California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
Fax (916) 327-6308
www.pharmacy.ca.gov

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: **October 20 & 21, 2004**

LOCATION: **Hyatt Regency San Francisco Airport**
1333 Bayshore Highway
Burlingame, CA 94010

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

BOARD MEMBERS ABSENT:
James Acevedo
Richard Benson

STAFF PRESENT:
Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Joshua Room, Deputy Attorney General
Dana Winterrowd, Department of Consumer Affairs Legal Counsel

CALL TO ORDER

President Goldenberg called the meeting to order at 9:06 a.m. on October 20, 2004.

President Goldenberg welcomed everyone to the board meeting and expressed the goal during his term as board president is to improve communication between licensees, the public and the board. President Goldenberg stated that in working towards that goal, the board's subscriber Web site notification system was activated earlier this month. This feature e-mails interested

parties about updates to the board's Web site and provides a link to the specific addition. Interested parties must subscribe themselves to the board's Web site, and be responsible for keeping their e-mail addresses current. There is no charge for this service.

President Goldenberg reported that within one day of activation, 24 individuals had subscribed to this service. He added that the board is the first agency in the department to use this feature, but other agencies will soon follow. The board will highlight this service in the next *The Script*.

COMMITTEE REPORTS AND ACTION

ORGANIZATIONAL DEVELOPMENT COMMITTEE

Chairperson Tilley stated that at the board's July Meeting, Board President Goldenberg conveyed his goal to obtain diverse opinions from as wide a cross section as possible on matters before the board for policy deliberations.

Chairperson Tilley stated that ideas developed during the Organizational Development Committee meeting included:

1. Inviting local chapters of pharmacist associations to encourage their members to attend meetings in their area.
2. Working with the schools of pharmacy to foster attendance by pharmacy students.
3. Awarding local pharmacists board acknowledgments for significant achievements or for years of service.
4. Notifying other agencies, such as the local Area Agency on Aging, AARP, Senior Outreach, Kiwanis and Rotary organizations about meetings in their communities.

Chairperson Tilley stated that President Goldenberg has pursued some of these ideas for this meeting to promote greater attendance by a more diverse audience. He noted that there were considerably more individuals in the audience than at some other board meetings.

Chairperson Tilley asked those in attendance for additional suggestions to improve communication with the board.

Dr. Schell asked the board to consider using the association's criteria for recognizing individuals for significant achievements and it was suggested that the board target individuals living near the board meeting location site so it would not impose substantial travel for those individuals recognized.

President Goldenberg asked Dr. Schell for assistance in providing the board with the association's criteria for recognition of pharmacists for the committee's review.

Steve Gray, representing Kaiser Permanente, suggested that the board also develop an integrated recognition system sponsored by the Board of Pharmacy with others such as the medical and nursing professions.

- **California Performance Review – A Proposal to Restructure State Government and its Proposal for the Board of Pharmacy**

  Chairperson Tilley stated that the Governor's proposal to restructure state government was released at the beginning of August. His plan is detailed in a 2,547-page report, developed by the California Performance Review (CPR), a group of 275 individuals charged to overhaul state government into a more logical and less costly organization. The CPR states that its reorganization will achieve $32 billion in savings over five years.

  Public hearings have been held to collect information from the public. The restructuring plan would eliminate 118 of 339 boards and commissions, as well as the Department of Consumer Affairs. The healing arts licensing boards of the department would be merged into a new Department of Health and Human Services, this includes the Board of Pharmacy. Most other regulatory boards in the department today have been targeted for elimination. The board's fund would be combined with the special funds of other boards merged into the new department.

  Dr. Fong stated that he supports the Governor's action to review all boards and their role and he added that he is confident that the board will demonstrate its success.

  Mr. Powers stated that the Governor has not taken any position on the recommendations and a Legislative Analyst Office's review of the proposals project that the savings would be considerably less than the $32 billion estimate from the CPR. He added that if adopted, these proposals would downgrade public services.

- **Budget Update and Report**

  1. 2004/05 and Future Year Budgets

     Chairperson Tilley stated that the state's budget for this fiscal year was approved by the Governor on July 31.

     The board's budget is essentially the same as it was last fiscal year with the exception of funding for the AG, which was increased due to the increased hourly fee charges for legal services.

     - **Revenue Projected: $5,444,287**

       The board's revenue for the year is projected to be comprised of $5,346,813 in licensing fees (98.2 percent) and $97,474 in interest (1.8 percent). The revenue

estimate projected from fees is conservative and traditionally is about 10 percent less than actual revenue will be. Not included in this figure is any money collected from cost recovery or citations and fines during the year.

- **Expenditures Projected: $7,360,000**

  The board's maximum expenditure authority for the year is $7.36 million. Personnel is the largest expenditure: $3,686,301 or 50 percent of the board's budget.

- **Redirections and Program Efficiencies to Offset Budget and Staffing Shortages**

  At the beginning of each month, the board submits a backlog report to the administration. This report reflects the status of the board's licensing and enforcement activities with respect to processing times. The board's priorities are to investigate consumer complaints and process applications.

  One of the greatest hurdles the board faces is responding to telephone inquiries. The board lacks even one full-time receptionist (both of the receptionist positions were lost due to budget restrictions and hiring freezes) and receives over 160,000 calls each year. The one part-time individual the board has performs this function but works at most only three days weekly. As a result, all staff are assigned to take turns answering the telephones. Status inquiries are not a priority and callers seeking assistance to be walked through the application process are directed to the Web site instead. This is extremely frustrating to applicants and to staff.

  In early October the board implemented a subscriber e-mail system that will allow interested parties to list their e-mail address with the board, and then be notified of new items posted on the board's Web site, which they can review. This system has the potential to increase communication with licensees and others at virtually no cost to the board. Someday it could eliminate publishing and postage costs for newsletters and *Health Notes*. It will allow the board to advise licensees of new law changes, new regulations, product recalls, and even action items from board meetings. The board is the first entity in the department to use this service, although others will soon implement their own systems.

- **Attorney General's Office Hourly Rates Increase**

  The Attorney General's Office rates increased twice at the end of the last fiscal year (April 1 and after June 30) to a total of $139 per hour for attorneys and $91 for legal assistants. This year the board received an augmentation in its AG budget of $216,034, to accommodate this rate increase. The board's total budget for the AG this year is $996,839 (or 13.5 percent of the board's budget).

3. **Closure Report: Budget Year 2003/04**

- **Actual Revenue Collected: $6,892,789**

  The board's revenue for last year was comprised of $5,641,127 in licensing fees, $70,306 in interest income, $874,532 in citation revenue, and $172,349 in cost recovery.

- **Expenditures for 2003/04 -- $6,816,770**

  The board's largest expenditure during the prior year was for personnel services (54 percent of all expenditures), which actually exceeded the budgeted amount by $30,580. This is even more significant since salary expenditures were not made for several inspectors and two managers during part or all of the year who were on parental leave. As a fixed expense, personnel services expenses are tracked closely by staff.

  Postage has been under-funded in prior years. During 2003/04 to reduce this expense, the board stopped mailing applications and newsletters to pharmacists. Despite these steps, the board still spent nearly $19,000 more in postage than budgeted (30 percent more).

  The board did not spend all of its budgeted amounts in other programs areas (notably printing), which compensates for the over-expenditures in other categories.

4. **Board Fund Condition**

During 2004/05, the board is projected to spend $1,915, 713 more than it will collect in revenue. Any difference between revenue and expenditures will come from the board's fund. Because the board is spending more than it collects in revenue, the board's fund projects a declining balance over the next three years.

- 2004-05: The board is projected to end this fiscal year with a reserve of 4.7 months of expenditures
- 2005-06: The reserve decreases to 1.3 months at the end of the year (June 30, 2006)
- 2006-07: A deficit of 2.3 months is projected (June 30, 2007)

These figures indicate that repayment of the $6 million loan borrowed by the state during 2002/03 will need to begin during mid to late 2005-06.

During the 2003/04 fiscal year, the board spent only slightly less than it made in revenue (specifically $75,000 less). However, the board collected more than $1 million in fines and cost recovery last year, and spent $350,000 less than authorized.

5. Relocation of the Department of Consumer Affairs

Chairperson Tilley stated that the lease for the building housing the main portion of the Department of Consumer Affairs, including the Sacramento office of this board, would end late in 2004.

Lease negotiations have not reduced the rent desired by the current building's landlord, and the department is likely to move to a new location in North Natomas (the original Arco Arena), where the rent is less. This location is about 8 miles north of the current location. If these arrangements are finalized, the board will have to move sometime during 2005. No lease has yet been signed for any space. However, the new building's owner has promised to pay for purchase and installation of new systems furniture as well as utilities and janitorial service.

- **Personnel Update and Report**

1. Hiring Freeze Ends

The hiring freeze in place since late 2001 expired July 1, 2004.

Recent budget instructions from the Department of Finance would have allowed the board to reinstate four positions lost during July 2002-03, when there was a hiring freeze and the board could not fill positions. However, the Department of Finance has narrowly interpreted this policy and advised the board that it cannot restore positions the board lost before 2003/04. As such, the board will be unable to restore any of the 10 positions lost since imposition of the hiring freeze.

2. Personnel Actions

The board has promoted three board employees, and converted a fourth individual to 75 percent of a full-time position (from a 50 percent level). Two seasonal employees have been hired as part-time employees to perform basic clerical functions, and the board has rehired its newsletter editor as a retired annuitant. The board will have to absorb the expense of these salaries.

3. Vacancies

Effective October 1, 2004, Chief of Legislation and Regulation Paul Riches accepted a position to become executive officer of the Board of Behavioral Science. Mr. Riches has been with the board five years and has made major contributions to improve and update

California Pharmacy Law. Recruitment is now underway for a new legislative coordinator.

At the beginning of September, part-time Receptionist Denise Wong transferred to a full time position in the Department of Health Services. Ms. Wong worked for the board for approximately five years. This leaves the board with one part-time receptionist. Staff will fill in at the front desk to provide receptionist duties.

Chairperson Tilley announced that the board's vacant second cashier position was recently filled.

The board has one inspector position vacant. It has recruited for this position, but cannot find an applicant with the qualifications needed by the board. Instead, the board has requested that the Department of Consumer Affairs conduct a new civil service examination for the inspector classification.

Chairperson Tilley recognized Paul Riches for his outstanding job performance in handling the board's legislative issues. He added that Mr. Riches would be missed.

Chairperson Tilley stated that the board has two public board member positions vacant; these positions were created January 1, 2004, and are Governor appointments.

The board has two staff on parental leave.

- **Petition from Students Seeking Alternatives from having their Addresses of Record Online**

President Goldenberg welcomed students in the audience who were in attendance to present their concerns about having their addresses of record online. Several students introduced themselves to the board. They were: Roxanne Leong, Jenny Espirity, Jerrod Mills and Nicolas Castro from the University of Pacific; Marshal Abdullah and David Truong from the University of Southern California and Chris Nguyen and Dan Zult from the U.C. San Francisco.

Mr. Truong thanked board members for the opportunity to come before the board.

Mr. Mills stated that this issue arose during a regional meeting in Arizona involving 11 schools of pharmacy. Many of the students were not aware that licensees' address of record are listed on the board's Web site.

Mr. Mills stated that during the meeting students raised concern about the privacy rights of licensees. Students representing six schools of pharmacy in California discussed the matter and came to a consensus that posting addresses on the board's Web site is inappropriate.

Mr. Mills stated that he feels that the problem lies with educating students about their rights. He asked the board for recommendations or advice on the best way to resolve the problem.

Mr. Jones stated that the board has addressed this topic to pharmacists throughout California and most of them are disturbed that their address are posted on the board's Web site. However, the state of California's consumer protection efforts promote public access to this information. He added that the board has advised pharmacists to use an alternate address or a post office box. Students sometimes work in several locations so it might be impractical to use an employer's address.

Mr. Schell suggested talking with the Student Affairs Office so the schools could establish some process to resolve this.

Chairperson Tilley stated that he did not feel that licensees should have to provide their address and thanked the students for attending the board meeting and presenting their concerns.

Ms. Harris stated that this issue will be presented to the Organizational Development Committee for discussion and brought back to the board in January. She added that a licensee's address is a public record that anyone can obtain this address by submitting a written request to the board. However, she cautioned that the address of record should be easily accessible to the licensee because this is the board's method of contact for mailing renewal notices, licenses and informational items.

Carlo Michelotti, representing the California Pharmacists Association, congratulated the students for their initiative at the mid-year meeting in Arizona this past week and then so quickly appearing before the board.

Chairperson Tilley expressed concern for all health care professionals handling dangerous drugs who must have their addresses available as a matter of public record.

President Goldenberg thanked all of the students for bringing this before the board. He encouraged their participation on future matters.

- **Board Acknowledgments**

President Goldenberg presented Carlo Michelotti with a plaque in recognition of his achievements as a pharmacy professional and his role as a pharmacist leader. Mr. Micholotti is leaving his executive vice president position with the California Pharmacists Association at the end of the year.

The inscription read:

Carlo Michelotti, RPh, MPH

The California State Board of Pharmacy recognizes and commends you for your years of service as a pharmacist and your role as a pharmacy leader during a time when pharmacy practice reached new heights. Your dedicated efforts to strengthen the role of pharmacists as health professionals will greatly benefit the public for years to come.

Mr. Michelotti thanked the board and stated that he is honored to receive this recognition from the Board of Pharmacy.

President Goldenberg also recognized and commended Teresa Ann Miller for her years of service and leadership to improve the quality of pharmacists care provided to California patients. Dr. Miller is leaving her executive vice president position with the California Society of Health Systems Pharmacists at the beginning of November. She was unable to attend the board meeting.

The inscription on Dr. Miller's plaque read:

The California State Board of Pharmacy recognizes and commends Teresa Ann Miller, Pharm.D., for your years of service and leadership to improve the quality of pharmacists care provided to California patients. Your efforts have allowed pharmacists to assume a broader and rightful place in managing the drug therapy of patients, and improving the quality of care provided to all.

- **Approval of Minutes**
  (July 21 and 22, 2004)

President Goldenberg asked if there were any corrections to the minutes.

Mr. Schell referred to pages 22 and 23 of the board minutes and the misspelling Jennigrace Bautista's last name.

MOTION: Approve the minutes of the July 21 and 22, 2004, Board Meeting after correcting the misspelling of the last name of Jennigrace Bautista.

M/S/C: SCHELL/TILLEY

SUPPORT: 8 OPPOSE: 0

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Chairperson Zinder reported on the committee's meeting of September 21, 2004.

- **Update on Health Notes and Proposal for Health Notes Issue on Pharmacy Services Following a Natural Disaster**

  Chairperson Zinder stated that RoseAnn Jankowski, chairperson of the board's Competency Committee, who is a hospital pharmacist, is also active as a disaster response team and leader in Orange County. Dr. Jankowski has contacted the board in hopes of developing a pharmacist disaster response monograph for the board. The board currently has no information in this area available to distribute.

  Dr. Jankowski is willing to coordinate this issue, without a fee, and has developed a list of articles and authors.

  Chairperson Zinder stated that the committee saw value in the development of such an issue that could readily be added to the board's Web site. Once the articles are written, federal money will be sought to pay for publication costs to expand distribution of this issue as well.

  The committee requested that Dr. Jankowski attend the board meeting to discuss this concept with the board. However, a prior commitment prevented her from attending this meeting.

  Chairperson Zinder stated that Dr. Jankowski would attend the January 2005 Board Meeting to discuss this monograph with the board.

  The board deferred action on this proposal until Dr. Jankowski can meet with the board.

- **Nancy Hall, Deputy Director of Board Relations, Department of Consumer Affairs**

  President Goldenberg welcomed Ms. Hall, the newly appointed deputy director for board relations, to the board meeting.

  Ms. Hall thanked the board and stated that she was there to observe the meeting and to answer any questions the board may have for her.

  President Goldenberg acknowledged his wife, Susan Goldenberg, who was also in the audience.

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

  Chairperson Zinder stated that at the April 2004 Board Meeting, the board approved a proposal by the committee to integrate pharmacy students into public outreach activities. This project will be coordinated by the UCSF Center for Consumer Self Care under the direction of R. William Soller, Ph.D.

The project will have students develop one-page fact sheets on diverse health care topics. The board will work with Dr. Soller to develop these fact sheets, using pharmacy students from UCSF and UCSD. A prototype format for a series of fact sheets will be developed. Each interested student will be acknowledged with a credit at the bottom of the fact sheet he or she develops. Review by professional staff at UCSF for content accuracy will occur as part of the process.

The goal is to develop three fact sheets per quarter. After one year and 12 fact sheets, the Communication and Public Education Committee and the Center for Consumer Self Care will reevaluate the project.

Dr. Soller attended the September meeting of the committee to demonstrate one proposal for a possible template for the fact sheet series.

The committee determined that the fact sheets should address consumer issues involving:

- Safety
- Cost
- Access
- Quality
- Awareness (use and self-use of medications)

Chairperson Zinder stated that over the next quarter Dr. Soller would oversee the development of drafts for the first three fact sheets.

- **Report on the California Health Communication Partnership**

Chairperson Zinder stated that during the July 2004 Board Meeting, the board agreed to join the California Health Communication Partnership as a sponsor and participant. The purpose of this group is to improve the health of Californians by developing and promoting consumer health education programs developed by the members in an integrated fashion. Dr. Soller, of the UCSF Center for Consumer Self Care, is the coordinator of this group.

Chairperson Zinder stated that two meetings of the partnership have been held since the July Board Meeting. The first meeting was held September 2, 2004. Present was a group of founding members called the Steering Committee that included members from the Board of Pharmacy, Medical Board of California, California Society of Hospital Pharmacists, California Medical Association, the UCSF, the Department of Consumer Affairs and via telephone, the National Consumers League and Federal Food and Drug Administration.

The core of the meeting was aimed at developing health priority topics for the partnership. A primary component was a review of consumer materials developed by the FDA in the last few years. Few of the individuals at the meeting were aware of all of the materials.

For the partnership's first integrated project, the partnership selected the FDA materials developed for practitioners and patients on antibiotic use misuse and overuse.

Chairperson Zinder stated that the second meeting continued discussions to promote materials warning of antibiotic misuse during flu season, from November through March. The materials prepared by the FDA will be the focus, and the newsletters of both the Board of Pharmacy and Medical Board will contain the FDA public service message for practitioners and the consumer materials the practitioners can download for their patients.

Ms. Herold added that the FDA has developed a number of communication modules for health care practitioners. She stated that many are not aware of the system on the FDA Web site. She added that The Medical Board of California would run the same materials in their action report for physicians in the January issue and the Board of Pharmacy will run the materials in its *Health Notes* in January. This will be the first time for the boards to fully communicate with all licensees (both pharmacists and physicians) regarding antibiotic misuse using an integrated campaign with the materials the FDA has already promoted. This will provide the board with an opportunity to test the partnership's goal for an integrated message system.

- **Discussion on How the Board of Pharmacy Can Improve and Facilitate Communications with the Public and Licensees**

Chairperson Zinder stated that at the board's July Meeting, Board President Goldenberg expressed his ideas on how he planned to achieve his goal of improving communication with the board and licensees. President Goldenberg's goal is to obtain diverse opinions from as wide a cross section as possible on matters before the board for policy deliberations.

Ms. Zinder noted that the board has a number of procedures it uses to elicit comments from the public and stakeholders.

- Quarterly board meetings, where public input for each agenda area has public input scheduled as a component.
- Web site information
- Consumer education materials
- Co-sponsorship of public education events (e.g., 2003's Hot Topic Seminars with the UCSF School of Pharmacy)
- Attendance at continuing education fairs
- Attendance/staffing at public education fairs and events
- A subscriber e-mail notification system about major new information added to the board's site (about to be implemented)
- The board has at least 19 public meetings annually, where an agenda is mailed and posted on our Web site 10 days before a meeting.
- *The Script* newsletter

- Presentations by board members and supervising inspectors of the board's CE outreach programs to groups of pharmacists, typically at professional meetings (at least 34 presentations were provided during 2003/04)
- Attendance and staffing of information booths at major educational fairs hosted by the major pharmacist associations
- In rare cases, letters are mailed directly to licensees advising them about major changes in programs (for example, changes in wholesaler requirements or foreign graduation evaluations)
- *Health Notes,* a health monograph developed by the board in a particular area that contains current drug treatment modalities, and which provides continuing education for pharmacists in subjects of importance to the board.
- Inspections (2,582 inspections were conducted during 2003/04)
- Written, faxed and telephone inquiries directly to the board.
- Surveys of all complainants following closure of their complaints
- Coming is a "Web site User Survey" (currently the board's Web site is being redesigned. One new component will be a "Web site user survey" to seek feedback on the Web site. This information will be used to enhance our Web site)

During the committee meeting, President Goldenberg noted that only five individuals (including two board members) were in the audience. He encouraged the committee to elicit comments from a number of sources.

The committee noted that the board's Web site is an important means for communication with licensees and the public, and this will likely grow in importance in the future. A referral to the board's Web site address could be added to the board's pre-recorded messages on the telephone system to facilitate this form of communication. An interactive Web site is important; however, current board staffing prevents this form of communication with the board's staff at the current time.

Another suggestion made during the committee meeting is to categorize questions received by the board's staff and add these to agendas for discussions during committee meetings. Also discussions with consumers at public education events may help identify items of concern to the general public.

President Goldenberg proposed that holding board meetings during evening hours may increase attendance and he asked that this be an agenda item.

- **Establishment of Internet Subscriber Lists for Board Materials**

Chairperson Zinder stated that in early October, the board activated its subscriber Web site notification system. This feature e-mails interested parties announcing that the board's Web site has been updated, the nature of the update and provides a link to the specific addition. Interested parties must subscribe themselves to the board's Web site, and be responsible for

keeping their e-mail addresses current. There is no charge for this service and no workload to the board to keep the e-mail addresses up to date.

Chairperson Zinder reported that within one day of activation 24 individuals have already subscribed to this service.

The board is the first agency in the department to use this feature, but other agencies will soon follow. The board will highlight this service in the next *The Script*. According to the department, this e-mail list is not considered a public record under the Public Records Act. The e-mail addresses of others receiving the notifications will not be visible to other subscribing parties as well. Department of Consumer Affairs Legal Counsel Mr. Winterrowd clarified that technically, this is considered to be a public record but the board will consider it confidential and personal and not in the public domain.

Ms. Herold stated that the board's purpose for the e-mail notification system is to communicate with the public and those interested in what the Board of Pharmacy does.

- **Update on *The Script***

Chairperson Zinder stated that the state's hiring freeze ended on July 1, and the board has since been able to hire former Newsletter Editor Hope Tamraz as a retired annuitant. Ms. Tamraz will continue to develop *The Script* as a principal part of her duties.

Chairperson Zinder stated that the board is currently finalizing articles for a November-release edition of *The Script*. Alternatively, a single issue of *The Script* will be published in January 2005.

Chairperson Zinder stated that the last issue of *The Script* was published and mailed to pharmacies in March 2004, and was later reprinted by the CPhA's Pharmacy Foundation of California and mailed to California pharmacists in early June.

The board discussed the importance of *The Script* as a way to communicate with its licensees.

Mr. Micholotti reaffirmed CPhA's commitment to mail the newsletter to all licensees. The board thanked CPhA for its contributions to publish and mail this newsletter to pharmacists.

- **Update on <u>Health Notes</u>**

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. 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.

1. Pain Management Issue

The board's staff is still working to complete this new issue on pain management, which should be published by the end of the year. The new issue will contain new pain management therapies and the new prescribing and dispensing requirements for controlled substances. It will be an interdisciplinary issue for pharmacists as well as physicians, dentists, nurses and nurse practitioners.

2. Smoking Cessation

At the April 2004 Board Meeting, the board agreed to work with the UCSF to develop a *Health Notes* on smoking cessation. The UCSF is seeking funding for this issue from manufacturers of smoking cessation products. If a grant is provided to UCSF to do this issue, the manufacturers will have no editorial or review control over the developed manuscript.

The board will be responsible for the layout and design of the issue. If funding permits, the board will print and mail the issue. If the board lacks funding for this ($85,000), the issue will be placed on the board's Web site.

3. UCSF Monograph on Atrial Fibrilation (will not be called a *Health Notes*)

Chairperson Zinder stated that at the April 2004 Board Meeting, the board voted to become a cosponsor with the UCSF School of Pharmacy to produce a monograph on Atrial Fibrilation. The audience would be pharmacists and physicians. Funding for this issue would come from a drug manufacturer. Continuing education credit for those who complete the reading would be one outcome of this project.

The UCSF intends that in place of publishing this issue as a printed monograph (such as *Health Notes*), to instead place the issue on the Web site for downloading, possibly as a CE program. There would be no direct costs to the board.

- **Emergency Contraception/Pharmacy access partnership Liaison**

  Chairperson Zinder stated that since the July Board meeting, the board has updated the emergency contraception protocol to reflect a change in the manufacturers of emergency contraception drugs.

  The protocol is new on the board's Web site. Meanwhile the rulemaking to adopt the regulation incorporating the protocol into California Pharmacy Law was approved by the Office of Administrative Law and the regulation will be in November.

- **Presentation by the Center for Health Improvement: Pending Survey to Study the Impact of the Patient Consultation Mandate on Older Californians**

Chairperson Zinder stated that recently the board has been asked to collaborate on a study by the Center for Health Improvement assessing patient consultation requirements and their impact on older Californians aged 65 or older. The CHI is a health policy nonprofit agency based in California. The California Pharmacist Association's Education Foundation of California and the AARP are also collaborators of this project.

The goal for this two-year study is to analyze and improve the patient consultation process to patients aged 65:

- To assess the impact of the pharmacist consultation for persons 65+ through quantitative methods.
- To educate Californians, especially pharmacists about findings and recommendations through development and distribution of a policy brief.
- To begin discussions with policymakers and stakeholders about options for future action.

The committee reviewed written materials about CHI, the survey and the scope of this project.

Chairperson Zinder stated that she had requested that a representative from the CHI be invited to attend the board meeting to discuss the survey with the board but previous commitments prevented a representative from attending. She added that a representative would attend the January 2005 Board Meeting.

President Goldenberg suggested contacting the Long Term Care Management Council and the California Chapter of the American Society of Consultant Pharmacists for help in identifying areas of concern for seniors that are not in institutions. He added that this would also help bring awareness to pharmacists and pharmacies in California.

- **Update on the Board's Public Outreach Activities**

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

The board has a PowerPoint presentation about the board that contains key board policies and pharmacy law. This is a continuing education course, typically provided by a board member and a supervising inspector. The questions and answer session usually results in presentations lasting more than two hours, presentations that are well-received by the individuals present.

Since the beginning of 2004, the board has begun providing presentations on SB 151 and new requirements for prescribing and dispensing controlled substances in California. This information is also presented via telephone conference call to large numbers of individuals.

Since July 1, 2004, the board has staffed booths at six consumer fairs, provided CE presentations about the board and pharmacy law to six groups, and made 14 presentations to groups of health practitioners and law enforcement staff about new requirements for prescribing and dispensing controlled substances.

Chairperson Zinder that the committee appreciates staff and board member participation on this extensive outreach effort.

President Goldenberg thanked board members and inspectors for this valuable effort.

Mr. Jones stated that many outreach meetings are at the request of the licensees and he emphasized the importance of responding to these invitations. He encouraged organizations to announce at their meetings that the board is interested in meeting with licensees and talking about topical issues. He added that many groups are not aware that board members or inspectors will accept invitations to speak.

- **Kaiser Family Foundation/Harvard School of Public Health Survey: "Views of the New Medicare Drug Law"**

Chairperson Zinder stated that the cost of prescription drugs is a problem for many consumers. The board has three brochures and one information link directly related to buying drugs for less.

In mid-2004, the federal government rolled out its federal drug discount program, which will be in effect until January 2006, when a new Medicare program takes effect. The program has not been popular nor is it widely used. There were more than 70 discount cards and programs initially available. The committee reviewed a survey conducted by the Kaiser Family Foundation/Harvard School of Public Health in August 2004 regarding public opinion about the program.

With respect to this federal drug discount program, the board has created a one-page information sheet for the public that is available on the Web site. This information refers the reader to the federal government's Web site, and warns about possible fraud from those who contact individuals directly offering to sell them cards.

The federal government has an extensive Web site developed to aid the public, but because of the number of options, this is a very complicated area to provide consumer information.

LICENSING COMMITTEE

Chairperson Conroy reported on the Licensing Committee Meeting of September 22, 2004.

- **Proposed Omnibus Legislative Changes for the 2005 Legislative Session**.

Dr. Conroy stated that the committee identified four provisions for a future omnibus bill.

1. Elimination of the Rules of Professional Conduct (Bus. & Prof. Code sec. 4005)

Dr. Conroy stated that section 4206 of the California Business and Professions Code requires that each pharmacist sign off on the "rules of professional conduct" as part of the application for pharmacist licensure. This requirement was established in 1959 and was subject to technical amendments in 1965 and 1971. However, this requirement has remained essentially unchanged since that date. Subdivision (c) Section 4005 [formerly Section 4008.2] authorizes the board to adopt these "rules of professional conduct" through the rulemaking process specified in the Administrative Procedures Act.

The current "rules of professional conduct" is actually a listing of selected regulation sections (1714, 1715.6, 1717, 1761, 1764, 1765, 1793.1) and a statement that the applicant agrees to abide by these regulations. The statute appears to allow the board to establish "rules of professional conduct" above and beyond those included in the board's statutes and regulations. However, no such document has existed in the memory of any current board staff, which extends back over approximately 25 years.

Dr. Conroy stated that this requirement provides no public protection, as licensees must comply with the specified sections and all other sections of the Pharmacy Law. Accordingly, staff is suggesting the repeal of Section 4206, and the relevant portion of Section 4005, to streamline the pharmacist licensure process.

Section 4005 of the Business and Professions Code is amended to read:

4005. (a) The board may adopt rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public. Included therein shall be the right to adopt rules and regulations as follows: for the proper and more effective enforcement and administration of this chapter; pertaining to the practice of pharmacy; relating to the sanitation of persons and establishments licensed under this chapter; pertaining to establishments wherein any drug or device is compounded, prepared, furnished, or dispensed; providing for standards of minimum equipment for establishments licensed under this chapter; pertaining to the sale of drugs by or through any mechanical device; and relating to pharmacy practice experience necessary for licensure as a pharmacist.

(b) Notwithstanding any provision of this chapter to the contrary, the board may adopt regulations permitting the dispensing of drugs or devices in emergency situations, and permitting dispensing of drugs or devices pursuant to a prescription of a person licensed to prescribe in a state other than California where the person, if licensed in California in the same licensure classification would,

under California law, be permitted to prescribe drugs or devices and where the pharmacist has first interviewed the patient to determine the authenticity of the prescription.

(c) ~~The board may, by rule or regulation, adopt, amend, or repeal rules of professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession. Every person who holds a license issued by the board shall be governed and controlled by the rules of professional conduct adopted by the board.~~

~~(d)~~ The adoption, amendment, or repeal by the board of these or any other board rules or regulations shall be in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code**.**

Section 4206 of the Business and Professions Code is repealed.

4206. ~~The rules of professional conduct adopted by the board shall be printed as a part of the application for licenses and every applicant shall subscribe thereto when making an application.~~

2. Clarification of Designated Representative Requirements for Wholesalers (Bus. & Prof. Code sec. 4053)

Another proposed legislative change involves Section 4053. The existing section addresses the issuance of "certificates of exemption" to individuals handling dangerous drugs and dangerous devices in wholesale facilities. Senate Bill 1307 changes current board terminology to reflect usage in other states and names these individuals "designated representatives." The proposed change makes the section easier to understand and makes no substantive change in law. The proposed language parallels other sections that authorize the issuance of a personal license.

4053. (a) ~~Subdivision (a) of Section 4051 shall not apply to a veterinary food-animal drug retailer or wholesaler that employs a~~ Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall ~~adequately safeguard and~~ protect the public health and safety in the handling, storage and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer.,if the ~~, nor shall Section 4051 apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).~~

(b) An individual employed by a veterinary food-animal drug retailer or wholesaler may apply for an exemption from Section 4051. In order to obtain and maintain that exemption, the individual shall meet the following requirements:

(1) He or she shall be a high school graduate or possess a general education development equivalent.

(2) He or she shall have a minimum of one year of paid work

experience related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(A) Knowledge and understanding of state and federal law relating to the distribution of dangerous drugs and dangerous devices.

(B) Knowledge and understanding of state and federal law relating to the distribution of controlled substances.

(C) Knowledge and understanding of quality control systems.

(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.

(E) Knowledge and understanding of prescription terminology, abbreviations, dosages and format.

(4) The board may, by regulation, require training programs to include additional material.

(5) The board may, by regulation, require training programs to include additional material.

(6) The board shall not issue a certificate of exemption until the applicant provides proof of completion of the required training to the board.

(c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or an individual in possession of a certificate of exemption on its premises.

(d) Only a pharmacist or an individual in possession of a certificate of exemption shall prepare and affix the label to veterinary food-animal drugs.

(e) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative before January 1, 2006, amends or repeals that date.

(f) Section 4051 shall not apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410)

3. Technical Updates to Various Licensing Provisions (Bus. & Prof. Code sec. 4127.5, 4205 and 4206)

Section 4127.5 sets the fee for the issuance of a sterile compounding license. Existing board practice based on Section 4400 (a) is to exempt government owned and tribally owned pharmacies from this fee. The proposed amendment clarifies that this exemption applies to sterile compounding licenses as well.

> **4127.5**. The fee for the issuance of a non-governmental license, or renewal of a license, to compound sterile drug products shall be five hundred dollars ($500) and may be increased to six hundred dollars ($600).

Another proposed change would amend section 4205, which details the application requirements for hypodermic licenses. The proposed changes make minor technical changes to eliminate obsolete code section references.

4205. (a) A license issued pursuant to Section 4110, 4120, ~~4130~~, 4160, or 4161 shall be considered a license within the meaning of Section 4141.

(b) The board may, in its discretion, issue a license to any person authorizing the sale and dispensing of hypodermic syringes and needles for animal use. ~~use for animals and poultry.~~

(c) The application for a license shall be made in writing on a form to be furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of ~~this article~~. Article 9 of this chapter.

(d) A separate license shall be required for each of the premises of any person who sells or dispenses hypodermic syringes or needles at more than one location.

(e) A license shall be renewed annually and shall not be transferable.

(f) The board may deny, revoke, or suspend any license issued pursuant to this article for any violation of this chapter.

4. Fee Schedule Technical Changes (Bus. & Prof. Code sec. 4400)

This change would make technical amendments to section 4400. This section contains fee provisions and would make a range of changes as follows:

1. Eliminates an obsolete reference to medical device retailers.
2. Combines the application and issuance fee for exemptee licenses, which would permit the board to streamline issuing exemptee licenses.
3. Eliminates the fee for approval as an accrediting entity for continuing education consistent with other proposals under consideration to update the CE regulations.
4. Eliminates the fee for the foreign graduate application consistent with other proposals.
5. Makes a number of other technical changes to the section.

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be three hundred forty dollars ($340) and may be increased to four hundred dollars ($400).

(b) The fee for a nongovernmental pharmacy ~~or medical device retailer~~ annual renewal shall be one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250).

(c) The fee for the pharmacist application and examination shall be one hundred fifty-five dollars ($155) and may be increased to one hundred eighty-five dollars ($185).

(d) The fee for regrading an examination shall be seventy-five dollars ($75) and may be increased to eighty-five dollars ($85). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifteen dollars ($115) and may be increased to one hundred fifty dollars ($150).

(f) The fee for a non-governmental wholesaler license and annual renewal shall be

five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(g) The fee for a hypodermic license and renewal shall be ninety dollars ($90) and may be increased to one hundred twenty-five dollars ($125).

(h) ~~The fee for application and investigation for an exemptee license under Section 4053 shall be seventy-five dollars ($75) and may be increased to one hundred dollars ($100), except for a veterinary food-animal drug retailer exemptee, for whom the fee shall be one hundred dollars ($100).~~

(1)The fee for the application, investigation and issuance of a license as a designated representative pursuant to Section 4053 shall be one-hundred eighty-five dollars ($185) and may be increased to two-hundred fifty dollars ($250). If the applicant is not issued a license as a designated representative, the board shall refund seventy-five dollars ($75) of the fee.

(2)The fee for the annual renewal of a license as a designated representative shall be one-hundred ten dollars ($110) and may be increased to one hundred fifty dollars ($150).

(i) ~~The fee for an exemptee license and annual renewal under Section 4053 shall be one hundred ten dollars ($110) and may be increased to one hundred fifty dollars ($150), except that the fee for the issuance of a veterinary food-animal drug retailer exemptee license shall be one hundred fifty dollars ($150), for renewal one hundred ten dollars ($110), which may be increased to one hundred fifty dollars ($150), and for filing a late renewal fifty-five dollars ($55).~~

(1) The fee for the application, investigation and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be two-hundred fifty dollars ($250). If the applicant is not issued a license as a designated representative, the board shall refund one-hundred dollars $100) of the fee.

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one-hundred fifty dollars ($150).

(j) The fee for an out-of-state drug distributor's license and annual renewal issued pursuant to Section 4120 shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(k) ~~The fee for registration and annual renewal of providers of continuing education shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).~~

~~(l)~~ The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

~~(m) The fee for evaluation of applications submitted by graduates of foreign colleges of pharmacy or colleges of pharmacy not recognized by the board shall be one hundred sixty-five dollars ($165) and may be increased to one hundred seventy-five dollars ($175).~~

~~(n)~~

(1)The fee for an intern pharmacist license ~~or extension~~ shall be sixty-five dollars ($65) and may be increased to seventy-five dollars ($75). The fee for transfer of intern hours or verification of licensure to another state shall be fixed by the board not to exceed twenty dollars ($20).

~~(o)~~ (m)The board may~~, by regulation, provide for the waiver~~ waive or refund ~~of~~ the additional fee for the issuance of a certificate where the

certificate is issued less than 45 days before the next ~~succeeding~~ regular renewal date.

~~(p)~~ (n)The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change is thirty dollars ($30).

~~(q)~~ (o)The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, is sixty dollars ($60) and may be increased to one hundred dollars ($100).

~~(r)~~ (p)It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year' s operating expenditures.

~~(s)~~ (q)The fee for any applicant for a non-governmental clinic permit is three hundred forty dollars ($340) and may be increased to four hundred dollars ($400) for each permit. The annual fee for renewal of the permit is one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250) for each permit.

~~(t)~~ (r)The board shall charge a fee for the processing and issuance of a license ~~registration~~ to a pharmacy technician and a separate fee for the biennial renewal of the license ~~registration~~. The license ~~registration~~ fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50). The biennial renewal fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50).

~~(u)~~ (s)The fee for a veterinary food-animal drug retailer license shall be four hundred dollars ($400). The annual renewal fee for a veterinary food-animal drug retailer shall be two hundred fifty dollars ($250).

~~(v)~~ (t)The fee for issuance of a retired pharmacist license pursuant to Section 4200.5 shall be thirty dollars ($30).

MOTION: Licensing Committee: That the Board of Pharmacy approve the proposed legislative changes as omnibus items for the 2005 legislative session.

SUPPORT: 8 OPPOSE: 0

- **Proposed Legislative Changes to the Pharmacist License Renewal Process Related to the Continuing Education Requirement (Bus. & Prof. Code sec. 4231 and 4232)**

Chairperson Conroy stated that the California Pharmacists Association (CPhA) requested that the board's continuing education statute be amended to change the term "pharmaceutical" to "pharmacy" education throughout the statute. The CPhA also requested a similar change to the board's CE regulations.

The second change is to relocate to statute from regulation the board's authority to establish the current 30-hour continuing education requirement. Current statute allows the board to set the number of CE hours required for renewal by regulation up to a maximum of 30 hours. Current board regulations specify the maximum 30 hours for renewal. Given this situation, there is no need for both statute and regulation to set the CE hour requirement.

The next proposed change is to modify the existing CE exemption from the first two years following graduation to the first renewal of a pharmacist license. The existing statute exempts recent graduates from complying with the CE renewal requirement. Given that pharmacists moving to California from other states who graduated from pharmacy school more than two years ago must study for both the NAPLEX and the CPJE to become licensed, staff believes that such preparation for the exams should be given equal weight as 30 hours of CE. The revised language would exempt both recent graduates and those becoming licensed in California after graduation.

The last recommended change would specify that pharmacists who fail to provide proof of completed CE (currently proof is a signed statement attesting to completion) within 60 days of the renewal date would be issued an inactive license. Currently pharmacists who fail to certify their continuing education credits but do pay the renewal fee are unable to practice but have an uncertain license status. Their license is not delinquent (because the fee has been paid) and can remain in this uncertain status indefinitely. Their license is not subject to subsequent renewal. Existing law provides for an inactive pharmacist license, which prohibits the licensee from practicing but is subject to renewal. A pharmacist with an inactive license can reactivate that license at any time upon payment of the renewal fee and providing evidence of the required 30 hours of CE. Issuing an inactive license to these CE delinquencies will resolve the ambiguity of their license status and ease the administrative burden to the board for processing these renewals.

Concern was expressed that such a change may place an unfair burden to employers because a pharmacist with an "inactive" license would not be allowed to practice. It was noted that under existing law, pharmacists who fail to certify their CE, cannot legally practice now. President Goldenberg stated that during the Licensing Committee Meeting he was made aware of the audit of CE and discovered that 25 percent of those audited could not produce the CE units they claimed to have. He expressed concern that this situation needs improvement not only for consumer expectation but the pharmacy profession as well.

Dr. Gray suggested that the board consider an alternative to a statute change by separating the CE requirement from the license renewal process so CE is not completed because of a "glitch," this would not be a barrier to renewing a license and prohibiting a pharmacist from working. The board would still have the authority to take action if the CE requirements were not met.

Ms. Harris stated that the CE audit occurs after the license has been renewed. If a licensee does not sign the renewal certificate at the time of renewal, their license is placed on hold and the individual should not be licensed because he or she has not fulfilled the requirements for renewal.

Mr. Jones stated that CE is easy to obtain through pharmacy organizations that have done an excellent job in providing CE at little or no cost to pharmacists.

John Cronin, representing the California Pharmacists Association, expressed concern for the burden this places on employers to be more diligent in tracking active license status to avoid violations from the board.

Ms. Quandt suggested that the board highlight the area where a signature is needed and add an additional statement indicating that by not signing you have not completed 30 hours of CE.

Ms. Herold stated that the board is working on an online renewal system because the current system can be very time consuming and creates a tremendous workload, especially when licensees renew late in the renewal cycle. As a result, frequently they call the board for status and occasionally send in their fees in twice. The board then must refund the duplicate fee.

President Goldenberg stated that there are more pharmacists and pharmacies in California than any other state and this creates a significant challenge.

Mr. Tilley asked if a licensee has 60 days to obtain CE if an audit finds a deficiency.

Ms. Harris explained that in this situation the pharmacist now has a renewed license with a violation of law for not complying with the terms of renewal. She added that the proposed language specifies that pharmacists who fail to provide proof of completed CE (currently proof is a signed statement attesting to completion) within 60 days of the renewal date will be issued an inactive license.

Greg Speicker representing the California Rural Indian Health Community Board stated that the pharmacy profession is detailed oriented and pharmacists must be held accountable. He supports the proposal.

> **4231**. (a) The board shall not renew a pharmacist license ~~issue any renewal certificate~~ unless the applicant submits proof satisfactory to the board that he or she has successfully completed 30 hours of approved courses of continuing pharmacy ~~pharmaceutical~~ education during the two years preceding the application for renewal.
> ~~The continuing education required by this article shall consist of the number of clock hours, not to exceed 30 clock hours, designated by regulation adopted by the board. This section shall not apply to licensees during the first two years immediately following their graduation from a college of pharmacy or department of pharmacy of a university recognized by the board.~~
> (b) Notwithstanding subdivision (a), the board shall not require completion of continuing education for the first renewal of a pharmacist license.
> (c) If an applicant for renewal of a pharmacist license submits the renewal application and payment of the renewal fee but does not submit proof satisfactory to the board that the licensee has completed 30 hours of continuing pharmacy education within 60 days of the license expiration date, the board shall not renew the license and shall issue the applicant an inactive pharmacist license. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by complying with Section 704 of the Business and Professions Code.

4232. (a) The courses shall be in the form of postgraduate studies, institutes, seminars, lectures, conferences, workshops, extension studies, correspondence courses, and other similar methods of conveying continuing professional ~~pharmaceutical~~ pharmacy education.

(b) The subject matter shall be pertinent to the socioeconomic and legal aspects of health care, the properties and actions of drugs and dosage forms and the etiology, and characteristics and therapeutics of the disease state.

(c) The subject matter of the courses may include, but shall not be limited to, the following: pharmacology, biochemistry, physiology, pharmaceutical chemistry, pharmacy administration, pharmacy jurisprudence, public health and communicable diseases, professional practice management, anatomy, histology, and any other subject matter as represented in curricula of accredited colleges of pharmacy.

MOTION: Licensing Committee: That the Board of Pharmacy approve the proposed legislative changes relating to the continuing education (CE) requirements for the renewal of a pharmacist license as follows

SUPPORT: 8 OPPOSE: 0

- **Proposed Regulation Change to Implement SB 1913 related to Foreign Pharmacy School Graduates and the Certification Process by the Foreign Pharmacy Graduate Examination Committee (CCR, title 16, sec. 1720.1)**

Chairperson Conroy stated that section 4200 (a)(2)(B) requires an applicant for licensure as a pharmacist who has graduated from a foreign pharmacy school to, among other things, receive a grade satisfactory to the board on an examination designed to measure equivalency. Since the Governor recently signed SB 1913 a graduate from a foreign pharmacy school must now obtain full certification from the Foreign Pharmacy Graduate Examination Committee (FPGEC). This certification is designed to assess the educational equivalence of foreign pharmacy graduates. Forty-six states currently require FPGEC certification. The certification requirements include:

- Graduation from a pharmacy program that requires at least a four-year curriculum if education was completed prior to January 1, 2003, or a five-year curriculum after January 2003. An evaluation of the academic program is complete to ascertain whether it meets certain minimum criteria of length and content.
- Proof of licensure in the country the candidate earned the pharmacy degree.
- Passing scores on the Foreign Pharmacist Graduate Equivalency Examination, Test of Spoken English (50, the same as the board's requirement) and Test of English as a Foreign Language.

As a result of this change, the board will no longer require the submission of a foreign graduate application for the evaluation of foreign transcripts.

To ensure consistency with the statutory changes, the board needs to amend CCR 1720.1. The proposed amendment clarifies that the certification obtained by the FPGEC satisfies the educational requirements detailed in B & P Code section 4200.

A letter will be sent to those individuals with a foreign graduate application on file who currently are not licensed as a pharmacist, notifying them of these changes that will take effect January 1, 2005.

Ms. Harris stated that the FPGEE is part of the National Association of Boards, in existence since the board initially changed the law in 1985.

§ Graduates of Foreign Pharmacy Schools.

Graduates of foreign pharmacy schools who have been certified by the Foreign Pharmacy Graduate Examination Committee shall be deemed by the board to have satisfied the requirements of paragraphs (3) and (4) of Business and Professions Code Section 4200(a)

~~(a) Each applicant for admission to the pharmacist licensure examination, whose eligibility is based on the provisions of Business and Professions Code section 4200(a)(2)(B), shall be required to demonstrate that the education obtained at the foreign school is equivalent to that required of domestic graduates by receiving a grade satisfactory to the board on the Foreign Pharmacy Equivalency examination administered by the National Association of Boards of Pharmacy.~~

~~(b) Each applicant for admission to the pharmacist licensure examination whose collegiate study was in a foreign country shall provide transcripts and other reference material sufficient for the board to evaluate an applicant's collegiate equivalency pursuant to Business and Professions Code section 4200(a)(3). If the applicant cannot provide documents sufficient to determine collegiate equivalency, the board may accept the findings of a foreign credentials evaluation service. This service shall be required at the discretion of the board and may include authentication, translation and or evaluation of such documents as deemed necessary by the board. Any costs for the review shall be paid directly to the evaluation service by the applicant.~~

Authority cited: Section 4005, Business and Professions Code. Reference: ~~Section~~ Sections 851 and 4200, Business and Professions Code.

MOTION: Licensing Committee: That the Board of Pharmacy approve the proposed change to CCR, title 16, sec. 1720.1 to implement SB 1913 related to foreign pharmacy school graduates.

SUPPORT: 8 OPPOSE: 0

- **Proposed Regulation Change to Implement SB 1913 Related to the Application Process for the Pharmacist License Examination and the Internship Requirements (CCR, title 16, sec. 1728)**

Chairperson Conroy stated that as part of the board's ongoing efforts to streamline application requirements, a number of changes to the intern pharmacist program have been pursued. Section 4209 is a new section that will be added to statute detailing the intern requirements an applicant must satisfy before applying for the pharmacist licensure examinations. (This was done via SB 1913, which was recently signed by the Governor). This statute now contains the intern requirements previously listed in the board's regulation CCR 1728.

To clarify the specific intern requirements, amendments are being proposed that:

- Remove the first year maximum cap on intern hours (currently 250 hours).
- Remove the seven required areas of experience listed and instead require that the experience satisfy the requirements for the introductory and advanced pharmacy practice experienced established by the ACPE.
- Require proof that the applicant gradated from a recognized school of pharmacy.
- Require both a state and federal criminal history.

To implement these proposed changes, staff will be revising its application procedures and affidavits.

Mr. Cronin asked if there is still a delay in obtaining criminal history background checks.

Mr. Riches stated that Live Scan results are returned within one or two weeks. He added that delays are more of an issue for out-of-state applicants or foreign graduates.

§1728. Intern Experience--Requirements for <u>Examination</u> Licensure.

~~(a) Minimum Hours: All intern pharmacists must complete 1,500 hours of experience as a prerequisite to licensure.~~

~~(1) First Year Maximum: A maximum of 250 of the 1,500 hours may be obtained during the first year of pharmacy education in a program sponsored by a school of pharmacy recognized by the Board.~~

~~(2) Preceptor Supervision: A minimum of 900 of the required 1,500 hours must be obtained in a pharmacy under the supervision of a preceptor.~~

~~(3) Board Approved Experience: A maximum of 600 of the required 1,500 hours may be granted at the discretion of the Board for other experience which substantially relates to the practice of pharmacy.~~

~~(b) Required Areas of Experience: Effective January 1, 1986 all applicants for licensure must complete experience in both community pharmacy and institutional pharmacy practice in settings in the following areas:~~

~~(1) Receiving and interpreting the prescription;~~

~~(2) Patient medication profiles;~~

~~(3) Prescription preparation;~~

~~(4) Consultation;~~

~~(5) Record keeping;~~

~~(6) Over the counter products;~~

~~(7) Drug information.~~

~~(c) Proof of Experience: All intern pharmacists are required to submit proof of their experience on Board approved affidavits which shall be certified by the preceptor under whose immediate supervision such experience was obtained.~~

~~(d) Out-of-State Exemption: One who is licensed as a pharmacist in any state and who has practiced as a pharmacist in that state for at least one year, as certified by the Board of Pharmacy of that state, shall be exempt from the pharmaceutical requirements of this section.~~

(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by Section 4200 of the Business and Professions Code applicants shall submit to the board the following:
  (1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:
    (A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.
    (B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy
    (C) Experience in both community pharmacy and institutional pharmacy practice settings.
    (D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experience established by the Accreditation Council for Pharmacy Education.
  (2) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.
  (3) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code Section 144.
  (4) A signed copy of the examination security acknowledgment.

(b) Applicants who hold or held a pharmacist license in another state shall provide a current license verification from each state in which the applicant holds or held a pharmacist license prior to being authorized by the board to take the examinations.

(c) Applicants who graduated from a foreign school of pharmacy shall provide the board with satisfactory proof of certification by the Foreign Pharmacy Graduate Examination Committee prior to being authorized by the board to take the examinations.

Authority cited: Sections 4005 and 4114, Business and Professions Code. Reference: Sections 4114 and 4200, Business and Professions Code.

MOTION: Licensing Committee: That the Board of Pharmacy approve the proposed change to CCR, title 16, sec. 1728 related to the application process for the pharmacist license examination and the internship requirements.

SUPPORT: 8 OPPOSE: 0

- **Proposed Omnibus Regulation Changes to Implement SB 1913 and Update of Licensing Requirements**

Senate Bill 1913 (Chapter 695, Statutes of 2004) and the adoption of the NAPLEX requires the board to alter existing regulations relating to the pharmacist licensing process to reflect the new statutes and to streamline board operations. Although a number of the changes are substantive, many are minor or technical.

Section 1706.2 – This amendment relocates existing provisions for the abandonment of applications by pharmacist applicants into this one section. It adds a new provision that will require an individual to take the pharmacist licensure examination(s) within one year of being deemed eligible and will require licensure as a pharmacist within one year of passing the examination. Currently an applicant has two years to become licensed.

§1706.2. Abandonment of Application Files.

(a) An applicant for a ~~permit~~ license to conduct a pharmacy, non-resident pharmacy, sterile injectable compounding pharmacy ~~manufacturer,~~ wholesaler, ~~supplier,~~ out-of-state distributor, or clinic~~, medical device retailer or warehouse of a medical device retailer~~ 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 ~~which are~~ in effect at the time of reapplication.
(b) An applicant for a pharmacy technician license ~~registration~~ 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.

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~sections 4029, ~~4033, 4034,~~ 4037, 4043, 4110, 4112, 4115, 4120~~,~~ 4127.1, 4160, 4161, 4180, 4190, ~~and~~ 4200, 4201, 4202, 4203, 4204, and 4205, Business and Professions Code.

Section 1719 – This section recognizes schools of pharmacy that are accredited by or granted candidate status by the ACPE, which is a change that was previously approved by the board. The provisions relating to foreign graduates have been eliminated because of SB 1913, which

requires all foreign graduates must be FPGEC certified which includes the existing requirements.

§1719. ~~Requirements for Admission to Examination.~~ Recognized Schools of Pharmacy.

As used in this division, "recognized school of pharmacy" means a school of pharmacy accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education or otherwise recognized by the board.

~~(a) Applicants for the pharmacist licensure examination shall have completed all requirements for graduation from a school of pharmacy accredited by the American Council on Pharmaceutical Education or recognized by the Board.~~

~~(b) All candidates for the pharmacist licensure examination shall have completed a minimum of 1,000 hours of experience prior to applying for the examination.~~

~~(c) All candidates for the pharmacist licensure examination who are graduates of a foreign pharmacy school (any school located outside the United States of America) must demonstrate proficiency in English by achieving a score specified by the board on the Test of Spoken English administered by the Educational Testing Service. For candidates taking the Test of Spoken English after June 30, 1995, a score of at least 50 must be achieved. For candidates taking the Test of Spoken English before June 30, 1995, a score of at least 220 must be achieved.~~

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~sections ~~851, 4005 and~~ 4200 of the Business and Professions Code.

Section 1720 – This section is changed to reflect the current exam structure.

§1720. Application for Pharmacist Examination and Licensure. ~~Registration.~~

(a) An application for examination shall be submitted on the form provided by the board, and filed with the board at its office in Sacramento.

(b) The fee required by ~~Section 1749,~~ subdivision (d) of section 1749 of this Division shall be paid for each application for initial examination and for any application to retake the examination described in section 4200.2 of the Business and Professions Code. The fee is nonrefundable.

(c) ~~An applicant who fails to pay the fee required by Section 1749, subdivision (f) within one year after being notified of his or her eligibility for a license as a pharmacist shall be deemed to have abandoned the application and must file a new application and meet all of the requirements which are in effect at the time of reapplication.~~

~~(d)~~ Each applicant shall be solely responsible for applying to and complying with the requirements imposed by the administrators of the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California for the administration of those examinations.

~~(e) An applicant for examination who does not take the examination within one year of the date the applicant is determined by the board to be eligible to take the examination shall be~~

~~deemed to have abandoned the application and must file a new application in compliance with all of the requirements which are in effect at the time of reapplication.~~

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~Section~~ sections 4200 and 4200.2, Business and Professions Code.

Section 1725 – This section is changed to conform to Section 1719.

§1725. Acceptable Pharmacy Coursework for Examination Candidates with Four Failed Attempts.

(a) Coursework that meets the requirements of section 4200.1 of the Business and Professions Code is any pharmacy coursework offered by a ~~pharmacy~~ recognized school of pharmacy. ~~approved by the American Council on Pharmaceutical Education or recognized by the board.~~
(b) A final examination must be a part of the course of study.
(c) When a candidate applies for reexamination after four failed attempts, he or she shall furnish evidence of successful completion of at least 16 semester units or the equivalent of pharmacy coursework. Evidence of successful completion must be posted on a transcript from the pharmacy school sent directly to the board.

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~section 4200.1, Business and Professions Code.

Section 1726 – This section is changed to eliminate reference to "preceptor." Preceptor is no longer a relevant term as interns may be supervised by any pharmacist in good standing.

§1726. ~~Preceptor.~~ Supervision of Intern Pharmacists.

(a) The pharmacist supervising an intern pharmacist shall be responsible for all professional activities performed by the intern under his or her supervision.~~A preceptor is a pharmacist registered in any state whose license is not revoked, suspended or on probation in any state in which he or she is now or has been registered.~~
(b) The ~~preceptor~~ pharmacist supervising an intern pharmacist shall ~~supervise the intern's activities to~~ provide the experience necessary ~~to make~~ for the intern pharmacist to become proficient in the practice of pharmacy. ~~provision of pharmaceutical services.~~
~~(c) The preceptor shall be responsible for all professional activities performed by the intern under his or her supervision.~~

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~sections 4030, 4114 and 4200, Business and Professions Code.

Section 1727 – This section is repealed. Similar provisions have been added to the Business and Professions Code (SB 1913).

§1727. Intern Pharmacist.

~~(a) An intern pharmacist is a person who holds a valid intern card.~~
~~(b) An intern card shall be issued for a period of:~~
~~(1) One to five years for the person who is currently enrolled in a school of pharmacy recognized by the Board.~~
~~(2) One year to a person who is a graduate of a school of pharmacy recognized by the Board.~~
~~(3) One year to a foreign graduate who has met educational requirements described in Business and Professions Code Section 4200.~~
~~(4) One year to an out-of-state licentiate who is awaiting the administration of the next licensure examination.~~
~~(c) Registration as an intern may be renewed or extended at the sole discretion of the Board for:~~
~~(1) Persons who have not completed experience requirements.~~
~~(2) Persons who have completed experience requirements but have not taken or passed the licensure examination. Intern cards shall not be extended or renewed for a person who failed the licensure examination three or more times.~~
~~(d) An intern shall notify the Board within 30 days of any change of address. An intern shall return his or her intern card, by registered mail, within thirty (30) days of a change of eligibility status.~~
~~(e) An intern pharmacist may perform all functions of a pharmacist at the discretion and under the supervision of a preceptor in accordance with Business and Professions Code Section 4114.~~

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~sections 4030, 4114 and 4200, Business and Professions Code.

Section 1749 – This section is amended to make numerous technical changes. The amendments also include the elimination of the foreign graduate application fee consistent with the changes made to foreign graduate licensing requirements. The amendments also eliminate the fee for registering continuing education accreditation entities to be consistent with changes proposed for continuing education regulations.

§1749. Fee Schedule.

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with ~~S~~section 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a ~~permit to conduct a~~ pharmacy license is three hundred forty dollars ($340). The fee for the annual renewal of ~~said permit~~ pharmacy license is one hundred seventy-five dollars ($175). The penalty for failure to renew is eighty-seven dollars and fifty cents ($87.50).

(b) The fee for the issuance of a temporary license ~~permit~~ is one hundred seventy-five dollars ($175).

(c) The fee for the issuance of a pharmacy technician license shall be fifty dollars ($50). The fee for the biennial renewal of a pharmacy technician license shall be fifty dollars ($50). The penalty for failure to renew a pharmacy technician license is twenty-five dollars ($25). (d) The fee for application and examination as a pharmacist is one hundred fifty-five dollars ($155).

(e) The fee for regrading an examination is seventy-five dollars ($75).

(f) The fee for the issuance of an original pharmacist license is one hundred fifteen dollars ($115).

(g) The fee for the biennial renewal of a pharmacist's license is one hundred fifteen dollars ($115). The penalty fee for failure to renew is fifty-seven dollars and fifty cents ($57.50).

(h) The fee for the issuance or renewal of a wholesaler's license ~~permit~~ is five hundred fifty dollars ($550). The penalty for failure to renew is one hundred fifty dollars ($150).

(i) The fee for the issuance or renewal of a hypodermic license is ninety dollars ($90). The penalty for failure to renew is forty-five dollars ($45).

(j) The fees for a certificate of exemption under the provisions of sections 4053~~,~~ or 4054 ~~and 4133~~ of the Business and Professions Code are as follows:

(1) For the application and investigation of the applicant, the fee is seventy-five dollars ($75).

(2) For the issuance or renewal of an original certificate for an application approved by the board the fee is one hundred ten dollars ($110). The penalty for failure to renew is fifty-five dollars ($55).

(k) The fee for the issuance or renewal of a license as an out-of-state distributor ~~manufacturer or wholesaler~~ is five hundred fifty dollars ($550). The penalty for failure to renew is one hundred fifty dollars ($150).

(l) The fee for ~~registration as~~ an intern pharmacist license ~~or extension of the registration~~ is sixty-five dollars ($65). The fee for transfer of intern hours or verification of licensure to another state is ten dollars ($10).

(m) ~~The fee for the reissuance of any permit, license, certificate or renewal thereof, which has been lost, or destroyed or must be reissued because of name change, is thirty dollars ($30).~~ The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is sixty dollars ($60).

(n) ~~The fee for registration and annual renewal of providers of continuing education is one hundred dollars ($100). The penalty for failure to renew is fifty dollars ($50).~~
~~(o)~~ The fee for evaluation of continuing education courses for accreditation is forty dollars ($40) for each hour of accreditation requested.
~~(p) The fee for evaluation of an application submitted by a graduate of a foreign college of pharmacy or college of pharmacy not recognized by the board is one hundred sixty-five dollars ($165).~~
~~(q)~~ (o) The fee for the issuance of a clinic license ~~permit~~ is three hundred forty dollars ($340). The fee for the annual renewal of a clinic license ~~said permit~~ is one hundred seventy-five dollars ($175). The penalty for failure to renew is eighty-seven dollars and fifty cents ($87.50).
~~(r) The fee for the issuance of a permit for a warehouse of a medical device retailer is one hundred seventy dollars ($170). The fee for the annual renewal of said permit is eighty-seven dollars and fifty cents ($87.50). The penalty for failure to renew is forty-three dollars and seventy-five cents ($43.75).~~

Note:

Authority cited: ~~S~~sections 163.5 and 4005, Business and Professions Code. Reference: ~~S~~sections 163.5, 4005, 4110, 4112(h), 4120, ~~4130,~~ 4196, 4200~~(c)~~, 4400~~(a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), (o), (q), (r), (s), (t), (u), (v), (w)~~, 4401 and 4403, Business and Professions Code.

Section 1750 – This section is repealed as the underlying statute was repealed in 2003.

§1750. Fee Schedule--Health and Safety Code.

~~The fee for issuance and renewal of a warehouse license as provided by Section 11127 of the Health and Safety Code is one hundred dollars ($100). The penalty for failure to renew is twenty-five dollars ($25).~~

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code; and ~~S~~section 11127, Health and Safety Code. Reference: ~~S~~s ection 11127, Health and Safety Code.

MOTION: Licensing Committee: That the Board of Pharmacy approve the proposed omnibus regulation changes to implement SB 1913 and update of licensing requirements

SUPPORT: 8 OPPOSE: 0

- **Proposed Regulation Change to Update Continuing Education Provisions (CCR, title 16, sec. 1750)**

Chairperson Conroy stated that at the July meeting, the board approved the recommended changes to the CE regulations as proposed by the California Pharmacists Association (CPhA). CPhA provided the board with suggested amendments. One reason for this request was that in January 2004, the activities of the Accreditation Evaluation Service (AES) moved from the California Pharmacists Association (CPhA) to the CPhA Pharmacy Foundation of California. In addition the following changes were included:

- Change the term "continuing pharmaceutical education" to "continuing pharmacy education"
- Change AES from a "continuing education provider and coursework review component of the California Pharmacists Association" to "the accreditation agency for providers of continuing pharmacy education in California"
- Change the role of AES and ACPE from "approvers" to "accreditors"
- Change the ownership AES to the CPhA Educational Foundation
- Change the language from "organization" to "accreditation agency"
- Change the review/audit requirement 10%
- Change the term "certificates of completion" to "statements of credit"
- Require the provider to furnish the "statement of credit" to participants who complete the requirements for course completion
- Require that the material be current in order for it to be considered valid CE

Upon further review of the CE regulations, it was noted they had not been updated for over 10 years. Therefore, the draft amendments include the CPhA amendments, a reorganization of the law and clean up of the existing language. While the changes represent a substantial reorganization of the existing regulatory provisions, there are a relatively few changes in the substance of the regulations. The draft is footnoted to indicate the location of existing provisions that were moved and to note those provisions that were altered or eliminated.

MOTION: Licensing Committee: That the Board of Pharmacy approve the proposed changes to the continuing education (CE) regulations

§1750. Fee Schedule--Health and Safety Code.

~~The fee for issuance and renewal of a warehouse license as provided by Section 11127 of the Health and Safety Code is one hundred dollars ($100). The penalty for failure to renew is twenty-five dollars ($25).~~

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code; and ~~S~~section 11127, Health and Safety Code. Reference: ~~S~~s ection 11127, Health and Safety Code.

SUPPORT: 8 OPPSOSE: 0

- **Report on the Implementation of North American Pharmacist Licensure Examination (NAPLEX and the California Pharmacist Jurisprudence Examination (CPJE) – Status Report on the Restructuring of the Competency Committee**

Chairperson Conroy stated that the board transitioned to the new examination structure in January 2004 and began administering the California Pharmacist Jurisprudence Examination (CPJE) in March 2004. She added that 2,500 applications had been received to take the California license exams as of early October, and 108 of these are retake applications. Since mid-June, 1,000 individuals have become licensed as pharmacists. A total of 1,838 individuals have been made eligible to take the licensure examinations and 94 individuals have also been requalified to take the exams (they failed one of the exams, and had to requalify). The board has also verified 1,368 individuals as qualified to take the NAPLEX for California to the NABP (and this includes score transfers). The board has administered 1,299 CPJE examinations. The board has performed 17 regrades of the CPJE, which resulted in no change in the score. The CPJE's pass rate is 86 percent.

There are three ways that an individual may provide a NAPLEX score to the California Board of Pharmacy:

1. The individual becomes qualified by California as eligible to take the pharmacist licensure examinations, with California as the primary state.
2. The individual becomes qualified in another state to take the pharmacist licensure examination, but designates California as a "score transfer" state -- before he or she takes the NAPLEX. Then once California qualifies the individual as eligible to take the licensure examinations here, the NABP will transfer the score to the board.
3. The individual qualifies for the NAPLEX examination in another state and becomes licensed there. Later, at some point, the individual wants to become licensed in California. In some states, the state where the individual is licensed is willing to "assign" the NAPLEX score to California via a process the NABP calls "license transfer" (however, the applicant still needs to fulfill all other requirements for licensure in CA, including passing the CPJE).

Chairperson Conroy stated that since January, the board has been using options 1 and 2 to obtain NAPLEX scores for eligible candidates. She stated that NABP recently surveyed all other states regarding option 3 and their willingness to accept a NAPLEX score from California, after an individual is licensed here. The NABP calls this "License Transfer" or "assignment of a score by licensure." Thirty states responded and not all these states indicated that they are willing to do this. The states willing to accept an "assignment of NAPLEX score" from California are: AK, DE, FL, HI, IL, KS, MN, MO, NE, NH, NY, ND,

OH, OR, SD, TN, TX, VA, WI. The states that replied "no" are: AZ, AR, GA, ID, LA, MD, NV, PA, WA and WY.

Those that answered yes indicated that they would accept the NAPLEX score earned after January 1, 2004, for a pharmacist licensed in California – and they would allow a score earned in their state to be used by California for purposes of licensure. In such cases, these candidates would not need to retake the NAPLEX if they want to become licensed in the other state, although there may be other requirements for licensure (in California, the individual would still need to pass the CPJE if the NAPLEX score was earned after January 1, 2004 and transferred here by an agreeable state).

For those states that answered no, there would be no sharing of NAPLEX scores unless a score transfer (option 2) was requested before the individual took the NAPLEX. Instead these candidates would need to retake the NAPLEX.

For those 19 states that didn't respond, the NABP and the board do not know whether NAPLEX scores could be transferred after licensure in one state to another state. California is willing to share the score even if the state that would receive the score will not allow candidates to transfer their score to California.

Ms. Herold reported that at the April Board Meeting, the board approved the restructuring of the Competency Committee. This committee develops and scores the CPJE. The committee will be restructured into a two-tier structure – a core committee and a group of item writers.

The item writers would develop questions for the examination, and the core committee would select items and refine them for the examination, select cut scores and oversee issues arising from administration of the examination.

The board is now seeking to identify new members for the two committees. In the next board newsletter, the board will seek nominations from interested pharmacists to serve in either capacity.

The board's president will appoint members to the committees. To apply for appointment, an applicant needs to submit one CV/resume and three letters of reference. This material needs to be submitted to the board (Competency Committee Appointments, Board of Pharmacy, 400 R Street, Suite 4070, Sacramento, CA 95814). The new committee structure should be in place early next year.

The National Association of Boards of Pharmacy also periodically seeks item writers for the NAPLEX examination. The board is interested in forwarding to the NABP the names of individuals interested in serving as NAPLEX item writers. The NABP selects its item writers. This will also be discussed in the board's next newsletter as well.

- **Report on the Workgroup on Compounding**

  Dr. Conroy stated that last April, the Board of Pharmacy agreed to form a workgroup with the Department of Health Services, State Food and Drug Branch to address pharmacy-compounding issues. The workgroup held its third meeting September 22, 2004. At this meeting, the workgroup discussed and provided comments on a draft proposal on general compounding. The proposal establishes a regulatory framework for general compounding by a pharmacy. The workgroup and other interested parties were asked to provide comments by November 1, 2004.

  Dr. Schell stated that it was a good meeting and, based on the work of the first two meetings, a draft was developed that explained compounding. He encouraged those who have specific comments to attend the December meeting in Burbank when the committee will refine the language. He added these meetings have been very well attended.

- **Competency Committee Report – Job Analysis Survey**

  Ms. Herold stated that the most critical issue facing the Competency Committee is the job analysis questionnaire of the pharmacist profession that will be mailed in November to 3,000 California-licensed and residing pharmacists in November. The Department of Consumer Affairs recommends that this job analysis be undertaken every three to seven years. It has been five years since the last job analysis.

  Ms. Herold added that the board awards three hours of continuing education credit to encourage completion of this six-page questionnaire because of its importance and the deliberation required. She added that submissions are confidential and anonymous.

  The board is exactly six months behind a similar analysis conducted by the NABP and consequently the board's analysis is very timely.

  She explained that the job analysis measures tasks performed by pharmacists and the importance of each task. The statements are then aggregated by the Competency Committee who generate a series of task statements that define and describe the California pharmacy practice. From this, a content outline will be developed through the Competency Committee to structure the CPJE. She added that the board must assure that its exam does not test the same things as the NABP's test.

  Dr. Conroy thanked Mr. Riches for his assistance in explaining the many law items to her throughout the last year.

- **Recognition of Paul Riches**

  Ms. Harris announced that Paul Riches has accepted a position as executive officer of the Board of Behavioral Science Examiners. She added that Mr. Riches has been with the board five years and has made major contributions to improve and update California Law.

  Ms. Harris expressed appreciation for Mr. Riches' outstanding job performance with the Board of Pharmacy, and awarded him a commemorative clock to thank him.

ENFORCEMENT COMMITTEE

Chairperson Powers reported on the Enforcement Committee Meeting of September 29, 2004.

- **Proposed Legislative Change to Update the Law Regarding the Pharmacist Recovery Program (Bus. & Prof. Code section 4360-4373)**

  Chairperson Powers stated that the purpose of the proposed changes is to update the statutory provisions related to the Pharmacists Recovery Program (program). Most of the proposed changes are minor technical revisions to more closely conform the statute to the current operation of the program; however, there are some substantive changes.

  A substantive change effects section 4362. This section specifies who is eligible to enter the program and the terms of entry into the program. First, a licensee can be referred to the program instead of or in addition to disciplinary action. Second, a licensee can enter the program voluntarily. The substantial change proposed is that licensees who enter the program voluntarily will not have their identities withheld from the board. Current law indicates that such "self-referrals" are confidential and the board is generally not informed of their identities. This "confidentiality" can be voided if the program administrator believes the licensee may present a threat to the public. However, participants sign disclosure agreement upon entering the program that permits the program to release their identity to the board. This statutory change would conform to existing practice by the program.

  The draft proposal would prohibit the board from taking enforcement action against a self-referred licensee based on his or her entry into the program or any information obtained from the licensee while participating in the program. This change more closely mirrors the diversion programs operated by other boards in the department. The proposal does allow the board to take enforcement action against a licensee in the program if the board independently obtains information supporting such an action.

  Another substantial change proposed is to section 4368, which removes the mandate that the board enter into a contract with a professional association to promote the program and coordinate outreach to encourage voluntary participation. The board has not entered into such a contract with a professional association for over five years. Given the current fiscal

constraints on the board, it is unlikely that such a contract would be reestablished in the foreseeable future and removing the statutory mandate seems appropriate. The board can use other means to educate licensees about the availability of the program. Moreover, the board could always enter into such a contract, if it desired, without the statutory mandate.

A question was asked whether pharmacy technicians should be included in the program. It was noted that the intent is to rehabilitate pharmacists so that they may return safely to the practice of pharmacy. As a health professional, the pharmacist has much more invested in his or her education and training and thus more incentive to seek treatment. The program also encourages the pharmacist's participation and rehabilitation while providing the oversight necessary to ensure patient safety without undue punishment to the impaired pharmacist.

Dr. Schell expressed support of the proposal to include pharmacy technicians in the program but asked if the board has any other way to handle impaired pharmacy technicians and rehabilitate them.

Ms. Harris stated that currently an impaired pharmacy technician is placed on probation and part of the stipulation may be to participate in a program. The board would monitor the progress and be made aware of the program they were participating in. She added that this program would not be sanctioned by the board but would have the same parameters and testing abilities required for pharmacists.

MOTION: Enforcement Committee: That the Board of Pharmacy support a statutory change to Business and Professions Code sec. 4360 – 4373 to update the law regarding the Pharmacist's Recovery Program

SUPPORT: 8 OPPOSE: 0

- **Proposed Legislative Change to Update the Pharmacy Technician Program (Business and Professions Code sec. 4038, 4114, 4115, 4115.5 and 4202)**

Chairperson Powers stated that these proposed changes to the pharmacy technician program are primarily technical and designed to make the statutes clearer. The most significant change is standardizing the terminology relating to the supervision of ancillary personnel. The different code sections used slight variations of language requiring the supervision of ancillary personnel. This draft adopts the most common verbiage of "direct supervision and control" of the pharmacist and applies this same supervision to interns.

The other changes are mostly technical clean up to eliminate duplicative and unnecessary language. However, one substantive change to 4115 would eliminate the exemption that permits unlicensed personnel to act as a pharmacy technician during their first year of employment at the Department of Corrections, California Youth Authority, Department of Mental Health, Department of Developmental Services or the Department of Veterans Affairs. This provision was initially added to allow personnel to work in those facilities until they

could accumulate enough hours to qualify for licensure as a pharmacy technician. However, experience is no longer a means of qualifying for licensure as a pharmacy technician and this provision is no longer appropriate.

Chairperson Powers stated that during the Enforcement Committee Meeting, comments were made that provided general support with the proposed changes with an opportunity for the board to consider some possible enhancements. It was reiterated that the intent of this legislative proposal was not to change the ratio or the basic authority of pharmacy technicians. As legislation is introduced, the opportunity to address these issues is always available.

Steve Gray, representing Kaiser Permanente, stated that Kaiser supports this proposal because it would offer the pharmacist-in-charge a better understanding of their responsibilities and technicians a better understanding of their relationship with pharmacists.

John Cronin, representing the California Pharmacists Association, stated that both the CPhA and CSHP have interest in expanding this proposal and actually rewriting section 4115 and they are in the process of developing language.

MOTION: Enforcement Committee: That the Board of Pharmacy support a statutory change to Business and Professions Code sec. 4038, 4114, 4115, 4115.5 and 4202 related to the pharmacy technician program as proposed.

SUPPORT: 8 OPPOSE: 0

- **Proposed Legislative Change Related to Letter of Admonishment (Bus. & Prof. Code sec. 4315)**

Chairperson Powers stated that section 4315, which authorizes the executive officer of the board to issue a letter of admonishment for a violation of the Pharmacy Law, was added last year to provide the board with a broader range of enforcement options. One requirement in the new section is that the licensee receiving the letter of admonishment must keep a copy of that letter in the pharmacy for three years. This requirement is problematic for licensees who do not work regularly in the same pharmacy or do not work in a pharmacy at all (exemptee, wholesaler, etc.).

MOTION: Enforcement Committee: That the Board of Pharmacy support a statutory change to Business and Professions Code section 4315 related to the Letter of Admonishment.

SUPPORT: 8 OPPOSE: 0

- **Proposed Regulation Change to Implement SB 1913 Related to the Use of Technologies to Record the Identification of a Reviewing Pharmacist**

Chairperson Powers stated that Senate Bill 1913 amended Section 4115 to permit the board to allow the use of electronic technology to satisfy the requirement that a pharmacist sign off on prescriptions filled by pharmacy technicians. The proposed regulation text would allow the use of electronic methods of identifying the reviewing pharmacist. This section would also be an alternative means of documenting the pharmacist's review as required by CCR, title 16, sec. 1717(b)(1) and 1717(g).

Mr. Jones referred to an e-mail dated October 19, 2004, from Fredrick Mayer, President of PPSI, in opposition to this proposed regulation change which states that it appears that the board is advocating an identifiable form of tracking instead of advocating who handled the prescription and when. Mr. Jones clarified that the board is not approving automation, but basically saying that if a pharmacy uses automation, it is the pharmacy or the pharmacist-in-charge that is responsible for assuring safe procedures for consumer protection and if an error occurs, the pharmacy or pharmacist-in-charge would be held accountable.

Chairperson Powers agreed that those who use new technology must ensure that it operates in a reasonable safe and secure way.

MOTION: Enforcement Committee: That the Board of Pharmacy support a proposed regulation change to implement SB 1913 related to the use of technology to record the identification of a reviewing pharmacist.

SUPPORT: 8 OPPOSE: 0

- **Proposed Regulation Change to Amend CCR, title 16, sec. 1715 – Proposed Revisions to the Self-Assessment Forms for Community and Hospital Pharmacies**

Chairperson Powers stated that this regulation section 1715 requires that a pharmacist-in-charge (PIC) perform a self-assessment by July 1 of every odd-numbered year. The self-assessment forms need to be updated with the many law changes in advance of the July 1, 2005 mandate. To do this, the board needs to notice and act on the regulation change at the January Board Meeting. The board reviewed the updated self-assessment forms for community and for inpatient pharmacies.

MOTION: Enforcement Committee: That the Board of Pharmacy consider a proposed regulation change to CCR, title 16, sec. 1715, an update of the pharmacy self-assessment forms.

SUPPORT: 8 OPPOSE: 0

- **Request by Longs Drug Stores for Waiver of CCR, title 16, sec 1717(e) to install a 24-Hour Kiosk for Patients to Drop off their Prescriptions.**

Chairperson Powers stated that Longs Drug Stores Inc., has requested a waiver of CCR, title 16, sec. 1717(e) to install secure and private, 24-hour prescription drop kiosks. The plan is to install the kiosk adjacent to or in the parking lot at various Longs Drug Stores in California, for patients to use as an easy means to drop off their prescriptions for the pharmacy to fill. The kiosk would be similar to a mailbox or drop off container used by video stores.

Chairperson Powers referred to an article on hygienists sent from Lowell McNicol on dental hygienists that was provided to board members at Mr. McNicol's request because it had bearing on the discussion regarding "kiosks" and the next agenda item regarding "automated dispensing devices."

The board's legal counsel has advised that a waiver of the prohibition in 16 CCR § 1717(e) is required to permit Longs to move forward with this proposal.

The Enforcement Committee referred to the Board of Pharmacy this request from Longs Drug Stores for waiver of 1717(e) to use a 24-hour prescription drop kiosk; however, the committee did not make a recommendation regarding the request.

Prior to the presentation by Longs Drug Stores, board member David Fong recused himself from the discussion.

Mike Cantrell and Cooky Quandt, representing Longs Drug Stores, Inc., appeared before the board to make a request for this waiver and to answer questions.

John Cronin, representing the California Pharmacists Association, stated that the CPhA has serious concerns about this request and stated that the board should discuss this more fully to determine the impact this would have on the role of pharmacists. He stated that this technology has the potential to completely replace pharmacists. He added pharmacist's role must be maintained for evaluating new prescriptions as well as for refills.

Mr. Cronin referred to the board mission to promote and protect the public's health and safety and ensure that consultation and information is provided to patients and other health care providers about drug therapy. The board also ensures that drugs are dispensed and used correctly and requires that pharmaceutical therapy is provided by highly educated and trained pharmacists that meet the professional standards set by the board.

Chairperson Powers stated that this proposal is only for filling refills. He stated that there are not many times when interaction with a pharmacist is needed for a refill.

Mr. Tilley left the board meeting at this point in the discussion.

Ms. Zinder stated that she agrees with Mr. Cronin but consumers are driven to mail order because it saves money and there did not appear to be a difference between mail order and the 24-hour prescription drop kiosk.

Mr. Jones stated that the error rate in an automated setting is very low compared to a setting with distractions, and that consumers should have a choice. He added that automated environments are monitored by people and that both systems have positive aspects and both have limitations.

Dr. Schell stated that he appreciates the comments made by the board and as a public advocate for over 20 years he sees his role on the board exactly how Mr. Cronin explained -- as one providing expertise in the area that he practices. He added that he sees this technology as an opportunity to enhance the role of pharmacists which is to optimize positive medication outcomes, regardless of how this is accomplished.

President Goldenberg stated that new technology should allow pharmacists the opportunity to either be more accurate in dispensing or better in sharing their cognitive knowledge. He added that the technology the board considers is not as important as the board's philosophy to create an opportunity for service that the public may not know exists.

Steve Gray, representing Kaiser Permanente, stated that years ago when the board pursued mandatory patient consultation, Kaiser funded a multi-million dollar project to study the value of patient consultation in health care. The results of the study found that all consultation had value including consultation for refill prescriptions. As a result of the study, Kaiser designed its central fill operation to avoid mail-order and would prefer not to have it, but the market demands that it provide mail order benefits.

Dr. Gray stated that the role of the pharmacist when filling refill prescriptions has not been expressed by the board. He added that over 90 percent of pharmacists feel that they have no responsibility to interact with patients when filling refill prescriptions.

A student in the audience commented that in school all the latest, greatest and cutting edge practice is taught and presented. He added that the profession has expanded and pharmacists are now part of a medical team caring for patients and improving health. He stated that no one would argue against the use of technology that will free the pharmacists to use their clinical skills, but this technology basically would cut away from everything that the profession has fought for.

Another comment from the public stated that several studies revealed that pharmacists by far are the most easily accessed health care providers. Any technology that limits or eliminates contact with pharmacists hinders all that the profession has striven for.

Mr. Cantrell responded that this technology was developed in response to numerous requests from patients to provide a more convenient method for consumers to drop off their prescriptions.

Mr. Cantrell stated that convenience translates into better patient compliance and improved therapeutic outcomes. He added that this is a secure device in which to deposit a prescription or dispense refill medications and pharmacists control access to the contents of the unit.

Mr. Jones asked if patients have after-hour access to a pharmacist.

Mr. Cantrell stated that this technology enables the patient to deposit a prescription in the kiosk and then later return to the pharmacy to pick up the prescription that would be dispensed in a face-to-face setting.

Mr. Cantrell stated that Longs has specially designed envelopes to be used by patients that have all the relevant patient information on them including allergies, etc. that was solicited from patients in person when they come into the store. Information will be provided directly on the drop-off box as to when the contents are actually removed each day and the time when the prescription will be filled.

Dr. Schell stated that he did not feel he is ready to make a decision.

Mr. Powers stated that he is not in favor of supporting a waiver. He asked staff to present their views on any conditions that should be addressed.

Ms. Harris stated that the language drafted by staff for a proposed regulation in this area, states that a patient or patient's agent may deposit a prescription in a secure container that is at the same address or adjoining the licensed premises, the pharmacy shall be responsible for the security and confidentiality of the prescription deposited in the container.

Supervising Inspector Ratcliff stated that this service would provide convenience for the patient, security of the prescription and posted notification indicating when the prescription will be pulled from the container and filled.

M/S/C: JONES/CONROY

MOTION: That the Board of Pharmacy approve the request from Longs Drug Stores for a waiver of 1717(e) to install a 24-hour kiosk for patients to drop off their prescriptions, consistent with the language proposed for the regulation change to section 1713; specifically, authorizing Longs Drugs Stores to install and use a 24-hour prescription drop kiosks at its pharmacies. The board granted the waiver with the condition that the container is secured and it is at the same address or adjoining the licensed premises. In addition the pharmacy is responsible for the security and confidentiality of the prescriptions deposited in the containers.

SUPPORT: 4 OPPOSE: 3

- **Request from Longs Drug Stores for a waiver of CCR, title 16, Sec. 1717(e) to Install and Use a Self-Service Dispensing Unit for Refill Medications**

  Lowell McNicol, Pharm.D., asked the board to keep an open mind and realize that the intent is not to reduce pharmacy positions or the role of the pharmacist, but instead, to provide alternatives.

  Board Member David Fong recused himself.

  Bob Hansen, Pharm.D., Vice President of Pharmacy Services from Asteres presented a Power Point on ScriptCenter. The ScriptCenter is an automated, self-contained machine that allows patients to obtain their filled prescriptions without directly going to the pharmacy counter. The intent is to install the units in close proximity to the pharmacy area. To improve patient convenience and therapeutic compliance, a patient could access the units during pharmacy hours or during those times when the main store is open, but the pharmacy is closed.

  According to Dr. Hansen, a survey of 450 Longs customers regarding the ScriptCenter recently resulted in: 99 percent it was easy to use it, 92 percent are likely to use it, 31 percent gave e-mail addresses to "tell me when and where in use."

  At the request of the patient and through the use of a secure method designed to guard against inappropriate access, a patient may retrieve his/her filled prescription from the unit at their convenience. New prescriptions, or those prescriptions requiring consultation, would not be available through these units.

  Prescriptions would be filled by a pharmacist and placed into the units either by a pharmacist or pharmacy personnel, under the supervision of a pharmacist. As medications are placed into the units, security measures are used to ensure accurate dispensing.

  The board's legal counsel has advised the board that a waiver of the prohibition in 16 CCR § 1717(e) is required, under the authority of that section, to permit Longs and/or Asteres to move forward with this proposal.

  The Enforcement Committee advanced to the Board of Pharmacy this request from Longs Drug Stores for waiver of 1717(e) to use a self-service dispensing unit; however, the committee did not make a recommendation regarding the request.

  Mr. Cantrell stated that the machine enhances therapeutic outcomes. Moreover, there is a pharmacist shortage almost in every county in California. This machine would provide greater opportunity for patients to pick up their medications.

  Mr. Powers stated that the number of positions lost to automation is significant.

Mr. Jones asked if there was a 24-hour pharmacist on-call to handle a patient's questions after they pick up their medications.

Mr. Cantrell stated that for those situations where a patient needs or wants to contact a pharmacist, calls would be routed directly to a 24-hour store.

Dr. Gray, representing Kaiser Permanente, stated that Kaiser is studying whether there is an application such as this for their organization. He added that Kaiser would expect their pharmacists to follow-up on patient therapy and this needs to be expressed to all pharmacists in California.

Ron Bayman, Corporate Pharmacy Director for Safeway, stated that Safeway has also considered this technology because the need for this convenience to the patient is clear, based on market driven requests. He added that it is up to the public and the board to consider providing a valued service in a responsible way for consumers.

The board discussed whether to request that a study be done in advance of granting a waiver. President Goldenberg stated that he welcomed and encouraged public comment regarding use of and patient acceptance of these machines.

Deputy Attorney General Joshua Room stated that any waiver granted by the board can be withdrawn. It is a prohibition that is being waived, not a right that is being granted. Moreover, the pharmacy and pharmacists are still responsible for all dispensing.

Supervising Inspector Ratcliff stated that from an enforcement perspective, he did not see a problem with the board granting a waiver. He suggested a language change from "the device is located at the same address or adjoining the licensed premises" to "the device is located at the same address adjacent to the pharmacy."

Dr. Conroy stated that many pharmacies have different layouts and it may be more practical not to restrict the unit to be adjacent to the pharmacy.

Greg Spieker, representing the Rural Indian Community, cautioned that this technology could allow the pharmacy to cut hours and then cause the market to be drawn to this ATM type of service resulting in the future in limited hours of business, or increased fees for those patients who actually want help inside the pharmacy.

MSC: SCHELL/CONROY

MOTION: That the Board of Pharmacy grant a waiver of 1717(e) to install and use a self-service dispensing unit for refill prescriptions by Longs Drugs, Inc., with recommendation to modify the language to assure that the system is either inside or adjacent to the licensed pharmacy area. Specifically, the board granted the waiver with the condition that the

device is for refilled prescriptions only; however, the pharmacist is not to use the device to dispense refilled prescriptions if the pharmacist determines that the patient requires consultation pursuant to section 1707.2(a(2). The device must be located in reasonable proximity to the licensed pharmacy premise. The device must have the means to identify the patient and only release that patient's prescriptions. The device is secure from access and removal by unauthorized individuals. The pharmacy must provide a means for the patient to obtain consultation with a pharmacist if requested, and the pharmacy is responsible for the patient to obtain consultation with a pharmacist if requested, and the pharmacy is responsible for the prescriptions stored in the device. The patient must "opt in" to use this device.

SUPPORT: 4 OPPOSE: 3

- **Proposed Regulation Change to CCR, title 16, sec, 1717(e) and to Add Section 1713 to Authorize a Pharmacy to Use an Automated Dispensing Device and/or Other Secured Means to Depot prescription Medications**

  Chairperson Powers stated that based on the request from Longs Drug Stores to permit the use of a secure drop box for receiving prescription orders from patients and to use a self-serving secure device for dispensing filled prescriptions, staff drafted a regulation change that would permit both these activities should the board grant the waivers.

  The prescription drop boxes would allow patients to drop off prescriptions in a secure container that is at the same address of the pharmacy or adjoining the licensed premises. The secure devices would be for dispensing refill prescriptions not subject to the consultation requirement and originally was limited to when the pharmacy was closed. However, as counsel advised, the proposed regulation would need to be modified to allow the use of these devices when the pharmacy is open as well as closed. It was modified after the Enforcement Committee meeting by removing the "closed pharmacy" restriction. The proposed draft relocates existing provision 1717(e) into a new section 1713 and provides the authorization for both the drop boxes and self-service dispensing devices.

  Currently, the law doesn't require pharmacist consultation on refill prescriptions (only in the pharmacist's professional judgment or upon a patient's request); however, it was argued that the use of these self-service dispensing devices would remove the pharmacist completely away from the process. It was noted that Pharmacy Law doesn't require the pharmacist to physically provide the patient with the refill medication; a cashier does this.

  The Enforcement Committee moved this proposed regulation to the Board of Pharmacy for its consideration. The committee did not provide a recommendation.

Mr. Jones asked if the board wanted to wait before considering this matter until it had a chance to review how the waivers worked.

Mr. Cronin suggested that a provision be added to limit use of the machine to hours the pharmacy is open.

M/S/C: FONG/CONROY

MOTION: Enforcement Committee: That the Board of Pharmacy consider a proposed regulation change to add CCR, title 16, sec. 1713 related to the delivery of prescriptions and prescription medications. Specifically, the secure container must be located at the same address or adjoin the licensed premise. The section would also be amended to allow a pharmacy to use a device to dispense refilled prescriptions provided that the device is located in reasonable proximity to the licensed premises, the device has a means to identify the patient and only release that patient's prescriptions, the device is secure, the pharmacy provides a means to the patient to obtain consultation from a pharmacist, and the pharmacist is not to use the device if the prescription requires consultation pursuant to section 1707.2(a)(2). The patient must "opt in" to use this system.

SUPPORT: 5 OPPOSE: 2

Ms. Harris stated that because the board will not have a regulation coordinator for several months due to Mr. Riches transfer to a new position, it will be about six to nine months before the board can act on this proposal to notice it and for the board to adopt it.

President Goldenberg stated that he feels that there are could be gaps, and would like a study. Additional discussion ensued that included belief that other waivers will be requested.

Mr. Riches stated that there would be ample time within the process without additional conditions to make a reasonable judgment whether this is a good idea for policy in California.

The board asked to continue this regulation on the committee's agenda for the future.

- **Importation of Prescription Drugs**

Chairperson Powers stated that the Governor had vetoed the various legislative proposals that would assist Californians in obtaining prescription drugs from Canada. One bill, AB 1957 (Frommer) would have required the Department of Health Services (DHS) to establish a program that would provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices and would require DHS to establish a web site before July 1, 2005 describing various drug benefit programs including Canadian

pharmacies that meet certain standards. One of the standards is that the Canadian pharmacy meets the requirements of a nonresident pharmacy.

Another bill, SB 1149(Ortiz) would have required the Board of Pharmacy to establish an interactive Internet Web site to identify licensed Canadian pharmacies that meet specified standard criteria for the safe acquisition, shipment, handling, and dispensing of prescription drugs to persons in California. One of the standards is that the Canadian pharmacy meets the requirements for licensure by the board. The board opposed this bill at its last meeting.

The committee was also given a copy a letter from Governor Schwarzenegger to Secretary Tommy Thompson dated August 20, 2004, expressing concern about the growing cost of prescription drugs and his strong desire in identifying approaches that can make medicine more affordable for California's most at-risk consumers. In the letter, California also encouraged the Bush Administration to aggressively pursue its discussions to achieve fairer pricing of pharmaceuticals in the international marketplace and an equitable distribution of the costs of drug research and development.

In an effort to do this, the Governor put forward a "California Rx" program that seeks to provide assistance to these Californians. The proposal would establish a drug discount program for low-income uninsured residents through a state contract with a pharmacy benefit manager (PBM). The intent is for Californians who lack insurance to present a discount card at their local pharmacy to receive a discount on their prescription drugs. The PBM would negotiate discounted prices with drug manufacturers for program participants. The program would be available to low-income seniors and uninsured Californians up to 300% of the federal poverty level ($47,000 for a family of three) to secure meaningful discounts in prescription drug costs.

There was general discussion regarding "California Rx." The board was strongly encouraged to take an active role in the development of this proposal. While a legislative proposal hasn't been drafted, the information will be included if a bill is introduced next year. The board is very sensitive to this issue and is tasked with balancing consumer access to affordable prescriptions against the safety and effectiveness of drugs obtained from foreign sources, and the importance of the Governor's proposal to improve that access through "California Rx" as alternative to importation.

The Senate Health and Human Services Committee held on an informational hearing on the Administration's proposal. The hearing included an in-depth overview of "California Rx", the timeline for implementation, and the estimated cost savings. Representatives were invited to present a critical analysis of the proposal, its feasibility and overall benefit when compared to some of the drug importation proposals that were introduced over the past legislative session.

- **Implementation of SB 151 – Changes to the Prescribing and Dispensing of Controlled Substances**

More questions and answers were provided on the implementation of SB 151 and the changes to the law regarding the prescribing and dispensing of controlled substances. These questions and answers have been added to the board's Web site.

There being no additional business, President Goldenberg adjourned the meeting for the meeting for the day at 4:00 p.m.

The Legislation and Regulation Committee convened its public meeting convened its Public Meeting.

Mr. Powers thanked and commended Paul Riches for his work as Chief of Legislation and Regulation for the board.

Mr. Riches provided an overview.

LEGISLATION AND REGULATION COMMITTEE

Chairperson Jones provided an update on legislation and regulations affecting the practice of pharmacy. He stated that the Legislation and Regulation Committee would meet after the board meeting is adjourned. He added that there were significant regulatory and legislative changes achieved during the year and he thanked Paul Riches for his efforts.

Mr. Powers stated that as a former lobbyist, he is well aware of the responsibility to get bills through the Legislature and he also commended Mr. Riches for his efforts. He added that Mr. Riches has demonstrated a grasp of the issues and provided the board with excellent references and advice.

Regulations Report and Action

Approved by the Office of Administrative Law

- **Section 1709.1 – Pharmacist-in-Charge at Two Locations**

  This regulation permits a pharmacist to serve as pharmacist-in-charge at two locations within 50 miles of each other. This regulation became effective October 2, 2004.

- **Section 1710 – Hospital Central Fill**

  This regulation permits central refill operations for hospitals. This regulation became effective October 22, 2004.

- **Section 1711 – Patient Notification**

This regulation clarifies patient notification requirements in the event there is a medication error. This regulation will become effective October 22, 2004.

- **Section 1717.1 – Common Electronic Files**

  This regulation requires pharmacies using common electronic files to adopt policies ensuring patient confidentiality. This regulation will become effective October 22, 2004.

- **Section 1717.4 – Authentication of Prescriptions**

  This regulation will clarify that pharmacists ensure the authenticity of electronically-transmitted prescriptions. This regulation became effective October 22, 2004.

- **Section 1720 – Pharmacist License Process**

  This regulation will require pharmacists to pay the licensing fee in a shorter time frame and require applicants to take the examination within one year of applying. This regulation will become effective October 22, 2004.

- **Section 1721 – Pharmacist Exam**

  This regulation specifies the penalties for cheating on the pharmacist licensure examination. This regulation becomes effective October 22, 2004.

- **Section 1724 – Passing Score**

  This regulation specifies the methodology of determining the passing score on the pharmacist licensure examination to comply with changes made by Senate Bill 361. This regulation becomes effective October 22, 2004.

- **Section 1746 – Emergency Contraception**

  This regulation will codify the statewide protocol for pharmacists to dispense emergency contraception that was approved by the board and the Medical Board of California earlier this year. This regulation is undergoing review by the Office of Administrative Law.

- **Sections 1749 and 1793 et seq. – Pharmacy Technicians**

  These regulations conform regulations relating to pharmacy technicians to reflect changes made by Senate Bill 361. This regulation becomes effective October 22, 2004.

- **Section 1751 et seq. – Sterile Compounding**

This regulation will establish guidelines for the compounding of sterile drug products. This regulation takes effect October 29, 2004.

- **Section 1793.3 – "Clerk-Typist" Ratio**

  This regulation eliminates the clerk/typist ratio. This regulation became effective October 3, 2004.

Awaiting Notice

- **Section 1715 – Pharmacy Self Assessment**

  This regulation will update the pharmacy self-assessment form to reflect recent changes in pharmacy law. Board supervising inspectors have updated these forms, which were contained in the board packet materials.

LEGISLATION REPORT AND ACTION

Board-Sponsored Legislation

- **Senate Bill 1307 (Figueroa) and Assembly Bill 2682 (Negrete McLeod)**

  The Governor signed SB 1307 and AB 2682. The bills implement the board's proposed changes to wholesaler regulation including the imposition of bond requirements, establishment of a drug pedigree system, licensing requirements for non-resident wholesalers who ship drugs into California , and increased fines for specified violations.

- **Senate Bill 1913 (Business and Professions Committee)**

  The Governor signed SB 1913. This bill makes numerous technical and non-controversial changes to pharmacy law, including that a pharmacist can supervise two pharmacist interns, an applicant for the pharmacist exam must have 1,500 intern hours of the equivalent before qualifying to take the examination.

Status Update for Bills with Board Position

- **AB 320 (Correa) – Gag Clauses**

  This bill would have prohibited "regulatory gag clauses" in malpractice settlements. The board had a support position on this bill. The Governor vetoed the bill.

- **AB 2126 (Bogh) – Fraudulent Use of a License**

This bill would have added the theft of professional license numbers to identity theft statutes. This bill failed passage in committee.

- **AB 1957 (Frommer et al) – Drug Importation**

  The board opposed this bill that would have required the Department of Health Services and the Board of Pharmacy to establish a Web site for approved Canadian pharmacies. The Governor vetoed this bill.

- **AB 2184 (Plescia) – Automated Dispensing Devices**

  This bill was signed by the Governor (Chapter 342, Statutes 2004) and will allow expanded use of automated dispensing machines in skilled nursing facilities. The board supported this bill.

- **AB 2660 (Leno) – Pharmacist DEA Registration**

  This bill was signed by the Governor (Chapter 191, Statutes 2004) and will allow pharmacists working under protocol to obtain DEA registration numbers, among other provisions. The board supported this bill.

- **SB 1149 (Ortiz) – Importation**

  The Governor vetoed this bill. This bill would have required the board to list Internet sites selling prescription drugs that have violated recognized standards for good practice. The board would have also designated Canadian pharmacies that meet California's standards for pharmacy practice. The board opposed this bill.

- **SB 1159 (Vasconcellos) – Hypodermic Needles**

  This bill was signed by the Governor (Chapter 608, Statutes 2004) and repeals the prescription requirement for needles and syringes, and allows pharmacists under specified conditions to sell 10 needles without a prescription. The board supported this bill.

- **SB 1427 (Ackerman) – Counterfeit Drugs**

  This bill would have imposed a felony for drug counterfeiting. The board supported this bill. The bill failed in committee.

- **SB 1735 (Figueroa) – Special Fund Agencies**

  This bill would have exempted the Department of Consumer Affairs boards and bureaus from the state's hiring freeze that ended June 30, 2004, and restored vacant positions recently

eliminated over the last two years. The board supported this bill. This bill failed in committee.

NEW BUSINESS

President Goldenberg stated that he would like to have further discussion on the automated delivery machine and the possibility of a study. He added that the board's goal is to have a full grasp of the issue for informed decision-making. He stated that this issue will remain an agenda item for future meetings.

ADJOURNMENT

There being no further business, President Goldenberg adjourned the meeting at 5:21 p.m.