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

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

DATE: **April 26 and 27, 2006**

LOCATION:

April 26, 2006
Red Lion Hotel
1401 Arden Way
Sacramento, CA

April 27, 2006
Department of Consumer Affairs
1625 N. Market Blvd., 1st Floor Hearing Room
Sacramento, CA 95834

BOARD MEMBERS PRESENT:

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

STAFF PRESENT:

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

CALL TO ORDER

President Goldenberg called the meeting to order at 8:34 a.m. on April 26, 2006.

PRESIDENT'S REPORT

President Goldenberg acknowledged former board president Richard Mazzoni who was in the audience.

President Goldenberg acknowledged Oren Peacock, recently elected as President of the National Association of Boards of Pharmacy, who was in the audience.

ORGANIZATIONAL DEVELOPMENT COMMITTEE

- **Report on the April 2006 Meeting**

  Chairperson Conroy stated that the Organizational Development Committee met twice in nonpublic, teleconferenced meetings since the February 1 and 2, 2006 Board Meeting.

  1. On March 1, the committee met to discuss the board's update to the strategic plan.
  2. On April 6, the committee met to discuss the board's update to the strategic plan and to discuss the normal business of the committee.

  Chairperson Conroy stated that later during this board meeting, the board will work in public session with Lindle Hatton, PhD, on updating the board's strategic plan.

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

  Chairperson Conroy stated that at the July 2005 Board Meeting, the board identified those pharmacists with 50 years of licensure as a pharmacist and publicly commended them. The pharmacists so honored receive a letter from the board's president and a commendation. Each is invited to a future board meeting to be publicly recognized. Additionally, his or her name is published in *The Script.*

  Since July 2005, the board has acknowledged 516 pharmacists:

July 2005:	450	pharmacists
Oct. 2005:	50	pharmacists
Jan. 2006:	8	pharmacists
Apr. 2006:	8	pharmacists

Chairperson Conroy stated that recognition of the pharmacists with 50 years of service who attend this board meeting will occur during the break at this meeting.

- **Recognition of Those Who Provided Disaster Response to Victims of the Gulf Coast Storms:** Chairperson Conroy stated that following the October 2005 Board Meeting, the board created a special location on its Web page to highlight the activities of those pharmacists who provided relief to Gulf Coast storm victims. This feature was highlighted in the October 2005 *The Script.* At the January Board Meeting, the board played a video montage set to music prepared from photos taken principally at the New Orleans Airport by California Pharmacist Michael Sohmer. Until mid-March, the board received no other information about pharmacists' activities providing relief to Gulf Coast storm victims. In March, the board received a list by county of pharmacists who provided relief as part of DMAT teams.
  Chairperson Conroy stated that each of the individuals on this list received a commendation and personal thank you from Board President Goldenberg.
  Each of these individuals has been invited to a future board meeting, where each can be publicly commended. Recognition of those pharmacists who are able to attend this board meeting will be will occur during the break.
  Chairperson Conroy reported that at the National Association of Boards of Pharmacy National Meeting in April, Executive Officer Harris moderated a segment on Structuring an Effective Disaster Plan. Pharmacy responses to the Gulf Coast Storms from a number of states, primarily Mississippi and Louisiana were the focus of this presentation. Additionally, Dr. Sohmer's video montage of the early days of Katrina relief at the New Orleans Airport, which he had shortened from the version shown at the February Board Meeting, was shown to an appreciative NABP audience.
  The board again thanked Dr. Sohmer for his DMAT efforts and his video that displayed photos of New Orleans relief.

- **2006 - 2011 Strategic Plan Revision**
  Chairperson Conroy invited the public to attend the strategic planning meeting on April 27.
  The board truly manages its operations by its strategic plan. The current structure, objectives, and reporting mechanisms seem up to date. However, other sections, dealing with internal and external factors that influence the board may need revision. A half day will be devoted to this.

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

Chairperson Conroy stated that the board moved into its new office the weekend of December 9 as scheduled.

The board is still working with the department to secure modifications to the phone system. The new computer-based telephone system is not functioning optimally for the board's callers, and will have to be reprogrammed. One problem is that the new system relies upon individual phone numbers, and not extension numbers as the board used in its former location. Obtaining the individual phone numbers of the desired staff person requires the caller to listen to a lengthy phone tree message – the system does not allow the entering of a "0" to reach a live operator until the very end of the phone tree message.

Once the department is ready to aid the board in modifying the system, board managers will revamp the system to improve service.

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

  Chairperson Conroy stated that this year, two of the National Association of Boards of Pharmacy major meetings will occur in California:

  - California April 2006: The NABP annual meeting took place in San Francisco.
  - October 2006: The NABP Districts VII and VIII meeting will be in Anaheim.

At the NABP April Annual Meeting, the board staffed the "Hospitality Suite" on April 8 and 9. The board also participated in a poster session involving the new "Notice to Consumers" poster. Board President Goldenberg opened the first business session on April 9 with "words of welcome."
Executive Officer Harris moderated a discussion section on April 11 involving disaster response to the Gulf Coast storms by pharmacists and pharmacies.

- **Proposed Meeting Dates for 2007**

  Chairperson Conroy stated that proposed meeting dates for the rest of 2006 and 2007

  ar**2006**

  - July 19 and 20 – San Diego
  - October 25 and 26 – San Francisco/Bay Area *(CSHP's Seminar is in Sacramento on Oct. 12-15)*

  2007

  - January 31 and February 1 -- Orange County/Los Angeles *(CPhA's Outlook is February 15-18 in Palm Springs)*
  - April 18 and 19 – Sacramento *(NABP's Annual Meeting is in Portland, Oregon in May)*
  - July 25 and 26 – San Diego

- October 24 and 25 -- San Francisco/Bay Area *(CSHP's Seminar is October 18-21 in Palm Springs)*

- **Sunset Review:**

The board was scheduled to undergo "sunset review" by the Legislature this fall. During a sunset review, all aspects of the board's consumer protection activities are analyzed in detail by a subcommittee of the Legislature. The goal is to eliminate unnecessary licensing agencies, and assure that all DCA boards and bureaus are effectively providing efficient and valuable consumer protection. If the Legislature deems that a board is not worthwhile, it "sunsets" or folds into the Department of Consumer Affairs, and the board is dissolved.

Due to a number of factors (including that this is election year, the end of the senate term of Chairperson Liz Figueroa, who was a key advocate for sunset review, and a large number of agencies set for review this year), the board's sunset date will be delayed two years – until 2008. Legislation will be introduced to contain this delayed date.

- **Budget Update and Report**

I. Budget Report for 2005/06

The current fiscal year ends June 30, 2006. This fiscal year the board received repayment of $3.2 million borrowed in 2001 to offset a deficit in the state's General Fund. This repayment is classified as revenue for the year. Three million dollars is still owed to the board from the 2001 loan.

- ***Revenue Projected: $9,010,133***

The board's revenue for the year is projected to be comprised of:

Licensing Fees (estimated):	$5,360,000
Interest	$90,000
General Fund Loan repayment	$3,227,000
Cite & Fine (actual as of 3/31/06)	$202, 408
Cost Recovery (actual as of 3/31/06)	$130,725
	$9,010,133

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

The board's maximum expenditure authority for the year is $7.9 million.

II. Governor's Proposed Budget for 2006/07

Ms. Herold stated that the Governor's proposed budget for the next fiscal year starting July 1, 2006, was provided to the Legislature in mid-January. In late March, the Senate and Assembly

budget subcommittees began their review of the budget. There are currently no issues with the board's budget.

Over the next few months, the Legislature will hold hearings and likely modify the proposed state budget. The Legislature is required to complete its review and pass a budget bill by June 15, 2006. The Governor may then deduct items from the budget enacted by the Legislature (called a "blue pencil veto") but cannot add money to any budget item.

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

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

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

  Expenditures for next year are $240,000 more than those projected for this fiscal year; this increase includes:

  -- Restoration of 2.5 of the 10 positions the board lost during the budget restrictions of the early 2000s. ($208,000)

  -- An increase of $91,000 to cover increased hourly fees that will be charged by the Office of the Attorney General for legal fees (the hourly rate will be $158, up from $112 (or $120 for the LA Office) in 2003)

  Note: Funding to program areas have increased or decreased; the net effect is a budget of $240,000 more than this year.

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

III. Board Fund Condition

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

The board must watch its fund condition, however, because if it gets low or into a deficit, the board will run out of money for annual operations (since expenditures exceed revenue collected). The Business and Professions Code provides that the board should maintain a reserve of 12 months of annual expenditures as a prudent reserve. However, state budget officials do not agree

that this much money needs to be kept as the board's reserve. They prefer a reserve of 3-6 months.

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

The board's fund condition projections on June 30 over the next few years (as estimated in early January 2006) are:

- 2005-06: The reserve is estimated at 7.1 months (after repayment of the $3 million).
- 2006-07: A reserve of 2.9 months is projected.
- 2007-08: A reserve of 2.1 months is projected (includes planned repayment of $2.5 million borrowed in 2001).
- 2008-09: A deficit in the reserve of is projected of –1.7 months (includes the last repayment of $500,000 borrowed in 2001)

A fee increase will be needed to take effect July 1, 2008 to prevent a deficit during 2008-09. Board staff will continue to watch these figures closely.

IV. Board Member Expenditures and Reimbursements

Dr. Conroy stated that the travel expenses and compensation of board members claimed this fiscal year was provided in the board packet.

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

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

Ms. Harris stated that the DCA is now moving ahead with a proposal so other agencies can offer online application and renewal of licenses. A feasibility study report has been approved by the Department of Finance, and the board is in the first tier of new agencies that may be able to offer this service in the future.

However, at the direction of the Department of Finance, all work on the project has been stopped until the next fiscal year (July 1). A budget change proposal will need to be written and approved for the board to participate in this project in the future as well. The DCA will be developing this budget change proposal for all participating agencies.

No costs are yet available for this conversion, and it will be approximately two years before implementation at the board.

- **Personnel Update and Report**

  Ms. Herold stated that there have been a number of personnel changes at the board in the last three months.

  First, Rosario Navarro, a board cashier, died in March after a long illness. Ms. Navarro worked for the board for six months before becoming ill. Staff has sent condolences and heart-felt sympathy to Ms. Navarro's family.

  Supervising Inspector Dennis Ming has announced his plans to retire on July 1. Dr. Ming has been with the board for six years – three years as an inspector and three years as a supervising inspector. Dr. Ming was instrumental in establishing the sterile compounding pharmacy licensure program and is a supervisor of the compliance team. Dr. Ming will remain on the board's staff as a retired annuitant. Dr. Ming brought strength to the board from his years as an educator and a pharmacist. Dr. Conroy commended Dr. Ming for his work on the sterile compounding pharmacy licensure program.

  Inspector Nahal Bahrampour resigned at the end of February. Dr. Bahrampour worked for the board for about five years. This leaves the board with one inspector vacancy.

  The board will also gain one inspector position July 1 with the new state budget.

  Consequently, the board is now seeking the department's support in scheduling two civil service examinations from which pharmacists can be hired to work for the board as inspectors and as a supervising inspector. This process will take at least four, and possibly six months.

  Other staff changes:

  - Legislative Coordinator Jan Perez is ending her training and development assignment with the board at the end of April, and will return to the Department of Fish and Game.
  - Licensing Unit Manager Anne Sodergren will become the board's new legislative coordinator.
  - Associate Analyst Sue Durst has been transitioned into the board's computer support position. She will continue to be the board's CURES analyst as well.
  - Analyst Kim DeLong has become the board's Web site coordinator. She is currently working on restructuring the board's Web site, and will continue to work on mail votes.
  - Technician Judi Collins has been transitioned into the board's enforcement unit to work on disciplinary background checks of applicants and licensees.
  - Veronica Hagen will become the board's renewal cashier. Ms Hagen is currently a part-time receptionist, and began work for the board six months ago.
  - Technician Eleonor Steiner will become the licensing technician for wholesalers and designated representatives.
  - The board has hired Analyst Victor Perez from the Department of Health Services. Mr. Perez will work in the enforcement unit and we will use his graphic arts skills for all our

publications, newsletters and forms.

Board Member Positions:
The board itself has two public board member positions and one professional member position vacant.

Additionally, John Jones is completing the year of grace on his second term. He will end his tenure on the board on June 1. Dave Fong and Richard Benson are both completing their year of grace on their first terms. Both are eligible for reappointment, but unless reappointed, cannot serve on June 1. This leaves the board with exactly a quorum of seven members on the board.

- **Approval of Full Board Minutes (February 1 and 2, 2006)**

President Goldenberg asked if there were any corrections to the minutes of February 1 and 2, 2006.

MOTION: Approve the board minutes of February 1 and 2, 2006.

M/S/C: POWERS/SCHELL

SUPPORT: 9 OPPOSE: 0

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Chairperson Zinder reported on the public meeting of the Communication and Public Education Committee meeting held in Sacramento on April 4, 2006.

There were three pharmacists who attended this meeting who requested 2 hours of CE credit in accordance with the board's new policy.

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

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

At the April 2006 meeting, the committee reviewed nine fact sheets that are now being distributed. The fact sheets contain general information on the topic, and contain questions consumers can discuss with their pharmacists on making wise decisions in the subject area.

These fact sheets are:

General Pharmaceutical Care Issues

1. "Is Your Medicine in the News?"
2. "Generic Drugs . . . Real Medicines at High Quality, Low Cost"
3. "Lower Your Drug Costs So You Can Keep On Taking Your Medicines"
4. "Don't Flush Your Medicines Down the Toilet"

Medicine Safety

5. "What's the Deal with Double Dosing? Too Much Acetaminophen, That's What!"
6. "Ever Miss a Dose of Your Medicine? Here Are Some Tips"
7. "Thinking of Herbals? Check Carefully Before You Take Them with Medicines"

Health Topics

8. "Diabetes – Engage Your Health Team"
9. "Did You Know? Good Oral Health Means Good Overall Health"

The fact sheets will be distributed at consumer outreach fairs and will be listed on the board's Web site. The board will also announce their availability in the next *The Script* and via a subscriber alert.

The Center for Consumer Self Care is working with other students to develop additional fact sheets.

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

  Chairperson Zinder reported that last year, the board voted to become a founding member of the California Health Communication Partnership. This group is spearheaded by the UCSF's Center for Consumer Self Care to improve the health of Californians by developing and promoting consumer health education programs and activities developed by the members in an integrated fashion. The function of the group is to develop or disseminate integrated public information campaigns on priority health topics identified by the partnership members.

  At the April Communication and Public Education Meeting, Bill Soller, PhD, of the Center for Consumer Self Care, made a presentation about the recent activities of the partnership.

  Past campaigns are:
  2004-05: Preserve the Treasure – avoiding antibiotic overuse
  2005: Generic Medicines – same as brand names at lower costs
  2005: It's Your Life – breast cancer and prostate cancer screening.

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

This cancer screening campaign was among the most successful campaigns ever released by this distribution firm in terms of the number of messages published and aired.

Proposed for future campaigns are:
2006: It's Your Life – breast and prostate cancer screening awareness
2006: Generic Medicine
2006: Diabetes and Aspirin

During the April meeting, the committee discussed the importance of public education campaigns about pharmacist-to-patient consultation since many consumers are not aware of this requirement and the importance of seeking and following a pharmacist's knowledge of drug therapy and how this can benefit their health. The committee also suggested that some form of outreach to educate other health care providers about a pharmacist's requirement to consult would benefit both providers and patients.

The committee thinks this is an important area for strategic planning discussions at the April Board Meeting.

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

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

Tom Stopka, a research scientist with the Office of AIDS attended the board meeting and provided information about this program to the board. Dr. Stopka provided information on SB 1159 and the disease prevention demonstration projects that are taking place across the state, and expressed interest in working with the board and opportunities to further collaborate.

Dr. Stopka stated that 19 percent of cumulative AIDS cases in California are attributed to injection drug use. Over 1,000 injection-related HIV infections occur each year in California. In terms of Hepatitis, as of 2001, approximately 6,000 HCV have occurred in California. He reported that approximately 60 percent of HCV cases are attributed to addiction drug use and 5,000 new HCV infections occur annually.

Dr. Stopka stated that SB 1159 was signed by Governor Schwarzenegger and became effective in January 2005. SB 1159 allows local health jurisdictions to establish a disease prevention demonstration project, eliminates the requirement for pharmacists to keep a log of syringe sales and decriminalizes possession of 10 or fewer syringes obtained from authorized sources. The law will expire in 2010.

Dr. Stopka stated that the average lifetime cost for treating a person with AIDS is approximately $195,000 and treatment of chronic liver disease related to HCV is approximately $20,000 per person per year. He added that by reducing the number of injection drug use-related HIV/AIDS and HCV cases can reduce the economic burden on county funded care and treatment programs.

Dr. Stopka stated that participating pharmacies are required to register within their county, store syringes behind the counter and provide for disposal of the syringes through on-site syringe disposal programs or furnishing or selling mail-back sharps containers, or furnishing or selling personal sharps containers.

The board published one article in a recent *The Script* to educate pharmacists, and distributed information about the program from a board information booth held at CPhA's annual meeting in February. A copy of a draft brochure, developed by the Office of AIDS will be promoted in a future issue of *The Script.*

The board supported the committee's suggestion for staff from the Office of AIDS to develop an article about how the program has been implemented in a pharmacy in California, for publication in the board's newsletter.

- **Update on *The Script***

Chairperson Zinder stated that the next issue of the board's newsletter is being developed for publication in July 2006.

In response to comments made by the committee and at the February Board Meeting, the newsletter will resume listing disciplinary actions taken. The name of the licensee will be listed along with the disciplinary action.

In a future newsletter, the board will publish statistics on the top 10 corrections ordered during inspections and the types of fines the board has issued under the citation and fine program.

Chairperson Zinder acknowledged the Pharmacy Foundation of California who has recently found a sponsor to fund the printing and mailing to California pharmacists of the January 06 issue of *The Script*.

- **Mailing to Pharmacies of Revised "Notice to Consumers"**

Chairperson Zinder stated that the California Code of Regulations Section 1707.2 requires that pharmacies display a specifically worded "Notice to Consumers" poster that among other items, contains five questions that patients should understand about taking their medications. This poster has been required to be posted in pharmacies since 2002, and are important to

encourage patients' improved understanding about their drug regimens and foster a dialogue between patients and pharmacists.

Because of the board's new business address and telephone number, the board recently updated the poster to reflect this new information. The board is now mailing these new posters to the state's 6,000 community pharmacies, along with a letter from Board President Goldenberg emphasizing the importance of pharmacist to patient consultation and the requirement to display this poster.

The poster is 17 x 22 inches and has been translated into Spanish, Chinese, Vietnamese, Russian and Korean.

- **Pharmacy Law Online and in Published Lawbooks**

Chairperson Zinder stated that pharmacy law is detailed and complicated and the board strongly encourages licensees to seek out answers to their legal questions by accessing pharmacy law. To make this easier, there are several ways individuals can access the provisions of pharmacy law.

1. The board has on its Web site a copy of all pharmacy laws and regulations. The address is http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf.

   There are several advantages of using this source for Pharmacy Law. It is free. It also contains a detailed index, developed and used by board staff, that is not published in either lawbooks listed below.

2. LawTech publishes a lawbook, and also has a cd version available for sale. Ordering information is available via a link from the board's Web site or by calling 1-800-498-0911 X 5.

   The cost for this Lawbook is $21.99.

   LawTech has published the board's lawbook for the last six years.

3. Lexis/Nexis has also produced its first version of the board's lawbook with a cd version of this publisher's lawbook available.

   This lawbook is available for $22, by calling 1-800-833-9844.

The board will promote this information in its next newsletter.

Chairperson Zinder continued that the board regrets that it lacks the staff to provide answers to all inquiries the board receives involving interpretations of pharmacy law. Discussions

with board inspectors during routine inspections and the self-assessment forms are two additional ways licensees can use to find answers to many of their questions.

The board advises licensees to contact their legal counsels for legal advice. Individuals may also submit questions in writing to the board; however, the board cannot personally answer all questions it receives. In the future, some of these questions and answers will be placed in the newsletter so they can be shared with all licensees.

- **New Consumer Brochures**

  Chairperson Zinder stated that board staff has developed four new consumer brochures and fact sheets.
  - "Medicare Part D – Selecting a Prescription Drug Plan"
  - "Children and Their Medicines"
  - "Do You Sometimes Forget to Take Your Medicines"
  - "New Easier to Read Prescription Drug Information"

  Under development are:
  - The Beers list of medications that should not be provided to elderly patients
  - Update of Facts About Older Adults and Medicines (revision)

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

  Chairperson Zinder stated that the board was a cosponsor of a recent survey on the mandated pharmacist to the patient consultation process and its effects on Californians aged 65 and over. A final copy of the report was recently printed and released.

- **Update on Public Outreach Activities**

  Chairperson Zinder stated that the board strives to provide information to licensees and the public. It develops and distributes consumer materials at health fairs and attends as many of these events as possible, where attendance will be large and staff is available.

  The board also has a Power Point presentation on the board containing key board policies and pharmacy law. This is a continuing education course, typically provided by a board member and a supervising inspector. Questions and answers typically result in a presentation of more than two hours, and is well received by the individuals present.

  Also in the spring, the board makes presentations on pharmacy law and on applying for the California pharmacist licensure examination to students in California's pharmacy schools.

Since the February 2006 report to the board, the board has made four presentations to licensees or law enforcement associations, attended two public health fairs and made presentations to students at four California schools of pharmacy.

Also noteworthy is that Board President Goldenberg provided welcoming remarks to the opening session of the National Association of Boards of Pharmacy Annual Meeting in San Francisco. Other board presentations at this annual meeting included moderation of a panel discussion by Executive Officer Harris on emergency preparedness including a video montage specifically prepared by Michael Sohmer, Pharm.D. for this event.

BOARD OF PHARMACY RECOGNITION

- **Richard Benson, Board Member**
  President Goldenberg recognized Richard Benson and announced that this would be his last board meeting as he was completing his term on the board. President Goldenberg stated that Mr. Benson would be invited to attend a future meeting so the board can formally acknowledge his service on the board. President Goldenberg added that Mr. Benson has served as president of the United Food and Commercial Workers since 1994 and has served the union as counsel. He was appointed by Chief Justice Ronald George to the Task Force of the Quality of Justice and also served on the subcommittee of Alternative Dispute Resolutions and the Judicial System. Mr. Benson earned his Bachelor of Arts Degree at Golden Gate University and while serving on the board, has been a member of the Communication and Public Education Committee and Licensing Committee. President Goldenberg stated that Mr. Benson has brought to the board a perspective in both the pharmacy aspect and labor aspect of the practice of pharmacy.
  Mr. Benson thanked the board.

- **John Jones, Board Member**
  President Goldenberg recognized John Jones for his hard work dedication and leadership while serving on the board. Mr. Jones set an example for all board members in decision-making based on evidence. He added that Mr. Jones' presence would be felt on this board for many years to come. President Goldenberg presented Mr. Jones with an inscribed clock.
  Mr. Jones stated that for some time he dreaded this day when it's time to say goodbye. Mr. Jones stated that serving on the board has provided him with one of the most rewarding experiences of his professional life; one that has truly shaped his identity. He added that he will miss everyone very much and he commended board members and staff on their exemplary actions. He thanked the board for the opportunity to serve.

- **Dennis Ming, Supervising Inspector**

President Goldenberg announced Dr. Ming's retirement from the Board of Pharmacy beginning in July. President Goldenberg stated that Dr. Ming has served the board in an exemplary fashion and has contributed greatly in making California a better place for all consumers. He added that we can all learn from his dedication, knowledge and commitment to excellence. Dr. Ming will continue working part time with the board as a retired annuitant.

Dr. Ming thanked the board, Ms. Harris and Ms. Herold, Supervising Inspectors Bob Ratcliff, Judi Nurse and Joan Coyne. He added that he found that his job with the board was the most professionally enjoyable of his careers; mainly because of the opportunity it provided him to make an impact on the pharmacy profession.

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

  - **Karl Hanke**

    Mr. Hanke attended the meeting and was recognized by the board for 50 years of licensure as a pharmacist. Mr. Hanke recognized his daughter Lisa Shelley who was in the audience and he stated that she graduated from the UOP Pharmacy School.

  - **Martha Gray Mason**

    The board recognized Ms. Mason for 50 years of licensure as a pharmacy. Ms. Mason stated that among all of the good and bad decisions made in her life, the decision to become a pharmacist was the best decision she has made.

  President Goldenberg stated that recognizing pharmacists who have 50 years of service has been one of the most rewarding systems that the board has developed.

  President Goldenberg encouraged community participation during disasters and stated that significant disaster response has to start at the community level. He added that the board will make this a part of its strategic planning session. He stated that each individual in the community can do his or her part to assist in a positive fashion during the occurrence of a disaster, since government may not be able to provide much support initially.

- **Report of the Subcommittee Meeting on Medicare Drug Benefit Plans on April 4, 2006**

  President Goldenberg noted that minutes from the boards Subcommittee on Medicare Drug Benefit Plans Meeting of April 4, 2006 have been prepared and are in the board packet materials. Representatives from the Centers for Medicare and Medicaid Services, patients, patient advocates and pharmacists attended this meeting.

LICENSING COMMITTEE

- **Report on the Meeting of March 22, 2006**

Chairperson Conroy reported on the Licensing Committee Meeting on March 22, 2006.

- **Request to Modify Intern Hours Earned for Pharmacy-Related Experience Outside a Pharmacy (16 CCR § 1728).**

  Chairperson Conroy announced that the Board of Pharmacy has postponed the decision on this issue until the next board meeting but will be taking comments. She added that the committee did bring this before the full board without a recommendation.

  Chairperson Conroy stated that pharmacy students from USC and other pharmacy schools presented a proposal requesting that the Board of Pharmacy amend its regulations to allow up to 1,000 of 1,500 hours of intern experience required to take the pharmacist license exam to be earned for pharmacy-related experience (under the supervision of a pharmacist) outside a pharmacy. Under current regulation, the board has the discretion to grant a maximum of 600 hours for experience substantially related to the practice of pharmacy and an intern must earn a minimum of 900 hours of pharmacy experience under the supervision of a pharmacist in a pharmacy. California pharmacy students earn the 600 non-pharmacy hours for school-required experiential training (clinical clerkship).

  Therefore, if adopted as proposed, an intern would only need to earn a minimum of 500 hours in a pharmacy and could earn a maximum of 1,000 hours of experience substantially related to the practice of pharmacy under the supervision of a pharmacist.

  It was noted that opportunities for pharmacists have expanded beyond the traditional areas of community and hospital practice settings. Many students would like the opportunity to gain experience in the pharmaceutical industry, managed care, regulatory affairs and association management, but are unable to do so because they cannot earn intern hours. As part of the pharmacy school curriculum, students complete various rotations in their first and fourth year in both community and hospital pharmacy. In the fourth year, pharmacy experience is more clinical. It was anticipated that a large percentage of pharmacy students would still earn the majority of the intern hours in a pharmacy. This option would be for those students that show proficiencies in the pharmacy settings and would like to expand their experience in other areas.

  The National Oncology Alliance, Inc. (NOA) spoke in support of the proposal and gave a presentation on opportunities that it has for interns outside a licensed pharmacy and under the supervision of a pharmacist. The intern would assist the NOA clinical team to prepare clinical summaries of articles in the medical literature, collect data about the status of drug approvals as it applies to NOA treatment guidelines and assist with the development and yearly revision of NOA treatment guidelines. NOA advocated that patient care activities meet the Accreditation Council for Pharmacy Education (ACPE) criteria and content outline of the California Pharmacy Jurisprudence Examination (CPJE).

Dean Koda-Kimble from the UCSF, School of Pharmacy submitted a letter expressing concern over the proposal and urged the board not to amend the regulation.

At the committee meeting, the committee discussed the board's responsibility to protect the public and felt that it is important that an intern pharmacist is capable of performing the core competencies of pharmacy practice. An intern has the authority to perform all the duties of a pharmacist under the supervision of a pharmacist. There was concern that a minimum of 500 hours of intern experience in a pharmacy is not sufficient to assure adequate public safety and the experience necessary to perform the duties of a pharmacist. It was not clear how experience with a pharmaceutical manufacturer, in regulatory affairs or association management would provide an intern with the skills critical to the practice of pharmacy. The core functions of pharmacy include patient consultation and quality assurance, key skill areas and knowledge that an intern can only gain in real life experience and daily practice in a pharmacy.

Four students from UOP and UCSD presented their remarks to the board, requesting more flexibility with earning intern hours.

Students at UCSD are conducting a survey that will be distributed to students, practitioners, and a random sampling of the people of California to determine out who is interested in this change.

The students explained how the 20-question survey would target practitioners and the industry such as potential employers to determine if people want this, is there support from students, practitioners and employers in California. It was anticipated that the study would be completed by June.

All seven schools of pharmacy agree that this effort would better the pharmacy profession.

President Goldenberg stated he is proud of the students for stepping forward on this issue and added that this item should remain on the board's agenda and if the report has not been completed by July, the students could provide an update at the board meeting on how the study is progressing.

Mr. Powers stated that he reviewed the material on this issue and he felt that the committee had concerns about how this would impact the number of intern hours of experience were earned in community and hospital pharmacy rotations. There was concern that students would graduate without being well rounded in the mechanics of prescription filling. He added that even if students do not choose as their profession the conventional practice of pharmacy, it is cited as a requirement that students understand the mechanics of the practice.

President Goldenberg suggested that the students also direct the survey to consumers.

Ms. Zinder questioned if students could perform their required 1500 hours in addition to seeking the alternative internships. The response was that student's schedules are too strict.

John Cronin referred to a letter dated April 18, from Dr. Koda-Kimble, Professor and Dean, UCSF, that states that the current regulation provides ample opportunity for students to pursue innovative experiences without jeopardizing their ability to complete the board's requirements before graduation. In the letter, Dr. Koda-Kimble requests that the board adopt a statement of competencies to be gained from internship experiences in licensed pharmacies to be used to guide both students and preceptors in creating experiences that develop core competencies and skills the public deserves. Mr. Cronin added that with a core list of competencies, you would know if 500 hours were enough and this should be the focus.

- **Request to Re-approve the Accreditation Commission for Health Care, Inc. (ACHC) and Community Health Accreditation Program (CHAP) as Accreditation Agencies for Pharmacies that compound Injectable Sterile Drug Products.**

  Chairperson Conroy stated that B & P § 4127.1 requires pharmacies compounding sterile injectable drug products to obtain a license from the board. In order to obtain such a license the pharmacy must first be inspected by the board and found in compliance with board standards for sterile compounding. The law exempts pharmacies that are accredited by the Joint Commission on the Accreditation of Healthcare Organizations or other accrediting agencies approved by the board from the license requirement as specified in Section 4127.1 (d). Exempted pharmacies must still comply with board regulations regarding sterile injectable compounding, but do not have to obtain a separate license.

  The board approved Accreditation Commission for Health Care (ACHC) as an accrediting entity in April 2003. The board granted this approval for three years. At that time, ACHC accredited both home infusion pharmacies and specialty pharmacies that deliver biotech drugs and other specialty products. Recently ACHC has been reviewed by the Center for Medicare and Medicaid Services (CMS) and granted Deeming Authority for Home Health Medicare.

  In July 2003, the board approved Community Health Care Accreditation Program (CHAP) as an accreditation agency. CHAPS is a national non-profit accreditation organization established in 1965 to accredit community-based health care organizations. Currently, one California pharmacy is CHAP accredited and two pharmacies have applied. There are 63 CHAP accredited pharmacies in 23 states and 16 pharmacies that have applied for accreditation.

  Supervising Inspector Dennis Ming reported that the board has not found any compliance issues with either ACHC or CHAP accredited pharmacies

  In 2003, the Licensing Committee developed criteria for the evaluation of applications by accrediting entities for board approval. It was decided that the evaluation of accrediting agencies for board approval under Business and Professions Code section 4127.1 should be based on the accrediting agency's ability to evaluate the pharmacy's conformance with California law and good professional practice standards and the following factors.

1. Periodic inspection – The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years.
2. Documented accreditation standards – The standards for granting accreditation and scoring guidelines for those standards must reflect both applicable California law and sound professional practice as established by nationally recognized professional or standard setting organizations.
3. Evaluation of surveyor's qualifications – The surveyors employed to perform site inspections must have demonstrated qualifications to evaluate the professional practices subject to accreditation.
4. Acceptance by major California payors – Recognition of the accrediting agency by major California payors (e.g., HMOs, PPOs, PBGH, CalPERS).
5. Unannounced inspection of California accredited sites – The board must conduct unannounced inspections of two or more accredited sites and find those sites in satisfactory compliance with California law and good professional practice.
6. Board access to accreditor's report on individual pharmacies.
7. Length of time the accrediting agency has been operating.
8. Ability to accredit out-of-state pharmacies. Non-resident pharmacies are eligible for licensure under the sterile compounding statutes and accreditation should be equally available to both resident and non-resident pharmacies.

MOTION: Licensing Committee: That the Board of Pharmacy re-approve the Accreditation Commission for Health Care, Inc. (ACHC) and Community Health Accreditation Program (CHAP) as accreditation agencies for pharmacies that compound injectable sterile drug products.

SUPPORT: 9 OPPOSE: 0

- **Recommendation to Adopt a Regulation on the Process and Criteria to Approve Accreditation Agencies for Pharmacies that Compound Sterile Injectable Drug Products.**

Chairperson Conroy stated that Business and Professions Code section 4127.1 requires pharmacies compounding sterile injectable drug products to obtain a license from the board. In order to obtain such a license the pharmacy must first be inspected by the board and found in compliance with board standards for sterile compounding. The law exempts pharmacies that are accredited by the Joint Commission on the Accreditation of Healthcare Organizations or other accrediting agencies approved by the board from the license requirement as specified in Section 4127.1 (d). Exempted pharmacies must still comply with board regulations regarding sterile injectable compounding, but do not have to obtain a separate license.

The board approved the Accreditation Commission for Health Care (ACHC) as an accrediting entity in April 2003. The board granted this approval for three years. In July 2003, the board also approved Community Health Care Accreditation Program (CHAP) as an accreditation agency.

Since both agencies have requested that the Board of Pharmacy approve them again as accreditation agencies, and if the approval is granted, it is being recommended that the board pursue a regulation to recognize these agencies in regulation as the Joint Commission on the Accreditation of Healthcare Organizations is recognized in statute.

In addition the regulation would include the application and approval process, the evaluation factors, require the board's self-assessment form for sterile injectable compounding pharmacies as part of the survey process, and that a copy of the survey report be submitted to the board. If the board agrees with this recommendation, proposed language will be drafted.

MOTION: Licensing Committee: That the Board of Pharmacy re-approve the Accreditation Agencies for Pharmacies that compound sterile injectable drug products.

SUPPORT: 9 OPPOSE: 0

- **Request to Extend the Waiver for the Study by UCSF School of Pharmacy and Cedars-Sinai Medical Center to Allow a Technician to Check a Technician in the Filling of a Unit-Dose Medication System in a Hospital Inpatient Pharmacy**

Chairperson Conroy stated that Peter Ambrose, Professor of Clinical Pharmacy at UCSF and Rita Shane, Director of Pharmacy Services for Cedars-Sinai Medical Center requested an extension of the waiver for the study by UCSF's School of Pharmacy and Cedars-Sinai Medical Center entitled, "Evaluation of the Impact of Pharmacists in the Prevention of Medication Errors Associated with Prescribing and Administration in the Hospital Setting." In April 2004, the Board of Pharmacy granted a two-year waiver for this study. After board approval, the study was subsequently reviewed and approved by the Institutional Review Board at Cedars-Sinai Center and the Committee on Human Research at UCSF. In order to complete the data collection, analysis and review the results, an extension until December 31, 2006 has been requested.

This study was a sequel to the experimental program that evaluated pharmacy technicians checking other pharmacy technicians in a unit-dose drug distribution system in a hospital pharmacy.

The purpose of the sequel study is to evaluate the impact of pharmacists in prevention of medication errors associated with prescribing and administering of medications as a result of pharmacists being re-deployed from unit-dose medication cassette checking to more clinical and professional patient-care functions. The special expertise of pharmacists in the management of drug therapy benefits patients.

Preliminary data from the study was provided to the board at its July 2005 meeting and a summary of results from June 21, 2004 – January 1, 2006, was included in the board packet.

At the February meeting, the board approved for hearing a proposed a regulation change to allow a specialized trained pharmacy technician to check another pharmacy technician in a unit-dose drug distribution system in a hospital pharmacy that has a clinical program. This hearing is set for this board meeting. If the board approves the proposed regulation, it will take approximately 6-9 months before the regulation would become effective.

Dr. Ambrose provided the board with an update to the study and the results to date. Dr. Ambrose stated that the study found that inpatient technicians who had been trained and certified in a closely supervised program that incorporated quality assurance mechanisms could safely and accurately check unit dose medication cassettes filled by other technicians. The current study is reviewing the impact of having pharmacists prevent medication errors that are associated with both the prescribing staff and the administration staff in acute care settings using unit dose medications to demonstrate what pharmacists are doing with their time. Approximately 1 hour and 15 minutes per pharmacist per day is redeploying into the clinical environment so instead of checking cassettes, pharmacists were in the patient care wards and interacting with physicians and nurses.

He stated that the results to date continue to demonstrate the positive impact on patient care and medication safety that can be achieved by creating time for pharmacists to interact with the nursing and medical staff rather than using pharmacists to perform the non-discretionary task of checking technician-filled unit-dose medication charts. Also, it was demonstrated and published in a peer-reviewed pharmacy how specially trained technicians can very accurately stock and check unit-dose medication carts while still incorporating a quality assurance system. It is the use of pharmacy technicians in this capacity that creates the time for pharmacists to utilize their clinical skills to assist physicians and nurses to reduce medication errors at the prescribing and administration steps. Dr. Ambrose's report can be downloaded from the board's Web site at www.pharmacy.ca.gov under the materials for the April 2006 Board Meeting, within the Licensing Committee section.

During the 80 weeks of the study so far:

- Pharmacists prevented 1,241 potential prescribing errors
- Pharmacists prevented 614 potential administration orders
- The leading types of errors intercepted were:
    - Omission errors 20.6%
    - Improper dose/quantity 25.6 %
    - Unauthorized drug 2.1 %
    - Extra dose 3.7 %
    - Wrong patient 4.1 %

- Pharmacists prevented 682 medication errors with potential harm – of which
    - 590 encounters prevented temporary harm
    - 28 encounters prevented permanent harm
    - 60 encounters prevented an increase in hospital stay
    - 4 prevented death

Dr. Ambrose stated that one aspect of the study is to develop a CQI process to see where problems are occurring, which drugs are most problematic, and whether there are certain prescribers that are problematic. This offers a chance to see where the problem is and change the system to avoid errors.

Dr. Rita Shane, representing Cedars-Sinai, stated that the study demonstrates the value of pharmacists. There have been a number of occasions when the pharmacist identified wrong orders because the pharmacist was aware of the patient's diagnosis and reviewed the patient's entire medication regimen.

Steve Gray, representing Kaiser Permanente, stated that he supports the study by Cedars-Sinai and UCSF School of Pharmacy because it will be very valuable to other organizations.

MOTION: Licensing Committee: That the Board of Pharmacy extend the waiver to December 31, 2006 to allow a technician to check a technician in the filling of a unit-dose medication system in a hospital inpatient pharmacy for the study "Evaluation of the Impact on Pharmacists in the Prevention of Medication Errors Associated with Prescribing and Administration of Medications in the Hospital Setting" by UCSF School of Pharmacy and Cedars-Sinai Medical Center.

SUPPORT: 9 OPPOSE: 0

- **National Association of Boards of Pharmacy Announcement Regarding the Evaluation Process for Foreign Pharmacy Graduates**

Ms. Harris stated that the National Association of Boards of Pharmacy (NABP) announced its partnership with the Educational Credential Evaluators, Inc. (ECE) for the educational credential evaluation of applicants to the Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification Program. This partnership will change the method by which foreign pharmacy graduates will be evaluated.

ECE will be responsible for verifying the educational background of the applicant and the NABP will verify the applicant's professional licensing and registration information. The foreign graduate will submit all documents directly to ECE for evaluation.

This new partnership is intended to address the increase of workload that this program has experienced over the last few years and reduce the processing time for these applicants.

California requires all foreign graduates to be FPGEC certified before they can apply to be licensed as an intern or pharmacist.

- **Changes to the Pharmacy School Accreditation Procedures by the Accreditation Council for Pharmacy Education (ACPE)**

Chairperson Conroy stated that ACPE recently announced changes to its accreditation procedures. After June 30, 2006, ACPE will require that any new doctor of pharmacy program seeking preaccreditation status must progress through both states of preaccreditation, which is precandidate and candidate phases, before consideration of full accreditation. Prior to this policy change, it was not essential that a program be granted precandidate status before students were admitted.

After June 23, 2006, a new program must achieve precandidate status before admitting students. Should a new program admit students without achieving precandidate status, this will preclude ACPE from considering the program's application for candidate preaccreditation status, and full accreditation cannot be considered until graduation of the first class. Students graduating from a program without candidate status will thus have graduated from a program with no accreditation status and will likely not be eligible for licensure.

This change in policy is consistent with the board's recent regulation change that states that the board will recognize a school of pharmacy that is accredited or granted candidate status by ACPE or schools recognized by the board. The board has recently "recognized" new schools of pharmacy that have been granted precandidate status so that the students can be registered as interns.

- **Report on ACPE Site Visits**

Chairperson Conroy stated that it was reported that board members have been actively participating on the ACPE evaluation teams for the California schools of pharmacy. President Goldenberg participated in the recent evaluation of Western University of Health Sciences College of Pharmacy. Former board member Darlene Fujimoto was on the team that evaluated UC San Diego Skaggs School of Pharmacy. The evaluation conflicted with the board's February meeting so Dr. Fujimoto graciously agreed to be the board's representative. Board member Ruth Conroy will be on the site team for Loma Linda University School of Pharmacy scheduled for April 18th – 20th. ACPE was scheduled to evaluate the Touro University California College of Pharmacy for candidate status on April 25-27, 2006, and former board member John Tilley agreed to represent the Board of Pharmacy because it conflicted with the board meeting.

- **Competency Committee Report**

Ms. Herold referred to the supplemental statistics for the CPJE for the last six months that ended April 1, 2006. The pass rate for the CPJE is 80.3 percent; the pass rate for California graduation is 89 percent. These statistics can be found at www.pharmacy.ca.gov.

Ms. Herold stated that the board posted the new content outline on the board's Web site and this was also included in the January 2006 newsletter. All exams administered since April 1, 2006 use this structure.

The California Pharmacy Jurisprudence Examination (CPJE) handbook is in the process of being updated and will include the new content outline. There is also a sample CPJE exam that is posted on the board's Web site.

The Office of Examination Resources (OER) within the Department of Consumer Affairs is renewing its contract with a vendor to provide computer based testing. The winning vender will be announced on May 8, 2006. The duration of the contract is 3 years with 2 one-year optional extensions.

ENFORCEMENT COMMITTEE

- **Report on the Meeting of the Workgroup on E-Pedigree of March 16, 2006**

  Chairperson Powers reported on the meeting of the Workgroup on E-Pedigree of March 16, 2006.

- **That the Board of Pharmacy Consider the Requests to Delay Implementation of the Electronic Pedigree until January 1, 2008.**

  Mr. Powers noted there was a detailed summary of the March 16, 2006 workgroup meeting contained in the board packet.

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

  Over the last year, the Enforcement Committee has been monitoring the implementation of this legislation especially the implementation of the pedigree requirement. The bill requires an electronic pedigree by January 1, 2007 and gives the board the authority to extend the compliance date to January 1, 2008. The Legislature may extend the compliance date for pharmacies to January 1, 2009. The purpose of the pedigree is to maintain the integrity of the pharmaceutical supply chain in the United States. At the February board meeting, the board agreed to form a Workgroup on E-Pedigree, which held its first meeting on March 16, 2006 and was attended by over 60 stakeholders.

  At this first workgroup meeting, there were several presentations. Supervising Inspector Judi Nurse presented on California's requirements for electronic pedigree. Mike Rose from Johnson and Johnson and Ron Bone from McKesson as Co-Chairs of the EPCglobal Healthcare and Life Sciences Business and Action Group presented on the state of electronic pedigree and Radio Frequency Identification (RFID) technology standards. Walt Slijepcevich of Pfizer presented on Pfizer's Viagra RFID authentication pilot program and Bob Dufour from Wal-Mart Stores gave an overview of its experience with RFID.

To address questions regarding the implementation of the e-pedigree requirement, a question and answer document was prepared.

Of greatest concern to the many that attended this March workgroup meeting was the implementation date of January 1, 2007. Business and Professions Code § 4034 and 4163 become operative on January 1, 2007, and as of that date prohibit any wholesale sales, trades, or transfers of prescription drugs, or any acquisitions of prescription drugs, absent a pedigree recording and accompanying the transaction. Pursuant to Sections 4163.5 and 4163.6, this prohibition and/or the requirement of a pedigree may be delayed by the Board of Pharmacy until January 1, 2008, upon a demonstration of need by the industry, and the by the Legislature (for pharmacies) until January 1, 2009.

The board has received requests for delay in implementation. At the September 2005 Enforcement Committee meeting, Amgen stated that it will be extremely difficult to meet the January 1, 2007 deadline.

In addition, the board has received letters from the Food Marketing Institute (FMI), National Association of Chain Drug Stores (NACDS), Biogen Idec seeking a delay in implementation to January 1, 2008, because of concerns that it is an unrealistic compliance date for the entire pharmaceutical supply chain, from manufacturers to pharmacies to implement and comply with the requirements of an electronic pedigree.

It was expressed that 12 states, including California, have adopted legislation requiring pedigrees for prescription drugs. However, no state has imposed requirements as broad and far-reaching as California. It was suggested that California consider as the other states have a provision that recognizes a "normal distribution channel." "Normal distribution channel" means a chain of custody during distribution of a prescription drug that goes from a manufacturer to a wholesaler distributor to a pharmacy to a patient or a chain of custody for a drug that goes from a manufacturer to a wholesale distributor to a chain pharmacy warehouse to their intercompany pharmacy to a patient. Direct sales of a prescription drugs by a manufacturer to a pharmacy or a chain pharmacy warehouse are within the normal distribution channel. Therefore, a prescription drug that is distributed through the "normal distribution channel" would not be required to have a pedigree.

However, the "normal distribution channel" concept was considered during the legislative process, but was not accepted by the board. The problems with a "normal distribution channel" or "authorized distributor" approach include the difficulty of monitoring and enforcing such relationships. Adopting a "normal distribution channel" or "authorized distributor" approach would presumably exempt a huge number of transactions from being part of the e-pedigree tracking system, which is inimical to the intent of the statute. This would take those transactions out of the verifiable e-pedigree domain, and increase the temptation for individuals, including even the employees of those "authorized distributors," to take advantage of this lack of oversight. The e-pedigree is a far more reliable method of tracking the flow of drugs.

Other alternatives included establishing a list of the most susceptible prescription drugs and require a pedigree for only those drugs on the list. Alternatively to provide exemptions to wholesalers that distribute incidental shipments of prescription drugs into California and exempt Third Party Logistics Providers from licensure as wholesalers.

The delay on the effective date of the pedigree provisions in the federal Prescription Drug Marketing Act (PDMA) expires December 2006. In February 2006, the federal Food and Drug Administration (FDA) held a Counterfeit Drug Task Force Public Workshop to receive comments. It was reported that the Task Force plans to issue its final report to the Commissioner in May. The FDA was requested to create uniform standards for pedigree implementation so that an interoperable system could be created to assist the states.

The board has received two more letters requesting a delay in implementation. The first letter is from the Generic Pharmaceutical Association (GPhA) stating its position that more time is necessary to ensure that a pedigree process can be properly and effectively implemented. This is because many generic companies manufacturer numerous products, which is far more than brand companies, thus, making it a greater burden on the generic manufacturer to implement a pedigree program.

The National Association of Chain Drug Stores (NACDS) and the California Retailers Association (CRA) submitted its second request for a delay based on the direction of the workgroup. They explained that their members would be participating in the newly formed coalition of community pharmacies, manufacturers and distributors to work on the California electronic pedigree implementation plans and milestones. The Health Distributors Management Association (HDMA) and its member wholesalers are organizing this coalition. It is anticipated that the first meeting will be April 25, 2006. They also noted that NACDS members have been actively involved with EPCglobal. NACDS commented that it is working diligently within EPCglobal to research and potentially develop an RFID enabled electronic pedigree system. NACDS stated that it needs more time to ensure that an electronic pedigree can be created that is interoperable among technology vendors and the various states and other stakeholders.

In addition, NACDS and CRA commented that the board should require that all software vendors that offer a solution for the California e-pedigree requirement certify that their software is interoperable. Once there is interoperable software, community pharmacies can begin to pilot and validate the systems to assure that the software can work in real-time so not to affect productivity. They anticipate that the process from the time that interoperable software is available through the phases of testing, validation and deployment across all pharmacies in California, could take as long as two years.

NACDS and CRA offered solutions in the interim such as not to require a pedigree for prescription drugs that are passed through the “normal distribution channel,” alerting and educating health care professionals in a timely manner about counterfeit drug products, and enforcing current law against drug importation by non-manufacturers.

Based on concern by the industry that they will be unable to meet the January 1, 2007 implementation date for the pedigree requirement, the Senate Business and Professions Committee has introduced SB 1476 to extend the implementation date to January 1, 2008. This bill also extends the board's sunset provision to January 1, 2010.

The Enforcement Committee members of the E-Pedigree Workgroup acknowledged the amount of work that the industry has done nationwide to implement the electronic pedigree requirement and while much of the discussion focused on why compliance could not be met by January 1, 2007, the committee asked stakeholders to set forth how compliance will be achieved and the milestones that will be used to reach this goal. To consider the requests for delay in implementation at the April board meeting, the committee requested that the stakeholders submit with their extension requests implementation milestones to the executive officer by April 1, 2006. Many stakeholders expressed concern that they could not meet the 2007 deadline because they are dependent upon the actions of others in the distribution chain.

At the conclusion of the Enforcement Committee meeting, Chairperson Powers and President Goldenberg again requested a progress report from stakeholders to help the board determine when the public can expect to be protected from counterfeiting and diversion of drugs, but noted that the board does not have this report yet.

Joshua Room, Deputy Attorney General, reported on the April 25 group meeting coordinated by the HDMA, titled the California Pedigree Working Group. The goal of the organizers for this group of industry representatives is to have a presentation to the board by the July board meeting.

- **Status on Setting the Standards for Electronic Pedigree – Presentation by Robert Celeste, EPCglobal**

Mr. Celeste attended the board meeting and stated that EPCglobal is an international standards body that develops standards for industries including the health care industry. Mr. Celeste clarified the terms of the standards such as pedigree, serialization, identification of products and carriers.

Mr. Celeste stated that pedigree is the regulatory document that communicates the custody history of a particular medication.

Serialization is a unique number that will be applied to each item within the supply chain and electronic product code is a number in the system that incorporates the numbers and keeps them separate from other numbers with other supply chains so each medication can be uniquely identified.

Mr. Celeste stated that the industry has received a number of requirements from manufacturers and distributors for the system. The process is difficult because all parties within the supply chain

must be identified with security measures for each in place with consideration of globalization. He added that for an example, in Europe there are at least nine different ways to identify pharmaceuticals and in Asia, there are at least four different ways to identify pharmaceuticals. As a global standards body, EPCglobal is trying to develop a unique way of identifying a pharmaceutical product any where in the world. He added that many of the drugs coming into California are produced in other countries and need to be uniquely identifiable in order to protect citizens.

Mr. Celeste stated that EPCglobal is also considering looking at the means to uniquely identify companies within the supply chain and to develop an automated process.

Mr. Celeste stated that they have already identified counterfeit pedigrees and pedigree is not the only solution and this also contributes to the complication of the process. He added that security measures are split between the physical device and the network environment so each would have to be copied to thwart the system.

Mr. Celeste stated that a standardized agreement is needed and the true nirvana of track and trace is being able to find any object within the world at any given time. Every time the product is moved through the supply chain it adds another layer to the pedigree document and this results in redundant data.

Mr. Powers stated that motivation for success in this process is facing the fact that perhaps 25 percent of all drugs in the near future will be counterfeited and this is unacceptable.

Mr. Celeste stated that the pedigree messaging standard is now being developed and will go through ratification and certification will be created around that standard. The work group is developing a working draft with performance requirements. In development of test cases, he described a prototype event where a number of vendors and end users meet with their products to assure they can interoperate with each other and develop standardized usage guidelines.

Mr. Jones asked Mr. Celeste if EPCglobal has considered a marketing effort to target those that must adopt the standard.

Mr. Celeste stated that EPCglobal's marketing efforts includes participating in the standards development effort and the standard is free and can be downloaded.

Joshua Room, Deputy Attorney General, asked for clarification on the reference Mr. Celeste made for an endorsement from the board or other regulatory agencies as to whether EPCglobal's standards meet the criteria for the laws and regulations.

Mr. Celeste stated that EPCglobal does not have this type of endorsement and it would be beneficial that this complies with California's requirements.

Oren Peacock, representing CVS Pharmacies, stated that they have been involved with EPCglobal from the beginning and the only thing missing is a target date.

Mr. Celeste stated that the last call working draft would most likely be available in the next four weeks and the prognosis for a ratified standard is October 2006. The conformance requirements are in development and the next event is a prototype event during the summer and once the standard has been ratified.

Gill Preston, representing Johnson and Johnson, expressed concern that it would be difficult to meet the compliance deadline of January 1, 2007, without a national standard in place. He added that Johnson and Johnson is interfacing with customers and making every reasonable attempt to meet various legislative deadlines but there are many variables.

Mr. Fong asked what steps have been taken within the generic drug industry to advocate a standardization that is supported by ECPglobal or another organization for implementation.

Mr. Preston responded that as members of the Generic Pharmaceutical Association, they attempt to adhere to the same standards.

Sean Brown, representing the Generic Pharmaceutical Association, stated that the association is currently in the process of an industry wide survey of all of their members for a consensus concerning action to take and a target date. He added that it is in everyone's interest to protect the security of the supply chain and patients' welfare.

Fred Mayer, representing Pharmacists Planning Services, Inc., stated that World Health Organization states that the 10 percent of all drugs currently in the world are counterfeit. As a consumer advocate, he asked if the pedigree could determine if drugs manufactured in another country could be authenticated. He expressed concern that this doesn't address the real issue when many are purchasing drugs from the Internet. He added that the high cost of drugs is the issue.

Elizabeth Gallenagh, State Director of Affairs, representing HDMA, stated that they hope to provide the board with a consensus on what needs to be achieved in order to reach implementation.

Steve Gray, representing Kaiser Permanente, commended McKesson for organizing and generously funding the meeting.

The board again requested a progress report on what industry has specifically done to implement California's standards, what remains to be done, and a timeline for implementation. The safety of the state's prescription drugs rest in the swiftest implementation.

The California Pedigree Working Group agreed to have this report to the board by July 1.

REGULATION HEARING

Prescription Drop Boxes and Automated Self-Use Delivery Device for Refill Prescriptions – Proposed Amendment to Repeal 16 CCR Section 1717(e) and to add 16 CCR Section 1713

President Goldenberg read the following instructions for the regulation hearing:

This hearing is to consider adopting requirements for prescription drop boxes and automated self-use delivery devices for refill prescriptions; proposed amendment to repeal 16 CCR § 1717(e) and to add 16 CCR 16, §1713, as outlined in the public notice.

At this time, the hearing will be opened to take oral testimony and/or documentary evidence by any person interested in these regulations for the record which is now being made by tape recorder. All oral testimony and documentary evidence will be considered by the Board pursuant to the requirements of the Administrative Procedure Act before the Board formally adopts the proposed amendment to these regulations or recommends changes which may evolve as a result of this hearing.

If any interested person desires to provide oral testimony there is a sign-up sheet in the back of the room. It will be appreciated if the person commenting comes forward and give his or her name and address, and if he or she represents an organization, the name of such organization, so that we will have a clear record of all those who appear.

Please keep in mind the following when making comments:

A. This is a public forum to receive comments on the proposed regulations. It is not intended to be a forum for debate or defense of the regulations.

B. Written testimony may be summarized but should not be read. The board will give equal consideration to written and oral testimony.

C. If you have a question about a proposed regulation, please re-phrase your question as a comment. For example, instead of asking what a particular subdivision means, you should state that the language is unclear, and explain why you find it to be unclear.

After all interested parties have been heard, the issue will stand submitted.

Are there any questions concerning the nature of the proceedings or the procedure to be followed here before we begin?

Testimony in Support:

Bob Hansen, PharmD., Vice President Pharmacy Services, Asteres Inc.

Dr. Hansen referred to the written testimony from Asteres, Inc., submitted on January 12, 2006, describing the ongoing contact with the Board of Pharmacy for guidance on the ScriptCenter, a prescription refill delivery kiosk, and the development of the ScriptCenter.

Dr. Hansen stated that California was the first state to approve the use of ScriptCenter or kiosk-type delivery box. Since then, eight states have approved its use and three more states are considering regulations that would allow the use of ScriptCenter. He added that there have been over 37,000 deliveries from the units and with two companies manufacturing the units, the numbers have increased. Asteris Inc. has 7,500 registered patient users.

Dr. Hansen stated that the initial premise of the automated system was to avoid long lines for patients during peak times. He reported that between the hours of 4 and 6 p.m., 33 percent of prescriptions are picked up at the pharmacy. After hours use only accounts for approximately about 5 or 6 percent usually on Saturday or Sunday when the pharmacy is closed between the hours of 5 and 6 p.m.

Dr. Hansen stated that the basic age group using the delivery unit is between 40 and 50 years of age, 7 percent average age 65 or older, and 6 percent are 26 or younger.

Dr. Hansen referred to written comments provided in the board packet which included the board's data reports on medication errors from citation and fines. He noted that the wrong patient getting medication occur 6.2 percent of the time. The ScriptCenter has delivered the correct bag of medications to patients every time.

Richard Mazzoni, representing Albertsons/Sav On

Mr. Mazzoni thanked the board for considering the regulation and he expressed support of the proposed regulation.

Bill Holmes, representing ddn Corporation

Mr. Holmes stated that the technology for the delivery machines is not new and the main focus is patient safety and the opportunity to prevent medication errors at the point of sale. He added that among thousands of deliveries, there hasn't been a single instance of delivery to the wrong patient. He added that we have the technology that can prevent errors. Their patients tell them that they appreciate that the use of the delivery machines allows them to start medication therapies earlier because they can pick up their medications when the pharmacy is closed.

Steve Gray, representing Kaiser Permanente

Dr. Gray acknowledged and thanked the board for the amendments incorporated into the language dated April 19 from the Legislation and Regulation Committee Meeting. He added that Kaiser Permanente supports the changes made.

Testimony in Opposition:

Fred Mayer, R.Ph., M.P.H., representing Pharmacists Planning Service, Inc. (PPSI)

Mr. Mayer also acknowledged the amendments to the proposed regulation to help clarify consumer issues.

Mr. Mayer stated that the PPSI has concerns and referred to the information and 18 exhibits they submitted for the October 25, 2005, Board of Pharmacy packet and he asked that this be reintroduced at this meeting and submitted to the Office of Administrative Law for review.

Mr. Mayer referred to section 201.57 of the Code of Federal Regulations, requiring pharmacists to distribute medication guides with prescriptions to patients. He referred to a study published by Public Citizen that revealed only one out of 20 pharmacies surveyed gave out medicine guides and the remainder did not. He introduced the study as exhibit 19.

Mr. Mayer expressed concern that pharmacists are not counseling patients enough now and that by using these delivery units, consultation will decrease even further. He added that it isn't clear what the definition of "up to the pharmacist's discretion" is and stated the proposed regulation is ambiguous.

Mr. Mayer introduced as exhibit 20, an article published in the September 26, 2005, titled "Duane Reade on fast track with DR Express. The article states that Duane Reade, a regional chain with 250 stores in New York and New Jersey has immediate video conferencing with pharmacy staff on all of their 212 kiosks.

Mr. Mayer also expressed concern about how patients would contact their pharmacist as they use the system. He added that another concern is for non-English speaking patients and he asked how the board would deal with this issue.

Mr. Mayer introduced as exhibit 21 a report titled "Probe Finds Food and Drug Needs More Muscle" that shows that two thirds of the studies conducted have no post market surveillance. He added that this is wrong. He stated that more consultation is needed, not less.

Mr. Mayer referred to SCR 49 and a prescription error study by Senator Jackie Speier and he asked the board to delay any action on the proposed regulation until the results of the study are revealed. He added that it would not improve prescription errors by using kiosks. He asked that the board delay action until the results of this study are revealed.

Mr. Mayer stated that if kiosks are approved, PPSI requests that all kiosks have video conferencing abilities for delivery of all medications, especially those with black box warnings.

Mr. Mayer introduced as exhibit 21, a Medication Guide for Non-Steroidal Anti-Infammatory Drugs (NSAIDs). He added that that 16,000 deaths occur based on a Stanford study. He added that after seven years of petitioning the Food and Drug Administration, black box warnings on non-steroidal drugs and medication guides will be distributed to everyone. He add that these drugs should not be used in kiosks.

Mr. Mayer stated that if kiosks are approved, PPSI requests that all kiosks have similar video conferencing such as the Duane Reade's DR Express available.

Mr. Mayer expressed concern that Constrolled Substance II-III prescriptions should not be available in kiosks. He added that there is an epidemic of overuse of Vicodin. He asked how the pharmacist would counsel patients on Controlled Substances III – V prescriptions.

Mr. Room referred to Mr. Mayer's question regarding the ability to use these machines under current regulations for all controlled substances. He added the regulation as currently constituted, would permit these machines to be used to deliver controlled substances. He added that if the board wishes to exclude these machines from delivering any scheduled drugs, then this would require an additional amendment.

John Cronin, representing the California Pharmacists Association

Mr. Cronin referred to written comments submitted on behalf of the California Pharmacists Association (CPhA).

Mr. Cronin stated that the CPhA believes that these devices are basically safe and represent a useful tool for consumers but the CPhA does not believe that the board's regulation ensures that the use of these machines will further a high standard of patient safety, promote good patient care and advance pharmacist-patient communication.

Mr. Cronin referred to section 1713(d) of the California Code of Regulations where the language states that a pharmacy may use an automated delivery device to deliver previously dispensed prescription medications, provided all the different things listed.

Mr. Cronin stated that "previously dispensed" indicates that the patient has had this drug before. In reading the comments, this was the intent of adding the language. He referred to CCR section 1713(g) where it states "because they have been previously dispensed to the patient by the pharmacy in the same dosage or strength with the same written directions." Mr. Cronin stated that this seems to imply that the prescription was filled at that pharmacy before. He added that the board's intent must to be consistent between the two sections.

Either the patient had the prescription before from another pharmacy, or, there is a requirement that the prescription must be filled in the pharmacy where the devices are located.

Mr. Cronin stated that the language should allow retail pharmacies to compete with mail order pharmacies. He added that mail order pharmacies never fill an original prescription, but prescriptions that have been filled before; because they are unable to perform face-to-face consultation and consequently do not want new prescriptions. He asked if this is the board's intent; that this refers to a previously dispensed medication that would qualify for inclusion in these devices.

Liberty Sanchez, representing the Law Offices of Barry Broad, on behalf of the United Food and Commercial Workers Union (UFCW) in Opposition of the Proposed Regulations.

Ms. Sanchez referred to written comments dated April 10, 2006, submitted to the board by the UFCW.

Ms. Sanchez stated that the UFCW requests the board to conduct a more thorough study of the issue prior to promulgating the regulations. The UFCW believes that as drafted, the regulations have a lot of statements and a lot of ambiguity. The UFCW has concern that the underlying purpose of adopting the regulations is more of a consumer convenience than of consumer protection and safety.

She added that specifically, the UFCW is concerned that the consent form the patient must complete isn't clear enough for patients to make what an informed decision about giving consent.

Ms. Sanchez stated that the regulation provides that "providing a means to speak to a pharmacist or make a call on a 1-800 number" when a patient makes such a request is not sufficient. She added that a "means" could be interpreted to mean, we have the phone, we have the 1-800 number, but no one is actually there to answer the 1-800 number.

Ms. Sanchez stated that the UFCW is concerned that there are different types of kiosks and some might be better than others and this hasn't been thoroughly investigated. The UFCW does not believe that the proposed regulations provide an appropriate method for patients who encounter a broken down machine to understand what to do to secure their medication in an alternative manner.

Ms. Sanchez stated that UFCW is very concerned about the lack of discretion afforded pharmacists in determining whether or not these machines can be placed in their pharmacies and if so, what types of prescriptions can be dispensed from the machines, particularly in light of the fact that the pharmacist would still be liable if errors are made if the machine breaks down, or if the machine erroneously dispenses the wrong drug, etc.

Ms. Sanchez stated the UFCW is requesting that the liability issues be addressed and amended into the regulations. She added that it needs to be clear that pharmacists have complete discretion over what prescription drugs are dispensed through the devices and in order to ensure that discretion; the pharmacist should be protected from any discipline or discharge from his or her employer when the pharmacist is exercising his good faith professional judgment. She stated that the UFCW is suggesting that the pharmacist be expressly immune from licensure sanctions if an automated delivery device malfunctions or an error results from the patient's use of the machine.

Ms. Sanchez stated that the UFCW is opposed to the proposed regulations and urges the board to study the issue further before adopting the regulations.

Mr. Powers asked Ms. Sanchez if there were other issues regarding vagueness that were not mentioned in Mr. Gusman's letter.

Ms. Sanchez responded that the only vagueness issues addressed were the lack of clarity in the written consent form and what it should look like and the type of communication needed between the pharmacy and the patient to convey how the machine works, what the patient needs to do and what recourse the patient has if the machine malfunctions, etc. She added that the issues she raised were the 1-800 number, the phrase in the proposed regulations "provide a means to immediately reach the pharmacist or a pharmacist via the 1-800 number." She added that "provide a means" is insufficient and should be clarified so patients have the ability for actual immediate contact, not just a means for immediate contact. Additionally, the UFCW is very concerned about the liability concerns and the lack of clarity there.

Ms. Sanchez stated that another issue Mr. Gusman raised in his letter was a discretion issue in relation to the pharmacy and the pharmacist regarding the ability to determine if kiosks should be placed in the pharmacy and what exactly can be dispensed in them.

President Goldenberg closed the public comment period, as there were no further comments.

Mr. Room referred to Mr. Cronin's comment about the use of the phrase "previously dispensed." Mr. Room stated that the language is from section 1707.2 of the California Code of Regulations and the intent was to use these machines synonymously in situations that consultation is not automatically required.

Mr. Room stated that if the board wants to respond to one of the clarification requests by the UFCW, it could change section (d) (5) to make it more of an affirmative duty to provide consultation by removing: "a means for each patient to request and obtain." The change could be adopted by the board as part of its vote and would require a 15-day notice period for further comment.

Ms. Harris stated that the board was provided with a copy of the April 19 version of the language with modifications received from the Legislation and Regulation Committee and

comments submitted in writing from the public. She added that the strikeout represents deletion of the language and the double underline represents language that was added.

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy adopt the proposed amendment to repeal 16 CCR Section 1717(e) and to add 16 CCR Section 1713 with an amendment to the April 19 version of the language in section 1713 (d)(5) as follows:

Adopt Section 1713 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1713. Receipt and Delivery of Prescriptions and Prescription Medications.

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.
(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.
(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.
(d) A pharmacy may use an automated delivery device to deliver previously dispensed ~~refilled~~ prescription medications provided:

(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.
(2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication ~~mediation~~ to that patient.
(3) The device has a means to identify each patient and only release that patient's prescription medications.
(4) The pharmacy does not use the device to deliver previously dispensed ~~refill~~ prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).
(5) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.~~The pharmacy provides a means for each patient to obtain an immediate telephone or in-person consultation with a pharmacist if requested by the patient.~~

(6) The device is located adjacent to the secure pharmacy area~~licensed pharmacy counter~~.

(7) The device is secure from access and removal by unauthorized individuals.

(8) The pharmacy is responsible for the prescription medications stored in the device.

(9) Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

(10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).

(e) Any pharmacy making use of an automated delivery device as permitted by subdivision (d) shall maintain, and on an annual basis review, written policies and procedures providing for:

(1) Maintaining the security of the automated delivery device and the dangerous drugs within the device.

(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device.

(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filling procedures for the automated delivery device.

(5) Orienting participating patients on use of the automated delivery device**,** notifying patients when expected prescription medications are not available in the device**,** and ensuring that patient use of the device does not interfere with delivery of prescription medications.

(6)Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.

(g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.

Note: Authority cited: Sections 4005, 4075, and 4114 Business and Professions Code. Reference: Sections 4005, 4052, 4116 and 4117 Business and Professions Code.

Amend Section 1717 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1717. ~~Pharmaceutical~~ Pharmacy Practice.

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.
Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:

(1) a patient med pak is reused only for the same patient;

(2) no more than a one-month supply is dispensed at one time; and

(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."

(b) In addition to the requirements of Business and Professions Code Section 4040, the following information shall be maintained for each prescription on file and shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist ~~preceptor~~ before they are dispensed.

(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and

(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.

(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing. Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.

(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.

(e) ~~No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy. However, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. The Board may in its sole discretion waive this application of the regulation for good cause shown.~~

~~(f)~~ A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, 1306.26.
Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of Section 1716. Information maintained by each pharmacy shall at least include:

(1) Identification of pharmacist(s) transferring information;
(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;
(3) Original date and last dispensing date;
(4) Number of refills and date originally authorized;
(5) Number of refills remaining but not dispensed;
(6) Number of refills transferred.

~~(g)~~ (f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Note: Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

SUPPORT: 8 OPPOSE: 1

Mr. Mayer requested that the board have the Office of Administrative Law consider the conflict of interest issue for pharmacist member of the board to be voting on this regulation.

MOTION: That the Board of Pharmacy delegate authority to the executive officer to respond to further comments regarding the proposed amendment to repeal 16 CCR section 1717(e) and to add 16 CCR section 1713 – Prescription Drop Boxes and Automated Self-Use Delivery Device for Refill Prescriptions unless new negative comments are received.

M/S/C: FONG/CONROY

SUPPORT: 8 OPPOSE: 0 ABSTAIN: 1

Pending Regulations

Board Approved – Pending Administrative Approval

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

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

Board Approved - Awaiting Notice

- **Proposed Amendment of 16 CCR Section 1706.2 – Abandonment of Application Files for Veterinary Food-Animal Drug Retailer, Hypodermic Needle and Syringes Distributor and Designated Representative**

  Chairperson Jones stated that this regulation would add veterinary food animal drug retailer, needle and syringe distributor and designated representative to the abandonment of files provisions of this section.

- **Proposed Amendment to 16 CCR Section 1709.1 – Replace the term "Exemptee-in-Charge" with "Designated Representative-in-Charge" (Section 100 Technical Change)**

  Chairperson Jones stated that the term "Designated Representative-in-Charge" was added to Pharmacy Law in 2005 by Senate Bill 1307 (Chapter 857, Statutes of 2004) and became effective on January 1, 2005. The board voted to amend this regulation during the February Board Meeting to conform with the law.

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

  Chairperson Jones stated that the purpose for repealing the regulation is to remove a barrier that prevents pharmacists, in certain situations, from having full knowledge of all the prescription drugs that a patient is taking. Removing this barrier will result in better patient care while protecting patient medical record privacy. Staff is in the process of drafting the initial Statement of Reasons and Notice documents.

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

  Chairperson Jones stated that this rulemaking would allow the board to use the 2006 revision of the Disciplinary Guidelines when deciding appropriate discipline action to take for violations of Pharmacy Law. The Guidelines will be ready for public notice and the formal start of the rulemaking process at the October board meeting.

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

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

- **Proposed Amendment to 16 CCR Section 1780 – Update the USP Standards Reference Material (Section 100 Technical Change)**

  Chairperson Jones stated that the board voted to revise section 1780 to update the USP standards to require the 2005 USP revision at the February 2006, board meeting.

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

  Chairperson Jones stated that during the February 2006 board meeting, the board voted to revise section 1780.1 and 1781 of the California Code of Regulations to replace the term "exemptee" with "designated representative" to conform to the passage of SB 1307 (Chapter 857, Statutes of 2004) which took effect January 1, 2006.

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

  Chairperson Jones stated that staff completed its internal review of the assessment form. It will be publicly noticed and brought to the board for action at a future meeting.

- **Proposed Repeal of 16 CCR Section 1786 – Exemptions for a Supplier (Section 100 Technical Change)**

  Chairperson Jones stated that this regulation requires a wholesaler to immediately return a certificate of exemption of a designated representative leaves the employment of the wholesaler. This regulation is based on past pharmacy law that required certificate of exemption to be linked to

a specific licensed wholesaler location, not to the designated representative as current law requires. Consequently, CCR Section 1786 is no longer a meaningful regulation and should be repealed.

Awaiting Board Review and Action

- **Addition to the California Building Code – 24 CCR Sections 490A.3 and 505.12.2 Related to Compounding Parenteral Solutions; Technical Changes to the Building Code Relating to Pharmacies.**

The California Building Standards Commission (CBSC) has asked the board to review and update pharmacy building standards in the building code, in preparation of the CBSC adoption of the 2006 International Building Code and 2006 International Fire Code, the 2005 National Electrical Code, and 2006 Uniform Mechanical Code and Uniform Plumbing Code, in CCR, Title 24. The CBSC anticipates adopting the new standards in early 2008.

Staff reviewed and updated the relevant building code sections. The board needs to review the proposed changes, and if acceptable, vote to allow the CBSC to move forward with the code revisions.

John Cronin, representing the California Pharmacists Association, referred to the reference in this regulation that refers to compounding areas and states that the pharmacy shall have a designated area for preparation of sterile products for dispensing. He added that this did not seem to limit the requirement to pharmacies that dispense sterile compounded products. It seems to imply that it applies to all pharmacies. He asked for clarification. He referred to sections 390A.3 and 505.12.2.

490A.3 Compounding Area for Parenteral Solutions. The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall:

1. In accordance with Federal Standard 209 (b), Clean Room and Work Station Requirements, Controlled Environment, as approved by the Commission, Federal Supply Service, General Service Administration meet standards for Class 100 HEPA (high efficiency particulate air) filtered air such as laminar airflow hood or clean room.
2. Have nonporous and cleanable surfaces, ceilings and ceiling tiles, walls, floors and floor coverings.
3. The pharmacy shall be arranged in such a manner that the laminar-flow hood is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral solution.

There shall be sufficient space, well separated from the laminar-flow hood area for the storage of bulk materials, equipment and waste materials.

4. A sink with hot and cold running water must be within the parenteral solution compounding area or adjacent to it.
5. Any pharmacy that compounds sterile injectable products from one or more nonsterile ingredients must compound the medication in one of the following environments:
   (a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.
   (b) An ISO class 5 cleanroom.
   (c) A barrier isolator that provides an ISO class 5 environment for compounding.

Note: For additional pharmacy mechanical standard requirements, see Chapter 5, California Mechanical Code.

Notation
Authority: B & PC § ~~4008~~ 4005
Reference(s): B & PC §§ 4008 and 4081 4005, 4127.7. and 4201

505.12 Pharmacies – Compounding Area for Parenteral Solutions. (For CA – Board of Pharmacy) Any pharmacy that prepares sterile injectable products shall have a designated area for the preparation and dispensing shall:

1. Be ventilated in a manner not interfering with laminar air low.
   NOTE: For additional pharmacy building atandard requirements, see Chapter 4A, Section 490A, California Building Code.

505.12.1 Pharmacies – laminar flow biological safety cabinet. (For CA – Board of Pharmacy) In all pharmacies preparing parenteral cytotoxic agents, all compounding shall be conducted within a certified Class II Type A or Class II Type B vertical laminar airflow hood with bag in – bag out design. The pharmacy must ensure that contaminated air plenums that are under positive air pressure are leak tight.

5-5/12/.2 Pharmacies Compounding Parenterial Solutions from One or More Nonsterile Ingredients. Any Pharmacy that compounds sterile injectable products from one or more nonsterile ingredients must compound the medication in one of the following environments:

(d) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.
(e) An ISO class 5 cleanroom.
(f) A barrier isolator that provides an ISO class 5 environment for compounding.

_____

MOTION: That the Board of Pharmacy amend the language in the California Building Code, Title 24, California Code of Regulations, sections 490A.3 and 505.12 related to Compounding Parenteral Solutions; Technical Changes to the Building Code Relating to Pharmacies as follows:

M/S/C: FONG/SCHELL

SUPPORT: 9 OPPOSE: 0

REGULATION HEARING

Pharmacy Technician Checking Pharmacy Technicians in an Acute Care Hospital Pharmacy – Proposed Amendment to 16 CCR Sections 1793.7 and 1793.8.

President Goldenberg read the following instructions for the regulation hearing:
This hearing is to consider adopting requirements to allow the use of pharmacy technicians in hospital inpatient pharmacies to check other pharmacy technicians filling floor stock, ward stock and unit dose cassettes; proposed amendment to 16 CCR section 1793.7 and to add 16 CCR section 1793.8, as outlined in the public notice.

At this time, the hearing will be opened to take oral testimony and/or documentary evidence by any person interested in these regulations for the record which is now being made by tape recorder. All oral testimony and documentary evidence will be considered by the Board pursuant to the requirements of the Administrative Procedure Act before the Board formally

adopts the proposed amendment to these regulations or recommends changes which may evolve as a result of this hearing.

If any interested person desires to provide oral testimony there is a sign-up sheet in the back of the room. It will be appreciated if the person commenting comes forward and give his or her name and address, and if he or she represents an organization, the name of such organization, so that we will have a clear record of all those who appear.

Please keep in mind the following when making comments:

A. This is a public forum to receive comments on the proposed regulations. It is not intended to be a forum for debate or defense of the regulations.

B. Written testimony may be summarized but should not be read. The board will give equal consideration to written and oral testimony.

C. If you have a question about a proposed regulation, please re-phrase your question as a comment. For example, instead of asking what a particular subdivision means, you should state that the language is unclear, and explain why you find it to be unclear.

After all interested parties have been heard, the issue will stand submitted.

Are there any questions concerning the nature of the proceedings or the procedure to be followed here before we begin?

Testimony in Support

Peter Ambrose, University of San Francisco, School of Pharmacy

Dr. Ambrose stated that he is the primary investigator of the study to evaluate the accuracy of technicians and pharmacists in checking unit dose medication cassettes that was presented to the board earlier during this meeting. He offered the board his assistance in answering questions on the study during the regulation hearing and added that he is impressed with the nature of the data that demonstrates that pharmacists have a positive impact on improving medication safety.

Rita Shane, Director of Pharmacy Services, Cedars-Sinai Medical Center

Dr. Shane stated that during the last 13 years while in discussions with the Board of Pharmacy regarding this issue, she was struck by the evolution of professional awareness of the pharmacist's role in the area of patient safety. She added that the focus has been whether this is safe for patients in California and that every decision to change regulatory language weighs risk versus benefit.

Dr. Shane stated that during her participation with the board as part of the study, she observed the literature and the abundant data demonstrating the value of pharmacists. She added that she supports the regulation; not just for the patients that come to Cedars-Sinai Medical Center, but any acute care practice setting. Her concern is that without the regulation, they now have data demonstrating real harm to patients in California.

Dr. Shane stated that she is encouraged by ongoing initiatives to provide safety to every patient, regardless of where they access the health care system. She added that this study is one example and she hopes that the evidence and all of the information presented over the last 13 years is compelling enough. She stated that she continues to see the practice of pharmacy move forward in the state, focusing on patients.

Kelli Haase, Pharm.D., FCSHP

Dr. Haase referred to written testimony that was provided in the board packet. She stated that she is a clinical pharmacist at St Joseph's Medical Center in Stockton California. She added that she was asked to come and say a few words from a clinical pharmacist point of view of the type of activities that the pharmacist could be involved in if they weren't involved in checking cassette drawers that were filled by certified pharmacy technicians.

Dr. Haase stated that during the course of her day is in a decentralized service, or a service that the pharmacist offers outside the pharmacy, is to interact with the other medical professionals in the hospital and also with the patient. The time spent outside the pharmacy, allows her to look for drug-drug interactions and spend significant amounts of time with the patients and providing patient counseling.

Dr. Haase thanked the board for the opportunity to testify before the board.

Ann Rosenblack, Nursing Manager, Cedars-Sinai Medical Center

Ms. Rosenblack stated that the purpose of her testimony is to offer a clinical perspective of the amended changes from the nurses' point of view. Ms. Rosenblack added that this is her 35th year in the nursing profession and she has worked for the last eight years at Cedars-Siani Medical Center. She stated that the physical presence of the pharmacist on the floor assisting patients and nurses at the hospital is invaluable.

Ms. Rosenblack referred to the Institute of Medicine Report regarding the deaths that occur yearly at the hands of caregivers and the movement during the last few years for public awareness of safety.

Dr. Fong referred to Cedars-Sinai's training and commitment and asked how other hospitals can replicate this effort with the same assurances and achieve the same objective.

Ms. Rosenblack stated that the main focus of the study is safety because of the results from Institute of Medicine Study. She added that the study did not take a lot of money or extra people but it did focus on teaching pharmacy technicians and this can be replicated in any area.

John Cronin, representing the California Pharmacists Association

Mr. Cronin stated that the California Pharmacists Association supports this regulation and the proposed regulation is consistent with what the board should be doing and consistent with CPhA's policy as well.

Mr. Cronin stated that the board received approximately 38 comments in favor of the proposed regulation, primarily from pharmacists and this attests to the importance of the regulation.

Robert Mower, Pharmacist, UC David Medical Center, on behalf of the California Society of Health-System Pharmacists

Mr. Mower referred to the written testimony he provided to the board and he demonstrated a medication cassette and explained the process when a fill list is generated by a physician's order. The pharmacist then puts the information into the pharmacy information system and then prints a fill list. The fill list is taken by the pharmacy technician to pull the drugs and place them in a drawer. The pharmacist then checks the order to make sure it is accurate. He added that a technician can very easily verify that orders placed in the drawers are accurate. He added that he supports the proposed regulation and that it will help move the pharmacy practice forward and allow a pharmacist to be on the floor with the nurse and the physician, to assure that the correct medications are prescribed.

Darren Besoyan, Pharmacy Technician III UC Davis Medical Center, Representing the California Society of Health-System Pharmacists

Mr. Besoyan presented the following testimony:

> Good afternoon, My name is Darren Besoyan and I am currently a Supervising Pharmacy Technician at UC Davis Medical Center. I started my career over 19 years ago in the acute inpatient setting working closely with pharmacists in an Operating room satellite pharmacy. I also serve as a Student Pharmacy Technician Internship Coordinator.
>
> Technicians provide a vital role in facilitating quality patient care through their trained field of expertise. Technicians can, and should be used to a greater extent. When technicians perform technical medication filling and checking activities, pharmacists can then pursue duties in their field of expertise, medication management at the patient's bedside. Both the pharmacist and the technician along with physicians and

nurses are needed to ensure appropriate, safe and timely medications are provided to patients in the hospital. We, as technicians, are capable of so much concerning patient medication safety, especially when it comes to performing the repetitive, non-discretionary functions related to the practice of pharmacy. This proposed "tech-check-tech" regulation, will provide the infrastructure necessary to improve patient medication safety in an inpatient setting, by allowing properly trained technicians to function at their maximum and allowing pharmacists to utilize their medication expertise to provide direct medication management to patients. Thank you for taking the time to address this important consumer safety issue.

Jerry Gonzalez, Pharmacist registered in California for 25 years, representing CSHP and North Bay Health Care System

Dr. Gonzalez expressed concern about how we would replicate and assure that process control around the training and accountability for accuracy of pharmacy technicians. Mr. Gonzalez stated that at the last three hospitals where he practiced as director of pharmacy, that have implemented similar processes controls such as those practiced by Cedars-Sinai and Long Beach Memorial Hospital, to improve their performance of cart filling check by pharmacists. He added that he is confident that the CSHP can take the lead to provide a mechanism for education and program roll-out.

Opposing Testimony

Liberty Sanchez, from the Law Offices of Barry Broad, representing the United Food and Commercial Workers Union (UFCW)

Ms. Sanchez stated that the UFCW shares the concept that there is a problem, but they disagree with what the solution is. She added that the UFCW oppose the proposed regulations.

Ms. Sanchez stated that it is important for pharmacists to be available in all capacities, and in particular, in acute care facilities. She added that the appropriate solution to the problem is hiring more pharmacists, not doling out tasks that are appropriately within the statutory and regulatory confines of the pharmacist's profession to technicians.

Ms. Sanchez stated that the board's obligation is to ensure that patient and consumer protection is upheld. Any regulations that are adopted must not supersede or be contradictory to existing statutory law. She added that the proposed regulations are clearly contradictory to existing statutory and regulatory law.

Ms. Sanchez referred to the UFCW's written comments submitted on April 17 and the board minutes from the January 2001, October 2001 and October 24 and 25, 2002 meetings that include an opinion from former Deputy Attorney General William Marcus, that the board did not have the authority to promulgate regulations. Further, page 5 of the October 2002 board

minutes, states: "the board decided that the proposed changes would require legislation." She added that legislation proposed by Senator Aanasted in 2003 and 2005 (SB 393 and SB 592) failed passage in the Legislature. She added that now, four years after the board determined that it did not have the authority to promulgate regulations, that it before the board again. She stated the UFCW respectfully contends that the board does not have the authority to promulgate these specific regulations.

She stated that contrary to proponents' contention that the proposed regulation will promote patient safety in the acute care setting based on the idea that there will be additional training provided to pharmacy technicians who check the work of other pharmacy technicians. Due to a lack of specificity in the proposed regulations about what the advanced training and education is, particularly when you compare that to the truly advanced training and education that pharmacists have, there is no assurety that patient safety will be promoted by allowing pharmacy technicians to undertake this task. She expressed concern that if the proposed regulations pass, there would be additional requests in the future to expand the duties of technicians.

Ms. Sanchez stated that the underlying published study is not sufficient to make such a sweeping change in California. She added that the underlying published study in 1998 observed only 39 pharmacy technicians, 29 pharmacists and approximately 190,000 doses of medication. There was only a distinction of 0.3 accuracy rate of the pharmacist and the pharmacy technicians were above 99 percent. Ms. Sanchez added that the only rationale for the regulation is to reduce costs by reducing the need to have multiple pharmacists in the acute care setting.

Ms. Sanchez stated that liability issues are also a concern for both the pharmacist and the nurse who administers medication to a patient since nurses will be the final person to handle the medication. She added that they are strongly opposed to adoption of these proposed regulations.

Martha Mason, Pharmacist, San Quentin State Prison

Ms. Mason stated that the prison has 5000-6000 patients. She expressed concern about technicians checking other technicians because technicians have made errors. She added patients in the prison system are a captive audience and sometimes may not be aware that they were administered the wrong prescription. She expressed concern that there would be more complaints about lack of care if the regulation is approved and she added that mistakes are very common.

There being no further comments, President Goldenberg closed the regulation hearing.

The board discussed the regulation.

MOTION: The Board of Pharmacy adopt the proposed amendments to Title 16, California Code of Regulations, Sections 1793.7 and 1793.8 as follows:

Amend Section 1793.7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1793.7 Requirements for Pharmacies Employing Pharmacy Technicians.

(a) Except as otherwise provided in section 1793.8, any ~~Any~~ function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, the pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient.
(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.
(c) A pharmacy technician must wear identification clearly identifying him or her as a pharmacy technician.
(d) Any pharmacy employing or using a pharmacy technician shall develop a job description and written policies and procedures adequate to ensure compliance with the provisions of Article 11 of this Chapter, and shall maintain, for at least three years from the time of making, records adequate to establish compliance with these sections and written policies and procedures.
(e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.
(f) For the preparation of a prescription for an inpatient of a licensed health facility and for a patient of a licensed home health agency, the ratio shall not be less than one pharmacist on duty for a total of two pharmacy technicians on duty. Pursuant to Business and Professions Code section 4115(g)(1), this ratio shall not apply to the preparation of a prescription for an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

Note: Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.
Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

Adopt Section 1793.8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1793.8 Technicians in Hospitals with Clinical Pharmacy Programs.

(a) A general acute care hospital, as defined in Health and Safety Code 1250 (a), that has an ongoing clinical pharmacy program may allow pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed and approved by a licensed pharmacist. Only inpatient hospital pharmacies as defined in 4029(a) that maintain a clinical pharmacy services program as described in 4052 may have a technician checking technician program as described. The pharmacy shall have on file a description of the clinical pharmacy program prior to initiating a technician checking technician program.

(1) This section shall only apply to acute care inpatient hospital pharmacy settings.

(2) Hospital pharmacies that have a technician checking technician program shall deploy pharmacists to the inpatient care setting to provide clinical services.

(b) Compounded or repackaged products must have been previously checked by a pharmacist and then may be used by the technician to fill unit dose distribution systems, and floor and ward stock.

(c) To ensure quality patient care and reduce medication errors, programs that use pharmacy technicians to check the work of other pharmacy technicians pursuant to this section must include the following components:

(1) The overall operation of the program shall be the responsibility of the pharmacist-in-charge.

(2) The program shall be under the direct supervision of a pharmacist and the parameters for the direct supervision shall be specified in the facility's policies and procedures.

(3) The pharmacy technician who performs the checking function has received specialized and advanced training as prescribed in the policies and procedures of the facility.

(4) To ensure quality there shall be ongoing evaluation of programs that use pharmacy technicians to check the work of other pharmacy technicians.

Note: Authority cited: Sections 4005, 4007, 4038, 4115, and 4202, Business and Professions Code.
Reference cited: Sections 4007, 4038, 4115 and 4202, Business and Professions Code.

M/S/C: SCHELL/HIURA

SUPPORT: 7 OPPOSE: 2

Legislation Report and Action

Board Sponsored Legislation

- **AB 595 (Negrete McLeod) Pharmacy: Compounding of Prescription Drugs**.

  Chairperson Jones stated that this bill is sponsored by the board to establish standards for pharmacies that compound drugs. The board approved this legislative proposal at its January 2005 meeting and the bill is now on the Senate Floor.

- **AB 2408 (Negrete McLeod) Pharmacists, Pharmacies, and Nonresident Pharmacies.**

  Chairperson Jones stated that this bill is sponsored by the board and would update the definition of a pharmacy, nonresident pharmacy, and the professional practice of pharmacy. The board approved draft legislation at its February 2006 meeting. This bill is currently before the Assembly Appropriations Committee.

  Steve Gray, representing Kaiser Permanente, had a number of questions regarding this bill at the committee meeting. One item the committee directed for board discussion at this meeting is whether the policy outlined in AB 2408 conforms to board recommendations adopted at the January Board Meeting regarding the Licensing Committee's recommendations for regulating pharmacists who provide services to Californians from outside California.

  In section 4051(c), if a pharmacist outside California provides cognitive services to Californians in this state, the pharmacist either needs to be licensed as a pharmacist in California, or work/be associated with a nonresident pharmacy that is licensed in California.

  Mr. Room stated that this language is consistent with how other professions regulate licensees and how the dispensing function is handled under current law.

  Dr. Gray expressed concern that it would be illegal if a specialty pharmacist called a consulting pharmacist in another state for an opinion.

  Mr. Room stated that only direct-to-patient services would require a license.

Mr. Gray also expressed concern that the statute would allow medical records to be reviewed by any authorized officer of the law without a search warrant, a subpoena or the patient's permission. He suggested a revision to the language to make a distinction between records related to drug dispensing and records that are kept by a pharmacist that are related to the management of drug therapy.

Mr. Room stated that he felt the distinction is already in statute in that the law makes dispensing and acquisition to disposition records accessible and only open for inspection by the board.

The board determined that technical changes to the bill would be addressed and directed staff to proceed.

- **SB 1475 (Senate Business and Professions and Economic Development Committee) Omnibus Bill.**

Chairperson Jones stated that the board approved eight proposals for the omnibus legislation, however only three of the eight proposals are currently in the bill. A hearing on this bill was held in the Senate Business and Professions and Economic Development Committee on April 24. Board staff will work to ensure the inclusion of these remaining provisions by the Senate Business and Professions Committee.

Approved Proposals in SB 1475

B&P 4104 Licensed Employee, Theft, Impairment: Pharmacy Procedures.
B&P 4162 Wholesalers Surety Bond Requirements.
B&P 4180-4182 and 4190-4192 Nonprofit or Free Clinics.

Approved Proposals NOT in SB 1475

B&P 4314 & 4315 Cite and Fine, Letter of Admonishment.
B&P 4084 Adulterated or Counterfeit Drug or Dangerous Device.
B&P 4160 Wholesaler License.
B&P 4127.1 Injectable Sterile Drug Products.
B&P 4073 Substitution of Generic Drug, Check off Box on Electronic Prescriptions.

Chairperson Jones that the board received a request from MedImmune, Inc. to amend Business and Professions Code section 4162.5(a)(4) related to surety bond requirements. On March 21, 2006 the board received a letter from Colleen Chawla, Government Affairs Manager for MedImmune, Inc.. MedImmune Inc., requesting that the board sponsor legislation for an amendment. Chairperson Jones stated that this is a technical change.

Mr. Room stated that anyone with a new drug application is exempted from wholesaler licensure requirements for that particular drug as long as it is the only drug they are selling.

For biologics there is a separate process for drug approval with the FDA although it is similar to a new drug application.

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy approve the request from MedImmune, Inc. to amend Business and Professions Code section 4162.5(a)(4) related to surety bond requirements as follows:

4162.5 (a) (1) An applicant for the issuance or renewal of a nonresident wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000), or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3

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

(3) For applicants who satisfy paragraph (2), the board may require a bond up to one hundred thousand dollars ($100,000) for any nonresident wholesaler who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(4) A person to whom an approved new drug application <u>or a biologics license application</u> has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application <u>or a biologics license application,</u> and is licensed or applies for licensure as a nonresident wholesaler, shall not be required to post a surety bond as provided in this section.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

(d) This section shall become operative on January 1, 2006, and shall become inoperative and is repealed on, January 1, 2011,

unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends those dates.

SUPPORT: 9 OPPOSE: 0

- **SB 1476 (Figueroa) Board Sunset Extension Bill.**

Chairperson Jones stated that this bill would extend the board's sunset date two years, from 2008 to 2010. The board's sunset report to the Legislature would be similarly delayed until September 2008. Additionally, the measure would move the implementation date of the electronic pedigree requirement from January 1, 2007 to January 1, 2008. He added that SB 1476 was heard on April 24 in the Senate Business and Economic Development Committee.

The board expressed concern about supporting a delay in implementation of the pedigree requirement. However, after discussion, the board agreed to support this provision.

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy write a letter of support of SB 1476 (Figueroa), expressing appreciation to the author for her long standing consumer protection efforts and conveying the board's reservation in delaying the implementation date of the electronic pedigree because of its public health impact while recognizing that the industry is moving forward.

SUPPORT: 9 OPPOSE 0

2006 Bills of Interest

- **AB 2308 (Plesca) Ambulatory Surgical Centers**

Chairperson Jones stated that this bill requires the Department of Health Services (DHS) to convene a workgroup to develop licensure criteria to protect patients receiving care in ambulatory surgical centers, and to submit workgroup conclusions and recommendations to the appropriate policy committees of the Legislature no later than March 1, 2007, and revises existing law to replace the term "licensed surgical clinic" with "ambulatory surgical centers."

Ms. Harris stated that a licensed surgical center or clinic must be licensed as a clinic with the Board of Pharmacy to co-mingle drugs. This bill expands the surgical clinic to a surgical center and includes licensed Medicare certified facilities and expands the number of facilities that require licensure with the Board of Pharmacy.

A comment made from the bill sponsors at the California Ambulatory Surgery Association was that the bill attempts to change the definition of a surgical clinic under California Code of Regulations section 1204, to ambulatory surgical centers to make it consistent with federal

law and makes various conforming changes to the language. An ambulatory surgery center would have to be licensed to purchase drugs at wholesale for physicians to distribute.

- **AB 2583 (Nation) – Dispensing Prescription Drugs and Devices: Refusal to Dispense**

  Chairperson Jones stated that AB 2583 requires the Board of Pharmacy to create and provide all licentiates a notice that must be posted by licentiates that inform patients of their right to timely access to prescribed drugs and devices even if licentiate refuses to dispense the drug or device based on ethical, moral, or religious grounds. The board is not the regulator of all these licentiates. Moreover, if licentiates comply with legal requirements for these with moral, ethical or religious grounds there must be procedures to ensure patients get their drugs on time regardless.

  MOTION: Legislation and Regulation Committee: That the Board of Pharmacy oppose AB 2583 (Nation), unless amended.

  SUPPORT: 9 OPPOSE: 0

- **AB 2743 (Matthews) Pharmacists: Ancillary Personnel.**

  Chairperson Jones stated that AB 2743 would limit the number of ancillary personnel in a pharmacy to eight and defines ancillary personnel as pharmacy technicians, pharmacy technician trainees, interns, clerks and typists. The intent is to increase the amount of pharmacy technicians in a pharmacy. A hearing was scheduled on April 25 in the Assembly Business and Professions Committee.

  John Cronin, representing the California Pharmacists Association, stated that CPhA is trying to establish a task force with the CSHP, the UFCW and the CRA, to address the entire issue of ancillary personnel. This bill will not be moved.

- **AB 2986 (Mullin) Controlled Substances: Prescription Requirements.**

  Chairperson Jones stated that AB 2986 would require that Schedule IV drugs be added to CURES, along with additional data fields for everything Schedule II-IV drugs dispensed in California.

  Steve Gray, representing Kaiser Permanente, stated that this bill is intended for California to receive available federal funds to enhance the CURES system. He added that it adds a tremendous financial burden on all pharmacies and prescribers and will increase the costs of the CURES system. The Department of Justice is the sponsor of this bill.

- **SB 1366 (Aanestad) Controlled substances.**

Chairperson Jones stated that this bill proposes to eliminate security printers and security forms for prescribing controlled drugs and would rely on the CURES program for monitoring the prescriber and dispensing of controlled drugs.

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

  Chairperson Jones stated that the California Legislature would memorialize the Congress and President of the United States to enact H.R. No. 3861, "The Medicare Informed Choice Act of 2005" to amend the Medicare Part D Drug Program requirements for the nation's disabled and seniors. A letter will be sent to the author's office.

Other 2006 Bills the Committee will Watch

AB 1908 (Karnette) Medi-Cal: Pharmacy Reimbursement.

AB 2057 (Cogdill) Controlled Substances.

AB 2373 (Plescia) Automated Drug Delivery Systems.

AB 2730 (Nation) Medi-Cal: Contract Drug List: Advertising.

AB 2856 (Hancock) Informed Consent: Prescription Medication Off-Label Use.

AB 2877 (Frommer) Prescription Drugs: Importation: Procurement.

AB 2911 (Nunez) California Discount Prescription Drug Program.

ELECTION OF OFFICERS

Treasurer

MOTION: Elect Ruth Conroy as treasurer of the Board of Pharmacy.

M/S/C: JONES/SCHELL

SUPPORT 9 OPPOSE: 0

Vice President

MOTION: Elect Ken Schell as vice president of the Board of Pharmacy.

M/S/C: POWERS/CONROY

SUPPORT: 9 OPPOSE: 0

President

MOTION: Elect Bill Powers as President of the Board of Pharmacy.

M/S/C: ZINDER/JONES

SUPPORT: 8 OPPOSE: 0

Mr. Powers stated that Stan Goldenberg has served as president of the Board of Pharmacy for two years and during this time he has served extraordinarily well for the public and the board; providing initiative and leadership in a variety of areas that are remarkable. Mr. Powers added that President Goldenberg will be a difficult role model to follow and he acknowledged President Goldenberg's many accomplishments.

Mr. Jones also commended President Goldenberg for his commitment as board president and noted that he gave 100 percent.

President Goldenberg stated that it is a true honor to serve on the Board of Pharmacy and he commended staff and board members for setting a level of professionalism, possessing a commitment to serving the public as well as showing a passion for the profession of pharmacy.

NEW BUSINESS/AGENDA ITEMS FOR FUTURE MEETINGS

John Cronin, representing the California Pharmacists Association, asked how lack of a quorum would affect committee meetings.

Ms. Harris stated that the board would continue with the committee meetings, however, some committees may have fewer members.

She added that President Powers would announce his appointments to the new committee assignments at the July Board Meeting.

CLOSED SESSION

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

ADJOURMENT

There being no further business, President Goldenberg adjourned the board meeting at 5:15 p.m.

Thursday, April 27, 2006

STRATEGIC PLANNING 2006-2011

Lindle Hatton, PhD, lead the board in the strategic planning process that began at 8:00 a.m. This session ended at noon.

PETITIONS

- **Petition for Reinstatements**
  Kirk Bolas
  Dr. Tracey Moore

- **Early Termination and Reduction of Penalty**
  Morris Stavnezer

CLOSED SESSION

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