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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: **February 1 and 2, 2006**

LOCATION: **Hilton Los Angeles Airport**
5711 W. Century Blvd.
Los Angeles, CA 90045

BOARD MEMBERS PRESENT:
Stanley Goldenberg, President
William Powers, Vice President
Marian Balay
Richard Benson
Ruth Conroy
David Fong
Clarence Hiura
John Jones
Kenneth Schell
Andrea Zinder

STAFF PRESENT:
Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judith Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Dennis Ming, Supervising Inspector
Joshua Room, Deputy Attorney General
LaVonne Powell, Department of Consumer Affairs Legal Counsel
Jan Perez, Legislative Coordinator

CALL TO ORDER

President Goldenberg called the meeting to order at 9:00 a.m. on February 1, 2006.

PRESIDENT'S REPORT

- **Recognition of Those Who Provided Disaster Response to Victims of the Gulf Coast Storms:** President Goldenberg began the board meeting with a video produced by Michael Sohmer, PharmD., of the early days of Katrina relief at the New Orleans Airport. Dr. Sohmer was one of the individuals publicly recognized at the board's October meeting for his aid to the region, but his video was not viewed until this meeting.

- **Board of Pharmacy – Strategic Planning**

  President Goldenberg stated that at the April Board Meeting, the board would revise its strategic plan. As an adjunct, President Goldenberg stated that at some point after the April meeting, his goal is to create a summit involving all those involved in the pharmacy profession to participate and help develop a better understanding of the direction pharmacy practice will take in the 21st century. He asked for everyone's help in this effort.

- **Announcements**

  President Goldenberg acknowledged former board presidents, Richard Mazzoni and Robert Toomajian who were in the audience.

ORGANIZATIONAL DEVELOPMENT COMMITTEE

Chairperson Ruth Conroy gave the report from the January 17, 2006, Organizational Development Meeting.

Chairperson Conroy welcomed Marian Balay to the committee, WHO REPLACED President Goldenberg on the committee.

- **Recognition of Those Who Provided Disaster Response to Victims of the Gulf Coast Storms:**

  Chairperson Conroy stated that at the October Board Meeting and in the October 2005 *The Script,* the board commended board licensees who provided services as part of hurricane relief efforts to victims of the Gulf Coast storms.

  She added that the board has since received no additional information to recognize others who provided disaster relief and she encouraged those who have experience to share to come forward so the board can recognize them.

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

Chairperson Conroy stated that in July 2005, the board recognized 450 pharmacists who have been licensed with the board for at least 50 years. At the beginning of October, an additional 49 pharmacists were added to this list of pharmacists when they completed their 50 years of licensure since July 1. Between November 1, 2005 and January 31, 2006, an additional eight pharmacists reached this milestone.

To acknowledge those with 50 years of service, the board mails a congratulatory letter and award certificate to each pharmacist. The letter also invites the pharmacist to a future board meeting. Additionally, each pharmacist has his or her name published in an ongoing feature in *The Script* to acknowledge those who have achieved this milestone. Acknowledging these pharmacists is a regular component of each board meeting.

Dr. Conroy stated that later during this meeting the board would individually recognize those pharmacists with 50 years of service in attendance at this meeting.

- **Strategic Plan Update 2006-2011 Will Be Initiated in April 2006:**

  Chairperson Conroy stated that at the April 2006 Board Meeting, the board will revise its strategic plan. It has been three years since the plan has been substantially modified, and four years since the board began the initial steps to creating the current structure of the strategic plan.

  The board has hired Lindle Hatton, PhD, to assist in this update. Dr. Hatton has led the board in this process before. Over the next few months, the Organizational Development Committee will work with Dr. Hatton in preparation for the April revision.

  The board truly manages its operations by its strategic plan. The current structure, objectives, and reporting mechanisms seem up to date. However, other sections, dealing with internal and external factors that influence the board, its mission and its stakeholders, need revision.

  In addition to the role of board members in revising the plan, all staff will also be involved in the update of the plan before it is submitted for board participation and action in April. Chairperson Conroy stated that as conveyed by President Goldenberg, stakeholders would also be given an opportunity for comment in late March via an announcement on the board's Web site and via a subscriber alert.

- **NABP National Meeting in San Francisco in April 2006, and Districts VII and VIII Meeting in Anaheim in October 2006:**

  Chairperson Conroy stated that this year, two of the National Association of Boards of Pharmacy major meetings would occur in California:
  - California April 8-11, 2006: The NABP annual meeting will take place in San Francisco at the Westin St. Francis Hotel.
  - October 2006: The NABP Districts VII and VIII meeting will be in Anaheim.

The NABP annual meeting will be held in San Francisco on April 8-11 at the Westin St. Francis Hotel.

Chairperson Conroy stated that the NABP has suggested that as the host state, the board may want to perform certain activities.

1. Staff the "Hospitality Suite" on April 8 (Saturday) from 1-5 p.m. The NABP suggests that California board members or staff plan to greet those from other states who will attend the meeting. Three or more individuals are suggested for this function.
2. Staff a "State Information Table" that is open during registration hours, continental breakfasts and refreshment breaks from April 9 (Sunday) through 11 (Tuesday). At this table, brochures about interesting sights, restaurants and attractions in San Francisco are featured. The board's staff will seek brochures from the Visitors/Convention Bureau distribute.
3. The president of the board will open the first business session on April 9 (Sunday) with "words of welcome" before introducing a city or state dignitary.

Chairperson Conroy stated that the board, now a full voting member of the NABP, needs to designate its delegate to the annual meeting. This is the voting member on behalf of California. Additionally an alternate delegate should be designated in the event the delegate is unavailable for a vote.

MOTION: The Organization Development Committee: The board's president shall serve as the official delegate to the annual meeting of the National Association of Boards of Pharmacy. If the president cannot attend the meeting or is absent for a portion of the meeting, the president shall designate an alternate delegate to the meeting to vote on matters before the NABP's sessions.

SUPPORT: 9 OPPOSE: 0

Chairperson Conroy stated that this new policy would now be added to the *Board Member Procedure Manual.*

- **Proposal to Award 2 Hours of Continuing Education for Attending a Committee Meeting:**

Chairperson Conroy stated that beginning with the April 2003 Board Meeting, the board has awarded 6 units of continuing education credit to pharmacists who attend the full business day of a board meeting. This CE can be earned once a year, but cannot be earned by board members or board staff. This opportunity is published in *The Script,* on the agenda of every board meeting and on the board's Web site.

Since January 2005, the board has also allowed pharmacy technicians to earn 6 hours of CE for attending one board meeting per year. (Pharmacy technicians who are certified by the Pharmacy

Technician Certification Board must earn 20 hours of CE every two years, one hour of which must be in pharmacy law.)

Chairperson Conroy stated that during discussion in 2005 at a committee meeting, a suggestion was made for the board to award 2 hours of CE to pharmacists who attend public board committee meetings. A maximum of 4 hours of CE from attending committee meetings was suggested as part of the recommendation.

This proposal was routed to the Organizational Development Committee for consideration. The committee discussed it, but made no recommendation and instead seeks the board's comments during this meeting. For discussion purposes, the proposal is drafted as:

> Proposal: Award two hours of CE to pharmacists (and pharmacy technicians?) who attend Board of Pharmacy committee meetings. However, a maximum of four hours earned from attending board committee meetings may be earned in a year (or within a renewal period – two years).

Mr. Jones stated that the board's committees determine the important issues that come before the board and serve as the initial screening process. He encouraged the public to attend these meetings because often a more in-depth understanding of the issues can be obtained and well worth two hours of CE.

Ms. Zinder stated that she also agrees with the proposal and supports the inclusion of technicians as well. She suggested that more committee meetings be scheduled in Southern California to provide a greater opportunity for licensee attendance.

MOTION: That the board allow a maximum of four hours of CE credit per year to be earned by pharmacists and technicians who attend two different committee meetings and earn two hours for each committee meeting attended.

M/S/C: JONES/CONROY

SUPPORT: 9 OPPOSE: 0

- **Report on the California Pharmacy Council**

Chairperson Conroy stated that the California Pharmacy Council has been formed and is comprised of the deans of the schools of pharmacy, California pharmacist associations and the board.

President Goldenberg stated that the California Pharmacy Council is looking at topics to review and to receive input from the health care community for improvements. Currently, the council is establishing how it will function and the topics to be considered such as all aspects of consulting work and whether changes are needed in that area. He added that the experience was enlightening

and it was his hope that the council would also participate in the board's strategic planning to offer its input and unbiased vision.

Chairperson Conroy stated that at the January 2006 meeting, the committee reviewed the council's proposed charter and administrative regulations for its activities.

The committee had no comments or recommendations, and the board took no action.

- **Sunset Review**

Chairperson Conroy stated that the board is scheduled to undergo sunset review by the Legislature this fall. A comprehensive report responding to the Legislature's standard questions and data requests will be due September 1, 2006. The board's staff is preparing for this project, which represents significant workload.

Ms. Herold stated that the Sunset Review provides the board with an opportunity to go before the Legislature and demonstrate whether or not the board provides a public function that is beneficial to continue. Evaluation occurs on whether the board pursues public safety, that the board is appropriately licensing people and functioning efficiently. In the event that the board cannot demonstrate that the board has met its public protection mandate, the legislature can subsume the board into the Department of Consumer Affairs or sunset the board.

- **Budget Report**

I. Budget Report for 2005/06

Chairperson Conroy stated that the new fiscal year started July 1, 2005. The board's budget for this fiscal year is generally the same as for last year, except for repayment of $3.2 million borrowed in 2001 to offset a deficit in the state's General Fund. This repayment is classified as revenue for the year. An additional $3 million is still owed to the board from the 2001 loan.

- ***Revenue Projected: $8,677,000***

The board's revenue for the year is projected to be comprised of $5,360,000 in licensing fees and $90,000 in interest. The revenue estimate projected from fees is conservative and traditionally is about 10 percent less than actual revenue will be. The board also received $3,227,000 as partial repayment and interest on the 2001 General Fund loan.

- ***Expenditures Projected: $7,954,121***

The board's maximum expenditure authority for the year is $7.9 million. This is the same expenditure authorization as the board received last year.

II. Governor's Budget for 2006/07

The Governor's proposed budget for the fiscal year starting July 1, 2006, was provided to the Legislature in mid-January. Over the next few months, the Legislature will hold hearings and likely modify this proposed budget. The Legislature is required to complete its review and pass a budget bill by June 15, 2006. However, in recent years this deadline has not been met. The Governor may then deduct items from the budget enacted by the Legislature (called a "blue pencil veto") but cannot add money to any budget item.

- ***Revenue Projected: $5,356,000***

  Revenue for the next fiscal year is projected to be comprised of $5,316,000 in fees and $40,000 in interest on money in the board's contingency fund.

- ***Expenditures Projected: $8,446,000***

  Expenditures for next year are $240,000 more than those projected for this fiscal year. There are a number of adjustments to the budget, some of which are:
  -- Restoration of 2.5 of the 10 positions the board lost during the budget restrictions of the early 2000s. ($208,000)
  -- An increase of $91,000 to cover increased hourly fees that will be charged by the Office of the Attorney General for legal fees (the hourly rate will be $158, up from $112 (or $120 for the LA Office) in 2003)

  Also:
  -- A $72,000 reduction in workers' compensation insurance fees, which skyrocketed in the last few years
  -- A $96,000 reduction in facilities expenses due to the board's new office location
  -- A $92,000 reduction in pro rata expenses to the Department of Consumer Affairs (essentially due to lower Office of Information Services charges)

  note: for brevity, not all budget adjustments are listed above

  The board will receive restoration of one inspector position, one receptionist position and one half-time public outreach position.

III. Board Fund Condition

The board's fund condition is a snapshot of its "solvency," in this case meaning whether the revenue collected is sufficient to sustain its expenditures. Over the last few years, the board's annual expenditures have exceeded its annual collected revenue. Normally this would be a huge problem that would trigger budget cutbacks or fee increases, but the board has had a surplus of money in its fund. The board has been trying to spend down this surplus for several years, eliminating a surplus condition caused by the 1999 repayment of a loan to the state's General Fund (during another budget crisis in the early 1990s).

The board must watch its fund condition, however, because if it gets low or into a deficit, the board will run out of money for annual operations. The Business and Professions Code provides

that the board should maintain a reserve of 12 months of annual expenditures as a prudent reserve. However, state budget officials do not agree that this much money needs to be kept as the board's reserve. They prefer a reserve of 3-6 months.

The board ended the last fiscal year (on June 30, 2005) with a reserve of $4,111,000. This is 6.2 months of expenditures

The board's fund condition projections over the next few years are:

- 2005-06: The reserve is estimated at 7.1 months (after repayment of the $3 million).
- 2006-07: A reserve of 2.9 months is projected.
- 2007-08: A reserve of 2.1 months is projected.
- 2008-09: A deficit in the reserve of is projected of –1.7 months.

According to the DCA's Budget Office, in 2007/08 the board will likely receive repayment of at least $2.5 million of the $3 million remaining unpaid from the 2001 loan. Another $500,000 would be repaid in 2008/09. These repayments have been built into the fund condition figures above.

A fee increase will be needed to take effect July 1, 2008 to prevent a deficit during 2008-09.

- **CURES Data Requested for Study Aimed at Limiting Drug Abuse without Limiting Appropriate Medical Treatment**

  Chairperson Conroy stated that Scott Fishman, MD, chief of the Division of Pain Medicine at the UCD Med Center has notified the board that the Robert Wood Johnson Abuse Policy Research Program has invited Dr. Fishman to seek funding to study CURES data. The goal is to develop policies that limit drug abuse without limiting appropriate medical treatment.

  Dr. Fishman has asked for staff's input of how to evaluate the CURES data with respect to whether physician practices have adjusted successfully to the new security prescription forms.

  Executive Officer Harris is involved in the board's assistance to this group.

  President Goldenberg recommended that pain management pharmacists be involved in the study to cover all aspects.

  Bruce Young, representing the California Retailers Association, stated that another dialogue involving CURES is using a CURES system for real-time reporting of pseudoephedrine sales. He added that he hopes that the AG's office will work with the board's staff on this because it serves a vital purpose.

- **Update on I-Licensing Project – Online License Application and Renewal:**

  Chairperson Conroy stated that 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 now moving ahead with a proposal 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 second tier of agencies that may be able to offer this service in the future. No costs are yet available for this conversion, and it may be at least one year from implementation at the board.

- **Relocation of the Department of Consumer Affairs and Board of Pharmacy:**

Chairperson Conroy stated that the board moved into its new office the weekend of December 9 as scheduled. As of late January, staff is still settling in. Construction is ongoing in the building as the building was not ready for occupants at move-in time.

The board plans eventually to hold meetings within the building. Currently the Holiday Inn has been the location of most of the board's public meetings, although the Northern Office Conferences were held in the board's suite in mid-January.

Chairperson Conroy stated that the board is in the process of revising all forms containing the board's old address and/or phone numbers. New business cards have been ordered for staff and board members. The board's Web page highlights the board's new location as well as a cover story on the board's January 2006 *The Script.*

Ms. Herold stated that the new computer-based telephone system is not functioning optimally for the board's callers. A major problem is that the new system relies upon individual phone numbers, and not extension numbers as the board used in its former location. Obtaining the individual phone numbers of the desired staff person requires the caller to listen to a lengthy phone tree message – the system does not allow the entering of a "0" to reach a live operator until the very end of the phone tree message. Board managers are in the process of revamping the system to improve our service.

The phone numbers of key staff will be published in the January *The Script* and will be posted online.

- **Personnel Update and Report**

Ms. Herold reported that in November, the board lost two key staff to other agencies.

- Kim Madsen, a complaint analyst, left to become the assistant executive officer of the Board of Behavioral Science.
- Stephanie Holland, who was the board's computer guru and public information specialist, left to go to the Bureau of Automotive Repair where she will perform contract duties.

The board is recruiting for the following positions (all but the last position listed below are permanent positions):

- A management technician to process wholesaler applications
- An associate analyst to perform consumer complaint resolution
- An associate analyst to perform computer administration duties and respond to public information requests
- A seasonal employee to assist with filing and mailing duties.

The board hired a part-time receptionist, Veronica Hagen, who started working for board in November. Additionally Leah Wright has returned to the board following parental leave, and is working as the board's second (and part-time) receptionist.

The board itself has two public board member positions and one professional member position vacant.

- **Specialized Training**

1. There was a three-day inspector workshop held in November. All inspectors attended and were pleased with the training.

2. All board managers and board members completed sexual harassment (prevention) training by January 1, 2006, as required.

- **Nomination of Bill Powers to SCR 49 Medication Errors Panel**

Chairperson Conroy stated that last year, SCR 49 (Speier) was enacted to recommend improvements, additions or changes to recommend ways to reduce errors in the delivery of prescription and over-the-counter medication. The resolution required a meeting by October 1, 2005, a draft report by March 1, 2006 and a final report by June 1, 2006.

The committee is behind in starting the required meetings and may be delayed in completing its work.

Recently Board President Goldenberg wrote a recommendation in support of Bill Powers' nomination to this panel.

- **Approval of Full Board Minutes (October 25 and 26, 2005)**

Two corrections were submitted to the minutes.

MOTION: Approve the board minutes of October 25 and 26, 2005, once corrected.

M/S/C: HIURA/JONES

SUPPORT: 9 OPPOSE: 0

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

- **Report on the Meeting of January 17, 2006**

  Ms. Zinder reported on the meeting held in Sacramento on January 17, 2006.

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

  Ms. Zinder stated that over one year ago, the board approved a proposal to integrate pharmacy students into public outreach activities. The project chosen was the development of a consumer fact sheet series by student interns. This project is being coordinated by the UCSF Center for Consumer Self Care.

  By January 2005, the program had been initiated. As of January 2006, ten fact sheets have been developed. The fact sheets contain general information on the topic, and contain questions consumers can discuss with their pharmacists on making wise decisions in the subject area.

  At the July 2005 Board Meeting, the board agreed to establish a joint Web site with the Center for Consumer Self Care to house the many fact sheets that should soon be developed through this collaboration because 11 students have agreed to develop three fact sheets each during this school year. The Center for Consumer Self Care will develop and maintain the Web site. The board will appear as co-host. As of this time, no work has yet begun on this Web site.

  The fact sheets that have been developed and are undergoing final staff and legal review are:
  - Generic Drugs – High Quality, Low Cost
  - Lower Your Drug Costs
  - Antibiotics – A National Treasure
  - Is Your Medicine in the News?
  - Did You Know? Good Oral Health Means Good Overall Health
  - Have You Ever Missed a Dose of Medication?
  - What's the Deal with Double Dosing? Too Much Acetaminophen, That's What
  - Don't Flush Your Medication Down the Toilet!
  - Thinking of Herbals?
  - Diabetes – Engage Your Health Care Team

  After review, the fact sheets will be available online and distributed at public health events.

There were over 2, 000,000 hits to the board's Web site last year; however, the board has no way to determine how many of these hits were targeted at the fact sheets. The goal of the UCSF fact sheets was to develop a whole diversity of topics for consumers and distribute them at public events.

The committee also plans to target a future mailing to seniors. The factsheets will also be highlighted in *The Script* .

- **Need for New Consumer Brochures**

Chairperson Zinder stated that the committee encourages the development of new consumer materials.

Three brochures and fact sheets are under development by board staff:

-- consumer information about the importance of Black Box warnings
-- the Beers list of medications that should not generally be prescribed to seniors, and
-- a revision to the board's "Facts About Older Adults and Medicines"

Information about bird flu for practitioners and the public:

There is now a government site for information about bird flu: www.pandemicflu.gov. As this is still an emerging area of public health, the board will add a link from the board's Web site.

There are also two additional sites: www.cdc.gov/flu/pandemic and www.hhs.gov/nvpo/pandemics/dhhs.html

- ***Improving Use of Prescription Medications: A National Action Plan***

The committee reviewed the executive summary of a report prepared by the National Quality Forum and funded by The California Endowment. Released in October 2005, the report consists in part of a literature review of more than 3,000 articles showing the importance of medication compliance and the impact on patient health when patients are noncompliant. The goal is to lead to the development of "a national action plan for broadly improving consumer use of prescription medications in the United States."

During the January meeting, the committee discussed the importance of patient consultation in this process and the key role played by pharmacists. The committee generally believes that people are not taking their medication properly, and this is a serious health issue. Patient medication compliance is a big health problem, and part of it may be addressed through better patient counseling.

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

Chairperson Zinder stated that last year, the board voted to become a founding member of the California Health Communication Partnership. This group is spearheaded by the 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. The function of the group is to develop or disseminate integrated public information campaigns on priority health topics identified by the partnership members.

The third project of this group was an education campaign about early detection tests for cancer (breast cancer and prostate cancer). This project aired in September and October 2005. This project was funded by a grant from a private foundation, which enabled use of a firm (the North American Precis Syndicate) that specializes in dissemination of public service announcements and prewritten articles to a diversity of media outlets nationwide. The board used the same firm for similar dissemination services in the late 1990s.

This cancer screening campaign was among the most successful campaigns ever released by this distribution firm in terms of the number of messages published and aired. The North American Precis Syndicate will provide the partnership a certificate and award for achieving record outreach.

The next campaign of the partnership is on generics, and the California Retailers Association and board staff will be working with Dr. Soller on behalf of the partnership to promote the use of generics. The current plan is to follow a program along the lines of "Generics Makes Sense [Cents,$]," a campaign to raise awareness among consumers about cost-savings of generic medicines.

At the January meeting, the committee discussed the importance of public education campaigns about pharmacist-to-patient consultation since many consumers are not aware of this requirement and the importance of seeking and following a pharmacist's knowledge of drug therapy 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.

- **Request for Joint Public Outreach with the Department of Health Services Office of AIDS to Increase Awareness of access to Syringes in Pharmacies without a Prescription**

Ms. Zinder stated that at the October 2005 Board Meeting, the board agreed to collaborate in an informational campaign with the DHS Office of AIDS, aimed at educating pharmacists and the public about the provisions of a new law that allows local health jurisdictions to authorize nonprescription syringe sales by pharmacies to prevent HIV and Hepatitis (Senate Bill 1159, Vasconcellos, Chapter 608, Statutes of 2004).

Tom Stopka and Alessandra Ross of the Office of AIDS attended the January committee meeting to provide an overview of the project and outreach effort. They indicated that needle purchase programs have been implemented in 15 counties in California. Their office is interested in working with the profession, professional associations, schools of pharmacy, the board's inspectors and other entities as part of their educational outreach program, and they

are particularly interested in reaching pharmacists and pharmacies. One component will be a CE course on this subject that they hope the board will place on its Web site.

The committee agreed to place future articles in *The Script* to continue the educational process of pharmacists. Board staff offered to distribute information about the program from a board information booth to be held at CPhA's annual meeting in February.

The committee invited representatives of the Office of AIDS to a future board meeting where they could directly provide information about the program to the board. This presentation will be scheduled at the April Board Meeting, since the representatives of the Office of AIDS could not attend the February Board Meeting.

- **Update on *The Script***

Chairperson Zinder stated that the January 2006 issue of *The Script* was distributed to board members prior to the meeting and will be mailed to pharmacies, wholesalers and pharmacist interns.

The January 2006 issue focuses on new pharmacy laws enacted in 2005. President Goldenberg's column is directed at pharmacist interns, encouraging them to become involved in board activities.

The Pharmacy Foundation of California printed the October 2005 issue and mailed it to California pharmacists in December.

Staff is now initiating work on the July 2006 issue.

Chairperson Zinder stated that the committee discussed the need to reincorporate the disciplinary actions section back into the newsletter. Several members strongly felt that this was an important educational element for pharmacists. This feature was temporarily stopped several years ago due to staffing issues required to perform the specialized research needed to write the column, coupled with a lack of space in the newsletter due to erratic publishing schedules. At one point the staff planned on adding this information to the Web site.

Board Members agreed this was an important feature of the newsletter, and supported its resumption. Comments from the audience emphasized that this information was useful especially since the board no longer holds Southern and Northern Interim Conferences where the audience could learn from the discussion about problem situations in pharmacies.

The board ended the discussion stating that this information when published in *The Script* serves as a deterrent to other pharmacists and the public has the right to know that these problems and situations exist.

- **Update on *Health Notes***

Chairperson Zinder stated that *Health Notes* is a monograph, produced by the board that contains up-to-date drug therapy guidelines for a specific subject area. Because the board produces *Health Notes*, it conveys what the board believes is current drug treatment in a particular area. Pharmacists can earn continuing education credit by completing a test published at the back of the monograph. Thus the board provides information and actually is sponsoring CE in an area of importance to the board. Seven issues have been produced since 1996. Regrettably, no issues have been published in the last two years due to lack of staff resources to commit to this project.

Under development are two issues:
1. Pain Management
2. Pharmacy Emergency Response to Patients in a Declared Disaster Area

Chairperson Zinder added that neither publication is ready for publication, but articles for both have been written.

- **Update on Public Outreach Activities**

Chairperson Zinder stated that the board strives to provide information to licensees and the public. The board has a number of consumer materials to distribute at consumer fairs and attends as many of these events as possible, where attendance will be large and staff is available.

Additionally, the board has several PowerPoint presentations about the board, on new pharmacy law and on requirements for prescribing and dispensing controlled substances. This information is presented as continuing education courses or presentations where a number of individuals will be present, and are provided by board members or senior staff.

Since the last board meeting, there have been four presentations to students in pharmacy school or pharmacy technician training, and six presentations to professional or law enforcement groups.

- **Center for Health Improvement Report: "Opportunities for Improving the California Pharmacist-Patient Consultation Process"**

Chairperson Zinder stated that the board was a sponsor of a recent survey on the mandated pharmacist to patient consultation process and its effects on Californians aged 65 and over.

The study is now complete and the findings were released in November to a group of stakeholders involved in health policy. She stated that Board President Goldenberg, Vice President Powers, Patricia Harris and Virginia Herold attended this meeting.

President Goldenberg stated that at stakeholders' meeting he was concerned with comments from patients in the focus groups who stated that they did not want consultation because they did not want to interrupt the pharmacist or go to the trouble of requesting consultation. President Goldenberg stated he is interested in having the board explore how to create an environment that

will encourage full consultation. He added that the future of biotechnology medications will require very specific consultation to patients, and the board may need to consider this as part of this evaluation.

President Goldenberg concluded that in light of the information showing poor patient medication compliance and the results of this study of patient consultation of seniors, the board may want to consider addressing patient consultation in the future as a strategic objective.

- **Report of the Subcommittee Meeting on Medicare Drug Benefit Part D held January 17, 2006**

  President Goldenberg stated that on January 17, he and Mr. Powers co-chaired a Medicare Part D Drug Benefit Subcommittee. He added that he hopes that the implementation improves quickly. President Goldenberg stated that he is very proud of the efforts made by pharmacists in dealing with this difficult situation. He encouraged public comment and participation.

  Mr. Powers stated that the problem is that the Part D program is too complex and it was not designed to make it easy for consumers to get their benefits.

  Mr. Powers stated that the initial implementation of the program has affected the sickest and frailest people in the state; the very same people that should have been the last people to be affected. Mr. Powers stated that he would like to thank all pharmacists; including his pharmacist in Sacramento, for stepping up to the plate and dispensing drugs until the problems could be resolved. He added that they have proven that they are the best profession.

  Ms. Mentra, a home infusion pharmacist and general manager of a company in Sacramento, stated that the prescription drug benefit issues have yet to be resolved. She expressed frustration with the difficulty in getting through to the prescription drug plans, remaining on hold for hours at a time and trying to help people navigate the system.

  Ms. Mentra stated that even if you are successful in reaching the prescription drug plan, the customer service representative doesn't know what home infusion is. Even though consumers were guaranteed access to these services, there are no providers in their network. Also, the plans have extremely restrictive formularies that cover very few intravenous medications.

  Geographic coverage has been a major issue particularly in Northern California and this cannot work for home infusion care. She expressed frustration that if she, as a professional cannot navigate the system, how can consumers be expected to access the system.

  Another patient treated with chemotherapy in Grass Valley at home has yet to obtain the next cycle of chemo that is due in a few days must face the option of getting transportation to

Sacramento every day for treatment in one of the infusion rooms or being admitted for a week.

Ms. Mentra stated that their company couldn't determine who the provider of care is supposed to be for another patient they have had for the last eight years.

And yet another patient was given an unreconstituted dry antibiotic powder and sent to another pharmacy for a solution to find the supplies and equipment to administer this.

Ms. Mentra stated that this has been the most catastrophic situation that she has seen in the 20+ years she has in the home infusion practice and 30 years in pharmacist practice. She urged that the board to ask CMS to place home infusion out of Medicare Part D and into Medicare Part B as a professional service where all other payors cover it, before serious injury occurs.

Terry Mulfin, Crescent Health, Pharmacy Director in Anaheim, home infusion.
April Cable, Accounts Receivable Manager, Crescent Health Care
Celia Chavez, Intake Manager, Crescent Health Care

Celia Chavez, Intake Manager, Crescent Health Care, stated that they have also experienced similar situations. She added that patients couldn't understand this complicated system. She stated that a patient in Modesto was released to her home on a double antibiotic treatment where one of the drugs was on the formulary and the other was not. Another request was submitted and a provider in Florida was authorized to supply the drug. The vials were delivered without supplies. The patient is now in danger and the family doesn't know what to do.

Mr. Jones encouraged Ms. Chavez to file a complaint with the board.

President Goldenberg encouraged others to let the board know of other situations so the board can investigate.

Ms. Mulfin, Crescent Health Care, stated that most of their pharmacists are home infusion pharmacists, unfamiliar with on-line billing. On-line billing does not allow for compounded products. She added that the drugs must be individually entered and some of the items require prior authorization and some the drugs are not covered, such as multi-vitamins. She stated that to further complicate matters, 23 different prescriptions must be entered for the compounded drug and the patient receives 23 different co-pays.

Ms. Cable, also of Crescent Health Care, stated that on-line rejection is common, even with prior authorization. She added that currently, they do not have a way to bill a TPN because this will generate co-pay for each of the items. She added that another concern is 3-way split billing, now required for therapy.

Mr. Jones suggested that they contact the CMS and make them aware of the problems. He added that they could make changes if they know the details.

John Cronin, representing the California Pharmacists Association, commended the board's effort to deal with the problems of Medicare Part D. He added that however, the board is not in a position to do anything about the problem and that Congress must address these issues.

President Goldenberg stated that the board is very frustrated and it is important to provide an opportunity for everyone to voice their opinions.

Mr. Jones stated that the Department of Managed Health Care licenses prescription drug programs and Medicare Advantage Drug Programs in California so they have some jurisdiction and the ability to communicate with their licensees. He suggested that the board relay its concerns to them.

President Goldenberg stated that he and Mr. Powers would create a letter to the editor of the Los Angeles Times to express the board's concern.

Mr. Cronin suggested that the board also work with the Department of Health Services.

Ms. Harris stated that the DHS has been working with the Governor's Office and the Department of Aging in weekly telephone conferences to discuss the issues.

- **Recognition Program for Pharmacists Who Have Been Licensed for 50 Years**

  President Goldenberg welcomed pharmacists who have been licensed for 50 years and asked them to come forward. The following pharmacists were recognized:

  Harry Weintraub – Graduate of University of Florida, licensed in 1939, served in the U.S. Air Force and owned two pharmacies in Los Angeles, and remained in business for 47 years. Mr. Weintraub retired in 1988.

  Neodros Bridgeforth – Licensed in 1952, worked for 1 year at Queen of Angeles Hospital, 15 years at Thrifty Drug Stores and in 1969 opened her own pharmacy until 1991. Ms. Bridgeforth was active in the CPhA until 1991.

  J. Wilbert Jones – Graduate of Xavier University in New Orleans in 1946. Worked for Queen of Angeles Hospital for 1 year and Thrifty Drug Stores for 13 years. Mr. Jones opened his own pharmacy in 1970 and later opened a second pharmacy.

  Van Bohrer – Graduated from Drake University in Iowa in 1954 and worked for an independent store. Mr. Bohrer bought his first pharmacy in 1961 in Westwood Village. Mr. Bohrer worked for Longs Drugs for 15 years, retired in 1994, worked

with friends for a few years in California then moved to Las Vegas in 2000. Mr. Bohrer is currently working part time with the VA Hospital at Nellis Air Force Base.

Rokuro Kurihara – Born and raised in Glendale, CA. Graduated from the University of Colorado where he met his wife. Worked USC, LA County Medical Center from 1954-1989, and worked from 1989 to the present at the JCHS.

President Goldenberg acknowledged former board member John Tilley in the audience. President Goldenberg added that Mr. Tilley assisted in the establishment of the 50-year recognition program.

President Goldenberg presented Mr. Tilley with a clock to commemorate his term as a board member. Mr. Tilley is the in-coming president of NCPA, formerly known as NARD.

Mr. Tilley stated that it was an honor and a privilege to serve on the Board of Pharmacy during his four-year term; he gained a great deal of knowledge and experience.

President Goldenberg presented former board presidents Richard Mazzoni and Robert Toomajian, who were also in the audience, with commemorative pins.

- **Request to Consider Reassessing a Portion of the 1600 Hours to Pharmacy-Related Experiences Other than the Traditional Community and Institutional Pharmacy Site Experience**

Fred G. Weissman, Associate Dean of USC, introduced the students who accompanied him to the board meeting. Dean Weissman stated that the purpose of the request is to expand student's experiences to an array of pharmacy-related opportunities that the board will recognize as important; to include such pharmacy-practice experiential areas as industrial pharmacy and managed care.

Dean Weissman stated that students have opportunity in the summer, usually after their 2nd year, to enter into various industrial programs and managed care programs that are not under the jurisdiction of the schools but are programs provided by various pharmacy industrial organizations as well as managed care organizations. As a result, it takes away from the patient care experiences.

He asked the board to consider allowing students to enter these programs as part of their intern hour experience. The following students were introduced:

Tom Wang, USC, 3rd year student
Jonathon Watanabe, USC, 3rd year student
Richard Young, President of the Student Industry Association, USC

David Truong, USC, 3rd year student
Erik Clausen, UOP, 2nd year student

President Goldenberg recommended that the issue be placed on the agenda for the next Licensing Committee Meeting, and he commended the students for their pro-active approach.

- **Acknowledgment**

President Goldenberg introduced Sheryl Butler in the audience, and he read the following from an article: "New Orleans native Sheryl Butler has been a local 770 business representative for four years, before that she was a Rite Aid pharmacist for 22 years. More than 30 of her immediate family members were left homeless after the catastrophic flooding that devastated her home town in the wake of hurricane Katrina."

President Goldenberg stated that he was approached by Ms. Butler who thanked him for keeping the memories of Katrina alive. Ms. Butler stated that progress in restoring the area has a long way to go and help is still needed.

President Goldenberg thanked Ms. Butler for her comments.

LICENSING COMMITTEE

- **Report on the Meeting of December 14, 2005**

Chairperson Conroy reported on the Licensing Committee Meeting held December 14, 2005.

- **Recommendation to Pursue Statutory Changes to Update the Definition of Pharmacy**

Chairperson Conroy stated that since December 2004, the Licensing Committee has been working to respond to inquiries and comments pertaining to the scope of practice of pharmacy, particularly to the practice of pharmacy outside of a traditional pharmacy setting, and to the provision of services to California patients by pharmacies, pharmacists, and ancillary staff outside state lines.

The committee agreed to address these issues through its quarterly meetings. The board encouraged the Committee to develop a concrete proposal in anticipation of the implementation of provisions of the Medicare Modernization Act (MMA) addressing pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act.

As the committee defined and discussed them, there were three primary areas in which further specification and possible statutory change was debated:

(1) Given what has been or may be an increase in the number of entities/premises, both within California and outside of California, that are mostly focusing on "prescription review" and/or

"cognitive services" separate from and/or in the absence of traditional "pharmacy" tasks such as the actual filling of prescriptions and dispensing of drugs, what can or should the Board do to license those entities/premises, as "pharmacies" or otherwise;

(2) When those "review" or "cognitive" services are provided by out-of-state pharmacies or pharmacists to California patients, particularly when out-of-state pharmacists are not located in a licensed premises, should the board require that: the out-of-state pharmacist have a California license, or an alternative California registration; that the pharmacist at least be affiliated with an entity, i.e., a "pharmacy," that is licensed in California; that out-of-state "pharmacies," however defined, have a pharmacist-in-charge (PIC) licensed in California; and/or should the Board depend on discipline by pharmacists' (and pharmacies') home states of licensure to ensure compliance;

(3) In order to conform California law to federal expectations, to permit California licensees to practice fully as professional pharmacists, and/or to maximize the opportunities available under Medicare Part D, should the definitions and scope of practice of pharmacy presently stated in Pharmacy Law be clarified by the board.

One of the primary topics that the committee discussed is the increase emphasis on provision of professional "cognitive services" (e.g., drug utilization review (DUR), medication therapy management (MTM) by pharmacists, which may or may not be provided out of a traditional "pharmacy" premises: (a) whether to license facilities, in California or outside of California, from which such services are provided (which do not otherwise fit the traditional definition of a "pharmacy") *at all*; and (b) if so, whether to license them as "pharmacies," some variant thereof, or as something else entirely.

The draft statutory proposal identified three separate *types* of pharmacies for licensure: (i) "Intake/dispensing" pharmacies - traditional pharmacies; (ii) "Prescription processing" pharmacies - offering prescription review services for another pharmacy or other provider; and (iii) "Advice/clinical center" pharmacies – providing clinical/cognitive services directly to patients or providers. The draft assumed that the three types would not be mutually exclusive, i.e., a given facility could overlap the categories.

There was considerable discussion and opposition to requiring a California licensed pharmacist to be licensed as an "Advice/clinical center pharmacy." It was emphasized that the board needs to recognize the independent practice of pharmacists and the proposal did not. It was argued that the public is adequately protected by licensure of the pharmacist and additional licensure as a pharmacy was not necessary. The recommendation provides pharmacists with an option to be licensed as an "advice/clinical care pharmacy."

Another question was why the board requires an entity that processes prescriptions to be licensed as a pharmacy. The processing of prescriptions under current pharmacy law constitutes the practice of pharmacy and therefore, must be practiced in a licensed pharmacy. It is the location that would receive telephonic and electronic orders for prescriptions and maintain the prescription and patient information, directing the prescription to a particular pharmacy for filling and dispensing. While the pharmacy law authorizes a pharmacist to

electronically enter a prescription or order into a pharmacy's or hospital's computer, the law does not allow other pharmacy personnel to process prescriptions under the supervision of a pharmacist. To allow such a practice outside a pharmacy would require explicit language. An option may be to allow the practice pursuant to a contract with a pharmacy as long as the original prescriptions records and record of the pharmacist's review be maintained by the filling pharmacy.

Another option discussed by the committee was to license the facilities but not call them "pharmacies." Other options included (i) licensing such entities as "pharmacies" under the current definition(s), without revision, (ii) not licensing these entities at all, (iii) deferring the licensure of these entities to some other agency or (iv) awaiting some consensus at the national level about interstate cooperation thereon.

A summary of the proposed amendments is as follows:

B&P § 4037 – Updates the definition of "pharmacy" to include a "dispensing pharmacy", a "prescription processing pharmacy" and an "advice/clinical center pharmacy." A pharmacy would not be required to store or dispense dangerous drugs and a California pharmacist practicing independently would not be required to be licensed as a "advice/clinical center pharmacy," however, the option would be available.

B&P § 4201 – Requires each application to conduct a pharmacy to specify the type or types of pharmacy and requires that the Board of Pharmacy be notified when there is a change to the pharmacy type either prior to or after licensure.

B&P § 4207 – Gives the Board the authority to investigate all matters related to the issuance of a pharmacy license including the furnishing of dangerous drugs or dangerous devices, or to the performance or provisions of prescription/drug order processing or review services and/or cognitive services.

Mr. Powers referred to prescription processing and asked for clarification. He also asked if the service would be downgraded by allowing technicians to perform this function.

Mr. Room explained that this is memorializing what is currently in practice. Many of these services are now being rendered in facilities or locations that are not considered traditional pharmacies, but have the same pharmacy licenses as the other pharmacies and therefore required to stock at least some drugs so they can perform these services. This proposal would make the law more consistent with the actual practice with an option to be licensed as an "advice/clinical care pharmacy where the focus is on that particular practice and not dispensing controlled substances or dangerous drugs.

During discussions at the committee meeting there was concern that pharmacists do not have to be a part of a licensed pharmacy. Also, concern was expressed that the board would require pharmacy licensure. The committee recommends that this would be an option should they

choose to be licensed as a pharmacy because this may provide them with an option to provide services outside of California.

Mr. Jones stated that this is desirable from an enforcement perspective because the California board must rely on other state boards of pharmacy to enforce its laws against their licensees. With a requirement for out-of-state pharmacy licensure, the board has a license in which to act on if problems occur.

Mr. Cronin stated that the CPhA continues to raise objections to this proposal and he hasn't heard anyone speak in favor of this approach at any of the meetings. Mr. Cronin stated that in order for the board to have jurisdiction and authority over individuals providing non-dispensing activities, the individuals must be registered with the board. He added that this would push services away from pharmacists and towards other health care professionals that don't have the same regulatory limitations.

The proposed statutory changes make no change to the ability of a California licensed pharmacist to practice a cognitive services pharmacy, whether it is within a pharmacy or outside a pharmacy. A California licensed pharmacist can practice regardless of the location. The only question is if the pharmacist wants the ability to acquire a pharmacy license for an entity, place or premises, or chooses to be licensed as an advice/clinical center pharmacy or prescription processing pharmacy.

Mr. Room stated that the law is designed so a California pharmacist can perform as a pharmacist, regardless of location. The board allows pharmacists and premises to be licensed as a pharmacy if they choose to be.

Mr. Cronin stated that the definition of a pharmacy should be narrowed so that it only applies to a site where prescription drugs are inspected, stored and dispensed. He added that the purpose of having a pharmacy license is for the security issues with regard to dangerous drugs and devices.

Mr. Cronin stated that out-of-state pharmacists providing care to California residents should be registered with the board as non-resident pharmacists.

Mary Ryan, representing Medco, stated that this proposal is truly identical to what most states already have in place. She added that Medco has call centers with no products within them and licensed pharmacists that are licensed in the state where the call center is. The call center provides services to anyone calling from all 50 states.

Ms. Ryan stated that Medco also has cognitive pharmacies that perform front-end prescription analysis, entry and processing, and contacting physicians before the prescriptions are dispensed. They use highly automated pharmacies to dispense the physical product. The pharmacist does a complete review of the prescription, the patient's profile, etc., and determines whether the correct drug is prescribed for the patient and then sends the actual

prescription to an entity or another pharmacy that dispenses the physical product. She added that MedCo has highly specialized pharmacists in three different types of pharmacies; physical product dispensing, prescription analysis and entry, cognitive services, drug utilization review and pharmacists who consult with patients on the telephone.

Mr. Gray, representing Kaiser Permanente, suggested that the board develop the proposed language so it is explicit regarding the option for California pharmacists practicing independently to be licensed as an "advice/clinical center pharmacy."

Mr. Powers stated that this is essentially a proposal to pursue a change in the law. The board is not changing anything by adopting this proposal. All of the issues that have been brought forward can be brought forward during the legislative process.

Ms. Harris stated that the board could introduce legislation this year once an author is found.

MOTION: Licensing Committee: That the Board of Pharmacy pursue a statutory change to update the definition of pharmacy to include prescription processing and review, patient consultation, drug utilization review, medication therapy management, and/or other cognitive pharmacy services for California patients. A pharmacy would not be required to store and dispense dangerous drugs and dangerous devices. Also, this proposed change would provide an option for California pharmacists practicing independently to be licensed as a"advice/clinical center pharmacy."

SUPPORT: 9 OPPOSE: 0

Chairperson Conroy stated that the committee also discussed whether and/or how to regulate those out-of-state pharmacists who provide cognitive services and/or prescription processing services to and/or for California patients and providers, particularly where those pharmacists are doing so not through affiliation with or employment by a licensed entity (e.g., nonresident pharmacy, advice center, or prescription processing center), but on a consulting or other non-site-specific basis. During all of the committee's discussions of this issue, there has been acknowledgment of a need to balance the board's primary duty to protect the public with its desire not to impede either patient access to services (particularly for California patients) or to create unnecessary barriers for pharmacists.

This issue has not arisen directly in the past, with regard to out-of-state pharmacists filling and/or dispensing prescription drugs, because until now those out-of-state pharmacists have worked in (or at least this has been the assumption) nonresident pharmacies that were themselves required to maintain licensure. So there has not previously been a perceived need to consider licensing out-of-state pharmacists separately (in California) from the entities in which they practice. However, the definition of a nonresident pharmacy needs to be updated

to include all pharmacy services not just the distribution of prescription drugs. The definition would be updated consistent with the definition for California pharmacies. (Attachment B)

It appears that there may be a growth in the number of pharmacists in other states providing services to California patients or providers who are not permanently or indivisibly affiliated with any particular (licensed) premises. This seems particularly likely with regard to cognitive/prescription processing services, which due to imaging/file-sharing advances, are not nearly as tied to a particular "place" as are (or were) dispensing functions.

Other considerations arose from the committee's discussion, including: whether to limit the requirement of California licensure to out-of-state pharmacists providing cognitive or prescription processing services, or to extend it to those dispensing medications as well; whether to require this licensure of all pharmacists providing such services to California patients and/or providers, or only those not affiliated with a licensed entity of some kind; whether to put primary responsibility for record-keeping pertaining to provision of services to California patients on the shoulders of a licensed entity, or on the shoulders of the pharmacist (whether or not licensed in California); and/or if out-of-state pharmacists are not required to be licensed in California, how best to enforce violations of (particularly, California) law committed by those pharmacists.

The wide-ranging discussion at the committee meetings seemed to acknowledge a possibility of choosing between (a) licensing all out-of-state pharmacists, (b) requiring out-of-state pharmacists to maintain some form of registration short of licensure, (c) licensing only entities under the auspices of which out-of-state pharmacists would (be required to) practice, and/or (d) requiring that the pharmacists-in-charge of these licensed entities also be licensed in California.

The draft statutory proposal considered by the committee included a combination of (a), (c), and (d), requiring licensure for all out-of-state pharmacists providing cognitive services or prescription processing services to California, and *also* requiring licensure of the pharmacist-in-charge of a nonresident pharmacy.

Concern was expressed that this requirement would be burdensome to nonresident pharmacies and out-of-state pharmacists. Various other options were discussed at the meetings such as a "registration program" for the nonresident pharmacist, some type of national license certification by the National Association of Boards of Pharmacy (NABP), reciprocity, and/or no additional licensure but a requirement that the out-of-state pharmacist meet California practice standards. Another possibility discussed was not require that the individual practitioner be licensed in California, instead require that the out-of-state pharmacist providing services (or drugs) to California patients practice under the auspices of an entity licensed as a nonresident pharmacy (or other form of site license), with a possible further requirement that the pharmacist-in-charge be a California licensee.

The NABP model rules require that a pharmacist providing telepharmacy services across state lines identify himself or herself to any patient as a "licensed pharmacist," notify patients of the jurisdiction in which he/she is currently licensed to practice pharmacy, and register (with relevant state boards) to practice telepharmacy across state lines and provide patients with the jurisdiction's Board address and phone number. Telepharmacy is defined as the provision of pharmaceutical care through the use of telecommunications and information technologies to patients at a distance.

Among the above-listed alternatives to requiring licensure of all out-of-state pharmacists (or at least the out-of-state pharmacist-in-charge (PICs) that have been discussed, two were presented to the committee in a possible statutory form: (1) the possibility of a non-licensure "certification" of some sort (perhaps supported by NABP), which would require conformance to California standards; and (2) the possibility that licensure would not be required of out-of-state pharmacists so long as services delivered to any California patient were delivered under the auspices of a California-licensed pharmacy/entity.

The California Pharmacists Association (CPhA) provided a similar proposal that would require an out-of-state pharmacist providing cognitive pharmacy services to register as a nonresident provider of pharmacy services.

The Licensing Committee took all the discussions into consideration and determined that the best approach would be to update the definition of a nonresident pharmacy to include prescription review and processing, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in this state and amend B&P § 4303 to strengthen the board's authority to discipline a nonresident pharmacy and not rely on the state where the pharmacy is located to take action first.

The committee did not recommend that the pharmacist-in-charge of the nonresident pharmacy be licensed in California nor require a pharmacist whether practicing as an employee of a nonresident pharmacy or practicing independently and providing cognitive pharmacy services to California patients be licensed in California. The Committee stated that the current licensing structure provided the necessary public protection if an out state pharmacist harms a California patient. If this should happen, the Board would rely on that state to take action. Currently California has such authority to take action against a California pharmacist should he or she harm a patient in another state. The committee did recommend that board amend B & P § 4301(j) and (o) to clarify the law to include violations of other state laws and regulations as unprofessional conduct.

A summary of the proposed amendments are:

B&P § 4112 – Updates the definition of "nonresident" pharmacy to include prescription review, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in California.

B&P § 4120 – Requires each application for a nonresident pharmacy to specify the type or types of pharmacy for which the application is submitted and requires the board to be notified when there is a change to pharmacy type either prior to or after licensure.

B&P § 4301 – Clarifies that a pharmacist would be subject to unprofessional conduct for violation of any statutes or regulations of this state, any other state or federal regulatory agency.

B&P § 4303 – Requires the board to report any violation of laws or regulations by a nonresident pharmacy to the appropriate regulatory or licensing agency of the state in which a nonresident pharmacy is resident. Authorizes the board to take appropriate action against a nonresident pharmacy on the same grounds that the board may take action against a resident pharmacy license.

MOTION: Licensing Committee: That the Board of Pharmacy update the definition of a nonresident pharmacy to include prescription review and processing, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for California patients. That the Board of Pharmacy amend Business and Professions Code Section 4303 to strengthen the board's authority to discipline a nonresident pharmacy.

SUPPORT: 8 OPPOSE: 0 ABSTAIN: 1

Chairperson Conroy stated that the committee also considered proposed amendments to update the statutory definition(s) of practice as a pharmacist to (i) better conform to existing practice, (ii) emphasize the professional development of pharmacy, and/or (iii) maximize California pharmacist practice as recognized by Medicare Part D.

Many of the suggested amendments/revisions are to recognize in statute that the practice of pharmacy means far more than simply counting and dispensing medications, that it is a professional practice, and that licensed professional pharmacists can practice both within and outside the four walls of a traditional pharmacy. The proposed changes also include the record keeping requirements that a pharmacist must maintain when practicing outside of a pharmacy, and includes additional acts or omissions that may be considered unprofessional conduct by a pharmacist.

In addition, the committee discussed additional revisions to B&P § 4052, which essentially subdivides current section 4052 and relocates subparts to sections 4052.1-4052.3.

Mr. Room stated that the substantive changes are to Business and Professions Code Section 4051 that is intended to be a comprehensive list of tasks that pharmacists perform and authorized to perform under their license. The remainder of the changes breakout section

4052 into sections 4052.1, 4052.2, 4052.3 to make it easier to track and follow what a pharmacist license authorizes a pharmacist to do in a particular setting.

A summary of the proposed amendments is as follows:

B&P § 4036 – Updates the definition of pharmacist and the authority for a pharmacist to practice pharmacy within or outside a licensed pharmacy.

B&P § 4050 – States that pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities.

B&P § 4051(a) – Provides the functions that are inherent to pharmacy practice such as interpreting, verifying, and implementing drug orders and prescriptions; dispensing pursuant to legitimate drug orders and prescriptions; ensuring proper drug storage, documentation, inventory, labeling and record-keeping; maintaining accurate, complete, and confidential patient profiles and records; supervising pharmacy technicians and other ancillary personnel in the pharmacy; designing and implementing quality assurance procedures and protocols; compounding drug products pursuant to prescription and for prescriber office use; maintaining safe, secure, and sanitary conditions in licensed premises; performing cognitive services, including drug utilization reviews and management, medication therapy reviews and management, and patient counseling and consultation; collaborating with prescribers and other care providers regarding patient care; implementing standardized procedures and protocols regarding patient care; administering or furnishing drugs or biologicals where permitted by law; initiating, adjusting, or implementing patient drug regimens where permitted by law; and such other pharmacy functions as are authorized by law.

B&P § 4051(c) – Specifies that it is unlawful for any person to perform prescription review, consultation, drug utilization review, medication therapy management, or other cognitive services for patients, prescribers, or other care providers in California unless it is a licensed California pharmacist.

B&P § 4051(d) – Includes "cognitive services" to the functions provided by licensed pharmacists and specifies the records that a pharmacist must maintain when providing cognitive services to patients. It requires the pharmacist to keep a complete log and description of all patient records and other patient-specific information, including any test results or other pertinent data, used, consulted or relied on by the pharmacist when performing cognitive services. The board also has the authority to define by regulation the required content of the log and description. The log and description must be maintained in a readily retrievable form, and provided to the board upon request. The records must be kept for a period of at least three years from the performance of such function. Where the pharmacist performs cognitive services in a licensed pharmacy, the obligation to keep and maintain these records extends to the pharmacy, its pharmacist-in-charge, and to the pharmacist performing the function. Where the function to which the log and description is performed outside the

premises of a licensed pharmacy, the obligation to keep and maintain the foregoing records extends only to the performing pharmacist.

B&P § 4052, 4052.1, 4052.2, 4052.3 – Makes technical amendments in that subparts of this section are being relocated to other sections of law. Clarifies in 4052 that pharmacists may administer immunizations pursuant to a protocol with a prescriber. Current law states that a pharmacist may administer immunizations under the supervision of a prescriber outside a licensed health care facility.

B&P § 4306.5 – Adds to the unprofessional conduct provision for a pharmacist acts or omissions that involve the failure to exercise or implement his or her best professional judgment and/or corresponding responsibility with regarding the dispensing of prescription drugs and/or the provision of cognitive services, acts or omissions that involve the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function and for pharmacists that practices outside of a pharmacy premise, unprofessional conduct may include acts or omissions that involve, the failure to maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

Steve Gray, representing Kaiser Permanente, referred to the issue that pharmacists have been allowed to compound a reasonable supply of medication for prescriber's office use. He added that the reality is that pharmacists also compound items for use in licensed facilities such as surgical clinics. He added that the statute must be clear if the board intends to authorize pharmacists to be the only ones that perform compounding.

Mr. Room stated that AB 595 currently describes compounding and this would need to be reviewed.

Mr. Cronin stated that he feels confident that everyone can work out the issues during the legislative process. He suggested that the board discuss this issue with the NABP for incorporation in the practice act to establish similar action by other state boards.

President Goldenberg stated that at the National NABP Meeting in New Orleans, he was part of a resolution committee and actually created a resolution seeking mutual cooperation between boards. He added that the national board is well aware of this significant topic.

Mr. Jones stated that the California Board of Pharmacy has taken a leadership role in standardizing licensing among other states and developing new approaches such as a nationwide licensing process.

MOTION: Licensing Committee: That the Board of Pharmacy sponsor a statutory change to update the definition of pharmacy practice to reflect the existing practice and the professional development of

pharmacists, amend the law to specify the recordkeeping requirements for pharmacists that practice outside a pharmacy and to pursue the suggested changes to B&P § 4052, which are technical in that subparts are being relocated to other sections of law, and amend B&P § 4306.5 regarding the unprofessional conduct of pharmacists.

SUPPORT: 9 OPPOSE: 0

- **Competency Committee Report**

New Content Outline for CPJE

Ms. Herold stated that at the October 2005 Board Meeting, the board approved the use of the new content outline for the California Pharmacist Jurisprudence Examination (CPJE) which will begin on or after April 1, 2006. The board posted the updated Content Outline on the Web site. The content out line that will be used until April 1, 2006, is posted on the Web site as well.

Ms. Herold stated that candidates are being notified as of January 10, 2006, through the updated letter sent to candidates when they become eligible to take the CPJE, informing them of the change in content outline and effective date of the change. The board has also notified by letter the candidates that were made eligible prior to January 10, 2006, but have not yet take the CPJE examination.

Ms. Herold stated that the Competency Committee has been working harder since the shift to the new exam format; there has not been a reduction in the work demands on this committee.

Test Administration Contract

The Office of Examination Resources with the Department of Consumer Affairs is renewing its contract with a vendor to provide computer based testing. The board uses this contract to administer the CPJE. The current contract expires December 1, 2006. The request for proposal's advertisement publication date was December 2, 2005. The bid submittal deadline for the request for proposal is March 17, 2006. The duration of the contract is three years with 2 one-year optional extensions.

NAPLEX Passing Rates

Ms. Herold stated that the National Association of Boards of Pharmacy (NABP) recently reported the pass rates since implementing the North American Pharmacist Licensure Examination's (NAPLEX) new passing standard. This standard was developed by Thomson Prometric staff using an Angoff procedure with a panel of qualified pharmacists representing a variety of backgrounds. With the implementation of the new passing

standard on May 1, 2005, the NAPLEX has had a slight decrease (approx. 5 percent) in passing scores.

President Goldenberg asked if there is tracking data available to show the movement of pharmacists into California since California began using the NAPLEX. He added that the board hoped that this would assist California in its shortage of pharmacists but there was also a concern that more pharmacists would leave the state than would be coming in.

Ms. Herold responded that the board's licensing statistics have increased from last year. She added that the current exam vendor for the CPJE was bought out by one of its parent companies that resulted in a major restructuring within the organization. Currently, there are only eight sites available to take the CPJE. The vendor assures the board that this is only temporary but this has greatly limited the availability of people from out-of-state to take the exam.

ENFORCEMENT COMMITTEE

- **Report on the Meeting of December 14, 2005**

  Chairperson Powers reported on the Enforcement Committee Meeting held December 14, 2005. He added that the committee did not have a quorum of members present.

- **Implementation of the Electronic Pedigree Requirement for Prescription Drugs Effective January 1, 2007 – Request to Convene Workgroup to discuss Questions Regarding Implementation and Requirements**

  Chairperson Powers stated that in 2004, the Board of Pharmacy sponsored SB 1307 (Figueroa), which was signed by Governor Schwarzenegger and became law on January 1, 2005. The bill made various changes to the wholesaler requirements and distribution of dangerous drugs. Most of the changes strengthened and clarified the requirements for the distribution of dangerous drugs and dangerous devices in California.

  The Enforcement Committee has been monitoring the implementation of this legislation, especially the implementation of the pedigree requirement. The bill requires an electronic pedigree by January 1, 2007 and gives the board the authority to extend the compliance date for wholesalers to January 1, 2008. The Legislature may extend the compliance date for pharmacies to January 1, 2009. The purpose of the pedigree is to maintain the integrity of the pharmaceutical supply chain in the United States.

  The industry anticipates that radio frequency identification technology (RFID) will be the method used to track a drug's pedigree. The manufacturer would tag the drug with a small chip and antenna. When the tag is in close proximity of a reader, it would receive a low-powered radio signal and interact with a reader exchanging identification data and other information. Once the reader receives data, it would be sent to a computer for processing.

During the last year, the Board of Pharmacy and the Enforcement Committee has had presentations from various companies displaying their electronic pedigree solutions. The first presentation was by T3Ci, an application software company that provides drug counterfeit, diversion detection and electronic drug pedigree for the pharmaceutical market. They demonstrated their technology solution for the electronic pedigree. The next presentations were by SupplyScape and Acerity Corporation. SupplyScape presented its electronic pedigree software program that enables a safe and secure pharmaceutical supply chain that complies with federal and state regulations to prevent counterfeit drugs. Acerity Corporation presented its security software program, which is an electronic authentication process. This system employs a cryptography technique in conjunction with RFID forming a multiplayer secure process, which provides numerous advantages and allows versatile applications.

At the September Enforcement Committee meeting, Lew Kontnik, Director of Brand Protection/Business Continuity for Amgen presented to the committee the challenges that Amgen has encountered in developing an electronic pedigree for its manufactured products. He demonstrated the challenges that their company is facing in the implementation of RFID technology to track the electronic pedigree of its liquid products. Primarily he showed how the placement of the radio frequency tag on the products have resulted with inconsistent and inaccurate readings by the scanner unless the scanner is in close proximity of the tagged item, which is not conducive to tracking large quantities of distributed product. He also stated that whatever mechanism is used to generate the electronic pedigree, it must be incompliance with good manufacturing practices (GMPs), which is regulated by the federal Food and Drug Administration (FDA).

Mr. Kontnik presented his company's position that it will be extremely difficult to meet the January 1, 2007 deadline to implement an electronic pedigree for its manufactured drug products.

The board also has been participating in the Uniform Drug Pedigree meetings. This is a group of participants that represents manufacturers, wholesalers, and regulators. The purpose of these meetings is to provide a cooperative effort to develop uniform standards and regulations regarding electronic pedigrees. As result of the board's participation with this group and others, a list of questions and answers were developed on the implementation of California's pedigree requirement. The questions and answers were provided in advance of the Enforcement Committee meeting.

As a result of the question and answer document additional clarification was sought and the suggestion made that an ad hoc committee or workgroup be formed to address the implementation of the electronic pedigree requirement and provide additional clarification. The board has taken a similar approach when it addressed various issues regarding compounding. A workgroup group of the Licensing Committee was formed that invited all interested parties to participate at the table. The board took a similar approach this year when it addressed pharmacy practice issues (see the Licensing Committee Report). The

committee developed a proposal to update the definition of pharmacy, nonresident pharmacy and pharmacist practice. Again all interested parties were invited to the table to participate.

While the Enforcement Committee has been addressing the implementation of the electronic pedigree requirement over the last year, one option is to continue to do so as part of the Enforcement Committee but extend the length of the meeting and the format – invite all participants to the table to discuss the implementation and to determine the appropriate means to clarify issues.

In January, the Federal Food and Drug Administration (FDA) announced a public workshop and vendor display on the use of radio-frequency identification (RFID) to combat counterfeit drugs. The meeting is scheduled for February 8 and 9, 2006, in Maryland. The goals of the meeting are to: (1) identify incentives and obstacles for widespread adoption of RFID throughout the United States drug supply chain, and to discuss ways of overcoming any impediments; (2) Solicit comment on the implementation of the pedigree requirements of the Prescription Drug Marketing Act (PDMA) and the use of e-pedigree; (3) Learn about the state of technology development related to electronic "track and trace" and e-pedigree technology solutions.

Chairperson Powers stated that while the committee did not have a quorum, there were many people there that expressed concern about the effective date of the electronic pedigree requirement. He added that it is his feeling that it is premature to consider any changes at this time. It was his feeling that the State must act on huge problem of counterfeiting because the Federal Government does not appear to be acting on this.

The committee recommended the establishment of an ad hoc committee to address the implementation of the pedigree requirement.

The board expressed support for an ad hoc committee, and agreed that companies need to express clearly where they are in the implementation process.

MOTION: That the Board of Pharmacy form a workgroup as part of the Enforcement Committee to address the implementation of the electronic pedigree requirement that becomes effective January 1, 2007, for wholesalers and January 1, 2008, for pharmacies.

M/S/C: POWERS/SCHELL

SUPPORT: 9 OPPOSE: 0

- **Proposal to Amend Business and Professions Code Section 4040(c) to Allow a Pharmacy to Accept a Fax Prescription From a Patient**

Chairperson Powers stated the Enforcement Committee discussed a proposal to amend B&PC § 4040(c) to allow a pharmacy to accept a fax prescription from a patient provided that the pharmacy has the original prescription before dispensing the prescription medication to the patient. The proposal came from a consumer as a result of a complaint. Current law only authorizes a pharmacy to accept a fax prescription from a prescriber. In the specific complaint, the pharmacy was accepting a fax from the patient; however, the pharmacy stopped the practice because of the law and the consumer was not happy that he could no longer fax the prescription.

The proposal is an option for pharmacies to implement. Concern was expressed that patients would fax their prescriptions (especially a controlled substance prescription) to various pharmacies to have it filled. There was also concern that accepting a fax from a patient would disrupt a pharmacy's workflow. It was discussed that this proposal is an option for pharmacies to implement as a service to patients if it chose to do so. Also, it would be incumbent on the pharmacy to obtain the original prescription prior to dispensing the medication to the patient to prevent the patient from having the same prescription filled at several different pharmacies. There was also discussion that the patient would more than likely forget to bring in the original prescription when picking up the dispensed medication. It was stated that the patient would have to return with the original prescription.

MOTION: That the Board of Pharmacy consider a proposal to amend Business and Professions Code section 4040(c) to allow a pharmacy to accept a fax prescription from a patient.

M/S/C: POWERS/ZINDER

Discussion continued that the decision to allow for a patient to fax a prescription would be a customer service decision that each pharmacy needs to make. Pharmacists should use their professional judgment in determining if this is an appropriate practice.

Deputy Attorney General Room stated the proposal would memorialize the option for a patient to fax a prescription to a pharmacy that would not be dispensed until the original was received by the pharmacy.

The board discussed the issue and determined that this proposal was unnecessary.

As opposed to pursuing a statutory change, the board will use its newsletter to discuss the option for patients to fax a prescription to a pharmacy in advance, and then provide the original before receiving the medication.

MOTION: Table the recommendation to consider a proposal to amend Business and Professions Code section 4040(c) to allow a pharmacy to accept a fax prescription from a patient.

M/S/C: JONES/HIURA

SUPPORT: 8 OPPOSE: 1

- **Proposal to Amend Business and Professions Code Section 4073(b) to Indicate the Prohibition of Generic Substitution by a Prescriber on an "Electronic Data Transmission Prescription"**

  Chairperson Powers stated that the committee discussed a proposed amendment to B&P § 4073(b) to update pharmacy law regarding the prohibition of generic substitution by a prescriber on an electronic data transmission prescription. Current law requires the physician to personally indicate either orally or on the prescription "Do Not Substitute" or words of similar meaning. If a prescriber checks a box indicating no substitution, then he/she must initial the box or checkmark.

  The purpose of the amendment is to clarify that a physician is not required to manually initial an electronic data transmission prescription in order to prohibit generic substitution. It is presumed that the prescriber is already electronically verified for the data transmission prescription and there is no additional need for the handwritten initial. Concern was expressed that software programs would automatically default to "Do Not Substitute."

  The Centers for Medicare and Medicaid Services (CMS) issued its final rule on November 7, 2005, that covers transactions involving the electronic transmission of prescriptions and certain other information for covered Part D drugs prescribed for Part D eligible individuals. Essentially CMS has interpreted the federal law to preempt all contrary state laws that are applicable to a prescription that is transmitted electronically not only for those individuals who are enrolled in Part D, but for all Part D eligible individuals. Categories that are anticipated by CMS include state laws prohibiting e-prescribing, state laws prohibiting transmissions through intermediaries, state laws requiring certain language if not consistent with the federal act and state laws requiring handwritten signatures. Therefore, this proposal is consistent with the final rule issued by CMS.

  MOTION: That the Board of Pharmacy propose to amend Business and Professions Code section 4073(b) to indicate the prohibition of generic substitution by a prescriber on an "electronic data prescription."

  M/S/C: POWERS/SCHELL

  SUPPORT: 9 OPPOSE: 0

- **Importation of Prescription Drugs**

Chairperson Powers stated that the importation of prescription drugs is an ongoing agenda item for the Enforcement Committee and the Board of Pharmacy meetings for the last three years. This has been a sensitive and controversial issue. The board has been tasked with balancing consumer access to affordable prescriptions against the safety and effectiveness of drugs obtained from foreign sources. The board has heard from many interested parties on this issue during its committee meetings and at its quarterly board meetings. The board's mandate is to protect the public, which includes patient access to "safe and affordable" prescription medications.

Chairperson Powers referred to articles that were provided to the board regarding recent developments on the issue of drug importation including a letter from Governor Schwarzenegger to Congressional leaders calling for a change in federal law to allow consumers to safely import prescription drugs from other countries.

LEGISLATION AND REGULATION COMMITTEE

Regulation Report and Action

Board Approved – Pending Administrative Approval

- **Adoption of Proposed Addition of 16 CCR Section 1727.1 – Exemption for Intern Addresses from Posting On-Line**

  Chairperson Jones stated that on October 25, 2005, the board approved CCR 1727.1 to exclude the posting of pharmacist intern addresses on the Internet. This proposed regulation is currently undergoing administration review. It is anticipated that this regulation will be effective in late spring 2006.

Board Approved - Awaiting Notice

- **Proposed Amendment to Repeal 16 CCR Section 1717.2 – Notice of Electronic Prescription files**

  Chairperson Jones stated that the purpose for repealing section 1717.2 is to remove a barrier that prevents pharmacists, in certain situations, from having full knowledge of all the prescription drugs that a patient is taking. Removing this barrier will result in better patient care while protecting patient medical record privacy. Staff is in the process of drafting the Initial statement of reasons and notice documents so action can be taken at the April 2006, or a future board meeting.

- **Proposed Amendment to 16 CCR Section 1760 – Disciplinary Guidelines**

  Chairperson Jones stated that this rulemaking would allow the board to use the 2006 revision of the Disciplinary Guidelines when deciding appropriate discipline action to take for

violations of Pharmacy Law. Staff anticipates it will complete its final internal review of the guidelines by the end of January 2006. At that time the guidelines will be ready for public notice and the formal start of the rulemaking process. The matter will be brought before the board at the board's April 2006, or a future meeting.

- **Proposed Adoption to 16 CCR Section 1784 – Self Assessment of a Wholesaler by the Designated Representative-In-Charge**

  Chairperson Jones stated that staff has completed its internal review of the assessment form for wholesalers. This regulation will be publicly noticed and brought to the board for action at the board's April 2006, or a future meeting.

Committee Recommendations

- **Consideration of Revised Language Incorporating Comments from the October 2005 Public Hearing to Repeal 16 CCR Section 1717(e) and to Add 16 CCR Section1713 Prescription Drop Boxes and Automated Self-Use Delivery Device for Refill Prescriptions.**

  Chairperson Jones stated that at the Legislation and Regulation Committee on January 26, 2006, staff presented the committee with a revised version of a proposed regulation for prescription drop boxes and automated delivery devices. This proposed regulation is based on public comment and board discussion received at the board's October 25, 2006, Board Meeting on the October 19, 2005 version of the regulation. The January 26, 2006 version of the regulation further strengthens consumer protections from earlier versions of the regulation. Specifically, the new language would require:

  1) a consumer to sign a consent form stating that the consumer has chosen to use the delivery device;
  2) a pharmacy to provide a means for each patient to obtain an immediate consultation with a pharmacist via phone or in person if the patient request a consultation;
  3) complaints received from patients to be reviewed as part of a pharmacy's quality assurance program;
  4) pharmacies to have procedures in place to notify patients when expected prescriptions are not available in the device; and
  5) pharmacies to have procedures in place to ensure the delivery of prescriptions to patients in the event that a device is disabled or malfunctions.

  Comments from the board members both supported or opposed the proposal. Mr. Powers stated that the pharmacy profession prides itself on its ability to promote "Talk to your Pharmacist." He added that it appears that this proposal only makes it more difficult to talk to the pharmacist.

President Goldenberg stated that the board currently grants waivers to allow for the use of these machines. This regulation would provide criteria for pharmacies to follow if they use these machines. Although the machines offer convenience to consumers, there is concern that they could negatively impact consumers. He added that these machines might actually reduce the ability of the pharmacist to interact with consumers. He asked for suggestions and comments from the audience.

Mr. Powers asked if there were any guarantees that freeing up the pharmacist would allow for more consultation.

Chairperson Jones stated that he is also concerned and would like to see solid consumer protection built in. He added that the machines seem to be even more accurate than a pharmacy clerk handing out the prescription because of the safeguards. The machines do not replace pharmacists; pharmacists must fill the prescriptions and load medication into the machine. He added that this is an adjunct to pharmaceutical practice and it is up to the practitioner on how medication is approved for delivery from the machine; however, pharmacists must continue to demonstrate their professional responsibility.

President Goldenberg stated that if abuses were discovered, the board would take action.

Ms. Zinder stated that studies reveal that barriers to consultation exist. She added that consumers are often reluctant to wait in a second line or bother the pharmacist. Often, patients receive their prescription and won't ask the questions they need to ask. She stated that authorizing the machines might provide an opportunity to enhance the consultation system.

Supervising Inspector Ming stated that he's had the opportunity to observe these machines and basically the machines could be described as will-call shelf. He added that usually when picking up a refill prescription, the person you come into contact with is the clerk.

Supervising Inspector Ming stated that he interviewed several patients using the machines in Longs in Del Mar and asked what they liked about the machine and the patients explained that they liked the convenience. Generally, if patients have questions, they ask to talk to the pharmacist.

Supervising Inspector Ming stated that the board receives many complaints due to pharmacy clerks handing out the wrong drugs.

Bill Holmes, representing the ddn Corporation, stated that it is a myth that these machines will replace pharmacists. He added that fewer than 5 percent of the transactions from their machines occur after the pharmacy is closed. Further, during three years of experience using the machines, there have been zero instances where the patient received the wrong drugs. This technology clearly improves the accuracy of the point of sale and non-English speaking patients have options to select another language on the machine whereby a pharmacy clerk

may have difficulty in deciphering the patient's name. Also, patients using these machines have expedited access to a pharmacist if the patients have questions.

Asteres, another manufacturer of the machines, reported that they have eight machines that have delivered over 22,000 prescriptions with almost 6,000 people registered (about 1,000 prescriptions are dispensed per week).

Gary Soloman representing UFCW, for Southern California, expressed concern about central fill because patients may walk away from intervention with a pharmacist.

John Cronin representing the California Pharmacists Association asked how this proposal to promotes the board's vision and mission statement. He also expressed concern that as a result of using these machines, pharmacies may cut hours and decrease access to pharmacists. He suggested that every pharmacy that wishes to use this technology should be required to develop a pharmacy service plan to measure progress.

Cookie Quandt, representing Longs Drugs, stated that Longs currently has 4,000 patients signed up to use the machines and approximately 19,000 prescriptions have been dispensed. She added that only 5 percent of those prescriptions are picked up after the pharmacy is closed. Frequently customers pick up their prescriptions between 4 and 7 p.m., during the busiest times in the pharmacy and patients see the machine as a convenience. Dr. Quandt added that pharmacists have discretion regarding the drugs to include in the unit and patients have the option of using or not the machine.

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy notice revised language to repeal 16 CCR section 1717(e) and to add 16 CCR section 1713 Prescription Drop Boxes and Automated Self-Use Delivery Device for Refill Prescription.

SUPPORT: 6 OPPOSE: 3

- **Request from the California Society of Health-System Pharmacists to amend 16 CCR section 1793.7 and 1793.8, to allow the use of pharmacy technicians in hospital inpatient pharmacies to check other pharmacy technicians filling floor stock, ward stock and unit dose cassettes.**

Chairperson Jones stated that at the October Legislation and Regulation Committee meeting, Maria Serpa representing the California Society of Health-System Pharmacists presented proposed language for a regulation that would permit general acute care hospitals to employ specially trained pharmacy technicians to check the work of other pharmacy technicians (TCT) filling floor stock, ward stock, and unit dose cassettes. The proposed regulation is similar to CSHP's sponsored Senate Bill 592 (Aanestead, 2005); SB 592 is a two-year bill that is currently in the Assembly Health Committee. At the October 2005 committee meeting, the committee directed staff to review SB 592 and the proposed regulation, and to bring an analysis of each to

the next committee meeting so board members could discuss the issue.

At the committee meeting on January 26, 2006 this item was discussed and the committee voted to move the proposal to the board. Mr. Jones, the committee chair, asked CSHP and the California Pharmacists Association to work out their differences and bring an amended proposal to the board meeting.

Chairperson Jones referred to a copy of the proposed regulation, SB 592 analysis, board history on the issue of TCT, a determination that the board has the authority to promulgate TCT regulations, and results from two studies conducted on effectiveness of TCT, a letter from CPHA, and testimony submitted by CSHP at the January 26, 2006 committee meeting.

Susan Ravnan, Pharm.D., FCSHP, Associate Professor, University of Pacific, Director of Government and Professional Affairs Externship, CSHP

Dr. Ravnan stated that she wished to provide supporting testimony to the board regarding the proposed regulations to enhance patient medication safety in the hospital setting by freeing pharmacists from checking unit dose and ward stock medications filled by technicians working in the hospital and deploying them to the patient care area to provide direct medication management.

She referred to handouts, specifically a cover page highlighting pertinent facts related to how this regulation improves patient medication safety. Additional information and references were provided to assist the board in its review and decision-making.

Specifically,

- A 43 percent decline in hospital deaths transpired as a result of direct medication management by pharmacists working in the hospital.
- A pharmacist working in the hospital and providing direct medication management prevented 1 death per day.
- 66 percent of medication errors occur when the prescriber writes the order.
- 32 percent of medication errors occur when the medication is administered to the patient in the hospital.

When pharmacists working in a hospital provide direct medication management, medication errors adversely affecting patient outcomes decrease by 94 percent. Dr. Ravnan stated that the prevailing issue is how can direct medication management by pharmacists in a health system be increased to improve medication safety. One way is by the help of properly trained pharmacy technicians. Pharmacy technicians working in a hospital play a vital role in medication safety because they allow the profession to better use pharmacists in health system settings to manage medication therapy. One example of how they improve medication safety is through checking unit dose and floor stock medications in the hospital setting. For well over 10 years, 5 states, which currently use pharmacy technicians working in a hospital to

check unit dose medications, report no adverse patient outcomes. Pharmacy technicians demonstrate a 99.88% accuracy unit dose-checking rate in the inpatient setting.

Dr. Ravnan added that the CSHP is encouraged that the board recognizes this issue as a critical consumer protection and demonstrates their support of inpatient pharmacy technicians checking unit dose medications legislation.

Dr. Ravnan stated that the change the CPhA and the CSHP made to the language is under section 1793.8 as follows:

> Section 1793.7 remains the same and section and section 1793.8 adds a paragraph as follows:
> Only inpatient hospital pharmacies (B&PC 4029) that maintain a clinical pharmacy services program as described in (B&PC 4051, 4052) may have a technician-checking technician program as described above. The pharmacy shall have on file a description of the clinical pharmacy program prior to initiating a technician checking technician program. The State Board of Pharmacy shall monitor the clinical pharmacy program by incorporating the program into the biennial self-assessment for hospital pharmacies. (Section 1715).

Ms. Powell stated that there are technical problems with the language submitted but these can be readily corrected.

Ochi Khoja, 4th year student at the University of Southern California, stated that she is currently doing an administrative clerkship at Desert Regional Medical Center in Palm Springs. Ms. Khoja stated that as a student, she is interested in the future and the direction of pharmacy and her ability to use her clinical training at USC to optimize patient outcomes, patient safety and improve healthy outcomes. With the growing need for pharmacists to be more engaged in clinical consultation and more patient related management, a tightly controlled role of technician has the potential to grow in the future. Clinical pharmacists are more involved in consultation such as parenteral nutrition, pain management, medication reconciliation, and medication safety.

In order to leave time for the pharmacists to maintain a focus on clinical consultation, it is advisable to establish a process by which the technicians can check other technicians in filling medication cassettes filling under a narrowly defined and strictly managed quality process.

John Cronin, representing the California Pharmacists Association, stated that the CPhA worked with the CSHP on this that this proposal and it does support the board's vision and its mission.

Ms. Harris added that the proposed language makes it very clear that it is specifically applicable only to acute care hospital inpatient operations.

Mr. Room stated that he and Ms. Powell would resolve technician problems with the language.

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy amend 16 CCR sections 1793.7 and 1793.8 to allow the use of pharmacy technicians in hospital inpatient pharmacies to check other pharmacy technicians filling floor stock, ward stock and unit dose cassettes.

SUPPORT: 8 OPPOSE: 0 ABSTAIN: 1

- **Board Omnibus Regulation Provisions for 2006**

Proposal to Repeal 16 CCR Sections 1786 – An Outdated Provision Related to Exemptees

Chairperson Jones stated CCR section 1786 is outdated and needs to be repealed. This 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 linked to an exemptee licensed to a specific licensed wholesaler location, not to the exemptee (or designated representative).

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy repeals 16 CCR section 1786.

Specifically:

~~**1786. Exemptions.**~~

~~(a) If a person, on the basis of whose qualifications a certificate of exemption has been granted under Business and Professions Code Section 4054, leaves the employ of a supplier, said supplier shall immediately return the certificate of exemption to the board.~~

~~Authority cited: Section 4005, Business and Professions Code.~~
~~Reference: Sections 4051, 4053 and 4054, Business and Professions Code.~~

SUPPORT: 9 OPPOSE: 0

Abandonment of Application Files - Proposed Revision to CCR 1706.2 that Would Add Veterinary Food-Animal Drug Retailer, Hypodermic Needle and Syringes, and Designated Representatives to the Regulation Section.

Chairperson Jones 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, or designated representatives to the regulation.

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy would revise CCR section 1706.2 to add veterinary food-animal drug retailer, hypodermic needle and syringes, and designated representatives to the regulation section.

Specifically:

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.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4029, 4037, 4043, 4110, 4112, 4115, 4120, 4127.1, 4160, 4161, 4180, 4190, 4200, 4201, 4202, 4203, 4204, and 4205, Business and Professions Code.

SUPPORT: 9 OPPOSE: 0

Proposed Revision to CCR 1775.4 That Would Allow a Person or Entity to Reschedule an Informal Office Conference Only One Time When Contesting a Citation. [Note: Approved by the committee on October 25, 2005.]

Chairperson Jones stated that in 2003, the board revised its system for issuing citations to make its procedures more consistent with the procedures used by other boards within the Department of Consumer Affairs. During the revision process, a provision in CCR 1775(a) that allows a person or entity to only reschedule an informal office conference one time was inadvertently left out of the revised regulations. This proposal would restore this provision to CCR 1775.4.

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy revise CCR 1775.4 to allow a person or entity to reschedule an informal office conference only one time when contesting a citation.

Specifically:

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. <u>Persons or entities may reschedule an informal office conference once.</u>
(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 to be 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.

Authority cited: Sections 125.9, 148 and 4005, Business and Professions Code. Reference: Sections 125.9 and 148, Business and Professions Code.

SUPPORT: 9 OPPOSE: 0

- **Proposed Regulations - Section 100 Changes**

Chairperson Jones stated that Section 100 changes are technical corrections made to existing regulations to make the regulations consistent with new laws or correct obvious or nonsubstantive errors. Section 100 rulemakings are an expedited process.

Proposed Revision to CCR 1709.1 to Replace the Term "Exemptee-in-Charge" with "designated representative-in-charge." The Term "Designated Representative-in-Charge" Was Added to Pharmacy Law in 2005 by Senate Bill 1307 (Chapter 857, statutes of 2004) and Became effective on January 1, 2006). [Note: Approved by the committee on October 25, 2005.]

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy revise CCR section 1709.1 to replace the term "exemptee-in-charge" with "designated representative-in-charge."

Specifically:

CCR 1709.1. (a) The pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.

(b) The pharmacy owner shall vest the pharmacist-in-charge with adequate authority to assure compliance with the laws governing the operation of a pharmacy.
(c) No pharmacist shall be the pharmacist-in-charge of more than two pharmacies. If a pharmacist serves as pharmacist-in-charge at two pharmacies, those pharmacies shall not be separated by a driving distance of more than 50 miles.
(d) No pharmacist shall be the pharmacist-in-charge of a pharmacy while concurrently serving as the ~~exemptee-in-charge~~ designated representative-in-charge for a wholesaler or a veterinary food-animal drug retailer.
(e) Notwithstanding subdivision (a), a pharmacy may designate any pharmacist who is an employee, officer or administrator of the pharmacy or the entity which owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis as the pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity which owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with documentation of the involvement of a pharmacist-in-charge designated pursuant to this subdivision with the pharmacy and efforts to obtain and designate a permanent pharmacist-in-charge.
(f) A pharmacist may refuse to act as a pharmacist-in-charge at a second pharmacy if the pharmacist determines, in the exercise of his or her professional judgment, that assuming responsibility for a second pharmacy would interfere with the effective performance of the pharmacist' s responsibilities under the Pharmacy Law. A pharmacist who refuses to become pharmacist-in-charge at a second pharmacy shall notify the pharmacy owner in writing of his or her determination, specifying the circumstances of concern that have led to that determination.
(g) A person employing a pharmacist may not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this section.

Authority cited: Section 4005, Business and Professions Code.
Reference: Sections 4081, 4113, 4305, and 4330, Business and Professions Code.

SUPPORT: 9 OPPOSE: 0

Minimum Standards for Wholesalers – Proposal to Revise Section 1780 to Update the USP Standards, to Require the 2005 USP Revision

The committee recommends noticing a proposed revision to CCR 1780 that would update the USP standards, to require the 2005 USP Revision. [Note: Approved by the committee on October 25, 2005.]

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy revise CCR section 1780 to update the USP standards to require the 2005 USP revision.

Specifically:

CCR 1780. The following minimum standards shall apply to all wholesale establishments for which permits have been issued by the Board:
(a) A wholesaler shall store dangerous drugs in a secured and lockable area.
(b) All wholesaler premises, fixtures and equipment therein shall be maintained in a clean and orderly condition. Wholesale premises shall be well ventilated, free from rodents and insects, and adequately lighted. Plumbing shall be in good repair. Temperature and humidity monitoring shall be conducted to assure compliance with the United States Pharmacopeia Standards (~~1990, 22nd~~ 2005, 28th Revision).
(c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.
(1) All facilities shall be equipped with an alarm system to detect entry after hours.
(2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
(3) The outside perimeter of the wholesaler premises shall be well lighted.
(d) All materials must be examined upon receipt or before shipment.
(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
(2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(e) The following procedures must be followed for handling returned, damaged and outdated prescription drugs.

(1) Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be placed in a quarantine area and physically separated from other drugs until they are destroyed or returned to their supplier.

(2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be placed in a quarantine area and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug shall be destroyed or returned to the supplier unless testing or other investigation proves that the drug meets appropriate United States Pharmacopeia Standards (~~1990, 22nd~~ 2005, 28th Revision).

(f) Policies and procedures must be written and made available upon request by the board.

(1) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for maintaining records to document proper storage.

(2) The records required by paragraph (1) shall be in accordance with Title 21, Code of Federal Regulations, Section 205.50(g). These records shall be maintained for three years after disposition of the drugs.

(3) Wholesale drug distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of wholesale drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.

(4) Each wholesaler shall provide adequate training and experience to assure compliance with licensing requirements by all personnel.

(g) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

Authority cited: Section 4005, Business and Professions Code.
Reference: Sections 4043, 4051, 4053, 4054, 4059, 4120, 4160, 4161 and 4304, Business and Professions Code.

SUPPORT: 9 OPPOSE: 0

Minimum Standards for Veterinary Food-Animal Drug Retailers - Proposed Revision to CCR 1780.1 and 1781 that Would Replace the Term "Exemptee" with "Designated Representative." (The term "designated representative" was added to Pharmacy Law in 2005 by Senate Bill 1307 (Chapter 857, statutes of 2004) and became effective on January 1, 2006)

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy revise sections 1780.1 and 1781 of the California Code of Regulations to replace the term "exemptee" with "designated representative."

Specifically:

CCR 1780.1. In addition to the minimum standards required of wholesalers by section 1780, the following standards shall apply to veterinary food-animal drug retailers.

a. Drugs dispensed by a veterinary food-animal drug retailer pursuant to a veterinarian's prescription to a veterinarian's client are for use on food-producing animals.

b. Repackaged within the meaning of Business and Professions Code section 4041 means that a veterinary food-animal drug retailer may break down case lots of dangerous drugs as described in 4022(a), legend drugs or extra label use drugs, so long as the seals on the individual containers are not broken. Veterinary food-animal drug retailers shall not open a container and count out or measure out any quantity of a dangerous, legend or extra label use drug.

e. When a vet retailer ~~exemptee~~ designated representative dispenses a prescription for controlled substances, the labels of the containers shall be countersigned by the prescribing veterinarian before being provided to the client.

f. Whenever a vet retailer ~~exemptee~~ designated representative dispenses to the same client for use on the same production class of food-animals, dangerous drugs, legend drugs or extra label use drugs prescribed by multiple veterinarians, the vet retailer ~~exemptee~~ designated representative shall contact the prescribing veterinarians for authorization before dispensing any drugs.

g. Refilling A Veterinarian's Prescription

(1) A veterinary food-animal drug retailer may refill a prescription only if the initial prescription is issued indicating that a specific number of refills are authorized. If no refills are indicated on the initial prescription, no refills may be dispensed. Instead, a new prescription is needed from the veterinarian.

(2) A veterinary food-animal drug retailer may not refill a veterinarian's prescription order six months after the issuance date of the initial order. Records of any refills shall be retained by the veterinary food-animal drug retailer for three years.

h. Labels affixed to a veterinary food-animal drug dispensed pursuant to Business and Professions Code section 4041 shall contain the:

(1) Active ingredients or the generic names(s) of the drug
(2) Manufacturer of the drug
(3) Strength of the drug dispensed
(4) Quantity of the drug dispensed
(5) Name of the client
(6) Species of food-producing animals for which the drug is prescribed
(7) Condition for which the drug is prescribed
(8) Directions for use
(9) Withdrawal time
(10) Cautionary statements, if any
(11) Name of the veterinarian prescriber
(12) Date dispensed
(13) Name and address of the veterinary food-animal drug retailer
(14) Prescription number or another means of identifying the prescription, and if an order is filled in multiple containers, a sequential numbering system to provide a means to identify multiple units if shipped to the same client from the same prescription (container 1 of 6, container 2 of 6, etc.)
(15) Manufacturer's expiration date

i. A record of shipment or an expanded invoice shall be included in the client's shipment, and shall include the names of the drugs, quantity shipped, manufacturer's name and lot number, date of shipment and the name of the pharmacist or vet retailer ~~exemptee~~ designated representative who is responsible for the distribution. Copies of the records shall be distributed to the prescribing veterinarian and retained by the veterinary food-animal drug retailer for three years.

j. If a retailer is unable at any one time to fill the full quantity of drugs prescribed, the retailer may partially ship a portion so long as the full quantity is shipped within 30 days. When partially filling a veterinarian's prescription, a pharmacist or vet retailer ~~exemptee~~ designated representative must note on the written prescription for each date the drugs are shipped: the quantity shipped, the date shipped, and number of containers shipped, and if multiple containers are dispensed at one time, each container must be sequentially numbered (e.g., 1 of 6 containers), If a retailer is unable to dispense the full quantity

prescribed within 30 days, a new veterinarian's prescription is required to dispense the remainder of the drugs originally prescribed.
k. Upon delivery of the drugs, the supplier or his or her agent shall obtain the signature of the client or the client's agent on the invoice with notations of any discrepancies, corrections or damage.
l. If a person, on the basis of whose qualifications a certificate of exemption has been granted under Business and Professions Code Section 4053 (the vet retailer ~~exemptee~~ designated representative), leaves the employ of a veterinary food-animal drug retailer, the retailer shall immediately return the certificate of exemption to the board.
m. Training of Vet Retailer ~~Exemptee~~ Designated Representative:

(1) A course of training that meets the requirements of section 4053(b)(4) shall include at least 240 hours of theoretical and practical instruction, provided that at least 40 hours are theoretical instruction stressing:

(A) Knowledge and understanding of the importance and obligations relative to drug use on food-animals and residue hazards to consumers.

(B) Knowledge and understanding of state and federal law regarding dispensing of drugs, including those prescribed by a veterinarian.

(C) Knowledge and understanding of prescription terminology, abbreviations, dosages and format, particularly for drugs prescribed by a veterinarian.

(D) Understanding of cautionary statements and withdrawal times.

(E) Knowledge and understanding of information contained in package inserts.

(2) As an alternative to the training program specified in paragraph (1), other training programs that satisfy the training requirements of 4053 include fulfillment of one of the following:

(A) Possessing a registration as a registered veterinary technician with the California Veterinary Medical Board.

(B) Being eligible to take the State Board of Pharmacy's pharmacist licensure exam or the Veterinary Medical Board's veterinarian licensure examination.

(C) Having worked at least 1,500 hours within the last three years at a veterinary food-animal drug retailer's premises working under the direct supervision of a vet retailer ~~exemptee~~ designated representative. The specific knowledge, skills and abilities listed in sections 1780.1(m)(1)(A-E) shall be learned as part of the 1500 hours of work experience. A vet retailer ~~exemptee~~ designated representative who vouches for the

qualifying experience earned by an applicant for registration must do so under penalty of perjury.

Authority cited: Sections 4005 and 4197, Business and Professions Code. Reference: Sections 4040, 4041, 4053, 4059, 4063, 4070, 4081, 4196, 4197, 4198 and 4199, Business and Professions Code.

SUPPORT: 9 OPPOSE: 0

Legislation Report and Action

Chairperson Jones reported on the January 26, 2006, Legislation and Regulation Committee Meeting. He stated that the Legislature reconvened on January 4, 2006 for the 2006 Legislative Session and few bills impacting the practice of Pharmacy have been introduced so far. Currently there are 14 bills remaining from the 2005 session. The board has positions on eight and watch positions on six.

Board Sponsored Legislation

- **AJR 40 (Chan) Medicare Prescription Drugs**

Chairperson Jones stated that this resolution was introduced on January 19, 2006. Legislation has been introduced in the Congress, H.R. 3861, "The Medicare Informed Choice Act of 2005," that extends the deadline for enrollment in Medicare Part D until December 31, 2006, permits Medicare beneficiaries to change plans once in 2006 if they have made a poor selection, and protects those with retiree health benefits who may not be aware that purchasing Medicare drug coverage could cost them their retiree benefits. This resolution memorializes the Congress and the President of the United States to enact H.R. 3861 to protect our nation's disabled and senior citizens who are Medicare beneficiaries.

MOTION: That the Board of Pharmacy support AJR 40 by sending a letter of support to the authors of the resolution and encourage Congress to pass this measure to extend the enrollment date to December 31, 2006.

M/S/C: POWERS/BALAY

SUPPORT: 9 OPPOSE: 0

- **AB 132 (Chapter 2, Statutes of 2006) Medi-Cal: Rx Drug Benefit**

Chairperson Jones stated that this bill recently enacted, requires the Department of Health Services, beginning on January 12, 2006, and concluding 15 calendar days later, to provide drug benefits, when any of specified conditions exists, to a Medicare-eligible person who is also eligible for Medi-Cal prescription drug benefits and who is not able to obtain drug

benefits from his or her prescription drug plan under the Medicare program. The bill allows the Governor to extend coverage for these drug benefits from the close of the initial 15-day period for up to an additional 15-calendar-day period. The bill appropriates $150,000,000 from the General Fund for the purposes of the bill. This bill declares that it is to take effect immediately as an urgency statute.

Proposed Legislation

- **Request from the Medical Board of California to amend B&P section 4301(e) related to "excessive" furnishing.**

  Chairperson Jones stated that at the October 25, 2005, Legislation and Regulation Committee meeting, Dave Thornton, Executive Director of the Medical Board of California (MBC) reported on a legislative proposal MBC's Pain Management Task Force is developing for the 2006 Legislative Session. One of the amendments would have affected Pharmacy Law, specifically Business and Professions Code section 4301(e). He reported that the task force would not move forward with this amendment, after concerns were expressed by the Board of Pharmacy. However, the MBC will move forward with other amendments.

  Chairperson Jones stated that during the Legislation and Regulation Committee meeting, the board was encouraged to monitor these developments to assure that the amendments are consistent with pharmacy law.

  Another comment made during the meeting was that pharmacists now prescribe controlled substances so standards that apply to excessive prescribing could become the Board of Pharmacy's to enforce as well.

- **Request from the Department of Justice to align California's Prescription Monitoring Program (CURES) with the National All Schedules Prescription Electronic Reporting Act of 2005.**

  Chairperson Jones stated that the Department of Justice (DOJ) submitted a legislative proposal to Senator Torlakson to align California's Prescription Monitoring Program (PMP) with the federal National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER Act). This proposal will ensure state compliance with new federal mandates.

  The NASPER Act requires all states to establish a PMP or enhance their current state PMP.

  The NASPER Act imposes several new mandates not previously required by CURES. These mandates include:

  1. Capturing Schedule IV controlled substances data.
  2. Requiring dispensers to submit data within one week of each dispensing of a controlled substance

3. Requiring specific data to be recorded, such as the patient's telephone number, number of refills, and whether the prescription is for a refill or a first-time prescription.

- **The Legislation and Regulation Committee (committee) recommends that the board sponsor a provision in the 2006 omnibus bill to amend B&P sections 4314 and 4315 to authorize the issuance of citations and fines for violation of law related to the voluntary drug repository and distribution program for prescription drugs in county pharmacies.**

Chairperson Jones stated that SB 798 (Chapter 444, Statues of 2005) authorizes a county to establish, by local ordinance, a repository and distribution program for purposes of distributing surplus unused medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. SB 798 placed the provisions of the measure in Health and Safety Code (HSC) sections 150200-150207. The board does not have authority to cite and fine or issue letters of admonishment for violations of SB 798's provisions because the provisions are outside of Pharmacy Law. The board supplied a number of amendments in late August 2005 to make the measure implementable; however, the administrative discipline amendments could not be incorporated without making the bill a two-year bill. This legislative proposal would amend B&P sections 4314 and 4315 to allow the board to use these sanctions for violations of HSC sections 150200-150207.

Amend Sections 4314 and 4315 of the Business and Professions Code, to read:

4314. (a) The board may issue citations containing fines and orders of abatement for any violation of Section 733 or for any violation of this chapter or regulations adopted pursuant to this chapter, in accordance with Sections 125.9, 148, and 4005 and the regulations adopted pursuant to those sections, and Health and Safety Code Sections 150200 through 150206.
(b) Where appropriate, a citation issued by the board, as specified in this section, may subject the person or entity to whom the citation is issued to an administrative fine.
(c) Notwithstanding any other provision of law, where appropriate, a citation issued by the board may contain an order of abatement. The order of abatement shall fix a reasonable time for abatement of the violation. It may also require the person or entity to whom the citation is issued to demonstrate how future compliance with the Pharmacy Law, and the regulations adopted pursuant thereto, will be accomplished. A demonstration may include, but is not limited to, submission of a corrective action plan, and requiring completion of up to six hours of continuing education courses in the subject matter specified in the order of abatement. Any continuing education courses required by the order of abatement shall be in addition to those required for license renewal.
(d) Nothing in this section shall in any way limit the board from issuing a citation, fine, and order of abatement pursuant to Section 4067 or Section 56.36 of the Civil Code, and the regulations adopted pursuant to those sections.

4315. (a) The executive officer, or his or her designee, may issue a letter of admonishment to a licensee for failure to comply with Section 733 or for failure to comply with this chapter or

regulations adopted pursuant to this chapter, or Health and Safety Code Sections 150200 through 150206, directing the licensee to come into compliance.

(b) The letter of admonishment shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the statutes or regulations violated.

(c) The letter of admonishment shall inform the licensee that within 30 days of service of the order of admonishment the licensee may do either of the following:

(1) Submit a written request for an office conference to the executive officer of the board to contest the letter of admonishment.

(A) Upon a timely request, the executive officer, or his or her designee, shall hold an office conference with the licensee or the licensee's legal counsel or authorized representative. Unless so authorized by the executive officer, or his or her designee, no individual other than the legal counsel or authorized representative of the licensee may accompany the licensee to the office conference.

(B) Prior to or at the office conference, the licensee may submit to the executive officer declarations and documents pertinent to the subject matter of the letter of admonishment.

(C) The office conference is intended to be an informal proceeding and shall not be subject to the provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).

(D) The executive officer, or his or her designee, may affirm, modify, or withdraw the letter of admonishment. Within 14 calendar days from the date of the office conference, the executive officer, or his or her designee, shall personally serve or send by certified mail to the licensee's address of record with the board a written decision. This decision shall be deemed the final administrative decision concerning the letter of admonishment.

(E) Judicial review of the decision may be had by filing a petition for a writ of mandate in accordance with the provisions of Section 1094.5 of the Code of Civil Procedure within 30 days of the date the decision was personally served or sent by certified mail. The judicial review shall extend to the question of whether or not there was a prejudicial abuse of discretion in the issuance of the letter of admonishment.

(2) Comply with the letter of admonishment and submit a written corrective action plan to the executive officer documenting compliance. If an office conference is not requested pursuant to this section, compliance with the letter of admonishment shall not constitute an admission of the violation noted in the letter of admonishment.

(d) The letter of admonishment shall be served upon the licensee personally or by certified mail at the licensee's address of record with the board. If the licensee is served by certified mail, service shall be effective upon deposit in the United States mail.

(e) The licensee shall maintain and have readily available a copy of the letter of admonishment and corrective action plan, if any, for at least three years from the date of issuance of the letter of admonishment.

(f) Nothing in this section shall in any way limit the board's authority or ability to do either of the following:

(1) Issue a citation pursuant to Section 125.9, 148, or 4067 or pursuant to Section 1775 of Title 16 of the California Code of Regulations.

(2) Institute disciplinary proceedings pursuant to Article 19 (commencing with Section 4300).

Mr. Cronin stated that SB 798 would involve the pedigree requirement for the drugs returned from nursing homes to a county's redistribution program and needs to be addressed by the Pedigree Task Force.

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy sponsor a provision in the 2006 omnibus bill to amend B&P sections 4314 and 4315 to authorize the issuance of citations and fines for violation of law related to the voluntary drug repository and distribution program for prescription drugs in county pharmacies.

SUPPORT: 9 OPPOSE: 0

- **Amend B&P section 4162, resident wholesalers, to waive the surety bond requirement for government owned and operated wholesalers.**

Chairperson Jones stated that under the current law all wholesalers operating in California are required to submit a surety bond of $100,000 or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the bond is to secure payment of any administrative fine imposed by the board and any cost recovery. Government agencies are self-insured and do not purchase surety bonds. Currently there are eight government-owned and operated wholesalers licensed with the board. These entities store drugs for public safety and emergency preparedness. Given that government agencies are self-insured, the board would like to exempt government owned and operated wholesalers from the bond requirement.

Amend Section 4162 of the Business and Professions Code, to read:

4162. (a) (1) An applicant, that is not a government owned and operated wholesaler, for the issuance or renewal of a wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purposes of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars ($100,000) if the annual gross receipts of the previous tax year for the wholesaler is ten million dollars ($10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars ($25,000).

(3) A person to whom an approved new drug application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application, and is licensed or applies for licensure as a wholesaler, shall not be required to post a surety bond as provided in paragraph (1).
(4) For licensees subject to paragraph (2), or (3), the board may require a bond up to one hundred thousand dollars ($100,000) for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.
(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days after the order imposing the fine, or costs become final.
(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.
(d) This section shall become operative on January 1, 2006, and shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends those dates.

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy Amend B&P section 4162, resident wholesalers, to waive the surety bond requirement for government owned and operated wholesalers**.**

SUPPORT: 9 OPPOSE: 0

- **Licensed Employee, Theft, Impairment: Pharmacy Procedures**

Chairperson Jones stated that in 2004 the board approved an amendment to Section 4104. A drafting error was made when the amendment was included in SB 1111 (Chapter 621, Statues of 2005) Omnibus bill. The proposed change would delete the word "detecting" and replace it with "addressing." No action is needed by the board on this proposal.

Amend Section 4104 of the Business and Professions Code, to read:

4104. (a) Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.
(b) Every pharmacy shall have written policies and procedures for ~~detecting~~ addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.
(c) Every pharmacy shall report to the board, within 30 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy:

(1) Any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice.
(2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs.
(3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.
(4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual.
(5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice. (6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs.

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

- **Adulterated or Counterfeit Drug or Dangerous Device**

Board inspectors periodically have need to restrict misbranded drugs as well as counterfeit drugs. (Any drug or device is misbranded if its labeling is false or misleading in any way.) The proposed change would add the term "misbranded" to Section 4084 to permit inspectors to embargo misbranded drugs or devices.

Amend Section 4084 of the Business and Professions Code, to read:

B&P 4084. (a) When a board inspector finds, or has probable cause to believe, that any dangerous drug or dangerous device is adulterated, misbranded, or counterfeit, the board inspector shall affix a tag or other marking to that dangerous drug or dangerous device. The board inspector shall give notice to the person that the dangerous drug or dangerous device bearing the tag or marking has been embargoed.

(b) When a board inspector has found that an embargoed dangerous drug or dangerous device is not adulterated, misbranded, or counterfeit, a board inspector shall remove the tag or other marking.

(c) A board inspector may secure a sample or specimen of a dangerous drug or dangerous device. If the board inspector obtains a sample prior to leaving the premises, the board inspector shall leave a receipt describing the sample.

(d) For the purposes of this article "counterfeit" shall have the meaning defined in Section 109905 of the Health and Safety Code.

(e) For the purposes of this article "adulterated" shall have the meaning defined in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(f) For the purposes of this article "misbranded" shall have the meaning defined in Article 3 (commencing with Section 111330) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy sponsor a provision in the 2006 omnibus bill to correct a drafting error in Section 4084. The proposed changes are technical. [Note: Approved by the committee on October 25, 2005.]

SUPPORT: 9 OPPOSE: 0

- **Wholesaler License Required**

Chairperson Jones stated that the committee approved a proposed change to clarify that a drug manufacturer's licensed premises is exempt from Sections 4160 and 4161, requiring a wholesaler license. This change would correct a drafting error from SB 1307 (Chapter 857, Statutes of 2004).

Amend Section 4160 of the Business and Professions Code, to read:

B&P 4160. (a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.
(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.
(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.
(d) The board shall not issue or renew a wholesaler license until the wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of that designated representative. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. A wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. A pharmacist may be identified as the designated representative-in-charge.
(e) A drug manufacturer <u>premises</u> licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.
(f) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as a wholesaler.
(g) This section shall become operative on January 1, 2006.

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy sponsor a provision in the 2006 omnibus bill to correct a drafting error

in Section 4160. The proposed change is technical. [Note: Approved by the committee on October 25, 2005.]

SUPPORT: 9 OPPOSE: 0

- **Nonprofit or Free Clinics – Provision in the 2006 omnibus bill to correct inconsistencies in Sections 4180-4182 and 4190-4192, between the requirements for nonprofit or free clinics and surgical clinics licenses issued by the board.**

  Chairperson Jones stated that a clinic license issued by the board allows the purchase of drugs at wholesale and allows for a common stock of dangerous drugs and devices that are then dispensed by authorized prescribers. Without a clinic license, each prescriber must maintain a separate drug supply.

  In 2005, staff reviewed the licensing requirements for clinics and found inconsistencies between the requirements for nonprofit or free clinics and surgical clinics. The proposed statutory changes will streamline the application process, better define who is accountable for the license, and make consistent the two types of licenses issued by the board. The proposed changes were discussed at the board's Licensing Committee meetings on March 16, 2005 and June 15, 2005. Additionally, the board discussed the changes at the full board meeting on July 20, 2005 and approved the changes for inclusion in the omnibus bill.

  Amend Sections 4180-4182 and 4190-4192 of the Business and Professions Code, to read:

Nonprofit or Free Clinics
B&P 4180. (a) (1) Notwithstanding any provision of this chapter, any of the following clinics may purchase drugs at wholesale for administration or dispensing, under the direction of a physician, to patients registered for care at the clinic:

(A) A licensed nonprofit community clinic or free clinic as defined in paragraphs (1) and (2) of subdivision (a) of Section 1204 of the Health and Safety Code.
(B) A primary care clinic owned or operated by a county as referred to in subdivision (b) of Section 1206 of the Health and Safety Code.
(C) A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of Section 1206 of the Health and Safety Code.
(D) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than 20 hours per week as referred to in subdivision (h) of Section 1206 of the Health and Safety Code.
(E) A student health center clinic operated by a public institution of higher education as referred to in subdivision (j) of Section 1206 of the Health and Safety Code.
(F) A nonprofit multispecialty clinic as referred to in subdivision (l) of Section 1206 of the Health and Safety Code.

(2) The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of ~~seven~~ three years for inspection by all properly authorized personnel.

(b) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board. ~~Each license shall be issued to a specific clinic and for a specific location.~~ A separate license shall be required for each of the clinic sites owned and operated by a single county, tribe or tribal organization, non-profit corporation or public institution of higher education. A clinic that changes location, shall notify the board of the change of address on a form provided by the board.

(c) The addition or deletion of a member of the Board of Directors of a tax-exempt clinic's non-profit corporation shall be reported to the board within 30 days on a form to be furnished by the Board.

4181. (a) Prior to the issuance of a clinic license authorized under Section 4180, the clinic shall comply with all applicable laws and regulations of the State Department of Health Services relating to the drug distribution service to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.

~~(b) These policies and procedures shall include a written description of the method used in developing and approving them and any revision thereof.~~

(c) The dispensing of drugs in a clinic shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

4182. (a) Each clinic that makes an application for a license under Section 4180 shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.

(b) The consulting pharmacist shall certify in writing ~~least twice a year~~ quarterly that the clinic is, or is not, operating in compliance with the requirements of this article, ~~and the most recent of those written certifications shall be submitted with the annual application for the renewal of a clinic license~~. Each written certification shall be kept on file in the clinic for three years after it is performed and shall include corrective actions recommended if appropriate.

(c) For the purposes of this article, "professional director" means a physician acting in his or her capacity as medical director or dentist or podiatrist acting in his or her capacity as a professional director in a clinic where only dental or podiatric services are provided.

(d) Any person who has obtained a license to conduct a clinic shall notify the board within 30 days of a change in professional director on a form provided by the board.

Surgical Clinics

B&P 4190. (a) Notwithstanding any provision of this chapter, a surgical clinic, as defined in paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code may purchase drugs at wholesale for administration or dispensing, under the direction of a physician, to patients registered for care at the clinic, as provided in subdivision (b). The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of ~~seven~~ three years for inspection by all properly authorized personnel.

(b) The drug distribution service of a surgical clinic shall be limited to the use of drugs for administration to the patients of the surgical clinic and to the dispensing of drugs for the control of pain and nausea for patients of the clinic. Drugs shall not be dispensed in an amount greater than that required to meet the patient' s needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.

(c) No surgical clinic shall operate without a license issued by the board nor shall it be entitled to the benefits of this section until it has obtained a license from the board. ~~Each license shall be issued to a specific clinic and for a specific location.~~ A separate license shall be required for each of the premises of any person operating a clinic in more than one location.

(d) Any proposed change in ownership or beneficial interest in the licensee shall be reported to the board, on a form to be furnished by the board, at least 30 calendar days prior to (i) execution of any agreement to purchase, sell, exchange, gift or otherwise transfer any ownership or beneficial interest, or (ii) any transfer of ownership or beneficial interest, whichever occurs earlier.

4191. (a) Prior to the issuance of a clinic license authorized under this article the clinic shall comply with all applicable laws and regulations of the State Department of Health Services and the board relating to drug distribution to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are carried out in a manner that is consistent with the promotion and protection of the health and safety of the public. ~~These policies and procedures shall include a written description of the method used to develop, approve, and revise those policies and procedures.~~ The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and clinic administrator.

(b) The dispensing of drugs in a clinic that has received a license under this article shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

4192. Each clinic that makes an application for a license under this article shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the

professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.
(b) The consulting pharmacist shall certify in writing least quarterly that the clinic is, or is not, operating in compliance with the requirements of this article. Each written certification shall be kept on file in the clinic for three years after it is performed and shall include corrective actions recommended in appropriate.
(c) For the purposes of this article, "professional director" means a physician acting in his or her capacity as medical director or dentist or podiatrist acting in his or her capacity as a professional director in a clinic where only dental or podiatric services are provided.
(d) Any person who has obtained a license to conduct a clinic shall notify the board within 30 days of a change in professional director.

Chairperson Jones stated that this was provided as information.

NEW BUSINESS

Steve Gray, representing Kaiser Permanente, stated that he attended the Joint Council on Pharmacist Practitioners (JPPC) where all the CEOs of the national pharmacists' organization and their presidential officers met to coordinate the industry direction.

Dr. Gray stated that the JPPC recognized that there are many problems with the Medicare Prescription Drug Program and they are vigorously addressing the issues. He reported that the JPPC made approximately 155 visits to congressional offices to raise issues.

Dr. Gray stated that the CMS needs to know if specific prescription drug plans PDPs or MAPDs have certain misunderstandings or violations affecting dual eligibles. The program ran smoother in areas where pharmacies were involved with assisting patients in obtaining the best plans. CMS will reconsider how much pharmacies can get involved.

Dr. Gray stated that another area of concern is counterfeit non-prescription drugs found in this country. He suggested that the Board of Pharmacy consider its role in this area.

ADJOURNMENT

There being no further business, President Goldenberg adjourned the meeting at 5:47 p.m.

CLOSED SESSION

The board moved into Closed Session pursuant to Government Code section 11126(c)(3) to deliberate upon disciplinary cases.

February 2, 2006

PETITIONS

- **Petition for Reinstatement**
  Jacob Aynechci

- **Early Termination and Reduction of Penalty**
  Margo Cantrell

- **Reduction of Penalty**
  Laura Fujisawa

CLOSED SESSION

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