on February 20.

Some of the issues that will be addressed by EPCglobal in the coming weeks will also involve use of NDC numbers involving controlled substances, which may be an issue for the DEA.

A copy of the EPCglobal presentation is available in the meeting minutes for the December 12, 2006 Enforcement Committee.

Display of Track and Trace Technology:

Craig Asher, IBM Project Manager, Solution Architect, Co-Chair with EPCIS and Data Exchange described some goals IBM envisions for E-Pedigree:

1. Any E-Pedigree system should be compliant with the law.
2. Technology should be available for deployment.
3. Solution should be cost effective for the pharmacies and all other players.
4. Provides a Return on Investments (ROI) to the supply chain members.
5. Should be standard spaced.

Mr. Asher presented slides showing the track and trace framework and described how it is set-up in three layers:

1. Data Capture
2. EPCIS (Electronic Product Code Information Service)
3. Registry

AmerisourceBergen initiated this project with IBM in the belief that it has an opportunity to either be a leader or follower with respect to electronic tracking of drug products. In this regard, ABC had concerns with the size of the massive data that result from document-based pedigree that would be passed from one owner to the next as a drug product moves through the distribution channel. At each successive step in the distribution channel, more data would be added to the database for each drug product, resulting in massive redundant data repositories, especially for those near the end of the distribution channel. There is little other use that a company will gain from such repositories, except for compliance with requirements.

Instead ABC is testing a "track and trace" model using IBM's technology. This system passes only a minimal amount of data as the product moves through the distribution channel, but that at any point, full data describing all items and all ownership can be quickly accessed and obtained by legitimate users. The system can also be accessed to obtain real time receiving and shipping information and for better management of inventory.

The ABC pilot will use ultra high frequency, 2-D bar codes and new high frequency tags on the drug products tested. Inference will be one component evaluated as products are shipped from manufacturer to wholesaler. Inference also will be evaluated on mixed totes of products from wholesalers to pharmacies.

Board staff indicated at the Enforcement Meeting that these practices will be carefully reviewed for compliance with California requirements as the data is collected during the pilot.

Chairperson Powers stated that Cardinal Health also provided a presentation at the Enforcement Committee. The results of this study indicate that it is feasible for these RFID tags to be added to product containers and be read throughout the system – under this pilot, they were read 95 to 97 percent of the time. Cardinal Health believes after some adjustment, readings near 100 percent can be accomplished, without disruption to the distribution channel.

Two different types of containers were tested, a round container and a square container. Tagging at various places (container, pallet, etc.) was also tested.

The results indicate:

1. RFID tags can be successfully inlaid under existing FDA-approved pharmaceutical label stock.
2. Packaging lines can be run at validated speeds while encoding and verifying RFID tag application.
3. A single frequency (UHF) has the potential to work in critical points from pharmaceutical packaging to pharmacy receipt.
4. No tag failures were encountered in any stage of the pilot.
5. Item-level reads are not possible when cases are stacked on a pallet
6. Unit read rates within mixed totes exceed 99 percent, but are not at 100 percent.
7. 100 percent read rates at the case level on pallets are potentially obtainable
8. Case read rates on a moving conveyor at shipping and receiving had read rates exceeding 99 percent.

The conclusion of the study was that RFID technology is feasible for tracking and tracing item level drugs in the pharmaceutical chain, but collaboration among the supply chain partners will be needed. Cardinal added that there has been more collaboration within the last six months among industry partners than in the last 18 months. Generation 2 UHF tags are superior in quality to the Gen 1 tags.

Demonstration of Technology for Tagging Products

Chairperson Powers also stated that Secure Packaging Systems provided a demonstration of a form of electronic tagging that would be positioned in the cap of a medicine container. Such tags could be beneficial for high cost biologicals and are in use in Europe. They are also capable of being developed with Braille markers and with color-coded caps.

During discussion, mention was made about testing of biological products for stability following 48 hours of exposure to high frequency fields without any change in the medication inside the containers.

California Retailers Association

Chairperson Powers also stated that the California Retailers Association (CRA) provided comments to the committee on behalf of chain store pharmacies in California in a letter dated December 1, 2006.

The CRA's members are concerned that the 2009 date for implementation of electronic pedigrees in California will be impossible for the state's chain-store pharmacies because they are at the end of the distribution channel, and the technology put in place by manufacturers and wholesalers will need to be readable, adopted and installed in pharmacies before pharmacies can comply with the requirements.

Moreover, pharmacies are concerned that they will need to develop methods for storing and accessing electronic pedigrees, and these databases will be huge databases at the store level to manage and maintain. There are also concerns about whether there will be adequate staff available to install these systems and provide training to pharmacy staff about how to use them. These latter tasks cannot be initiated or planned for until the manufacturers and wholesalers fully implement and integrate the systems for electronic pedigrees that will be passed to the pharmacies.

The CRA stated that the pharmacies would need time beyond 2009 to be able to implement the standards.

- **Enforcement Statistics**

Chairperson Powers recommended that everyone review the statistics in the board packet to allow them to understand what type of enforcement actions are taking place.

- **Discussion and Action Regarding Medicaid Program: Prescription Drugs, Proposed Rule 42 CFR Part 447**

Board Member Goldenberg stated that pharmacy cost reimbursement and access to medication are tied hand-in-hand and that the board has a responsibility to protect the public.

A proposed federal rule would change how reimbursement is made to pharmacies providing Medicaid services, and in turn, California's MediCal services. The proposed regulations rely on average manufacturers prices (AMP) using formulas that will drive some pharmacies out of business, and other pharmacies will discontinue service to MediCal recipients. Board Member Goldenberg further stated that the federal government is the driver of cost in this industry, and pharmacies will not be able to continue to provide access for consumers when costs of medication do not cover the expenses of purchasing and dispensing medicine. As proposed, Rule 42 CFR Part 447 will result in a significant decrease in reimbursement to pharmacies in California below their costs in acquiring medicine and thus is not in the best interest of consumers.

Board Member Goldenberg led the board in a discussion on the issue, and asked whether the board should take a position as the new pricing system is being developed.

Board Member Hough stated that creating a shortage of any product results in increased demand to businesses that still provide that product. If fewer pharmacies are available to consumers, the remaining pharmacies will experience more business.

Board Member Goldenberg stated that the proposed rule is part of a deficit reduction plan (Deficit Reduction Act of 2005), the effects of which will kick in around July 2007. Mr. Room clarified that the legislation was passed years ago, and the regulations are just now being

promulgated. Mr. Room added that comments submitted now could have a specific and direct affect on the regulations.

Board Member Swart stated it appears that the federal government doesn't understand where the AMP prices are coming from, and added that it's fictional pricing. Board Member Conroy suggested that the dispensing fees should be based on real data, not just changing to reimbursement based upon the AMP.

President Powers stated that the proposed rule would affect health care to the poorest consumers among us. He supported a written communication from the board to CMS; deadline for comment is February 20, 2007.

Board Member Goldenberg supported the board in sending a letter out, but also recommended sending a copy to the Governor's Office to state the board's position that the proposed rule will affect access to medication for California's consumers.

Board Member Schell supported sending written comments to the Federal Register, as well as the Governor, House Speaker Nancy Pelosi, and the chairs of applicable committees.

Ms. Herold suggested that if the board provides comments on the proposed rule, the comments should be (both) general in nature and provide specific examples.

Chairperson Goldenberg asked if there were any comments from the public attendees regarding Proposed Rule 42 CFR Part 447.

Kathy Lynch, Esq., Vice President of Government Affairs for the California Pharmacists Association (CPhA), stated this reimbursement issue definitely affects access and cost dispensing. CPhA is joining with other national and state pharmacy organizations to coordinate comments on the proposed federal rule regarding AMP. They will refine the comments by providing a system for submitting comments electronically at Outlook, to be held February 15-18 in Palm Springs.

Ms. Lynch further stated that the Department of Health Services (DHS) commissioned another survey of pharmacy acquisition and dispensing costs. Myers and Stoffer are surveying 2,000 pharmacies in California to get across-the-board data. The survey should be completed by May 2007. CPhA staff will be meeting with DHS to discuss the details of this effort. Ms. Lynch stated that the latest information provided shows the change to AMP-based reimbursement for generic drugs will result in a reduction of reimbursement of $91.6 million (state and federal funds) during fiscal year 2007-2008.

John Cronin stated that the impact, using today's numbers for AMP, would be on average 36% below the cost to procure drugs – pharmacies would not be able to buy drugs for what they would be reimbursed. CMS is trying to define three things: what goes into the fee, what goes into the price, and what goes into the retail class of trade. Dr. Cronin further stated that

comments on the proposed rule must show why AMP will not work, not just that AMP is bad. It's a significant complex issue, and very difficult to deal with.

Mary Staples, National Association of Chain Drug Stores, stated that she wants to raise visibility of the issue. She supported a letter writing campaign, and had sample letters available for people to write to members of congress. Ms. Staples provided the samples to President Powers.

Dr. Richard Mirigian stated that a letter to AARP would have a great impact because AARP is supportive of keeping pharmacies accessible to consumers.

Bruce Lott, Vice President of Government Affairs for the Generic Pharmaceutical Association (GPhA), stated that he is also concerned about the proposed rule. The GPhA is supportive of the board weighing in on the issue, and Mr. Lott offered his support to the board in preparing written comments.

A motion was raised that the board provide a response to the proposed rule.

MOTION:	That the Board of Pharmacy respond to Proposed Rule 42 CFR Part 477 before the Federal Register deadline of February 20, 2007, and authorize the Executive Officer to compile language submitted for a written response.
M/S:	POWERS/GOLDENBERG
SUPPORT:	9 OPPOSE: 0

ORGANIZATIONAL DEVELOPMENT COMMITTEE

Chairperson Goldenberg provided a summary of the committee's teleconferenced meeting held January 16, 2007. A summary is in the Board Meeting materials.

- **Recognition of Pharmacists Who Have Been Licensed 50 Years:**

At the July 2005 Board Meeting, the board initiated a program to identify and publicly commend those pharmacists with 50 years of licensure as pharmacists.

Since July 2005, the board has acknowledged 603 pharmacists, 12 pharmacists reached this milestone between the October 2006 and January 2007 Board Meeting.

Chairperson Goldenberg stated that the board is pleased with this ongoing program.

- **Board Recognition of Notable California-Licensed Pharmacists:**

Chairperson Goldenberg stated that the committee continued to discuss parameters for board acknowledgment of high-functioning or particularly noteworthy licensees who could and should be commended by the board.

The committee has identified three possible processes, and seeks board discussion on each:

1. Acknowledge pharmacists who have received accolades from other organizations or institutions,
2. Acknowledge preceptors who have contributed significantly to the training and development of new pharmacists, and
3. Publicly acknowledge Competency Committee Members for their efforts to develop the CPJE or the prior California Pharmacist Licensure Examination.

Mr. Dazé suggested dedicating a page or section for those being recognized for their accomplishments and publishing them in *The Script*.

Ms. Herold replied that this procedure would need to be reviewed by 2 or 3 board members in order to review and confirm that the information received is legitimate. The process could be open so that anyone could nominate a pharmacist for his or her significant contribution to pharmacy with supporting documents is being looked upon and would later be viewed by the Organizational Committee.

Chairperson Goldenberg mentioned possible opportunities for the power of the students to vote for preceptors or even preceptor of the year.

The committee will refine and develop a program.

- **Personnel Update and Training Report:**

Chairperson Goldenberg stated that there have been a number of changes in the board's staff since the beginning of October. He referred the board to the detailed report in board packet.

Ms. Herold introduced Karen Abbe as the new public outreach analyst who will be developing and editing informational materials and Gloria Schultz as the board and executive administrative assistant support from the Secretary of State's Office.

Executive Officer Herold provided an update on the reclassification of the assistant executive officer position.

For the past 10 years there have been several attempts to reclassify the position to reflect a classification commensurate with the duties as part of a departmental wide reclassification.

Ms. Herold further stated that about a year ago the committee directed staff to pursue a reclassification of the assistant executive officer position to a more appropriate level, commensurate with the duties expected of the position. A reclassification request was pursued in 2002-03, but was ultimately denied by the State Personnel Board. A follow-up reclassification request was submitted in 2005 at a lower level, but the Department of Personnel Administration denied this request in June 2006 as being a poor fit for the duties and recommended another classification – the same classification that was denied by the State Personnel Board in 2003.

The board directed Ms. Herold to pursue the reclassification.

Inspector and Supervising Inspector Vacancies:

The board has four inspector vacancies and one supervising inspector vacancy.

In early June, the board submitted a proposal to create a recruitment and retention salary differential of $24,000 annually, raising inspector salaries to about $103,000 and supervising inspector salaries to $112,000, matching a differential provided to a number of other state pharmacists who perform duties comparable, and perhaps less difficult, to that performed by board inspectors. At the July Board Meeting, the board unanimously supported this proposal. In August and September, the board received positive support for the proposal from the Department of Personnel Administration and the Department of Finance. In November, the board received notice that it would be able to conduct new civil service exams listing "pending Administration approval is a $2,000 monthly recruitment and retention differential." The Governor's 2007-08 budget contains funding for this salary augmentation.

Currently underway are new civil service examinations from which the pharmacist's inspectors can be hired to work for the board. The final filing date for applications to take these examinations is February 2. The board hopes to conduct the civil service interviews in March and April. Applications are on the board's Web site and highlighted in the January 2007 *The Script.* However, the recruitment and retention differential will be needed to secure a quality applicant pool.

Vacancies on the Board:

There are three openings on the Board of Pharmacy itself: two public members and one professional member. All are governor appointments.

- **Budget Report:**

Current Year's Budget 2006-07

- **Revenue Projected: $9,400,276**

The board is also 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 a period of California's budget crisis. There is an additional $233,000 in interest that will be paid that is linked to the loan.

Final revenue for the year also includes additional amounts actually collected from cost recovery and citations and fines. During the first quarter of this fiscal year, the board collected $266,527 in fines and $52,755 in cost recovery.

- **Expenditures Projected: $8,250,000**

Board Fund Condition

The board's fund condition projections over the next few years (as estimated in August 2006) are:

-- 2006-07: A reserve of 10.4 months is projected.
-- 2007-08: A reserve of 5.9 months is projected.
-- 2008-09: A reserve of 1.2 months is projected.

Fee Increase Coming

Ms. Herold noted that hopefully, beginning July 2007, the board will augment inspector salaries approximately $775,000 per year ($576,000 is the recruitment and retention differential, the remaining $200,000 is due to an increase in the salaries of inspectors awarded through collective bargaining). This increase, coupled with a declining fund reserve, means that the board needs to initiate steps to increase fees in the future 1.5 years.

The board will be able to increase revenue by over $1 million by increasing fess in regulations to the statutory maximum.

The board truly has not increased fees since the mid 1980s, except for a short period during mid 1990s, after the board's fund was loaned to the state's General Fund to avert a state fiscal crisis.

2007-08 Budget

Budget Change Proposals Approved and in Governor's Budget
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 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 will need to increase fees).

I-Licensing Project Update

Approximately seven DCA agencies have the ability to provide online license renewal due to participation in a project started under the Davis Administration. However, the state's budget crisis in the early 2000s prevented the Board of Pharmacy from joining this project, although the board has been striving to be added for years.

The DCA is moving ahead with a project so other agencies can 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. Executive Officer Herold is one of the project's "executive sponsors," which means she is participating in the steering committee for this project and may need to testify before the legislature or various other agencies to urge implementation of this project.

The board is projected to spend $50,000 this fiscal year on programming specifications needed for board 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.

Meanwhile, the board in late December 2006 and early January 2007 converted all its application systems to the Department of Consumer Affairs applicant tracking system, a conversion that went fairly smoothly, although there are still a few residual problems. Use of this system will facilitate the board's eventual conversion to the I-Licensing system.

The board is about two years away from implementing online renewals.

Board Member Expenditures and Reimbursements

Chairperson Goldenberg stated that travel expenses and compensation of board members claimed during this fiscal year were provided in the materials for the meeting.

- **CURES FEASIBILITY STUDY REPORT:**

Ms. Herold advised that California Health and Safety Code section 11165.5 requires the board to contract for a feasibility study report to evaluate the feasibility of real time reporting and access

to data on prescriptions submitted to CURES. (New California law requires this data to be reported weekly, before 2007 the data was required to be reported monthly.)

The law requires the board to work with Department of Justice and the Medical Board to contract with a vendor to develop the feasibility study report, using money voluntarily contributed to the board specifically for this purpose.

Board staff has developed a draft version of the proposed work for the feasibility study report (FSR), which is undergoing review by the Department of Justice. The DCA's Administration and Information Technology offices have concerns about whether the board is the correct entity to be contracting for this FSR, and recommends that since the Department of Justice has the CURES computer system, perhaps that agency should actually be doing the FSR. Board staff is working with the Department of Justice on this now.

- **New July Board Meeting Date:**

The board moved the July 2007 Board Meeting forward one day to become a Tuesday and Wednesday meeting in Los Angeles, July 24 and 25, 2007.

- **Approval of the Minutes of the October 25 and 26, 2006 Board Meeting**

MOTION: Approve the board minutes from the October 25 and 26, 2006 Board Meeting.

M/S: DAZÉ/SWART

SUPPORT: 9 OPPOSE: 0

NEW BUSINESS ITEMS FOR FUTURE MEETINGS

President Powers asked if there were additional matters from the board or audience for future board meetings.

There were no comments.

- **RECESS**

There being no further business, President Powers recessed the meeting for January 31, 2007 at 5:05 p.m.

FEBRUARY 1, 2007

CLOSED SESSION

At 8:00 am the board went into closed session to deliberate on disciplinary matters.

OPEN SESSION

President Powers recalled the public meeting to order at 9:00 am.

Public Forum on Medicare Part D Plans
Summary of the Meeting February 1, 2007
9:00 am – 11:35 a.m.

President Powers opened the meeting at 9:00 a.m. Mr. Powers observed that the Medicare Drug Benefit Plan was one of the most important changes in the history of the Medicare program since its inception in the 1960s. The Board of Pharmacy believes that it is important to hold these public forums to allow stakeholders to discuss how the Medicare Drug Benefit program is operating, their concerns with the program and those issues impacting the quality of services being provided to California patients.

President Powers reported that the board's subcommittee on the Medicare Drug Benefit Plan has been meeting for about a year and that committee members have heard testimony from various stakeholders on the concerns, problems, and successes of the program. Chairperson Goldenberg then thanked the members in the audience for their attendance and stated that the board wants to bring resolution to some of the problems brought before the subcommittee over the last year. He announced the meeting format of forum and that long term care representatives would make the first presentations.

Don Amorosi of Omnicare, Inc. thanked the board for holding the forum and stated that he and his colleague, Mary Lou Gradisek, will be presenting a PowerPoint presentation on the Medicare Part D challenges facing long term care (LTC). He provided a copy of LTC patient protections from Omnicare contracts with Part D plans, many of which were adopted by the Centers for Medicare and Medicaid Services (CMS) as part of its 2007 transition plan. He also provided copies of CMS memos concerning Part D transition of care policy and expectations for the 2007 contract year and "Best Available Data" policies for reconciling CMS low income subsidy status.

Mr. Amorosi's presentation centered around the Part D landscape in California and the challenges that face long term care under Medicare Part D in the areas of transition of care, long term care infusion therapy co-pays and subsidies, and recommended best practices. He included a brief overview of Omnicare's long-term care role in California, the shift in payer mix and the top five plans that service the institutionalized in California.

Mary Lou Gradisek then spoke on the CMS LTC transition policy changes for 2007 and the impact of these changes and the transition policy for LTC. She focused on emergency fills, multiple fills of non-formulary drugs and "refill too soon" limitations, prior authorization requirements for IV therapy medications, and best billing practices for IV therapy. Ms. Gradisek stated that the intent of the CMS transition policy is to make sure that the needs of a LTC patient are specifically addressed and that enrollees have enough time to receive the drugs that are prescribed by the physician and for those drugs that are not covered by the plan, that there is time available for an enrollee to acquire additional documentation, to change to a covered alternate or for the pharmacy to work with the physician to provide the documentation that justifies the medical need for those prescriptions.

Mr. Amorosi then provided a background on issues pharmacies are facing with co-payments and the inability of providing timely information to CMS and the plans regarding full subsidy eligibility for long term care patients. He stated that LTC patients have a combination of Medicaid and Medicare eligibility and are not subject to co-payments. However, there is a delay in getting that LTC eligibility information to CMS and the pharmacies are required by the plans to collect a co-payment before the medication is dispensed. Once a patient's dual eligibility is verified, the plans do not have a legitimate process in place, such as electronic submission capability, to retroactively update the system to reimburse pharmacies for the co-payments. Mr. Amorosi added that CMS has issued best available data guidelines for use at the point of dispensing to determine full-benefit dual eligibles and other low-income subsidy eligible individuals.

In summary, pharmacy liability for co-pays must be resolved, best practices include adoption of already defined industry standards and the continuity of LTC service models requires unique patient protections.

President Powers introduced Charlene Zettel, Director of the Department of Consumer Affairs. Director Zettel thanked the board members for their work and the contribution they make to the patients and consumers of California. She added that Governor Schwarzenegger is committed to increased access to health care and coverage for all Californians, and the Department of Consumer Affairs looks forward to working collaboratively with the board on outreach for the Medicare Drug Benefit Plans.

President Powers thanked the Director for her comments and invited the next presenter to the podium.

Kim Aksentijenic of Kyffin Pharmacy introduced herself and stated that her pharmacy serves Los Angeles County long-term care and assisted living patients. Ms. Aksentijenic clarified that the Part D program is a real time, point of sale process developed for ambulatory patients who can go to the pharmacy, get their prescriptions and the pharmacist processes a point of sale transaction and obtains a promise of payment from the Part D plan. The LTC environment however does not operate in real time and relies on the facility to provide information as to a patient's eligibility that oftentimes creates a rebilling issue due to erroneous information and the necessity of using clinical staff to resolve reimbursement issues.

Ms. Aksentijenic continued with the issues surrounding LTC prior authorizations and physician approval for prior authorizations. In the LTC environment, the facility, the consulting pharmacist, the dispensing pharmacist and the pharmacy all have the clinical information on a patient. The physician does not have the clinical data available to make a decision so it is a problem when the Part D plans require a physician to be the primary point person in the prior authorization process. Some physicians will not participate in the prior authorization process; this then may result in a LTC patient not getting the medication a physician has ordered. She added that compliance packaging has also proved to be an issue. LTC relies on compliance package to facilitate the patients receiving their medications correctly. A problem arises when a 31-day supply is dispensed, which results in a double co-pay for the patient.

Ms. Aksentijenic concluded by relaying incidents where LTC patients whose medications were previously approved under Part A were unable to receive medications due to Part D plans denying coverage. This denial prohibits a consistent treatment plan and the ability to properly control patient pain.

Chairperson Goldenberg questioned the time it takes to get prior authorizations signed. Ms. Aksentijenic explained the process and responded that she has an employee who processes prior authorizations full-time. She stated that some plans accept the form without a physician's signature and others contact the physician based on information provided on the form. She added that Kyffin is not notified of the approval or denial of a prior authorization. Her employee either has to call the Part D plan or submit a trial claim to determine approval. There is a lack of communication to the pharmacy as the actual provider and caregiver.

Ms. Aksentijenic agreed with Chairperson Goldenberg's comment that if the standardized form provided by CMS was available electronically and that the status of a prior authorization could be checked on-line, a significant amount of time would be saved.

David Solomon of Kyffin also thanked the board on the work they have been doing the past year on Part D and reported on the financial ramifications of Part D. He stated that Kyffin's personnel costs, delivery and receivables costs have increased but its overall business has not increased. He added that Kyffin is trying to deal with these changes while assuring that its clients experience the least amount of change in their daily medication routine. Kyffin has spent an enormous amount of time and money to ensure that prior authorizations are completed, that co-payments are collected and costs are not consistently absorbed. As with other pharmacy

caregivers, Kyffin is not forcing the facilities to reimburse for the co-pays or for non-covered charges – especially when an eligibility status occurs retroactively. The pharmacies are absorbing these costs.

Mr. Solomon reported that since 2005 Kyffin Pharmacy has sponsored numerous education outreach programs to their facilities addressing what information is needed by Kyffin from the facilities in order to provide continuation of care to their LTC clients. He noted that there seems to be a lack of support from CMS in this education process.

Chairperson Goldenberg reported he has queried facilities asking what they would do when a pharmacy is faced with a situation where the drug is so expensive they cannot provide it but the doctor feels the care and the medication must continue. The majority of the facilities responded that they would transfer the patient to an acute care hospital, which then creates additional costs and an enormous amount of trauma to an elderly patient. He added that the care of patients is being compromised, the cost of care increases with the changes in Medicare coverage and reimbursement, and the frail elderly patient is subject to trauma if transferred out of the facility. The system has to be resolved so that the frail elderly are not placed in harm's way. He stated that because a response has not been received from the plans and CMS concerning the problems and frustrations the subcommittee has been discussing the last year, the issue is being brought before the full board to address this concern of harm to the frail elderly as it is now time to take action.

Mr. Hough stated that an electronic database, enabling the proper identification of a patient's eligibility status is a key issue towards resolving the points introduced by the speakers. This is an authority matter where direction must be given to mandate the establishment of such a database.

Chairperson Goldenberg introduced representatives of CMS and thanked them for attending the forum and expressed a hope that they would provide a response to these concerns.

Jeff Flick, Regional Administrator for the San Francisco office of CMS, stated he appreciated the opportunity to participate in this forum. He introduced Lucy Saldana, Region 9 pharmacist with CMS. Mr. Flick stated that the information learned in the forum is very beneficial. He added that he feels very good about the Part D Program. Although there is room for improvement; the program has come an incredible distance in one year. Today, in the State of California, 97 percent of the Medicare beneficiaries have comprehensive prescription drug coverage, whereas 14 months ago only about 55 percent of the Medicare beneficiaries enjoyed comprehensive prescription drug coverage. With regard to the LTC portion of the Part D plans, Mr. Flick will take the specific issues and problems discussed in today's forum back to their industry collaborative (ICE), a roundtable of stakeholders who work together to solve Part D problems. In the last year, this collaborative effort has resulted in several policy changes although there are still concerns and issues that are being addressed.

He stated that ICE can address many of the issues discussed here today and he is very interested in pursuing electronic data transmission, keeping in mind the necessity of data security. Mr. Flick added that there are positive aspects to the program such as medication therapy management, e-prescribing and prior authorizations, but the stakeholders must keep working together to realize these benefits without a negative impact. The encouraging aspect is that the entire health care stakeholder community has a history of being able to work together to solve problems and to continue to improve the program.

Mr. Flick acknowledged that it has been difficult getting dedicated physicians for LTC patients who can respond quickly when problems arise. He agreed that nursing homes do need the ability to engage physicians quickly and that perhaps CMS could assist in resolving that problem.

Mr. Goldenberg asked Mr. Flick whether CMS's authority to speak directly to the plans is limited. He added that the feedback that the board is getting from all the stakeholders is that CMS has very little authority over the plans. Mr. Goldenberg asked how the board could be assured that CMS is working with the plans to resolve problems and that plans will listen to CMS.

Mr. Flick responded that CMS works well with the plans through the ICE collaborative efforts. There are times when an issue cannot be resolved through collaboration and cooperation and at these times, CMS does talk with their central office to deal with the specifics. He stated that every plan signs a contract with CMS, the terms of these contracts are very specific and CMS does have a lot of authority over those contracts and will terminate a contract for serious noncompliances. However, CMS does work with a plan to ensure compliance with the Medicare program.

President Powers stated that from listening to the presenters, there are systemic problems in the system that will need to be resolved through the ICE collaborative.

Mr. Flick responded that most of the issues that were raised today could be resolved through ICE. As in the past, CMS has changed policies based on recommendations from the collaborative.

Mr. Goldenberg questioned whether it would be a fair expectation of the board that the ICE collaborative would be discussing problems heard in today's forum and the board could anticipate some timely action by the plans and CMS to remedy these problems and help California's seniors.

Mr. Flick answered that CMS's focus is to work with ICE as a collaborative effort in resolving issues. CMS is not purposely mandating directions and timeframes. He stated that it was important to understand the environment of this collaborative effort – that there are requests from all the stakeholders, including the plans for assistance with certain issues, and that it makes for a better process to have the stakeholders working together.

Dr. Saldana of CMS stated that e-prescribing should resolve many of the issues that were discussed today. E-prescribing is on a fast track and by 2008 the ability for e-prescribing should be in place. There was a question from the board as to whether the health insurance plans would use e-prescribing and electronic databases and if CMS could work towards a legislative mandate to require the use of electronic databases. Mr. Flick responded that CMS does not lobby for legislative change, but he agreed that CMS could communicate to legislators where change is needed. It was commented that if California took the lead in this area, it would assist the Medicare Part D program nationally.

Chairperson Goldenberg announced that Terry Miller of the Department of Health Services would speak next, followed by representatives of the plans.

Dr. Miller reported that as Chairperson Goldenberg stated, that prior to Part D, the pharmacists could submit a treatment authorization request via facsimile through the Medicare program. Currently, with CMS requirements related to Part D, the treatment request must be submitted from the physician which then puts the onus on the physician who is not used to routinely working with the plans. The former system whereby pharmacies pursued authorizations for drug coverage worked well with the Medicaid and Medi-Cal programs in California, and now it is a significant issue for prescribers.

Dr. Miller stated that with respect to emergency drug benefits, the California Legislature approved an emergency drug benefit to assist patients who could not get their medications via the Part D plan for one year. Although this benefit recently expired, the Department of Health Services has seen a significant decrease over the last year in the number of claims submitted to the emergency drug program. Ms. Miller indicated that this decrease indicates a significant improvement in the Part D program. However, she agreed that there are still issues that need improvement, specifically in the arena of LTC and home infusion.

John Jones from Prescription Solutions stated that his organization serves two large prescription drug programs and that Prescription Solutions is a representative on the ICE collaborative. He stated that it is very difficult for ICE to address an issue on a conceptual basis. ICE works better responding to specific facts where they can develop mechanisms to prevent specific problems from reoccurring. ICE is committed to making the process better.

Mr. Jones stated that they are routinely communicating with CMS and notifying them of problems. He added that CMS does have authority over the plans and the plans performance is considered at the time of contract renewal. Customer service is important to Prescription Solutions, if there is a problem they need to know about it so they can fix it. These board forums and the ICE collaborative provide them with the opportunity to hear the issues. Mr. Jones agreed that e-prescribing would be very beneficial but many physicians are reluctant to go that route. However, by 2008 a financial leverage should be in place where electronic submissions by physicians will be required before payments are made.

Chairperson Goldenberg asked whether Mr. Jones's organization and its affiliates could address electronic connectivity now and not wait for the ICE collaborative. Mr. Jones responded that Prescription Solutions has a system that is currently working. He added that e-prescribing will move the industry toward an electronic interface. If the board is looking at an interim solution before e-prescribing, Mr. Jones questioned whether that would be a good use of resources as Prescription Solutions has a system in place that is currently working.

Chairperson Goldenberg indicated that the board heard today that the system is not working effectively and there are issues that need to be resolved. Mr. Jones stated that when he is notified of a problem and given the specific details of that problem, he would facilitate a resolution. He added that he would continue to assist with the facilitation of communication at all levels so that ICE can be a meaningful process.

Timothy Cutler, assistant clinical professor at the UCSF School of Pharmacy highlighted specific Medicare Part D issues facing providers, pharmacists, and patients in California. He provided examples of patients' confusion with plan options, misinformation from brokers, brokers attempting to sell additional coverage to patients and patients being over insured. He emphasized the large amount of misinformation that patients receive from the plans and brokers. He stated that with the number of eligible patients, number of prescription drug plans and number of brokers, there are not enough educators to provide Part D outreach educational activities to the seniors of California. Mr. Cutler added that brokers are not subject to the same regulatory provisions that pharmacists are in terms of information that can be provided to patients. That is a problem and something should be done to protect beneficiaries from those brokers who are imparting misinformation to patients. He also spoke to the continuing delays in coverage for the dual eligibles and provided patient examples of this gap in coverage.

Dr. Cutler then highlighted recommendations for improving the system such as the continued coordination of communication efforts between the plans and CMS to prevent gaps in coverage from occurring, and the communication must be easier between the patient, the health plan and the system. CMS should have one system in place, similar to Medi-Cal in terms of a safety net provided to patients and a standardized prior authorization process.

Michael Rigas of Crescent Healthcare, a home infusion company, reported on Crescent Healthcare's experience over the last twelve months with Medicare Part D program. He provided a PowerPoint handout and briefly summarized the highpoints from that handout. Crescent Healthcare serviced over 850 home IV patients in 2006. Very few of those patients were able to afford a co-pay unless they had assistance with a secondary plan or Medi-Cal and their costs to administer to those patients were two to three times the costs of other payment systems. The ability to manage these patients on an ongoing basis will become more difficult as processing gets more complicated. Dr. Rigas added that obtaining prior authorizations might take 5 to 7 business days for complex therapies. He provided a brief overview of special issues of importance to the home infusion industry that included billing issues with multiple ingredients – prescription billing is based on the most expensive first active ingredient only; concerns about the future stability of pricing structures and plans with specialty drug copays. Also, due to the

2007 changes made by the Part D Plans as a result of issues in 2006, Crescent Healthcare has to navigate through new copay policies that have a dramatic impact on their patients. Also many Part D Plans and MA-PDS have their own pharmacy out-of state, so when Crescent sends the prior authorization through, the prescription is filled by the plans' own pharmacies and the prescription arrives directly to the patient, with no items to mix it, no pump, no pharmacist or nurse, and no way to infuse it. He added, in response to a question from the board, that there is a delay in obtaining prior authorizations and once received, there is oftentimes a billing issue as a brand is approved, but not the generic.

Dr. Rigas then provided specific examples of home infusion patients who were having problems continuing to receive the treatment and medications that they had under previous coverage Part B coverage but can now not get under Part D. Dr. Rigas concluded that Part D does not provide adequate coverage for Home Infusion Therapy resulting in patients having to stay in a hospital, go to a skilled nursing facility, or having to pay large amounts of money out-of-pocket. He stated that there are definite benefits with Part D coverage, especially for patients who would have no coverage at all, but there are still significant issues relating to coverage and billing that need to be addressed.

Chairperson Goldenberg requested Jeff Flick and John Jones to provide their thoughts on today's presentations. Mr. Jones stated LTC and home infusion therapy are areas where the industry and CMS wants to work well but they were not areas that were initially part of the Part D congressional discussions. He complimented CMS on their handling of these issues and their methods of working with them.

Chairperson Goldenberg stated that there are significant issues involved - the health and well being of the patient, the health and well being of an industry that exists that offers much better care, and there it is more than just an issue of lower costs – it is better care at home. He added that the board would continue to meet to hear the issues and assist in the resolution process. He thanked everyone for coming and requested that they send in their suggestions as to what the board can do legislatively to help.

President Powers also thanked everyone for their participation and announced that due to continuing interest and today's time constraints that did not allow all interested attendees to address the board, the board will hold another public forum on Medicare Part D Plans in March. He added that written testimony may be submitted to the board's Executive Officer, Virginia Herold who will ensure that it is distributed to all board members.

The forum ended at 11:35 a.m.

OPEN SESSION

The board initiated petition hearings at 11:45 am.

PETITIONS FOR REINSTATEMENTS

An administrative law judge was present to conduct a hearing to consider petition for reinstatement submitted from:

- Evan Stein
- Richard Schweitz
- Kenneth Foresta

CLOSED SESSION

The board went into closed session pursuant to Government Code section 11126(c)(3) to deliberate on the requests for reinstatements.

The proposed decisions will be drafted by the judge and presented to the board for consideration via mail vote.

ADJOURNMENT

The meeting was adjourned at 4:00 pm.