State of California | Department of Consumer Affairs

Memorandum

To: **Board Members** **Date: January 25, 2006**

From: **Organizational Development Committee**

Subject: **Committee Actions and Update of the Meeting of January 17, 2006**

The Organizational Development Committee met in a nonpublic meeting on January 17, 2006. A meeting summary is provided at the back of this tab section as Attachment 1.

ITEM 1. Recognition of Those Who Provided Disaster Response to Victims of the Gulf Coast Storms:

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

The board has since received no additional information to recognize others who provided disaster relief.

Michael Sohmer, PharmD, was one of the individuals publicly recognized at the board's October meeting for his aid to the region. Dr. Sohmer brought to that meeting a video montage about his experiences. However, the board was unable to provide this presentation at the October meeting.

Instead, at this meeting, the board will start the meeting by showing the video prepared during the early days of Katrina relief at the New Orleans Airport. Dr. Sohmer has coupled the pictures with music, and the video is worth viewing.

ITEM 2. Recognition of Pharmacists Who Have Been Licensed for 50 Years:

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

To acknowledge those with 50 years of service, the board mails a congratulatory letter and award certificate to each pharmacist. The letter also invites the

pharmacist to a future board meeting. Additionally, each pharmacist has his or her name published in an ongoing feature in *The Script* to acknowledge those who have achieved this milestone. Acknowledging these pharmacists is a regular component of each board meeting.

ITEM 3. Strategic Plan Update 2006-2011 Will Be Initiated in April 2006:

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

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

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

In addition to the role of board members in revising the plan, all staff will also be involved in the update of the plan before it is submitted for board participation and action in April. Stakeholders will also be given an opportunity for comment in late March via an announcement on the board's Web site and via a subscriber alert.

ITEM 4. NABP National Meeting in San Francisco in April 2006, and Districts VII and VIII Meeting in Anaheim in October 2006:

This year, two of the National Association of Boards of Pharmacy major meetings will occur in California:

- California April 2006: The NABP annual meeting will take place in San Francisco.
- October 2006: The NABP Districts VII and VIII meeting will be in Anaheim. Again the board will have some "hosting" opportunities.

The NABP annual meeting will be held in San Francisco on April 8-11 at the Westin St. Francis Hotel. This February Board Meeting is the only board meeting before this convention.

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

1. Staff the "Hospitality Suite" on April 8 (Saturday) from 1-5 p.m. Whereas the NABP will provide refreshments for this suite, it does suggest that California board members or staff plan to greet those from other states who will attend the meeting. Three or more individuals are suggested for this function.

2. Staff a "State Information Table" that is open during registration hours, continental breakfasts and refreshment breaks from April 9 (Sunday) through 11 (Tuesday). At this table, brochures about interesting sights, restaurants and attractions in the host city are featured. The NABP encourages that those who staff this table be knowledgeable about sites of interest, particularly on April 9 and 10 when attendees are looking for local "hot spot" attractions. The board's staff will seek brochures from the Visitors/Convention Bureau distribute.
3. The president of the board will open the first business session on April 9 (Sunday) with "words of welcome" before introducing a city or state dignitary.

FOR ACTION:

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

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

If approved by the board, this policy will be added to the *Board Member Procedure Manual.*

ITEM 5. Proposal to Award 2 Hours of Continuing Education for Attending a Committee Meeting:

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

Since January 2005, the board has also allowed pharmacy technicians to earn 6 hours of CE for attending one board meeting per year. (Pharmacy technicians who are certified by the Pharmacy Technician Certification Board must earn 20 hours of CE every two years, one hour of which must be in pharmacy law.)

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

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

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

ITEM 6. Report on the California Pharmacy Council:

The California Pharmacy Council has been formed, comprised of the deans of the schools of pharmacy, California pharmacist associations and the board.

At the January 2006 meeting, the committee reviewed the council's proposed charter and administrative regulations for its activities.

The committee had no comments or recommendations.

Attachment A contains the draft charter.

ITEM 7. Sunset Review:

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

ITEM 8. Budget Report:

I. Budget Report for 2005/06

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

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

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

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

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

II. Governor's Budget for 2006/07

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

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

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

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

  Expenditures for next year are $240,000 more than those projected for this fiscal year. This increase includes:
  -- Restoration of 2.5 of the 10 positions the board lost during the budget restrictions of the early 2000's. ($208,000)
  -- An increase of $91,000 to cover increased hourly fees that will be charged by the Office of the Attorney General for legal fees (the hourly rate will be $158, up from $112 (or $120 for the LA Office) in 2003)
  Also:
  -- A $72,000 reduction in workers' compensation insurance fees, which skyrocketed in the last few years
  -- A $96,000 reduction in facilities expenses due to the board's new office location
  -- A $92,000 reduction in pro rata expenses to the Department of Consumer Affairs (essentially due to lower Office of Information Services charges)
  note: for brevity, not all budget adjustments are listed above

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

III. Board Fund Condition

The board's fund condition is a snapshot of our "solvency," in this case meaning whether our revenue collected is sufficient to sustain our expenditures. Over the last few years, the board's annual expenditures have exceeded its annual collected

revenue. Normally this would be a huge problem that would trigger budget cutbacks or fee increases, but the board has had a surplus of money in its fund (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 over the next few years are:

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

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

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

This data is presented in Attachment B.

IV Board Member Expenditures and Reimbursements

The travel expenses and compensation of board members claimed thus far for 2005/06 will be distributed at the February Board Meeting.

ITEM 9. CURES Data Requested for Study Aimed at Limiting Drug Abuse without Limiting Appropriate Medical Treatment

Scott Fishman, MD, chief of the Division of Pain Medicine at the UCD Med Center has notified the board that the Robert Wood Johnson Abuse Policy Research Program has invited Dr. Fishman to seek funding to study CURES data. The goal

is to develop policies that limit drug abuse without limiting appropriate medical treatment.

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

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

A copy of Dr. Fishman's proposal is provided in Attachment C.

ITEM 10. 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.

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 agencies that may be able to offer this service in the future. No costs are yet available for this conversion, and it may be at least one year from implementation at the board.

ITEM 11. Relocation of the Department of Consumer Affairs and Board of Pharmacy:

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

Perhaps by the end of January, the board will be able to hold meetings within the building. Currently the Holiday Inn has been the location of most of the board's public meetings, although the Northern Office Conferences were held in the board's suite in mid-January. We hope to be able to hold the April 2006 meeting in our new building.

All forms containing the board's old address and/or phone numbers have been modified. New business cards have been ordered for staff and board members. The board's Web page highlights how to reach us. Our new location is also the cover story on the board's January 2006 *The Script.*

The new computer-based telephone system is not functioning optimally for the board's callers. A major problem is that the new system relies upon individual

phone numbers, and not extension numbers as the board used in its former location. Obtaining the individual phone numbers of the desired staff person requires the caller to listen to a lengthy phone tree message – the system does not allow the entering of a "0" to reach a live operator until the very end of the phone tree message. Board managers are in the process of revamping the system to improve our service.

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

ITEM 12: Personnel Update and Report

In November, the board lost two key staff to other agencies.

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

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

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

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

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

Specialized Training:

- There was a three-day inspector workshop held in November. All inspectors attended and were pleased with the training.
- All board managers and board members completed sexual harassment (prevention) training by January 1, 2006, as required.

Nomination of Bill Powers to SCR 49 Medication Errors Panel

Last year, SCR 49 (Speier) was enacted to recommend improvements, additions or changes to recommend ways to reduce errors in the delivery of prescription and

over-the-counter medication. The resolution required a meeting by October 1, 2005, a draft report by March 1, 2006 and a final report by June 1, 2006.

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

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

Attachment A

California Pharmacy Council Proposed Charter and Regulations

PROPOSED CHARTER AND ADMINISTRATIVE REGULATIONS:

CALIFORNIA PHARMACY COUNCIL

~~September~~ November, 2005

Prepared by Robert Day (UCSF), Katherine Knapp (Touro University), and Max Ray (Western University) w/proposed edits by Council on 11/14/05.

Charter

The California Pharmacy Council is hereby created for the purpose of providing a forum on matters of common interest and concern to its active members. Those members include the following organizations each represented by a member(s) of its respective leadership: California Pharmacists Association, California Society of Health-System Pharmacists, California State Board of Pharmacy, Loma Linda University ~~College~~ School of Pharmacy, Pharmacy Foundation of California, Touro University California College of Pharmacy, UC-San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences, UC-San Francisco School of Pharmacy, University of the Pacific ~~College~~ School of Pharmacy and Health Sciences, University of Southern California School of Pharmacy, and Western University of Health Sciences College of Pharmacy.

The Council facilitates discussion on representative views of its active members on professional, educational, legislative and regulatory issues through analysis, interpretation and exchanges of views on relevant issues. The Council's discussions are conducted for the mutual education and edification of its members. The Council has no intrinsic authority to speak for its members.

The Council, through the discussion forums it conducts, strives to identify areas of agreement among its members that may be helpful in creating a shared vision for pharmacy practice and education in California. The Council may, from time to time and upon unanimous agreement of its active members, take a position for external distribution or undertake collaborative efforts in support of a common purpose.

Administrative Regulations

1. The Council will meet at least twice a year.

2. Members will be responsible for their own expenses.

3. No dues or membership fees will be assessed.

~~4. Each member will host the Council's meetings on a rotating basis. The host will be responsible for providing a meeting room and food and refreshments, but will not be responsible for any other costs.~~

~~5~~4. Members will be represented on the Council by the following individuals:

California Pharmacists Association: ~~Executive Vice President and current President~~ Chief Executive Officer and a Presidential Officer.
California Society of Health-System Pharmacists: Executive Vice President and ~~current~~ a Presidential Officer.
California State Board of Pharmacy: Executive Officer and ~~current~~ a Presidential Officer
Loma Linda University ~~College~~ School of Pharmacy: Dean
Pharmacy Foundation of California: ~~Executive Vice President and current President~~ Executive Director and a Presidential Officer
Touro University California College of Pharmacy: Dean
UC-San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences: Dean
UC-San Francisco School of Pharmacy: Dean
University of the Pacific School of Pharmacy and Health Sciences: Dean
University of Southern California School of Pharmacy: Dean
Western University of Health Sciences College of Pharmacy: Dean

~~6~~5. Each member ~~must~~ organization acknowledges the importance of the Council and is expected to be represented at each meeting. ~~In cases where a member has two eligible representatives, at least one of those representatives must attend each meeting.~~ In the cases of the schools and colleges of pharmacy, a dean may ~~occasionally~~ designate an associate or assistant dean to represent ~~him or her, but this should not be a regular practice~~ the school.

~~7. Only those organizations identified in the Charter may serve as active members. Only those representatives of active members (as identified in Rule 5 above) may sit at the table during Council meetings. Any other attendees invited to the meeting must sit in peripheral areas.~~

~~8. New active members may be approved by unanimous consent of the charter members.~~

~~9~~6. The Council may ~~authorize~~ invite other organizations to attend Council meetings in the capacity of observers.

~~10. The Council will not take binding votes on any issue, other than to amend the Charter or Administrative Regulations, since to do so would imply that it has authority to speak for its members.~~

~~11. Members' representatives will each serve as Chair on a rotating basis. A Chair for the Council's next meeting will be selected at each meeting.~~

~~12. The role of the Chair will be to facilitate discussion, and not to use the position as a platform for the particular member organization he or she represents.~~

~~13~~7. The Pharmacy Foundation of California, in addition to serving as an active member, will serve as the permanent Secretariat for the Council. The role of the Secretariat will be to convene and facilitate ~~assist the Chairs in planning for~~ Council meetings, to assist Council members in planning and developing meeting agendas, to select venues and handle meeting arrangements attempting to alternate meeting locations between north and south, to ensure appropriate communications with members between meetings, and to maintain permanent records of Council meetings.

~~14~~8. Upon thirty (30) days advance notice to the members, t~~T~~he Charter and/or the Administrative Regulations may be amended by ~~majority vote of the representatives~~ a two-thirds vote of ~~current active~~ members present and voting. All other votes of the Council shall also be by two-thirds vote of members present and voting. Each member shall have one vote.

9. Any statement of policy for external distribution shall require the unanimous agreement of all members.

Ratified by:

_____ _____
Signature Date

_____
Organization

_____ _____
Signature Date

_____
Organization

Etc.

Attachment B

Board of Pharmacy Fund Condition

0767 - State Board of Pharmacy
Analysis of Fund Condition

(Dollars in Thousands)

NOTE: $3.0 M GF Repayment Outstanding ($3.0M of orig $6.0M scheduled to be repaid in FY 2005-06)

Galley 2 Final (12-12-05)

	ACTUAL 2004-05	2005-06	2006-07	loan repay needed 2007-08	loan repay needed 2008-09	2009-10
BEGINNING BALANCE	$ 4,874	$ 4,111	$ 4,834	$ 1,990	$ 1,475	$ (1,236)
Prior Year Adjustment	$ 87	$ -	$ -	$ -	$ -	$ -
Adjusted Beginning Balance	$ 4,961	$ 4,111	$ 4,834	$ 1,990	$ 1,475	$ (1,236)
REVENUES AND TRANSFERS						
Revenues:						
125600 Other regulatory fees (REVISED)	$ 422	$ 38	$ 38	$ 38	$ 38	$ 38
125700 Other regulatory licenses and permits	$ 1,427	$ 1,258	$ 1,243	$ 1,291	$ 1,291	$ 1,291
125800 Renewal fees	$ 4,452	$ 4,006	$ 3,977	$ 3,928	$ 3,928	$ 3,928
125900 Delinquent fees	$ 81	$ 58	$ 58	$ 58	$ 58	$ 58
131700 Misc. revenue from local agencies	$ 8	$ -	$ -	$ -	$ -	$ -
141200 Sales of documents	$ -	$ -	$ -	$ -	$ -	$ -
142500 Miscellaneous services to the public	$ -	$ -	$ -	$ -	$ -	$ -
150300 Income from surplus money investments	$ 111	$ 90	$ 40	$ 29	$ -	$ -
150500 Interest Income From Interfund Loans	$ -	$ 227	$ -	$ -	$ -	$ -
160400 Sale of fixed assets	$ -	$ -	$ -	$ -	$ -	$ -
161000 Escheat of unclaimed checks and warrants	$ 4	$ -	$ -	$ -	$ -	$ -
161400 Miscellaneous revenues	$ 5	$ -	$ -	$ -	$ -	$ -
Totals, Revenues	$ 6,510	$ 5,677	$ 5,356	$ 5,344	$ 5,315	$ 5,315
Transfers from Other Funds						
F00001 GF loan per Item 1490-011-0767, BA of 2002	$ -	$ 3,000	$ -	$ 2,500	$ 500	$ -
F00683 Teale Data Center (CS 15.00, Bud Act of 2005)	$ 8					
Transfers to Other Funds						
T00001 GF loan per Item 1490-011-0767, BA of 2002	$ -	$ -	$ -	$ -	$ -	$ -
Totals, Revenues and Transfers	$ 6,518	$ 8,677	$ 5,356	$ 7,844	$ 5,815	$ 5,315
Totals, Resources	$ 11,479	$ 12,788	$ 10,190	$ 9,834	$ 7,290	$ 4,079
EXPENDITURES						
Disbursements:						
0840 State Controller (State Operations)	$ -	$ -	$ 5	$ -	$ -	$ -
1110 Program Expenditures (State Operations) - Galley 2	$ 7,368	$ 7,954	$ 8,195	$ 8,359	$ 8,526	$ 8,697
9670 Equity Claims / Board of Control (State Operations)	$ -	$ -	$ -	$ -	$ -	$ -
Total Disbursements	$ 7,368	$ 7,954	$ 8,200	$ 8,359	$ 8,526	$ 8,697
FUND BALANCE						
Reserve for economic uncertainties	$ 4,111	$ 4,834	$ 1,990	$ 1,475	$ (1,236)	$ (4,618)
Months in Reserve	6.2	7.1	2.9	2.1	-1.7	-6.4

NOTES:

A. ASSUMES WORKLOAD AND REVENUE PROJECTIONS ARE REALIZED

B. EXPENDITURE GROWTH PROJECTED AT 2% BEGINNING FY 2006-07

Attachment C

UCD Medical Center's Request to Study CURES Data

UNIVERSITY OF CALIFORNIA, DAVIS

BERKELEY • DAVIS • IRVINE • LOS ANGELES • RIVERSIDE • SAN DIEGO • SAN FRANCISCO

SANTA BARBARA • SANTA CRUZ

ANALGESIC RESEARCH PROGRAM

DIVISION OF PAIN MEDICINE
DEPARTMENT OF ANESTHESIOLOGY
& PAIN MEDICINE

ELLISON AMBULATORY CARE CENTER

4860 Y STREET, SUITE 3020
Sacramento, California 95817
Phone: (916) 734-6824 Fax: (916) 734-6827

Scott Fishman MD
Chief, Division of Pain Medicine

Barth Wilsey MD
Director, Analgesic Research and Director, Acute Pain Service

Paul Kreis MD
Medical Director

Gagan Mahajan MD
Assistant Professor

Aida Phelan MD
Assistant Professor

Donna Kalauokalani MD
Assistant Professor

John Eisele MD
Professor Emeritus

Jeanna Millman, BS
Post Graduate Research Associate

Carlos Casamalhuapa BS
Post Graduate Research Associate

January 3, 2006

Patricia Harris
Chief of Enforcement
California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

RE: Robert Wood Johnson Substance Abuse Policy Research Program

Dear Ms. Harris,

The above funding agency has invited our group to submit an application for a research grant to examine CURES data. The information obtained from this project will be offered to policy makers and health care professionals in other states who are struggling to develop policies that limit drug abuse without limiting appropriate medical treatment. We propose to examine the impact of the recent change from triplicates to California's new electronic monitoring/security paper prescription program and hold this out as a model to other states when considering the adoption of similar legislation. These research findings will be timely considering the federal government's current promotion of Prescription Monitoring Practices in response to recent increases in diversion of prescription medications.

I have discussed this project with Alberto Gonzalez who suggested that I contact you and other stakeholders in an attempt to convene a meeting. We wish to learn of your appraisal of how best to evaluate the CURES data. Our goal is to objectively obtain evidence that physician practices have adjusted successfully to the new Prescription Monitoring Program/security paper. We will do this by (1) entering CURES data into a statistical database, (2) enter the policies adopted in 1996 (Electronic Data Transfer + triplicate prescription form for Schedule II medications) and 2003 (Electronic Data Transfer + forgery-resistant prescription form for all scheduled medications) as the primary intervention variables, (3) conduct statistical model-building and related data analysis (i.e., results of surveys of hundreds of randomly selected physicians across the state), and (4) interpret significant explanatory coefficients.

Would it be possible for you to attend a meeting at 9am on Monday, January 9th to discuss the above grant proposal? We will hold the meeting in my office at the UC Davis Medical Center at the above address.

Sincerely Yours,

Scott M. Fishman, MD
Chief, Division of Pain Medicine
University of California, Davis Medical Center
4860 Y Street, Suite 3020
Sacramento, Ca 95817
Office: (916) 734-6824

Enclosures:
Robert Wood Johnson Foundation Invitation Letter for Full Grant Proposal

SUBSTANCE ABUSE
POLICY RESEARCH
PROGRAM

Substance Abuse Policy Research Program
Center for Creative Leadership
One Leadership Place
Post Office Box 26300
Greensboro, NC 27438-6300
Telephone: 336-286-4548
Facsimile: 336-286-4434
www.saprp.org

November 21, 2005

Dr. Scott Fishman
UC Davis Medical Center
Anesthesiology and Pain Medicine
4860 Y Street
Suite 3020
Sacramento, CA 95817

RE: Impact of Drug Control Policy on Pain Treatment in California: Are Physicians Unwilling to Prescribe Needed Medications? (T00830)

Dear Dr. Fishman:

Thank you for submitting a brief proposal to the Robert Wood Johnson Foundation *Substance Abuse Policy Research Program*. The Program staff has now had an opportunity to complete its review of proposals submitted for consideration in the Round X Special Solicitation for Projects Requesting $100,000 to $400,000. Based on the favorable assessment of your proposal, I am pleased to invite you to submit a full grant proposal for review.

In Rounds I through X and Special Solicitations I, II, and III we have received 3,307 brief proposals (both over and under $100,000), solicited 917 full grant proposals, and funded 284 grants to date. Please see our Web site (www.saprp.org) for more information on the program and its funded studies.

By now you are familiar with the Grantmaking Online system. To submit your full proposal, log in to the system as you have in the past, and you now will be able to access the full proposal stage to complete your application. We encourage you to think very carefully about the budget for your project because proposal reviews will take account of the costs, as well as benefits, of each project. For reference, we are enclosing copies of key guidelines from the online system. Complete guidelines—including instructions for updated features such as a new biographical sketch template and the electronic submission of appendices and supporting documents—are found in the online system.

We look forward to receiving your completed application. The deadline for submission of your completed application is **3:00 PM EST, February 16, 2006.** We will only accept proposals submitted by the deadline. Please note that this is a later due date than the original deadline listed in our Round X Call for Proposals. If you have any questions, please contact Andrea Williams, *SAPRP* Deputy Director, at 336-286-4414 or williamsa@leaders.ccl.org. Again, we appreciate your interest in the *Substance Abuse Policy Research Program*.

Sincerely,

David G. Altman, Ph.D.
Director, *Substance Abuse Policy Research Program*

Enclosures

Attachment 1

Summary of the Organizational Development Meeting
January 17, 2006

California State Board of Pharmacy
1625 N. Market, Suite N-219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

ORGANIZATIONAL DEVELOPMENT COMMITTEE
Meeting Summary
January 17, 2006
(a non-public meeting)

Present: Stanley Goldenberg, Board President
Ruth Conroy, Board Member
Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer

Chairperson Conroy called the meeting to order at 3:45 p.m.

Recognition of Pharmacists Who Have Been Licensed 50 Years

From November 2005 through January 2006, another eight pharmacists have reached the milestone of 50 years as licensed pharmacists. In early January, each was notified via a mailing of a certificate and invited to a future board meeting.

Since July 2005 when the board started this recognition program, 507 pharmacists have been recognized. Each issue of *The Script* will continue to highlight those reaching this achievement.

Development of the Board's Strategic Plan for 2006-2011

At the April Board Meeting, the board will amend its strategic plan. Lindle Hatton, PhD., will assist the board in this process. In doing so, he will work closely with this committee to secure the full participation of board staff, interested stakeholders and the board.

Both Ms. Harris and Ms. Herold believe the strategic plan's current structure is appropriate for the future; however, board involvement is needed to update some items including the environmental scan, which identifies factors that influence board activities and priorities. For example, the importation of Canadian drugs by patients, California's budget crises, and the nationwide pharmacist shortage.

Dr. Hatton will start working with this committee on revision plans in early March.

Recognition of Pharmacists Who Assisted in Disaster Response to the Gulf Coast Storms of 2005

Since the October 2005 Board Meeting, the board has not received any additional information to recognize additional pharmacists and other licensees who have provided disaster response to the Gulf Coast Storm victims.

There will be a description of some services provided during relief efforts in the January 2006 *The Script*.

At the October Board Meeting, Michael Sohmer, who was publicly recognized by the board for his efforts, provided the board with a video montage of pictures taken during the early days of Katrina relief at the New Orleans Airport. Whereas we lacked the equipment to show this video at the October meeting, the committee agreed that it could be shown at the start of the February 2006 Board Meeting. Dr. Sohmer has been notified and invited to this meeting.

Relocation of The Department of Consumer Affairs and the Board of Pharmacy

The board moved into its new office the weekend of December 9 as scheduled. As of this date, staff is still settling in. Construction is ongoing in the building as the building was not ready for occupants at move-in time.

Perhaps by the end of January, the board will be able to hold meetings within the building. Currently the Holiday Inn has been the location of most of the board's public meetings, although the Northern Office Conferences were held in the board's suite in mid-January.

All forms containing the board's old address and/or phone numbers have been modified.

New business cards have been ordered for staff and board members. The board's Web page highlights how to reach us. Our new location is also the cover story on the board's January 2006 *The Script.*

The new computer-based telephone system is not functioning optimally. A major problem is that the new system relies upon individual phone numbers, and not extension numbers as the board used in its former location. Obtaining the individual phone numbers of the desired staff person requires the caller to listen to a lengthy phone tree message – the system does not allow the entering of a "0" to reach a live operator until the very end of the phone tree message. The phone numbers of key staff will be published in the January *The Script.*

NABP Meetings Come to California

The NABP will hold its 2006 annual meeting in San Francisco on April 8-11 at the Westin St. Francis Hotel. This February Board Meeting is the only board meeting before this convention.

The NABP has suggested that as the host state, the board may want to perform certain activities. The first is to staff the "Hospitality Suite" on April 8 from 1-5 p.m. Whereas the NABP will provide refreshments for this, it does suggest that board members or staff plan to greet those from other states who will attend the meeting.

Additionally, there is a "State Information Table" that is open during registration hours, continental breakfasts and refreshment breaks from April 9 through 11. At this table, brochures about interesting sights, restaurants and attractions in the host city are featured. The NABP encourages that those who staff this table be knowledgeable about sites of interest, particularly on April 9 and 10. The board's staff will seek brochures to distribute from this table.

Lastly, the president of the board will open the first business session on April 9 (Sunday) with "words of welcome" before introducing a city or state dignitary.

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

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

Conroy/Goldenberg 2-0

If approved by the board, this policy will be added to the *Board Member Procedure Manual.*

Personnel Update and Report

In November, the board lost two key staff to other agencies.

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

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

- A management technician to process wholesaler applications
- An associate analyst to perform consumer complaint resolution
- An associate analyst to perform computer administration duties and respond to

public information requests
- A seasonal employee to assist with filing and mailing duties.

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

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

Specialized Training:

- There was a three-day inspector workshop held in November. All inspectors attended and were pleased with the training.
- All board managers and board members completed sexual harassment (prevention) training by January 1, 2006, as required.

Nomination of Bill Powers to SCR 49 Medication Errors Panel

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

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

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

Award 2 Hours of Continuing Education for Attending Committee Meetings

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

This proposal was routed to the Organizational Development Committee for consideration.

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

The committee discussed the proposal but was uncertain whether it should be made an action item for the board's vote. Instead, the committee suggested a discussion during the February board meeting.

California Pharmacy Council: Proposed Charter and Regulations

The California Pharmacy Council has been formed, comprised of the deans of the schools of pharmacy, California pharmacist associations and the board.

The committee reviewed the council's proposed charter and administrative regulations for its activities.

The committee had neither comments nor recommendations.

Budget Update

Ms. Herold provided a full budget report to the committee. This report will be provided to the board as well.

Budget Report for 2005/06

Revenue Projected: $8,677,000

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

Expenditures Projected: $7,954,121

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

Governor's Proposed Budget for 2006/07

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

Revenue Projected: $5,356,000

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

Expenditures Projected: $8,446,000

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

-- Restoration of 2.5 of the 10 positions the board lost during the budget restrictions of the early 2000's. ($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)
-- A $72,000 reduction in workers' compensation insurance fees, which skyrocketed in the last few years
-- A $96,000 reduction in facilities expenses due to the board's new office location
-- A $92,000 reduction in pro rata expenses to the Department of Consumer Affairs (essentially due to lower Office of Information Services charges)

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

Board Fund Condition

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

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

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

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

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

I-Licensing Progress

The board is working to secure the ability to provide online license renewal. Currently 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 from joining this project, and the board has been striving to be added for years.

The DCA is now moving ahead with a proposal so other agencies can offer online application and renewal processing. A feasibility study report has been approved, and the board is in the first tier of agencies that may be able to offer this service in the future. No costs are yet available for this conversion, and it may be at least one year from implementation.

Sunset Review

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

Request to Study CURES Data

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

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

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

Adjournment

There being no additional business, the committee meeting was adjourned at 5:30 p.m.

Strategic Plan Status Report
First Quarter 2005/2006
October 1, 2005 thru December 31, 2005

Organizational Development Committee

Goal 5:	**Achieve the board's mission and goals.** **Outcome:** An effective organization
Objective 5.1:	**Obtain 100 percent approval for identified program needs by June 30, 2006.** **Measure:** Percentage approved for identified program needs
Tasks:	**1. Review workload and resources to streamline operations, target backlogs and maximize services.** **October 2003:** ▪ Board implements and identifies a number of legislative and regulatory proposals to streamline applications and application processing, complaint resolution and investigation procedures. These include: ▪ Citations and fines being issued by the executive officer instead of a committee of the board. ▪ New requirements enacted for pharmacy technicians and use of NAPLEX exam. ▪ Status calls on applications pending less than 8 weeks are not answered. ▪ Processing of fingerprint clearances and conviction information altered. ▪ Statutory or regulation changes proposed for applicants for pharmacist, pharmacy technicians, interns, wholesalers and non-resident wholesalers. ▪ All Sacramento staff assigned to cover phones as routine duties ▪ Board's Web site will be revamped to make information more accessible. ▪ Enforcement actions against licensees will be integrated into the License Verification function of the Web page to facilitate disclosure of information to the public. **January 2004**: ▪ Board modifies procedures for processing pharmacy technicians so that all information required to make a licensing decision is submitted at one time (previously the various required components could each be submitted at any time, creating a substantial workload to match information to files.). The goal is to reduce the volume of individual pieces of application information that are submitted at different times. ▪ All staff are assigned to answer phones in four-hour blocks to fill behind the board's part-time receptionists and still provide phone coverage for the public. The telephone tree is redesigned to place calls immediately on hold, without the direct intervention of a board operator. ▪ Address of record information was placed online in mid-December. This eliminates the need for staff to provide this publicly releasable information. ▪ Enforcement information will be soon added to the Web site so complete license verification information will be available on the Web site. ▪ Board procedures for issuing citations and fines and changed to make it easier to respond to public inquiries. ▪ Data systems for monitoring enforcement cases assigned to board staff are integrated so that only one report is prepared monthly instead of two.

	March 2004 ▪ Contracts for CPJE in place; board begins notification of candidates for pharmacist licensure they may take CPJE examination. Over 750 applications processed by end of month. ▪ Board seeks subscriber service to board's Web site as a possible means for future communication with licensees, applicants and the public. **April 2004:** ▪ Pilot testing of Web site enforcement look up completed and process made available online. ▪ NAPLEX available to California applicants for pharmacist licensure. ▪ Security processes for data transfer among entities providing examination services under development. **June 2004:** ▪ Exam scores released and licensure of new pharmacist begins under new examination structure **October 2004:** ▪ Staff identifies a number of legislative and regulatory proposals to streamline applications and application processing, complaint resolution and investigation procedures in the future. These are brought to the board for pursuit as regulations or statutory changes. ▪ Subscriber alert feature added to board Web site to alert interested parties about new items placed on the Web site. **November 2004:** ▪ Board modifies application procedures for wholesalers and nonresident wholesalers, designated representatives and pharmacy interns. **December 2004:** ▪ New board contracts established for NAPLEX and CPJE exam administrations. ▪ New Web site activated that is compliant with Governor's Office requirements **January 2005:** ▪ Board acts on a omnibus package of regulation changes to update board regulatory programs affected by enactment of SB 361, SB 151, and SB 1913. Provisions for omnibus legislative changes are submitted to Legislative Counsel. **October 2005:** ▪ Board omnibus legislation enacted as SB 1111. Board rulemaking containing numerous provisions to streamline operations or make consistent with law takes effect October 7. **January 2006:** ▪ Board continues adjustments to operations following its move to new location in December. The new phone system will be modified to improve service to callers.
Task:	**2. Develop budget change proposals to secure funding for needed resources.** **August 2003:** ▪ Budget instructions from Department of Finance specify that no program augmentations will be made this year; any increase in resources must come via redirection from within an agency's budget. As such the board dissolves plans for BCPs to augment AG resources and fund a job analysis. **August 2004**: ▪ Budget instructions from Department of Finance specify that no program augmentations will be made this year; any increase in resources must come via redirection from within an agency's budget. As such the board dissolves plans for BCPs to augment AG resources and fund a job analysis. Legislative BCP for SB 1307 and AB 2682 to provide $85,000 for programming modifications to the board's

	wholesaler programs are denied; the board must redirect to cover from existing programs to fund these costs. **March 2005:** ▪ Concept paper submitted for proposed staff augmentation for the 2006-07 fiscal year. **June 2005:** ▪ Budget change proposals submitted for proposed staff augmentation for the 2006-07 fiscal year. **September 2005:** ▪ Budget change proposals submitted to the Administration for the 2006-07 fiscal year. **January 2006:** ▪ Board continues adjustments to operations following move to new location in December. The new phone system will be modified to improve service to callers. ▪ Governor's Proposed Budget for 2006/07 contains restoration of 2.5 positions lost during the prior four years of hiring freezes. One inspector, one receptionist and one-half position for public outreach are proposed. Another $96,000 is proposed to cover an hourly increase in AG expenses to $158 effective 7/1/06.
Task:	**3. Perform strategic management of the board through all committees and board activities.** **October 2003:** ▪ Strategic plan updates from all committees provided to board for review during board meeting. **January 2004**: ▪ Strategic plan updates from all committees provide to board for review during board meeting. Additionally committee readies plan for 2004 update of board strategic plan, planned for the April 2004 meeting. **April 2004:** ▪ Strategic plan for each committee and overall plan for the board reviewed and approved by board for 2005. **July 2004:** ▪ Strategic plan updates from all committees provided to board for review during board meeting. The cost of prescription drugs section of the Strategic Issues to be Addressed chapter is revised and approved by the board for inclusion in the strategic plan. **October 2004:** ▪ Strategic plan updates from all committees provided to board for review during board meeting. In advance of the board meeting, each committee holds a public meeting; one topic discussed at each meeting is how to increase communication between the board and the public and licensees. **January 2005**: ▪ Strategic plan updates from all committees provided to board for review during board meeting. Committee begins plans to revise strategic plan at the April Board Meeting. **April 2005** ▪ Strategic plan update from all board committees provided to board for review during board meeting. Board reviews, modifies and adopts plan for 2005-06. **July 2005**: ▪ Strategic plan updates from all committees provided to the board for review during the July Board Meeting. **September 2005:** ▪ Board hires a consultant to lead board in developing the 2006-2011 strategic plan. **October 2005:** ▪ Strategic plan updates from all committees provided to the board for review during

	the October Board Meeting. **January 2006:** ▪ Strategic plan updates from all committees provided the board for review during the January Board Meeting. ▪ Preparations continue for strategic plan update scheduled for the April 2006 Meeting.
Task:	**4. Manage the board's financial resources to ensure fiscal viability and program integrity.** **October 2003:** ▪ Full budget report provided to board on fund condition, revenue, expenditures, and mandatory budget reductions. **January 2004:** ▪ Budget report provided to board on fund condition, revenue, expenditures and mandatory budget reductions. **April 2004:** ▪ Full budget report provided to board on fund condition, revenue, expenditures, and mandatory budget reductions. Board pursues departmental assistance for a funding augmentation for 2004/05 for legal services from the Attorney General's Office to retain same level of service at higher fee rates now in effect by the AG's staff. **July 2004:** ▪ Full budget report provided to board on fund condition, revenue, expenditures, and mandatory budget reductions. Board receives notification it will receive a $135,000 funding augmentation for 2004/05 for legal services from the Attorney General's Office to retain same level of service at higher fee rates now in effect by the AG's staff. **September 2004:** ▪ Committee reviews full budget report on 2003/04 and future year budgets Board receives augmentation in AG budget of $216,000 to adjust for higher hourly rates charged by the AG's Office **October 2004:** ▪ Full budget report provided to board on fund condition, revenue, expenditures, and mandatory budget reductions. **January 2005:** ▪ Full budget report provided to board on fund condition, revenue and expenditures. **April 2005:** ▪ Full budget report provided to board on fund condition, revenue and expenditures. **July 2005**: ▪ Full budget report provided to the board on fund condition revenue and expenditures. ▪ Board receives a $3.2 million repayment of the 2001 loan to the state's General Fund as an augmentation to its revenue to forestall a possible fund deficit. Two hundred thousand of this is interest. **October 2005**: ▪ Full budget report provided to board on fund condition, revenue and expenditures for 2004/05 and 2005/06 **January 2006**: ▪ Full budget report provided to board on fund condition, revenue and expenditures.
Objective 5.2:	**Maintain 100 percent staffing of all board positions.** **Measure:** Percentage staffing of board positions.
Tasks:	**1. Continue active recruitment of pharmacists for inspector positions.**

	July 2003: ▪ Three vacant inspector positions lost due to executive order mandating elimination of any position vacant on June 30, 2003 **September 2003**: ▪ Department of Consumer Affairs notifies board that it is discontinuing the continuous application process for board inspector positions. The board has no vacant inspector positions and DCA can no longer dedicate staff to this function without a corresponding need by the board to have the civil service exam given. **January 2004**: ▪ Two inspectors on parental leave; however the board has no vacancies. Board requests the department to give an annual inspector exam so that the civil service list for this classification remains active. **February 2004**: ▪ One inspector formerly on parental leave resigns from board. Board seeks recruitment of pharmacists from other state agencies on layoff lists. No such pharmacists exist, and the board submits a freeze exemption to fill the position. **April 2004**: ▪ One inspector on parental leave. Freeze waiver for one vacant inspector position undergoing review by the Department of Finance. **June 2004**: ▪ Hiring freeze ends at end of fiscal year. Board initiates actions to fill vacant inspector position. Board also seeks recruitment of pharmacists from other state agencies. No one responds to position. **August 2004**: ▪ Pharmacists contacted on inspector civil service list to determine their interest in working for board. The board is not interested in those who respond. Board again requests department to give a new civil service examination for the classification. **September2004**: ▪ Board again requests the inspector exam. Board increases time base of one part-time inspector from 50 percent to 75 percent of one full-time position. **November 2004**: ▪ Board completes job analysis on inspector position. **December 2004**: ▪ Department sets date for examination. **March 11, 2005**: ▪ Final filing date for inspector classification. Resignation of one inspector leaves two inspector positions vacant. Interview date set for inspector classification interviews. **May 2005**: ▪ Interviews conducted for inspector classification **June 2005**: ▪ Resignation of one inspector leaves two positions vacant. **August 2005**: ▪ Interviews of inspector applicants conducted. **October 2005**: ▪ Three inspectors hired, leaving no inspector positions vacant. Board requests development of new inspector exam from the department. **January 2006**: ▪ All inspector positions filled. Board anticipates restoration via the 2006/07 budget lost during hiring freezes over the prior five years.
Task:	**2. Vigorously recruit for any vacant positions.**

	July 2003: ▪ Six vacant positions lost due to executive order mandating elimination of any position vacant on June 30, 2003 – three inspector positions, one receptionist, one office technician for site licensing, one associate analyst for site licensing. As a result, the board has no vacant positions. **January 2004**: ▪ The board has no vacant positions. **April 2004:** ▪ The board is seeking a freeze exemption for its vacant inspector position. **June 2004**: ▪ Freeze waiver not processed by the Department of Finance because freeze will end June 30. Board begins recruitment for vacant inspector position, and to hire seasonal staff. **July 2004:** ▪ Board begins recruitment for vacant office technician position. **August 2004**: ▪ Budget Letter indicates process to reinstate positions lost due to hiring freeze; however, implementation of the requirements require that only positions lost in 2003/04 qualify. The board did not lose any positions during this year; however, six vacant positions were lost due to executive order mandating elimination of any position vacant on June 30, 2003, and four were lost in June of 2002. Board seeks to hire temporary staff – two seasonals, and one retired annuitant. One part-time OT leaves board employment. **September 2004**: ▪ Board hires two seasonal staff and rehires its former newsletter editor as a retired annuitant. Board conducts interviews for office technician position. **October 2004**: ▪ Board hires office technician for cashier position. Board begins recruitment for vacant legislative position. One seasonal staff quits. **January 2005:** ▪ Board hires new legislative coordinator and one temporary clerical employee. Recruitment continues for another temporary clerical position. **February 2005.** ▪ Second part-time and temporary receptionist hired. One additional seasonal employee hired to aid in reducing miscellaneous filing backlogs and clerical duties. **July 2005:** ▪ One office technician resigns to accept a promotion at another agency. Recruitment begins to fill this position. **October 2005**: ▪ OT for exam desk filled, new PI receptionist hired, pending retirement of SSA is filled early for training purposes, recruitment begins for new MST for wholesaler application processing. Recruitment also underway for new SSA. **January 2006**: ▪ Additional PI hired to perform receptionist duties. Recruitment underway for an associate analyst for computer operations, an analyst for complaint mediation and a technician for application processing.
Task:	**3. Perform annual performance and training assessments of all staff.** **December 2003:** ▪ All inspectors have annual performance assessments done by their supervisors. State budget restrictions on training may impede the ability of the board to provide all training needed or desired by inspectors.

	December 2004: ▪ All licensing staff and most inspectors have annual assessments. The remaining assessments will be conducted in the next few months.
Objective 5.3:	**Implement 10 strategic initiatives to automate board processes by June 30, 2005.** **Measure:** Number of strategic initiatives implemented to automate board processes.
Task:	**1. Perform a feasibility study to establish the board's own computer system to track licensees and enforcement activities.** **July 2003:** ▪ Department of Finance issues budget instructions stating all computer installation projects and proposals are postponed due to budget crisis. ▪ Continue to work with the Department on the development and implementation of the Professional Licensing and Enforcement Management System (PLEMS). **November 2003**: ▪ Department of Finance denies Department of Consumer Affairs' PLEMS feasibility study report. Department discontinues project. Board suggests reassignment of existing information technology staff to resume programming modifications to existing CAS system which were reassigned to develop PLEMS. This will prevent board from realizing one finding of DCA's Internal Audits Office – to have only one tracking system in place at the board. **May 2004:** ▪ Board prepares parameters to join DCA's applicant tracking system to eventually enable online renewals in the future. **April 2005:** ▪ Board in first tier of agencies implementing applicant tracking. Implementation is still at least one year away. **June 2005:** ▪ Staff meets with DCA information specialists to discuss feasibility of working with CPhA on a joint information technology platform to allow e-mail addresses and online renewals. Technology, cost and legal issues will need research. **July 2005**: ▪ Board now in second tier of agencies implementing application tracking, where conversion will begin about January 2006. Meanwhile DCA is exploring online renewal for all departmental entities, possibly for a BCP for 2006-07. **August 2005:** ▪ Board EO signs on as executive sponsor of I-licensing project for the department. Staff participate in review of vendor software and systems to permit license renewal online. **January 2006:** ▪ FSR for I-Licensing project approved that will allow online license renewal. The board is in first tier for implementation which is at least one year away. ▪ Staff continues work needed for automated application tracking.
Task:	**2. CURES** **November 2003**: ▪ Board Inspector develops program to integrate CURES data into board's pharmacy inspection tracking program, so that summary CURES data is immediately retrievable when looking at a pharmacy's record.

	January 2005: ▪ Board approves $24,000 one-time annual increase in funding for CURES, at the request of the Department of Justice, for a total annual amount of $92,000 for contract services. **April 2005**: ▪ New operating system for CURES online. Board staff working to learn new system. List of problems and training issues begins being targeted for resolution. **July 2005**: ▪ The board's share of the CURES funding remains at $92,000 for 2005/06 **September 2005:** ▪ Preliminary steps underway to initiate FSR for online, real-time processing of controlled substances as provided by SB 734 (Torlakson) **January 2006:** ▪ Staff agrees to assist in a UCD Med. Center Study regarding implementation of a security prescription forms in California. ▪ Board is waiting for DOJ to write the FSR required by SB 734.
Tasks:	**3. Board seeks software to allow subscribers to the board's Web site to be notified when the Web site is updated.** **September 2004:** ▪ Board pilot tests system **October 2004**: ▪ Board activates system **October 2005**: ▪ More than 1,800 individuals are part of the board's subscriber system.
Task:	**4. Miscellaneous Projects** **January 2004**: ▪ Board purchases new printers for board office to provide more efficient use of board's new file server. **May 2004**: ▪ Board meets with department's OIS staff on board strategic priorities for automation. The need to allow online renewal is the board's #1 priority. The board stated its desire for online submission of applications, an automated tracking system (PLEMS) and the ability of applicants to identify the status of their applications online. **June 2005**: ▪ Tracking systems for enforcement case management under development. **September 2005**: ▪ In-house program developed to track probationers and PRP participants by inspectors in the field. **January 2006:** ▪ Testing is nearly complete on the PRP/probationer log. ▪ Staff develops training segments that pop up on specific lap top functions used by inspectors
Task:	**5. Pharmacist Licensure Examinations:** **March –June 2004:**

	▪ New and secured systems developed to transmit data to and from vendors of the NAPLEX and CPJE exams, provide results to candidates in an automated fashion as much as possible. **September – November 2005:** ▪ Quality assurance review underway, CPJE results held until completion.
Objective 5.4:	**Provide for communication venues to communicate within the board by June 30, 2005.** **Measure:** Number of communication venues to communicate within the board
Task:	**1. Continue the Communication Team to improve communication among staff and host quarterly staff meetings.** **July 2003:** ▪ Quarterly staff meeting made discretionary for board inspectors due to lack of a state budget. TCT hosts annual picnic for all Sacramento staff and a number of inspectors who travel to Sacramento. **September 2003:** ▪ TCT conducts mail-ballot election to replace vacancy of one analyst on the TCT **October 2003:** ▪ To reduce travel expenses, quarterly staff meetings are converted to biannual meetings (July and December), as such no TCT quarterly meeting held. **December 2003:** ▪ TCT hosts staff meeting and team building activities for all board staff. Board members provide Christmas lunch to staff. **March 2004:** ▪ LA-based inspector staff attend Enforcement Team Meeting in Burbank. **May 2004:** ▪ Inspectors hold inspector workshop in Fresno **June 2004:** ▪ TCT hosts staff meeting and annual staff picnic ▪ Sacramento-based inspector staff join other Sacramento staff to attend Enforcement Team Meeting **September 2004**: ▪ LA-based inspector staff attend Enforcement Team Meeting in Burbank **October 2004**: ▪ Team meetings of each inspector team occur in Sacramento during time of new equipment exchange **December 2004**: ▪ TCT hosts staff meeting. Board members provide a Holiday lunch for staff. **June 2005:** ▪ TCT hosts staff meeting and annual staff picnic. **July-October 2005**: ▪ TCT conducts fundraising for holiday party and begins planning for December meeting. **December 2006**: ▪ TCT hosts staff meeting.

Task:	**2. Continue Enforcement Team meetings with board members and enforcement staff.** **July 2003:** ▪ Enforcement team meeting held in Sacramento. To reduce travel expenses, quarterly team meetings with all enforcement staff will be converted to biannual meetings. Supervising inspectors will provide inspector meetings to update Los Angeles-based staff. **September 2003:** ▪ Enforcement team meeting held in Sacramento. Los Angeles inspectors not present, but supervisors hold inspector meeting in LA for these staff to reduce travel expenses. **December 2003**: ▪ Enforcement Committee and Enforcement Team meetings held with all board enforcement staff. **March 2004**: ▪ LA-based Enforcement Staff meet in Los Angeles as part of Enforcement Team Meeting. **June 2004**: ▪ Enforcement team meeting in Sacramento. Los Angeles inspectors not present **September 2004:** ▪ LA-based Enforcement Staff meet in Los Angeles as part of Enforcement Team Meeting. **December 2004**: ▪ Enforcement Team Meeting in Sacramento. **March 2005**: ▪ Southern California inspectors meet as Enforcement Team in Burbank in conjunction with Enforcement Committee Meeting. **June 2005:** ▪ Enforcement team meeting in Sacramento with all enforcement staff statewide. **December 2005:** ▪ No team meeting convened due to board's imminent move.
Task:	**3. Convene inspector meetings to develop standardized investigation and inspection processes and earn continuing education.** **July 2003**: ▪ Inspector meeting held in conjunction with Enforcement Team meeting. **September 2003:** ▪ Inspector meeting held in Northern and Southern CA. Topics include development of new procedures, case presentation and review, and workload discussions. **December 2003**: ▪ Inspector meeting held with all inspectors. Computer modifications incorporated onto all inspectors' computers. **March 2004:** ▪ Inspector meeting planned for late May to focus on improving investigation reports. **May 2004:** ▪ Inspectors hold four-day inspector workshop in Fresno to provide training and discussion of investigations. **June 2004:** ▪ Inspectors have one-day inspector meeting as part of semi-annual meetings. **August 2004**: ▪ Compliance team inspectors meet to identify and assign inspection locations through

	June 2005 **October 2004**: ▪ All inspector teams meet during reassignment of equipment **December 2004:** ▪ All inspectors trained in new Pharmacy Law provisions for 2005. **March 2005:** ▪ Drug diversion inspector team undergoes training for inspecting wholesaler facilities. **June 2005**: ▪ All inspectors attend inspectors meeting that focuses on new activity reporting system and use of Garmins for directions. **November 2005:** ▪ Three-Day Inspector workshop held in San Diego. **December 2005:** ▪ Inspector meeting held to discuss new laws and regulations.
Objective 5.5:	**Annually conduct at least 2 outreach programs where public policy issues on health care are being discussed.** **Measure:** Number of outreach programs conducted in one year
Task:	**1. Attend outreach programs.** **September 2003**: ▪ President Jones attends NABP's District VII and VIII meeting **October 2003:** ▪ Board participates in CSHP's Annual Seminar in Sacramento **November 2003:** ▪ Board participates in development of Emergency Contraception Protocol for pharmacists, as required by SB 490 (Alpert, Chapter 651, Statutes of 2003) **December 2003:** ▪ Staff attend USC Seminar in Balancing the Rx Cost/Benefit Equation **January 2004**: ▪ Board participates in CPhA's Outlook 2004 **March 2004**: ▪ Board convenes Workgroup on Pharmacy Compounding task force to determine parameters for distinguishing between compounding and manufacturing **April 2004:** ▪ Board members attend NABP's annual meeting. **June 2004:** ▪ Board participates in public policy discussion regarding importation of Canadian drugs hosted by the Pharmacy Foundation of California. Board holds second meeting of Workgroup on Pharmacy Compounding to determine parameters for distinguishing between compounding and manufacturing. **September 2004**: ▪ Board holds third meeting of Workgroup on Pharmacy Compounding to determine parameters for distinguishing between compounding and manufacturing. **October 2004**: ▪ Executive Officer attends Clearinghouse on Licensure and Enforcement Regulator (CLEAR) in Kansas City, she provides a presentation on doing more with less. **November 2004**: ▪ Supervising Inspector Ratcliff is keynote speaker at CSHP's annual meeting. Also, Board President Goldenberg and Supervising Inspector Ming provide presentations

	about the board and sterile injectable compounding. **December 2004**: ▪ Board holds fourth and final meeting of Workgroup on Pharmacy Compounding to determine parameters for compounding pharmacies. **January 2005**: ▪ Staff begin participation with the NABP on implementing radio frequency identification technology. **March 2005**: ▪ Board staff begin participation on two multi-agency work groups to develop pharmacy response teams to respond to natural disasters and declared emergencies. **April, May, June 2005:** ▪ Staff attend multiagency work groups to develop pharmacy response teams to respond to natural disasters and declared emergencies. Also, conference calls continue regarding implementation of radio frequency identification technology. **July 2005**: ▪ Board convenes Subcommittee on Medicare Prescription Drug Plans to discuss the coming changes in prescription drug coverage for Medicare- and Medicaid-covered. **September 2005**: ▪ Board participates in meeting of Northern California Pain Initiative. **October 2005**: ▪ Second meeting of Subcommittee on Medicare Prescription Drug Plans ▪ Executive Officer and board members attend NABP District VII and VIII meeting. ▪ Board President participates in NABP Task Force on Telepharmacy and the Implementation of the Medicare Drug Benefit Part D. ▪ Board continues to participate with the group implementing nonprescription syringe sales in specific counties. **December 2005:** ▪ Board initiates Workgroup on Pedigree Implementation to discuss issues involving the 1/1/07 requirement that all medication have a pedigree from manufacturer to wholesaler. **January 2006:** ▪ Board holds third subcommittee meeting on Implementation of the Medicare Plan D Benefit. ▪ Staff attends Northern California pain initiative meeting.

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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: **October 25 and 26, 2005**

LOCATION: **Crowne Plaza San Francisco Airport**
San Diego Mission Valley
1177 Airport Blvd.
Burlingame, CA 94010

BOARD MEMBERS PRESENT:

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

STAFF PRESENT:

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

CALL TO ORDER

President Goldenberg called the meeting to order at 9:00 a.m. on October 25, 2005.

ORGANIZATIONAL DEVELOPMENT COMMITTEE

- **Board President's Report**

  President Goldenberg welcomed everyone to the board meeting and discussed the meeting format for the day.

- **National Association of Boards of Pharmacy District VII and VIII Meeting**

  President Goldenberg announced that he and Patricia Harris, Ruth Conroy and John Jones attended the National Association of Boards of Pharmacy District VII and VIII Meeting in Jackson Wyoming on October 5-8, 2005. He added that Executive Officer Patricia Harris is now an elected member of the NABP's executive committee.

- **Lavonne Powell, Department of Consumer Affairs Staff Counsel**

  President Goldenberg welcomed Lavonne Powell who has returned to the board as staff counsel.

- **New Inspectors to the Board of Pharmacy**

  President Goldenberg welcomed new inspectors Anne Hunt, Simin Samari and Joseph Wong.

- **January 2006 Board Meeting is rescheduled:**

  President Goldenberg announced that the January 2006 Board Meeting has been moved to February 1 and 2, 2006. The meeting will be held at a hotel near LAX.

- **Report on the October 2005 Meeting**

  Dr. Conroy reported on the Organization Development Committee meeting on October 3, 2005, in a teleconference meeting.

- **Strategic Plan Update 2006-2010 will be initiated in April 2006:**

  Dr. Conroy stated that at the April 2006 Board Meeting, the board will revise its strategic plan. It has been three years since the plan has been substantially modified, and four years since the board began the initial steps to creating the current structure of the strategic plan. Dr. Conroy stated that the board manages its operations by its strategic plan. The current structure, objectives, and reporting mechanisms seem up to date. However, other sections,

dealing with internal and external factors that influence the board, its mission and its stakeholders, need revision.

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

In addition to the role of board members in revising the plan, all staff will also be involved in the update of the plan. Stakeholders will also be given an opportunity for comment via an online or mailed survey.

President Goldenberg stated that this is a major undertaking and he encouraged the board to consider whether additional objectives need inclusion in the strategic plan.

- **National Association of Boards of Pharmacy - National Meeting in San Francisco in April 2006, and Districts VII and VIII Meeting in Anaheim in October 2006**

  Dr. Conroy stated that this year, two of the National Association of Boards of Pharmacy major meetings would occur in California:
  - ✓ April 2006: The NABP's annual meeting will take place in San Francisco. Dr. Conroy stated that the board can provide ideas for hosting an event at this meeting.
  - ✓ October 2006: The NABP's Districts VII and VIII meeting will be in Anaheim. The board will have some "hosting" opportunities at this meeting.

- **Final Budget Report for 2004/05**

  Revenue for 2004/05: $6,815,250

  Ms. Herold stated that the final budget figures as provided by from the Department of Consumer Affairs are available. The board's revenue for last fiscal year was $6,815,520. This was comprised of 87 percent licensing fees ($5,959,557), 6 percent cite and fine revenue ($375,254), 3 percent cost recovery ($208,899) and 2 percent interest.

  Other key revenue facts:
  - ✓ Nearly 76 percent of licensing fee revenue comes from renewal fees.
  - ✓ Of all licensing fee revenue collected, pharmacist fees represent nearly 37 percent, pharmacy technicians 22 percent, and pharmacies 22 percent.
  - ✓ Of application fees collected during the year, pharmacist fees comprised 32.2 percent, pharmacy technicians comprised 22.5 percent and pharmacies comprised 17.3 percent.
  - ✓ Of renewal fees collected, pharmacists represent 37 percent of all renewal fee revenue, pharmacy technicians 21 percent, and pharmacies 23 percent.

  Expenditures for 2004/05: $7,429,310

Ms. Herold referred to a chart displaying the board's final expenses for 2004/05. As occurs each year, personnel expenditures are the largest expense: representing 53 percent of all expenditures. This is followed by enforcement expenses at 14 percent (AG billing fees, hearing expenditures, and other related expenses) and just under 14 percent for pro rata to the Department of Consumer Affairs. Travel expenses comprise approximately 4.5 percent of all expenses.

Board Member Expenditures and Reimbursements

Ms. Herold referred to a chart listing the travel expenses and compensation of board members for 2004/05. Board members were reimbursed for 1,029 hours of service reported to the board, and $19,787 for travel expenses claimed (approximately $32,800, or 0.4 percent of all expenditures).

Ms. Herold added that the amount reported in the chart under-represents total hours and travel expenses contributed and expended for board-member duties, as some members do not claim reimbursement for these items.

First Budget Report for 2005/06

Ms. Herold reported that the new fiscal year started July 1, 2005. The board's budget for this fiscal year is the same as for last year, except $3.2 million borrowed in 2001 to offset a deficit in the state's General Fund was repaid this year. This repayment is classified as revenue for the year. Three million dollars is still owed to the board from the 2001 loan.

Revenue for 2004/05: $8,677,000

The board's revenue for this fiscal year is projected to be comprised of $5,360,000 in licensing fees, $90,000 in interest on the board's fund and $3,227,000 as repayment and interest on the 2001 loan.

Expenditures for 2004/05: $7,982,000

The board's budget for the year is a maximum of $7.98 million. This is the same expenditure authorization as provided to the board last year.

Ms. Herold stated that the $3 million that is still owed to the board from the 2001 loan will assist the board in meeting its expenditures through 2007/08. However, at that time, the board will need to consider whether it will need to increase its fees. She added that this report is provided to the board at each meeting to keep board members informed of the board's budget status.

Update: Board Fund Condition

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

The board monitors its fund condition so it does not get low or into a deficit that could cause the board to run out of money for annual operations (since expenditures exceed revenue). 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 2004/05 with $4,111,000 remaining in the board's fund. This is 6.2 months of expenditures.

Projections for the board's fund condition at the end of the fiscal year for next few years are:
2005/06: 7.1 months
2006/07: 2.9 months
2007/08: 0.2 months

The board will likely require repayment of the remaining $3 million borrowed in 2001 at the end of 2006/07, or certainly at the beginning of 2007/08.

- **Relocation of the Department of Consumer Affairs/Board of Pharmacy**

Ms. Herold announced that the board is scheduled to move December 9 to a new location about 8 miles north of the current location. The rest of the department located at 400 R Street is also scheduled to move during December.

The board's new address is 1625 N. Market Blvd., Sacramento, CA 95834. The address and phone numbers will be posted on the board's Web site before the move and published in the next newsletter.

She added that staff has been spending one day per week getting ready for the move.

Meetings scheduled in Sacramento between December and March will need to be convened outside the board's current or future building. This will affect the board's

Enforcement Committee Meeting, currently scheduled for December 8, which will be scheduled in a Sacramento hotel.

Ms. Herold stated that it is the board's goal to transition to the new location as smoothly as possible to avoid any interruption to licensees.

- **Personnel Update and Report**

Dr. Conroy announced that the board hired three new inspectors who began working earlier in October. President Goldenberg introduced the new inspectors at the beginning of the meeting. They Are:

- Simin Samari, who managed medications for hospice patients in Orange County. Dr. Samari brings over 10 years of experience in compounding, consultant and drug therapy management skills to the board, in addition to seven years of practice in skilled nursing homes and the community pharmacy setting.
- Joseph Wong, a former pharmacy manager in Sacramento at Walgreens. He also worked as a pharmacist at Costco.
- Anne Hunt, who has worked in a diversity of community pharmacy settings. Dr. Hunt has spent a portion of her career doing patient education activities dealing with specific drug therapy.

Dr. Conroy stated that there are no inspector vacancies at this time. However, a new civil service list will need to be generated in the future so the board can retain a list of interested, eligible pharmacists if a vacancy becomes available.

Dr. Conroy stated that there are other staff changes.

Candy Place has been promoted. She will be doing budget functions as well as support to the executive office and board.

Amber Crosby has been promoted from receptionist to exam desk technician where she will process applications for the pharmacist exam and licensure.

Kim Madsen, an associate analyst with the board working on complaint mediations has accepted a promotion with the Board of Behavioral Sciences, and will leave for her new position at the end of October.

The board is also switching duties of Judi Collins and Eleonor Steiner for career development.

The board has recently hired one part-time receptionist, and is seeking another part-time receptionist. The board lost both positions during the budget restrictions and hiring freezes of the last few years, and must rely upon part-time and temporary help to provide

these services. All employees assist in answering the phones.

The board itself has three board member positions vacant: two public members and one professional member. All three positions are Governor appointments. The two public member positions were created January 1, 2004, and have not yet been filled.

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

- **Report on the Meeting of October, 2005**

  Ms. Zinder reported on the meeting on October 14, 2005, in Sacramento.

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

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

  By January 2005, the program had been initiated. By July, four fact sheets were developed, and a fifth was undergoing work by the board. The fact sheets contain general information on the topic, and contain questions consumers can discuss with their pharmacists on making wise decisions in the subject area.

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

  At the October committee meeting, the committee reviewed three new fact sheets. According to the Center for Consumer Self Care, several additional fact sheets are under development and will be shared with the board shortly.

  The committee will review this joint project with the Center for Consumer Self Care at the January 2006 committee meeting.

  Throughout the meeting, the committee identified topics for additional fact sheets, including the new labeling requirements that mandate a description of the medication be placed on a prescription container, the Beers list of drugs that should not be prescribed to individuals over 75 years of age, and the importance of information found on a container's label.

  The committee also discussed the public health issues that exist surrounding a feared global pandemic of the Avian flu. Staff will gather information about what the Centers for Disease

Control is doing in this area for the next meeting. The seriousness of this illness is a concern for health care policymakers as well as the public.

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

  Ms. 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.

  While there have been no meetings of the partnership since the July 2005 Board Meeting, the partnership has a campaign underway on screening tests for cancer (October and November 2005). The Center for Consumer Self Care received a grant to help promote these public service announcements with a private firm that specializes in promoting public information messages.

  The next campaign of the partnership will again focus on generics. During the winter months at public outreach events, the board will also promote the materials developed and disseminated on antibiotic misuse and resistance, the subject of the first partnership's project last year.

- **Update on *The Script***

  The next issue of the board's newsletter, *The Script,* is currently being printed and should be distributed by mid-October to pharmacies and drug wholesalers.

  Articles in this October issue promote the new recognition program for pharmacists who have been licensed for 50 years, as well as the Subcommittee on Medicare Drug Benefit Plans recently formed by the board. The bulk of the newsletter's articles will provide amplifications of Pharmacy Law, and the requirements of the board's new omnibus regulations (that took effect October 7, 2005).

  The Pharmacy Foundation of California will again print and mail this issue to California pharmacists in the near future.

  Staff is now initiating work on the next issue, a January 2006 issue that will focus on new pharmacy laws.

- **Update on *Health Notes***

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

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

She added that neither publication is yet ready for publication, but articles for both have been written. Likely publication date may be late spring or summer 2006. The board will seek outside funding once the manuscripts are finalized.

- **Update on Public Outreach Activities**

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

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

Public and licensee outreach activities performed since the last report to the board include staffing a booth at two consumer fairs and at CSHP's Seminar (CSHP's annual meeting), and presentations about the board at three meetings of pharmacists on law enforcement.

- **UCSD Study on Non-Prescription Syringe Sales**

Ms. Zinder stated that the board has been asked to assist in a study being conducted by UCSD researcher Richard Garfein, PhD, MPH.

The study is being conducted in conjunction with the Department of Health Services' Office of AIDS, to evaluate Senate Bill 1159 (Vasconcellos, Chapter 608, Statutes of 2004) that allows local health jurisdictions to authorize nonprescription syringe sales by pharmacies to prevent HIV and Hepatitis.

The board's assistance will include:

- Providing a mailing list of pharmacies and pharmacists for the survey that will be planned for mid-2006.
- Reviewing the survey document.
- Writing a cover letter supporting participation in the survey to be included as part of the survey packet.

- **Other Informational Items From the October Committee Meeting:**

The minutes of the Communication and Public Education Committee meeting contain information about other topics discussed by the committee not specifically included on the board meeting's agenda. These include:

- Dr. Schell will draft an article for publication in mid-2006 for the *American Journal of Health-System Pharmacy*. This is in response to a request from this publication regarding how boards view disciplining and investigate pharmacists for prescription errors.
- The committee notes the important consumer safety impact that will be available in January 2006, when all prescription containers must contain a physical description of the medication. Consumer alerts will be developed to make certain consumers learn this information will soon be on prescription containers.
  October is Talk About Prescriptions Month.

Ms. Zinder asked if there were any questions regarding the committee report.

Mr. Powers referred to the Consumer Fact Sheets and asked if they were available on the board's Web site. He added that he found the information contained in these to be a valuable source of information. He expressed concern that consumers needing this information the most are often unable to obtain it. He added that the board must assure that this is published and distributed as widely as possible.

The board also distributes the Fact Sheets at outreach and education events and will post it on the joint Web site developed with the UCSF. She added that an additional idea included distribution to senior groups.

Mr. Powers will assist the board in distributing packets of information to senior centers statewide.

President Goldenberg encouraged those in the audience to attend future meetings of the Communication and Public Education Committee to provide input on the committee's public outreach efforts to further benefit and educate consumers.

Mr. Jones referred to the emerging health issues surrounding the virulent avian flu and the potential for a global pandemic of this disease. He referred to the shortage of vaccine and the challenges pharmacists would face in dealing with patients affected by this as they come in to

pharmacies and the challenge of keeping staff healthy as well. He added that this would require local community action and planning.

Robert Brown, representing seniors, suggested that retired pharmacists meet with senior citizen groups and discuss the role of pharmacists in educating seniors.

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

President Goldenberg stated that in July 2005, the board recognized 450 pharmacists who have been licensed with the board for at least 50 years. Early in October, an additional 49 pharmacists were added to the list of pharmacists when they completed their 50 years of licensure between July 1 and October 31.

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

President Goldenberg welcomed the pharmacists in the audience and asked them to come forward: The following pharmacists were recognized:

John R. Kenny, Jr. – Class of 1943. Mr. Kenny praised the profession of pharmacy and stated that he was licensed in 6 states and still working as a pharmacist. Mr. Kenny traveled from Maryland to attend the board meeting.

Wayland C. Fuller – owned his pharmacy from 1962 – 1998. Mr. Fuller, along with his daughter, thanked the board for this recognition. Mr. Fuller continues to renew his license and obtain continuing education credit.

George T. Golish – began working at Walgreens at age 10 and Walgreens put him through college. Mr. Golish owned a pharmacy for 24 years in Castro Valley. Mr. Golish retired to part-time status in 1996 and hasn't worked for the last three years. He added that he has enjoyed the pharmacy profession very much.

Billy Bob Speck – Accepting this recognition on his behalf was his grandson Josh Speck. Mr. Speck stated that his grandfather graduated in 1953 from UCSF and was working so he could not attend the Board Meeting. Mr. Speck owns three independent pharmacies in Richmond, CA. Mr. Speck's grandson is also pursuing a career in pharmacy.

Nicholas J. Ivans – licensed in 1950 and graduated from USC. Mr. Ivans stated that he and his wife are pharmacists. Mr. Ivans stated that in 1954 polio paralyzed him but with his wife's assistance they managed to keep their store open. He added that he has enjoyed the pharmacy professions and the people he met.

Richard G. Barberian – licensed in 1953, owner of a neighborhood pharmacy for 38 years. He added that the profession represents a health care bargain for patients. He thanked the board for the opportunity to receive this recognition.

William A. Rose – licensed in 1952. Mr. Rose stated that because of the World War II, he was able to get his education and graduated from the Oregon School of Pharmacy in 1952. He eventually settled in Medesto, California. He thanked the board for the recognition.

William A. Siskin – licensed in 1940, graduated from the UCSF and a registered pharmacist for 65 years. Mr. Siskin stated that he was a community pharmacy owner for 31 years. He added that he is proud of his career and he enjoyed his relationship with his customers.

Robert D. Gibson – licensed in 1954, graduated from the University of Oregon. Mr. Gibson stated that he has enjoyed a successful and rewarding career. He noted that Ruth Conroy, Dave Fong and Ken Schell were former students of his and he is proud of all three. He has had the opportunity to travel worldwide. He added to the students in the audience that the pharmacy profession is a rewarding career.

Robert A. Brown – licensed in 1951, graduated from Purdue in 1951 and the owner of the Community Medical Pharmacy in Culver City, CA for 25 years. He recommended a career in pharmacy and encouraged pharmacists to consider owning a small compounding pharmacy.

Burton Freeman – Mr. Freeman stated that he is a second-generation pharmacist and he was in the first graduating class to take a test for a pharmacist license. He took the California exam in 1954. Mr. Freeman thanked the board for the recognition.

Frederick S. Mayer – licensed in 1954, owner of community pharmacy in Sausalito, CA for 40 years. Mr. Mayor praised the pharmacy profession and has enjoyed his career. Mr. Mayor recognized students in the audience and thanked the board for the honor of this recognition.

Howard J. Murphy – licensed in 1952, graduate of UCSF School of Pharmacy. Mr. Murphy thanked the board for this recognition and added that he is proud to be a pharmacist.

Joseph I. Rotenberg – Licensed 1955 in Bolder Colorado. Mr. Rotenberg stated that he owned a store a store in San Francisco where at that time; students Dave Fong and Dennis Ming began working in his pharmacy. He added that it is a great honor to receive this recognition.

David W. Schieser – Licensed in 1955, and began his career as a delivery boy while he attended grammar school. He received his PhD. From the USCF. He thanked the board for the recognition.

Warren W. Hirsch – licensed in 1944, after he escaped Hitler in Germany. Mr. Hirsch stated that he is honored to accept this recognition after having worked for 61 years and still works occasionally. He added that it is wonderful to hear the comments of his colleagues.

Roy S. Nishimura – Licensed in 1954. Thanked the board for this recognition and stated that it is a real honor.

John A. Benelli – Licensed in 1946. Mr. Benelli spoke of his career and thanked the board for the honor of this recognition.

President Goldenberg thanked everyone for coming and for sharing their experiences.

President Goldenberg welcomed Nancy Hall, Department of Consumer Affairs, Board Relations and George Pennebaker, President of CPhA who were in the audience.

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

  President Goldenberg stated that he asked that the board to recognize those pharmacists and other licensees who have provided disaster response to the Gulf Coast storm victims. The board is collecting these stories.

  In the October 2005 *The Script,* there is a brief description of some of the licensees who provided such services. They are:
  - Burton Sacks, PharmD, who established a program to match every dollar contributed to relief, up to $1,000 per day
  - Rite-Aid Corporation, that established money donation centers for the survivors
  - Walgreen Company, that established collection centers for donations and provided free prescription medications
  - Modern HealthCare of Monrovia, owned by pharmacists Ira Halpern and Richard Katz, whose employees donated $5,000 to relief instead of to a holiday party
  - Omnicare Incorporated, that provided free prescription medication.

  Also:
  - Board Member Ruth Conroy personally participated in dispensing medication to displaced residents of New Orleans
  - Pharmacist Michael J. Sohmer, Pharmacist Susan Leung, an unnamed pharmacy technician and Cardinal Health San Diego for their efforts which are detailed in an article written by Dr. Sohmer

President Goldenberg referred to the board's Web site where individuals can submit their stories to the board. The board plans to document these stories.

Dr. Sohmer thanked the board for recognizing all of the California pharmacists that assisted with the Katrina hurricane efforts. He added that he was deployed for two weeks with the Disaster Medical Assistance Team (DMAT) headquartered in San Diego. Dr. Sohmer described the efforts of the DMAT organization as they arrived in Baton Rouge and throughout their journey to assist victims and evacuees from New Orleans and the counties surrounding the city after hurricane Katrina struck.

Dr. Sohmer thanked his wife and son for their support during his deployment.

Mr. Jones presented Dr. Sohmer with a commendation that read:

> This is presented to Michael J Sohmer, registered pharmacist. The California State Board of Pharmacy commends you for your leadership, dedication and commitment to aid gulf coast hurricane victims during September 2005. Your efforts reflect positively on the profession of pharmacy and aiding disaster response. Thank you for your contribution in aiding these patients. Dated October 2005, Signed by Patricia Harris.

President Goldenberg recognized Ruth Conroy and her organization Walgreens for their efforts to aid Katrina hurricane victims. Dr. Conroy personally participated in dispensing medication to displaced residents of New Orleans.

Dr. Conroy described how Walgreens asked its employees to assist with this effort and assisted their own employees who worked in the disaster areas by allowing time off to care for their families.

Dr. Conroy stated that she assisted in Port Charles, Louisiana, a large evacuation area where she filled emergency prescription orders. She added that it was a very moving experience and she was thankful for the opportunity to help.

President Goldenberg encouraged the public to visit the board's Web site where other stories relating to the disaster can be shared.

LICENSING COMMITTEE

- **Report on the Meeting of September 21, 2005**

Dr. Conroy reported on the meeting of September 21, 2005. She encouraged continued public participation in these meetings.

- **Recommendation to Amend B & P Code § 4127.1 to Issue a Temporary Pharmacy Permit for a Change of Ownership to Pharmacies that Compound Injectable Sterile Drug Products.**

  Dr. Conroy stated that a pharmacy that compounds injectable sterile drug products is required to have a specialized pharmacy permit in addition to being licensed as a pharmacy. Under current law, when a pharmacy changes ownership, the board has the authority to issue a temporary pharmacy permit during the transition from the previous owner to the new owner. However, this same provision does not exist for the injectable sterile compounding pharmacies. This has caused some difficulties for change of ownership for pharmacies that can obtain a temporary pharmacy permit for their general pharmacy practice, but cannot obtain temporary permit for the compounding of sterile injectable sterile products. Thus, the pharmacy must cease this service until the change of ownership is completed.

  The committee was provided with proposed statutory language that would allow for the issuance of a temporary pharmacy permit when a change of ownership occurs for pharmacies that compound injectable sterile drug products.

  MOTION: Licensing Committee: That the Board of Pharmacy approve the proposed statutory change to Business and Professions Code, Section 4127.1 to issue a temporary pharmacy permit for a change of ownership to pharmacies that compound injectable sterile drug products.

  SUPPORT: 9 OPPOSE: 0

  Dr. Conroy stated that the proposed statutory changes would be introduced in 2006 as omnibus provisions in legislation.

- **Recommendation to Recognize the School of Pharmacy at Touro University**

  Dr. Conroy stated that Touro University College of Pharmacy is requesting that the Board of Pharmacy recognize its school of pharmacy for purposes of approving intern applications for its 64 students in the Class of 2009.

  Current regulation, 16 CCR § 1719, states that a "recognized school of pharmacy" means a school accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education (ACPE). Touro University currently has pre-candidate statues.

  Dr. Conroy introduced Dr. Katherine Knapp, Dean of Touro University. Dr. Knapp thanked the board for considering this request.

  Dr. Knapp stated that Touro University is a privately funded university with educational opportunities that lead to a Pharm.D. degree.

Dr. Knapp stated that Touro College would be reviewed by the ACPE for advancement to candidate status during the 2005-2006 academic year.

Dr. Knapp stated that she feels that the review will go well because they have addressed all of the concerns raised in the initial reports. She added that many schools have difficulty meeting the standards. She stated that Touro has modified its curriculum and she feels that they are in compliance with all of the expectations.

MOTION: Licensing Committee: That the Board of Pharmacy recognize the School of Pharmacy at Touro University.

SUPPORT: 9 OPPOSE: 0

- **Recommendation to Grant Six Hours of Continuing Education to Pharmacists that Complete the Pharmacist Assessment Mechanism (PSAM) Administered by the National Association of Boards of Pharmacy (NABP)**

At the last Licensing Committee meeting, the committee discussed the announcement by NABP regarding the development of the PSAM. The PSAM is an evaluation tool intended to assist pharmacists in obtaining objective, non-punitive feedback on their knowledge base. Material about and registration for the PSAM is available on NABP's Web site.

The PSAM is applicable to general pharmacy practitioners in all practice settings. It consists of 100 multiple-choice questions and is divided into three sections of equal length. Each section can be completed in as little as one hour, but a maximum of three hours per section is allowed. Pharmacists may take all three sections in one setting, or complete one section at a time, but once a section is begun it must be completed in its entirety. All three sections must be completed within 30 days of when pharmacists complete the first section. The fee for PSAM is $75.

The Idaho State Board of Pharmacy grants four hours of CE to pharmacists for completing the PSAM. Tennessee grants three hours of CE. NABP did pursue accreditation of the PSAM by the Accreditation Council for Pharmacy Education (ACPE), but the accreditation was denied.

President Goldenberg stated that use of the PSAM can greatly aid pharmacists in assessing their knowledge of current pharmacy law. The board should encourage pharmacists to study and take this assessment. He also challenged the pharmacist board members to take the PSAM.

MOTION: Licensing Committee: That the Board of Pharmacy grant 6 hours of continuing education to pharmacists that complete the Pharmacist Assessment Mechanism (PSAM) administered by the National Association of Boards of Pharmacy (NABP).

SUPPORT: 9 OPPOSE: 0

- **Request from University Compounding Pharmacy to Require Licensure of all Pharmacies that Compound**

At the September 2005, Meeting, Pharmacist Joe Grasela, representing University Compounding Pharmacy, requested that the Licensing Committee consider a requirement that all compounding pharmacies have a special compounding license. He stated that the sterile compounding license has been in place for two years and it has raised the quality of compounded products available to the public. He suggested that a special license be required for pharmacies whether they compound injectable sterile products or non-sterile products.

Mr. Grasela explained that this special compounding license for pharmacies is necessary to protect the public. He stated that capsules could do as much harm as injectables. Creams improperly used containing lidocaine can cause cardiac arrest. Oral inhalations, solutions and eye drops can be contaminated. Many other non-compounded non-sterile products can cause harm as an improperly made sterile product.

He also felt that by requiring this special compounding pharmacy license, California would be leading the way and demonstrating to the federal Food and Drug Administration (FDA) that California is regulating compounding pharmacies contrary to FDA's contention that Boards of Pharmacy are not doing enough in this area.

Pharmacist Grasela also stated that by having a special compounding pharmacy license, the board would be creating a new specialty of pharmacy. This new compounding specialty will be similar to nuclear pharmacy, home health care pharmacy, and hospital pharmacy and will provide credibility to the public and provide access to products that cannot be made by manufacturers.

There is concern regarding the compounding of inhalation and ophthalmic drug products. It was noted that both the original legislation and regulation proposals regarding sterile compounding included inhalation and ophthalmic drug products; however, because of the opposition, the legislation and regulations were limited only to compounded sterile injectable drug products.

Last year, the board's Workgroup on Compounding drafted legislation and regulations to govern compounding, which the board approved. While the bill, AB 595, was stalled this year due to opposition from the Department of Health Services (DHS), the board will eventually move forward with the regulations. The committee noted that the regulations are comprehensive and provide regulatory oversight for all compounded drug products, which includes training requirements of all pharmacy personnel who compound and a quality assurance component that guarantees that the compounded drug product meets the specified criteria of strength and quality. It was noted that the workgroup did not discuss whether a special license for all pharmacies that compounded was necessary to protect the public;

however, it was the board's position that the legislative and regulatory proposals were important consumer measures and will continue to pursue them actively.

The committee did not support the request that the board seek a special license for all pharmacies that compound drug products. The committee advised Mr. Grasela that the professional association may want to sponsor such legislation, at which time the board would take a position. Any proposal to require a special license would have a fiscal impact on the board and licensees. Pharmacies would have to pay an additional license fee of $500, and the board would be required to add more staff, if the same opening and annual inspection requirements were continued.

The board took no action on this proposal.

- **Request for Comments on the Definition of Pharmacist's Scope of Practice Consistent with Pharmacy Law for Disaster Response Teams**

  Dr. Conroy stated that since 2005, a group of individuals from various state and local agencies and some private associations held meetings to design an advance registration system to prescreen and identify medical providers for quick deployment in response to disasters and bioterrorism events.

  The group has been meeting under the authority of the state Emergency Medical Services Authority under a Health Resources and Service Administration Hospital Bioterrorism grant. This project is the "Emergency System for Advanced Registration of Volunteer Health Professionals" (ESAR-VHP). Assistant Executive Officer Virginia Herold has been participating as the board's representative.

  One item that has been requested is the scope of practice for pharmacists in emergency situations. Ms. Herold and Supervising Inspector Robert Ratcliff developed a preliminary scope of practice for which they seek comment and input.

  The final version will state in layperson's terms the duties pharmacists can perform under emergency conditions. For example, a draft version of the emergency scope of practice for dentists envisions the ability to suture outside the mouth or set bones in faces.

  The Licensing Committee will continue to work on this proposal.

- **Request from Accreditation Council for Pharmacy Education (ACPE) for Comments by November 1, 2005 on the Draft PharmD Standards and Guidelines**

  Dr. Conroy stated that the ACPE is the accreditation agency for all the pharmacy schools in the United States. California will only accept applications from students who have graduated from an ACPE accredited school of pharmacy. ACPE is revising its standards and guidelines

and is requesting comments by November 1, 2005. A copy of the revised guidelines can be obtained from their web site: www.acpe-accredit.org.

The board took no specific action on this item.

- **Development of Proposal to Update the Definition of a Pharmacy, a Nonresident Pharmacy, Pharmacist Practice and Licensure of Out-of-State Pharmacists**

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

The committee agreed to address these issues through its quarterly meetings. However, the committee was encouraged to develop a concrete proposal sooner rather than later in anticipation of the implementation of provisions of the Medicare Modernization Act (MMA) addressing pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act, which are expected to take effect in 2006.

Following an initial overview document prepared for the December 2004 meeting, a draft of proposed statutory changes was prepared for the March 2005 meeting. That draft was the basis for discussions and reactions at the March, June and September 2005 meetings.

Based on discussions and feedback at the March and June 2005 meetings, liaison counsel with the Attorney General's Office, DAG Joshua Room drafted statutory changes to frame the previous discussions in terms of the various policy choices presented. As always, the primary concern for the board is protection of the California public.

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

1. Definition of "Pharmacy"

One of the primary topics of Committee discussion has been, in light of the apparently increased emphasis on provision of professional "cognitive services" (e.g., DUR, MTM) by pharmacists, which may or may not be provided out of a traditional "pharmacy" premises: (a) whether to license facilities, in California or outside of California, from which such services are provided (which do not otherwise fit the traditional definition of a "pharmacy") *at all*; and (b) if so, whether to license them as "pharmacies," some variant thereof, or as something else entirely.

The draft statutory proposal prepared for the March 2005 meeting assumed that facilities in which "pharmacy" was being practiced (whether "pharmacy" as in prescription-filling, or "pharmacy" as in consultation, MTMP, etc.) would need to be licensed as pharmacies.

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

There was considerable discussion and opposition to requiring California licensed pharmacists to be licensed as an "advice/clinical center pharmacy." It was emphasized that the board needs to recognize the independent practice of pharmacists and this proposal doesn't. The public is adequately protected by the pharmacist licensure.

It was also questioned why the board requires an entity that processes prescriptions to be licensed as a pharmacy. It was explained that the processing of prescriptions under current pharmacy law constitutes the practice of pharmacy and therefore, must be practiced in a licensed pharmacy. It is the location that would receive telephonic and electronic orders for prescriptions and maintain the prescription and patient information, directing the prescription to a particular pharmacy for filling and dispensing. While the pharmacy law authorizes a pharmacist to electronically enter a prescription or order into a pharmacy's or hospital's computer, the law doesn't allow other pharmacy personnel to process prescriptions under the supervision of a pharmacist. To allow such a practice outside a pharmacy would require explicit language. An option may be to allow the practice pursuant to a contract with a pharmacy as long as the original prescriptions records and record of the pharmacist's review be maintained by the filling pharmacy.

Another option provided was to license the facilities but not call them "pharmacies." Other options included (i) licensing such entities as "pharmacies" under the current definition(s), without revision, (ii) not licensing these entities at all, (iii) deferring the licensure of these entities to some other agency (e.g., Department of Health Services), or (iv) awaiting some consensus at the national level about interstate cooperation thereon. None of these alternatives would require statutory revisions.

2. Out-of-State Pharmacists (and Pharmacies)

The committee has dismissed whether and/or how to regulate out-of-state pharmacists who provide cognitive services and/or prescription processing services to and/or for California patients and providers, particularly where those pharmacists are doing so not through affiliation with or employment by a licensed entity (e.g., nonresident pharmacy, advice center, or prescription processing center), but on a consulting or other non-site-specific basis. During all of the committee's discussion(s) of this issue, there has been acknowledgment of a need to balance the board's primary duty to protect the public with

its desire not to impede either patient access to services (particularly for California patients) or to squeeze pharmacists out of the marketplace.

This issue has not arisen directly in the past, with regard to out-of-state pharmacists filling and/or dispensing prescription drugs, because until now those out-of-state pharmacists have worked in (or at least this has been the assumption) nonresident pharmacies that were themselves required to maintain licensure. So there has not previously been a perceived need to consider licensing out-of-state pharmacists separately (in California) from the entities in which they practice. Now, however, there apparently has been or may be an industry growth in the number of pharmacists in other states providing services to California patients or providers who are not permanently or indivisibly affiliated with any particular (licensed) premises. This seems particularly likely with regard to cognitive/prescription processing services, which due to imaging/file-sharing advances, are not nearly as tied to a particular "place" as are (or were) dispensing functions.

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

The wide-ranging discussion at the March, June and September 2005 meetings has seemed to acknowledge a possibility of choosing between (this list is not exhaustive or exclusive, only reflective of those options primarily discussed) (a) licensing all out-of-state pharmacists, (b) requiring out-of-state pharmacists to maintain some form of registration short of licensure, (c) licensing only entities under the auspices of which out-of-state pharmacists would (be required to) practice, and/or (d) requiring that the pharmacists-in-charge of these licensed entities also be licensed in California.

The March 2005 draft statutory chose a combination of (a), (c), and (d), requiring licensure for all out-of-state pharmacists providing cognitive services or prescription processing services to California, and *also* requiring licensure of the pharmacist-in-charge of a nonresident pharmacy.

Concern was expressed at the March and June 2005 meetings that this requirement of licensure would be burdensome to nonresident pharmacies and out-of-state pharmacists. Various other options were discussed at the meetings such as a "registration program" for the nonresident pharmacist, some type of national license certification by the National Association of Boards of Pharmacy (NABP), reciprocity, and/or no additional licensure

but a requirement that the out-of-state pharmacist meet California practice standards. Another possibility would be striking the requirement that the individual practitioner be licensed in California, instead requiring that the out-of-state pharmacist providing services (or drugs) to California patients practice under the auspices of an entity licensed as a nonresident pharmacy (or other form of site license), with a possible further requirement that the pharmacist-in-charge be a California licensee.

NABP model rules would require that a pharmacist providing telepharmacy services across state lines identify himself or herself to any patient as a "licensed pharmacist," notify patients of the jurisdiction in which he/she is currently licensed to practice pharmacy, and register (with relevant state boards) to practice telepharmacy across state lines and provide patients with the jurisdiction's board address and phone number.

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

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

3. **Modify statutory definition(s) of practice as a pharmacist to (i) better conform to existing practice, (ii) emphasize the professional development of pharmacy, and/or (iii) maximize the potential for California pharmacist practice reimbursement under Medicare Part D.**

The statutory proposals pertaining to this subject area made along with the others for the March 2005 Licensing Committee meeting have not generated comment on specifics of the proposed language so much as they have inspired discussion about whether (and how) it is a good idea to expand and/or specify the practice definitions in this way. Therefore, the committee was provided with a verbatim reiteration of those statutory amendments pertaining to this subject that were presented in March 2005. Except as already specified above, at least some of these (particularly revisions to B&P 4052, which essentially just reduce the size of section 4052 and relocate subparts to sections 4052.1-4052.3) seem non-controversial. Others have not yet been fully debated.

In brief, the idea behind many of these suggested amendments/revisions is to recognize in statute that the practice of pharmacy means far more than simply counting and dispensing medications, that it is a professional practice, and that it can be practiced both within and without the four walls of a traditional pharmacy, by licensed professional pharmacists.

The committee discussed this final section and there was support for these changes and updates to pharmacy law. It was suggested that this section be separated from the first two sections of the proposal and be pursued legislatively.

The committee will continue the discussion on this proposal at its December meeting.

Dr. Conroy stated that the committee's initial goal was to have this ready by this board meeting. However, further evaluation is necessary because of its complexity.

- **Competency Committee Report – Approval of the Content Outline for the California Jurisprudence Examination Beginning April 2006**

Ms. Herold stated that the board recently completed its job analysis of the pharmacist profession for purposes of validating the licensure examination. This analysis is done every five years. The job analysis identifies the skills, frequency and importance of tasks performed by pharmacists. From these skill statements, the Competency Committee develops a content outline for the examination. All questions for the examination are developed according to this outline.

In late November 2004, the board mailed a job analysis questionnaire to 3,000 California pharmacists. By the deadline for submission (December 31, 2004), approximately 1,200 responses were received (a 40 percent return response).

The pharmacists surveyed by the board were asked to identify the tasks that they perform, and the frequency and the importance of the tasks. The responses were tallied by the board's examination consultant and were analyzed by the Competency Committee. The Competency Committee then created a new content outline for board approval.

Before the new content outline will be implemented, it will be released publicly so that candidates can prepare for the examination. The board's CPJE content outline does not include tasks tested by NAPLEX; these tasks were removed via analysis of the NAPLEX content outline.

Ms. Herold stated that the new content outline will be in use beginning April 1, 2006, and the board is asked to approve this document so it can be posted on the board's Web site and released to the schools so that it is available early enough for those taking the board's exam to have enough time to prepare.

President Goldenberg acknowledged the hard work of the Competency Committee.

MOTION: That the Board of Pharmacy approve the new Content Outline for the California Jurisprudent Examination Beginning April 2006.

M/S/C: POWERS/JONES

SUPPORT: 9 OPPOSE: 0

Sam Shimomura, representing Western University, asked if the survey conducted by the board could be shared with the curriculum committee at the school of pharmacy for development purposes.

Ms. Herold stated that the survey document could be shared but the NABP exam consultants may have concerns about releasing the results of the survey.

Steve Gray, representing Kaiser Permanente, stated that over the last few years there have been discussions about the need for pharmacy schools to teach compounding and compounding principals. He asked if the schools are considering this. He added that Kaiser continues to find that graduating students are not competent in compounding procedures and the pharmacy schools should be teaching this.

- **New Contract Underway for Administration of the California Pharmacy Jurisprudence Examination**

  The board's CPJE is administered through Experior Assessments, LLC, at test centers nationwide. Experior also administers California examinations for many other boards and programs of the Department of Consumer Affairs. There is a master contract for these test administration services, which is a convenience to all departmental entities because each agency does not need to go out to bid for separate test administration contracts. This master contract ends November 30, 2005.

  Previously, staff reported that the Department of Consumer Affairs had been preparing a request for proposals (RFP) for test administration services for the future. The successful vendor will provide test administration services for the department's entities for the next five years. Due to delays in the RFP process, the department was able to secure a one-year extension on the current contract until November 30, 2006.

APPROVAL OF FULL BOARD MINUTES

President Goldenberg asked if there were any corrections to the board minutes of July 20 and 21, 2005. There were none.

MOTION: Approve the board minutes of July 20 and 21, 2005.

M/S/C: POWERS/GOLDENBERG

SUPPORT: 9 OPPOSE: 0

LEGISLATION AND REGULATION COMMITTEE

Regulations Report and Action

REGULATION HEARING

- **Prescription Drop Boxes and Automated Self-Use Delivery Devices for Refill Prescriptions – Proposed Amendment to Repeal 16 California Code of Regulations Section 1717(e) and add 16 California Code of Regulations Section 1713**

President Goldenberg read the following:

> 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.

President Goldenberg asked if there were any questions concerning the nature of the proceedings or the procedure to be followed.

President Goldenberg stated that the board is conducting a regulation hearing to establish requirements for prescription drop boxes and automated self-use delivery devices for refill prescriptions; proposed amendment to repeal 16 CCR Section 1717(e) and to add 16 CCR Section 1713. The 45-day notice for the regulation hearing was published on August 16, 2005. A copy of the Notice, Initial Statement of Reasons, and proposed language was provided to the board as well as the public.

President Goldenberg stated that the board received eight written comments by the close of the comment period on October 10, 2005. He stated that Bill Marcus and the California Pharmacist Association (CPhA provided substantial comments. Upon review of the comments received, staff revised the proposed language to incorporate some of the recommended changes and drafted a new version of Section 1713, dated October 19, 2005.

The following comments were made:

- **Bill Marcus**

Mr. Marcus referred to the comments he submitted in a letter dated October 10, 2005. He was pleased that staff revised the regulation language (October 19th revisions) based on written comments received prior to the hearing. He referred to his disagreement with John Cronin regarding a waiver process and added that he did not feel that a waiver process is necessary.

Mr. Marcus stated that he has concerns about the use of kiosks because of the importance the board places on pharmacist contact with patients. Mr. Marcus believes that here is a demonstrated need to adopt the regulation with changes recommended by he and Mr. Cronin.

- **Frederick Mayer, representing PPSI**

Mr. Mayer presented written comments from six pharmacists to the board.

Mr. Mayer referred to the board's Notice to Consumer that states: "Talk to your Pharmacist" and he added that that this doesn't fit in when you stock a kiosk with drugs. Mr. Mayer stated that these devices are distinct from the role of the pharmacist

Mr. Mayer referred to page 16 of his written comments submitted at the hearing, where Etna plans to add a list of drugs to kiosks in doctor's offices and asked if the pharmacist does not have to counsel anymore or look at the screen. He asked if the doctors have to council patients and view the screen.

Mr. Mayer's main concerns were:

1. The location of the machines.
2. Hours of use of the machines.
3. Lack of consultation with a pharmacist
4. The types of drugs placed in the machines.

Mr. Mayer thanked the board for the opportunity to testify.

Mr. Mayer asked that board members Dave Fong, Ken Schell and Ruth Conroy recuse themselves from voting because he felt that this would be a conflict because of the companies they worked for.

- **David Schieser**

Mr. Schieser stated his concern was about the loss of patient consultation. He added that when he began practicing as a pharmacist, pharmacists were not allowed to talk to patients about their drugs because this was the doctor's job. He added that now pharmacists have the training and education, everything has changed, and he felt this was the wrong direction to take.

- **Jim Gross, representing the California Pharmacists Association**

Mr. Gross referred to the waiver process and the difference of opinion between Mr. Marcus and the CPhA.

Mr. Gross stated that the CPhA believes that it is appropriate and necessary for the entities that install and use these devices to have an established process to present to the board on how they will be used and monitored. He added that without this process, the waiver process would become automatic.

Mr. Gross referred to Mr. Mayer's comments about the problem of allowing these devices to be distinct from the role of the pharmacist. He added that he knows that the board does not want that to occur and values the cognitive role of the pharmacy, the oversight of the dispensing prescriptions. He added that the numerous changes made to the noticed language are reflected in the October 19th language. However, if the process is not to be reviewed by the board anyway, there is legitimate concern of falling victim to these devices. He encouraged the board to consider this requirement. He added that more pro-active steps should be required.

Mr. Gross referred to the October 19th revised language, section 1713 (d)(9), where it states: "Any prescription or delivery errors or omissions arising from use of the device are reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125, and he added that the CPhA feels that this fails to address a likely

occurrence from the consumer about whether the device is working correctly. And it does not provide for consent.

In response to Mr. Gross' comments, Mr. Room referred to the October 19th revised language, section 1713 (d)(1) where it states "Each patient using the device has chosen and signed a written consent form for delivery of prescriptions using the device."

Mr. Room referred to changes made from the notices version to the October 19th revised language to section 1713 (e)(5), where it states "Orienting participating patients on use of the automated delivery device and ensuring that patient use of the device does not interfere with delivery of prescription medications."

Mr. Gross added that the CPhA does not believe the October 19th revised language adequately addresses the problem of notifying patients when a prescription is not available and will not be dispensed in the device when it had been dispensed previously. He felt section 1713(e)(5) was too general. He added that it is important that entities have on-going communication with patients about any change to the system such as how prescriptions are dispensed or when certain drugs cannot be used in the unit.

- **Rod Bingaman, representing Safeway**

Mr. Bingaman commended the board on taking positive action to embrace new tools and robotics. He added that the board has taken a positive approach to this.

Mr. Bingaman referred to two suggestions he submitted in his letter dated October 7, 2005. He asked for more clarification on the word "adjacent." He clarified that the unit is basically for refill prescriptions only.

Mr. Bingaman asked the board to consider this as an evolving tool to technology. He added we need this type of technology for busy families.

Mr. Jones asked Mr. Bingaman if he wanted the board to specify how close the unit must be to the pharmacy.

Mr. Bingaman referred to the revised language that states "adjacent to the pharmacy counter." He added that this would require the unit to be next to the pharmacy area and cause pharmacy congestion. He suggested that the board include general language in a header of section 1713, authorizing the use of the unit when the pharmacy is closed and when a pharmacist is not present. He added that there are provisions for a 1-800 telephone number or contact that provides consumers with the ability to contact a pharmacist by telephone.

Mr. Bingaman suggested that a pharmacy could use mail delivery for prescriptions if a machine failed to work or shut down due to system failure.

- **Raymond Smith, representing the UCSD Medical Center**

  Mr. Smith stated that he supports the original proposed language and has general support for the modified language. He referred to section 1713 (d)(5) where it states "The pharmacy provides a means for each patient to obtain an immediate consultation with a pharmacist if requested by the patient." He added that consultation could be provided by telephone, and not necessarily provided in person. He asked for clarity.

  Mr. Smith referred to section 1713 (d)(6) where it states: "The device is located adjacent to the licensed pharmacy counter." He added that a hospital pharmacy or clinic pharmacy might not have a traditional pharmacy counter but instead have an opening in the wall in a lobby. He added that this could cause difficulty in interpretation.

  Mr. Smith stated that he prefers that the language state that the device be located within the licensed clinic facility or health care facility and not necessarily within sight of the pharmacy counter or pharmacy opening itself. He added that he would support either proposal as written.

- **Shane Gusman, Counsel, Ross and Barry Broad, on behalf of the United Food and Commercial Workers, representing pharmacists and pharmacy personnel in the retail setting**

  Mr. Gusman stated that this proposal seems to be going in the opposite direction of freeing up the pharmacist can provide patient consultation. He suggested that a study be conducted because there isn't enough information on these devices.

  Mr. Gusman referred to the regulation and stated that the consent form should include information on what to expect, such as when the machine breaks down. Also, the pharmacist is responsible if the machine breaks down and this is problematic.

  Mr. Gusman referred to the proposal to delete section 1717 (e) and he stated that he did not fee that deleting the entire paragraph is necessary. He suggested instead to only delete the statement "unless as required under section 1713" and leave in the remainder of the language.

  Mr. Fong referred to mail order pharmacy where patients have access to a pharmacist and have options for patients if the machine breaks down.

- **Bob Hansen, representing Asteres**

  Mr. Hansen stated that prescription receipts printed by the machine have a 1-800 number on them that a patient can call if they would like a consultation with a pharmacist after the patient has left the pharmacy. Additionally, a 1-800 number could be posted so if the machine fails to deliver a prescription, a patient could call the number and have their prescription delivered to them.

Mr. Hansen stated that many of the issues have already been addressed during previous meetings. He agreed that the pharmacist should be available for consultation and that patients need to know the type of drugs that will be dispensed from the machine.

- **William Holmes, President of ddn Corp.**

  Mr. Holmes represents another vendor for this type of technology. He stated that the machine was installed in Utah three years ago and no errors have been reported in using the machines.

- **Cookie Quandt, representing Longs Drugs**

  Ms. Quandt stated that last October the discussion of automated delivery system was first discussed. She stated that errors occur more frequently in the pharmacy so this system is even more reliable. No instances have occurred where the machine delivered the wrong prescription to the wrong patient. Sometimes clerks deliver the wrong prescription to the wrong patient.

  Ms. Quandt added that this is not a dispensing unit and she feels that there is some misconception. It does not dispense drugs into a vial for a patient. A pharmacist must first check a prescription even if it is filled by a technician, prior to going into the unit. Each and every prescription is checked. Also, a drug utilization review is conducted on the medication, check for therapeutic duplication.
  Ms. Quandt stated that the automated delivery system does not replace the pharmacist. The patient still comes into the pharmacy and the pharmacist is still available for the patient. For after hour prescriptions when patients have questions, a 1-800 number is provided. She added that the number of calls placed to pharmacists using the 1-800 number has only been 10 calls. She added that they have moved very slowly in implementing the units at Longs.

  Ms. Quandt referred to concerns about the consent forms and added that before patients sign up they are made aware of medications that would not be filled by the dispensing unit and it is the pharmacist's discretion whether to dispense from the unit.

  If a consumer chooses to discontinue using the unit, it is very easy for them to opt by telling the pharmacy staff and there is no pressure placed on the patient. She added that the unit provides greater HIPPA protection.

President Goldenberg closed the proceedings of the regulation hearing and thanked the audience for their testimony.

Chairperson Jones stated that staff published a 45-day notice on August 16, 2005, to establish requirements for the placement and use of secure prescription drop-off boxes and secure automated delivery devices. The notice period ended on October 10, 2005. He added that if the board adopts this regulation, the rulemaking package would be submitted for

administrative review in November 2005; the regulation should be in place by early 2006. If the board makes modifications, a 15-day comment period will be required.

MOTION: That the board adopt an amendment to repeal CCR § 1717(e) and to add 16 CCR 16 § 1713 – Prescription Drop Boxes and Automated Self-Use Delivery Device for Refill Prescriptions

M/S/C: CONROY/FONG

Mr. Hiura requested clarification of the meaning of adjacent to the pharmacy.

Staff Counsel LaVonne Powell stated that the pharmacy must have control of the area where the unit is placed and the area must be secure.

Chairperson Jones stated that if the patient receives their medication from the unit, and then feels that they need to speak to the pharmacist, the pharmacy should be in view of the unit.

Mr. Room recommended that the unit be no more than 10 feet from the pharmacy.

Mr. Fong stated that it is important to have proper controls, security and specific criteria for these units and he feels that these units compliment what is already offered by the pharmacy. He added that he supports having the unit in close proximity, if not adjacent to the licensed area.

Mr. Hiura expressed concern regarding the 24-hour telephone access and asked if this ties in directly with the pharmacy.

Mr. Powers stated that he continues to have concerns and although he supports new technology, it must be beneficial to consumers, rather than just a cost-saving money for corporation. He suggested that each pharmacy have a pharmacy plan and that a study be conducted. He cautioned the board not to move to quickly.

Mr. Fong stated that the regulation should address the areas of concern and options for patients if the machine does not work as well as telephone access.

Ms. Zinder recommended amendments to the language that pharmacist would not be disciplined for using their discretion and that the unit could only be used after the patient received consultation regarding the prescription.

MOTION: That the board table the motion to adopt the proposed amendment to repeal 16 CCR § 1717 (e) and to add 16 CCR 16, § 1713 – Prescription Drop Boxes and Automated Self-Use Delivery Device for Refill Prescription

M/S/C: POWERS/SCHELL

SUPPORT: 4 OPPOSE: 5

MOTION: That the board adopt the proposed amendment to repeal 16 CCR § 1717 (e) and to add 16 CCR 16 § 1713 – Prescription Drop Boxes and Automated Self-Use Delivery Device for Refill Prescription

Mr. Schell stated that he continues to have concerns regarding the proposed regulations.

SUPPORT: 3 OPPOSE: 5 ABSTAIN: 1

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

Chairperson Jones stated that staff published a 45-day notice on August 16, 2005, to exclude the posting of pharmacist intern addresses on the Internet. The notice period ended on October 10, 2005. There were no changes or comments made to this language. Additionally, no hearing was requested.

If the board votes to adopt this regulation, the rulemaking package will be submitted for administrative review in October 2005; the regulation should be in place by early 2006.

MOTION: That the Board of Pharmacy adopt the proposed addition of 16 CCR § 1727.1 – Exemption for Intern Addresses from Posting On-line.

M/S/C: ZINDER/POWERS

SUPPORT: 9 OPPOSE: 0

President Goldenberg thanked the students involved in this process and he commended their resolve.

Awaiting Notice

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

Chairperson Jones stated that the board has approved initiation of a rulemaking to repeal 16 CCR § 1717.2 – Notice of Electronic Prescription File. The repeal of 1717(e) is currently awaiting notice. It will be released for the 45-day comment period before the January 2006, board meeting.

Notice of Electronic Prescription Files

Board of Pharmacy
Specific Language

Repeal Section 1717.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~§1717.2. Notice of Electronic Prescription Files.~~

~~(a) Any pharmacy which establishes an electronic file for prescription records, which is shared with or accessible to other pharmacies, shall post in a place conspicuous to and readily readable by prescription drug consumers a notice in substantially the following form:~~

~~NOTICE TO CONSUMERS:~~

~~This pharmacy maintains its prescription information in an electronic file which is shared by or accessible to the following pharmacies:~~

~~By offering this service, your prescriptions may also be refilled at the above locations. If for any reason you do not want your prescriptions to be maintained in this way, please notify the pharmacist-in-charge.~~

~~(b) Whenever a consumer objects to his or her prescription records being made accessible to other pharmacies through use of electronic prescription files, it is the duty of the pharmacy to assure that the consumer's records are not shared with or made accessible to another pharmacy, except as provided in Section 1764. The pharmacist to whom the consumer communicated the objection shall ask the consumer to sign a form which reads substantially as follows:~~

~~I hereby notify (name of pharmacy) that my prescription drug records may not be made accessible to other pharmacies through a common or shared electronic file.~~

~~_____ _____~~
~~(date) (signature of patient)~~

~~_____ _____~~
~~(acknowledgment of pharmacist)~~

~~The pharmacist shall date and co-sign the form, and shall deliver a copy thereof to the patient. The original shall be maintained by the pharmacy for three years from the date of the last filling or refilling of any prescription in the name of the consumer.~~

~~Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.~~

Legislation Report and Action

Board-Sponsored Legislation

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

  Chairperson Jones stated that this is a board-sponsored bill that would define compounding of a prescription drug for the purposes of the Pharmacy Law and would make other related changes. This is a two-year bill. He added that the Department of Health Services (DHS) took an oppose position on the bill.

- **SB 1111 (B&P Committee) Omnibus Bill (Chapter 621, Statutes of 2005) - carrying board-sponsored provisions**

  Chairperson Jones stated that the board's omnibus bill includes eight changes the board proposed for the Business and Professions Code. This bill was signed by the Governor on October 6, 2005.

  The changes are:

  B&P 4005 & 4206
  Repeals outdated rules of professional conduct code.

  B&P 4053
  Makes technical amendments to clarify the requirements for designated representatives, the non-pharmacists who oversee the operations of drug wholesalers.

  B&P 4127.5, 4205 & 4400
  Amends 4127.5 to specifically exempt government and tribal governments from the license fee for sterile injectable compounding pharmacies. Deletes the reference to B&P Section 4130 in B&P Section 4205 because this section was repealed in 2000. Section 4400 has numerous changes.

  B&P 4231 & 4232
  Establishes in the B&P code 30 hours of CE for license renewal; specifies that a pharmacist who fails to provide proof within 60 days of license renewal of CE completion will be issued an inactive license and barred from practicing pharmacy; changes the requirement for the CE exemption from two years after graduation to the first renewal of a pharmacist license; and changes the term "pharmaceutical education" to "pharmacy education."

  B&P 4360-4373

Makes changes to the Pharmacist Recovery Program most of which are technical changes.

B&P 4023.5, 4038, 4114, 4115, 4115.5 & 4202
Updates the statutes for the pharmacy technician Program and establishes "direct supervision and control" as the standard for pharmacist supervision of pharmacist interns, pharmacy technicians, and pharmacy technician trainees.

B&P 4315
Deletes the requirement that a copy of a pharmacist's letter of admonishment be kept on the pharmacy's premises.

B&P 4104
Requires pharmacies to notify the board within 30 days of a pharmacist who engages in theft, diversion, or self-use of dangerous drugs. Additionally, requires pharmacies to handover evidence against pharmacists' engaged in these activities. This proposal would include a provision that would give immunity from liability to a person, who in good faith makes a report to the board.

Pending Legislation Relating to the Practice of Pharmacy

- **AB 21 (Levine) Pharmacists: Practice Requirements**

  Chairperson Jones stated that this bill would require a pharmacist to dispense a prescription except in specified circumstances. The bill would allow a pharmacist to decline on ethical, moral, or religious grounds to dispense a drug pursuant to a lawful request only if he or she satisfies certain conditions. The bill would make a violation of those provisions unprofessional conduct and would also make harassment, as specified, of a patient by a pharmacist unprofessional conduct, subject to disciplinary action by the board. (B&P 4069). The board has an oppose position on this two-year bill.

- **AB 225 (Negrete McLeod) Electronic Prescription Information**

  This bill would allow health care professionals to receive nonmonetary remuneration, in the form of hardware, software, or information technology and training services, necessary and used solely to receive and transmit electronic prescription information in accordance with the standards set forth in Section 1860D-4(e) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (42 U.S.C. Sec. 1395w-104), in specified circumstances. The board has a support if amended position on this two-year bill.

- **AB 446 (Negrete Mcleod) Settlement Agreements (Gag Clauses)**

  This bill was intended to close a loophole in current law that allows a licensee under the supervision of DCA to prohibit a consumer who settles a civil suit from also filing a

complaint or otherwise cooperating with a regulator. This is the second year Governor Schwarzenegger has vetoed these provisions. The board had a support position on this bill.

- **AB 497 (Negrete McLeod) Drug Wholesalers and Manufacturers: Nonresident Wholesaler License Surety Bond**

  This bill was signed by the Governor (Chapter 301, Statutes 2005). Existing law, operative January 1, 2006, to January 1, 2011, requires an applicant for the issuance or renewal of a nonresident wholesaler license to submit a surety bond of $100,000, or an equivalent means of security, for each site to be licensed by the nonresident wholesaler through which dangerous drugs or dangerous devices are to be shipped, mailed, or delivered to a site located in California. This bill would instead require a single $100,000 surety bond, or an equivalent means of security, to be submitted by an applicant for the issuance or renewal of a nonresident wholesaler license. The board supported this bill.

  Mr. Room stated that the form for the surety bond has been forwarded to the Office of Administrative Law by the Attorney General's Office.

- **AB 522 (Plescia) Automated Drug Delivery System**

  This bill was signed by the Governor (Chapter 469, Statutes 2005). This bill provides clean-up language for AB 2184 (Chapter 342, Statutes of 2004), Automated Dispensing Devices. Additionally, the measure prohibits the Department of Health Services (DHS) from paying for any prescription drug or other therapy to treat erectile dysfunction for registered sex offenders and authorizes the Department of Justice to share information with DHS concerning registered sex offenders. The board had a support position on this bill that took effective October 4, 2005.

- **AB 657 (Karnette) Pharmacies: Prescription Containers: Labels**

  This bill would revise the prescription labeling requirements to require a container to be labeled with, among other things, the "intended purpose" for which the drug was prescribed, if the intended purpose is listed on the prescription. The board has a support position on this two-year bill.

- **AB 896 (Matthews) Clinical Laboratories**

  This bill would authorize a pharmacist to serve as a laboratory director of a clinical laboratory that provides routine patient assessment procedures, as defined, under specified conditions. The board has a support position on this two-year bill.

- **SB 152 (Speier) Pseudoephedrine**

The bill would require 1) pseudoephedrine products to be sold in a pharmacy and by a pharmacist or pharmacy technician; 2) pseudoephedrine to be stored in a locked area in view of the pharmacist; 3) limit the quantity of product sold to no more than nine grams of pseudoephedrine in a within any 30 day period; 3) the purchaser produce photo identification; and 4) the purchaser to sign a document with specific information about the transaction. Senate Bill 152 would place these provisions in B&P 4051.1. The board has an oppose position on this two-year bill.

- **SB 401 (Ortiz) Medical information: Pharmacies: Marketing**

  This bill would define marketing to include written communication that is provided by a pharmacy to a patient about a different drug or treatment than that being dispensed by the pharmacy and that is paid for, or sponsored by, a manufacturer, labeler, or distributor of prescription drugs. Amendments: 1) Provide a means for consumers to opt out of receiving advertisements with their prescriptions. 2) Require advertisements to be marked with the entity paying for the advertisement. The board has an oppose unless amended position on this two-year bill.

- **SB 592 (Aanestad) Acute Care Hospitals: Inpatient Pharmacy Technician Services**

  This bill would permit general acute care hospitals to employ specially trained pharmacy technicians to check the work of other pharmacy technicians (TCT) filling floor stock, ward stock, and unit dose cassettes. The board has a support position on this two-year bill.

- **SB 644 (Ortiz) Dispensing Prescription Drugs And Devices Requirements**

  The bill was signed by the Governor (Chapter 417, Statutes 2005) and requires a health care licentiate to dispense drugs and devices pursuant to a lawful prescription or order except in specified circumstances, including on ethical, moral, or religious grounds asserted by the licentiate. (B& P 733) the board gained amendments that will allow the board to cite and fine or issue letters of admonishment for violations of the bill's provisions.

- **SB 734 (Torlakson) Controlled Substances**

  The bill was signed by the Governor (Chapter 487, Statutes 2005). This bill was sponsored the Department of Justice. The author's intent was to make clean-up changes to facilitate the effective operation of the CURES, the prescribing and dispensing of controlled substances, and the program duties of the Bureau of Narcotics Enforcement. Among other provisions it transfers the approval of security printers from the board to the Department of Justice. The board sought a technical amendment to cap board spending for CURES to the amount of money appropriated by the state budget. The board had an oppose unless amended position on this bill.

- **SB 798 (Simitian) Prescription Drugs: Collection And Distribution Program**

This bill was signed by the Governor (Chapter 444, Statutes 2005). This bill authorizes a county to establish, by local ordinance, a repository and distribution program for distributing surplus unused medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. The board provided substantial amendments to this bill that removed the board's "oppose" position to support. Ms. Herold stated that the board would contact the author's office thanking them for accepting the board's amendments and advise them that the board is interested to know what county is handling this.

- **SCR 49 (Speier) Medication Errors Panel**

  This bill was signed by the Governor (Chapter 123, Statutes, 2005) and creates a panel to study the causes of medication errors and recommend changes in the health care system to reduce errors associated with the delivery of prescription and over-the-counter medication to consumers. The measure required the panel to convene by October 1, 2005, and to submit to the Senate Committee on Health a preliminary report by March 1, 2006, and a final report by June 1, 2006. The board supported this measure.

- **AB 302 (B&P Committee) Omnibus Bill - carrying provisions for naturopathic doctors to furnish dangerous drugs**

  This bill was signed by the Governor (Chapter 506, Statutes 2005) and adds naturopathic doctors who prescribe or order drugs in specified circumstances to the list of persons authorized to furnish dangerous drugs and write or issue prescriptions under the Pharmacy Law and the Uniform Controlled Substances Act. The bill charges the Bureau of Naturopathic Medicine with certain responsibilities with respect to compliance with and enforcement of the Pharmacy Law with respect to its licensees.

Status of Bills of Interest

- **AB 71 (Chan) Pharmaceuticals: Adverse Drug Reactions: Office of Ca. Drug Safety**

  This bill would establish the Office of California Drug Safety Watch, which would require the construction of a public database of adverse prescription drug reactions. This is a two-year bill.

- **AB 72 (Frommer) Prescription Drugs: Clinical Trials**

  This bill would establish the Patient Safety and Drug Review Transparency Act in order to ensure that information regarding clinical trials of prescription drugs is available to the public, physicians, and researchers. This is a two-year bill.

- **AB 73 (Frommer) Prescription Drugs: Importation: Procurement**

The Governor vetoed this bill that would have established a state Web site to help patients purchase lower-cost prescription drugs from pharmacies in Canada, U.K., and Ireland.

- **AB 74 (Gordon) California Rx Prescription Drug Hotline**

  This bill would establish a hotline that state residents could call for information about state and federal prescription drug discount programs. This is a two-year bill

- **AB 75 (Frommer) Pharmaceutical Assistance Program**

  This bill would establish a prescription drug discount program for low-income state residents. This is a two-year bill.

- **AB 76 (Frommer) Office of Pharmaceutical Purchasing**

  This bill was vetoed by the Governor and would have placed the responsibilities of several state agencies under a new state Office of Pharmaceutical Purchasing to purchase prescription drugs.

- **AB 77 (Frommer) Medi-Cal: Clinics: Reimbursement**

  This bill was signed by the Governor (Chapter 503, Statutes 2005) and revises the pharmaceutical goods and services reimbursement formula for federally qualified health centers and rural health clinics.

- **AB 78 (Pavley) Pharmacy Benefits Management**

  This bill was vetoed by the Governor and would have revised the pharmaceutical goods and services reimbursement formula for federally qualified health centers and rural health clinics.

- **SB 19 (Ortiz) California Rx Program**

  This bill is a two-year bill sponsored by the Governor that would establish the California Rx Program to negotiate for lower price prescription drugs for lower income Californians.

ENFORCEMENT COMMITTEE

- **Report on the Enforcement Committee and Team Meeting of September 13, 2005.**
  Mr. Powers reported on the Enforcement Committee and Team Meeting of September 13, 2005.

- **Proposed Revisions to the Disciplinary Guidelines**

Mr. Powers stated that the Board of Pharmacy has adopted via regulation its disciplinary guidelines. The board follows these guidelines in its disciplinary actions. The guidelines are used by administrative law judges (ALJs) when issuing proposed decisions and the executive officer in negotiating stipulations. The last major revisions to these guidelines were in 2001.

Mr. Powers stated that the proposed revisions clarify language, ensure that the terms and conditions are consistent (where appropriate) for all license types, modify language to ensure consistency with statutory changes and add new terms of probation.

The significant changes to the standard terms and conditions are:

- Reporting to Board: Adds language clarifying that failure to comply with this term constitutes a violation of probation and results in an extension of probation.
- Notice to Employers: Requires that the direct supervisor, owner and pharmacist-in-charge (PIC) are required to be provided with notice of a respondent's probation; requires that each new PIC be notified of a respondent's probation; and clarifies that failure to comply constitutes a violation of probation.
- No Preceptorships, Supervision of Interns: Deletes the term "preceptorship" to reflect a corresponding change in pharmacy law and adds that a respondent cannot serve as a consultant and that assumption of any unauthorized supervision responsibilities constitutes a violation of probation.
- Reimbursement of Board Costs: Adds option of revocation of license without further notice or opportunity to be heard for failure to pays costs as directed, and clarifies that failure to pay costs will be considered a violation of probation.
- Tolling of Probation: Adds language that further defines the circumstances when probation is considered tolled, clarifies the definition of "cessation of practice" and provides that failure to comply with notification requirements in this provision constitutes a violation of probation.
- Violation of Probation: Adds language that clarifies clarify that automatic termination of any stay ordered by the board will take place as directed in specified conditions.
- Reexamination Prior to Resuming Work: Deletes this provision for an exemptee since examination of an exemptee is no longer required.

The significant changes to the optional conditions of probation for pharmacists and interns are:

- Actual Suspension: Moves the language to Model Orders.
- Restricted Practice: Adds the option of not working in a pharmacy licensed to compound injectable sterile drug products.
- Pharmacist Examination: Updates this condition to reflect new statutory examination requirements (Multi-State Jurisprudence Examination), and adds the requirement for additional semester units for failing to pass the exam after four attempts.
- Mental Health Examination: Adds clarifying requirements for submission of name and qualifications of a licensed mental health practitioner for board prior approval,

submission of commencement of psychotherapy, changes in treatment and practitioner, frequency of therapy and requirement of evaluation.

- Psychotherapy and Medical Evaluation: Adds a provision of ongoing treatment until a therapist recommends and the board approves that no further treatment is needed, and that a respondent must cease practicing any time the treating therapist finds that the respondent cannot practice safely.
- Pharmacists Recovery Program (PRP): Clarifies automatic suspension for participants not in compliance with their program, adds a requirement that a respondent pay administrative fees as invoiced by the PRP and adds the option of requiring the respondent to work in a pharmacy setting with access to controlled substances for a period of six months before successful completion of probation.
- Random Drug Screening: Clarifies automatic suspension for confirmed positive tests.
- Abstain from Drugs and Alcohol Use: Adds a provision that a respondent shall not be in the same physical location as individuals who are using illicit drugs even if a respondent is not personally ingesting the drugs.
- Supervised Practice: Adds a requirement that a respondent cannot practice pharmacy and that respondent's license is automatically suspended until the board approves the supervisor.

Proposed new terms and conditions of probation to be added to the disciplinary guidelines are:

- Coordination and Monitoring of Prescription Use (for chemically dependent pharmacists and interns): This optional term requires the coordination and monitoring of a respondent's prescription use for controlled substances and/or dangerous drugs by a physician, nurse practitioner or psychiatrist.
- Pharmacy Self-Assessment Mechanism (PSAM) (for pharmacists and interns): Requires a respondent to complete the Pharmacy Self-Assessment Mechanism administered by the National Association of Boards of Pharmacy.
- No Being Designated Representative in Charge (DRIC): As a standard condition of probation, that designated representatives (formerly called exemptees) cannot be designated representatives-in-charge.
- Posted Notice of Probation (premises): Requires all licensed premises on probation to post a notice of probation during the probation.

Supervising Inspector Joan Coyne, whose team monitors the probationers and PRP participants, noted that an increasing challenge to her team is the monitoring of probationers outside a licensed pharmacy. Language was added to the tolling provision to clarify when a pharmacist ceases to practice pharmacy and probation is then tolled; however, it is difficult to determine when a pharmacist ceases to practice if the pharmacist is not practicing in a pharmacy. Probationers may be working in positions that require licensure as a pharmacist but the positions are not in a pharmacy or entity licensed by the board. Examples of these practice sites include insurance companies, pharmaceutical benefits management companies (PBMs) and Department Health Services (DHS) MediCal.

The board often has no ability to monitor the respondent in these types of "practice" settings. She stated that a provision is being added to the probation condition for pharmacists who must participate in the PRP to require the pharmacist to practice in a pharmacy and have access to controlled substances for six consecutive months in order to successfully complete the PRP. This provision is important to assure public safety prior to the pharmacist completing probation. She suggested a similar approach for all licensees on probation.

The following is an option for board consideration:

> Employed as a "pharmacist" shall generally mean holding a position of employment for which licensure as a pharmacist is a job requirement. However, Respondent shall be employed for at least _____ hours per calendar month as a pharmacist in a licensed pharmacy setting that dispenses medication. After the first year of probation, Respondent may request to the Board or its designee, including but not limited to a Supervising Inspector overseeing Respondent's probation, a modification to this requirement. If Respondent fails to comply therewith, such failure shall be considered a violation of probation.

MOTION: Enforcement Committee: That the Board of Pharmacy consider the proposed revisions to the Disciplinary Guidelines.

SUPPORT: 9 OPPOSE: 0

MOTION: That the Board of Pharmacy rescind the motion to consider the proposed revisions to the Disciplinary Guidelines.

M/S/C: 9 OPPOSE: 0

MOTION: That the Board of Pharmacy adopt the revisions to the Disciplinary Guidelines as proposed by staff including the optional condition that for those probationers who desire to do so, can be required to spend some period of time, at least a year of their probation, in a licensed pharmacy setting that dispenses medication.

M/S/C: HIURA/SCHELL

SUPPORT: 9 OPPOSE: 0

Staff will prepare the necessary documents to release the language for the 45-day notice required to initiate a rulemaking.

- **Proposal to Require a Wholesaler Facility to Complete a Self-Assessment.**

Mr. Powers stated that Supervising Inspector Judi Nurse prepared a self-assessment form for wholesalers. This form is modeled after the self-assessment form for pharmacies and its

primary purpose is to promote compliance through self-examination and education. Supervisor Nurse manages the Fraud/Drug Diversion Team, which has the responsibility for routine compliance inspections of wholesalers, and it is anticipated that the self-assessment form would be a valuable tool for wholesalers to assure their compliance with pharmacy law. In addition, the form would assist with the routine compliance inspections. When wholesaler inspections are performed, usually the exemptee-in-charge is not available and the exemptee that is present is not familiar with the operations. With a completed and available self-assessment form, the inspector can perform a comprehensive review of the wholesale facility and operations.

Mr. Powers stated that it was suggested that the draft form be shared with the board's stakeholders for review and comment. The committee recommended that the board adopt a regulation to require the self-assessment form for wholesalers. The proposal would require wholesalers to complete the form by July 1 of every odd-numbered year, whenever a new wholesaler permit has been issued, or there is a change in the exemptee-in-charge. It was noted that until such time that a regulation is adopted, the form would be available to wholesalers for self-guidance and completion on a voluntary basis.

MOTION: Enforcement Committee: That the Board of Pharmacy adopt a proposal to require a wholesale facility to complete a self-assessment.

SUPPORT: 9 OPPOSE: 0

Staff will prepare the necessary documents to release the language for the 45-day public notice required to initiate a rulemaking.

- **Importation of Prescription Drugs**

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

Multiple articles regarding recent developments on the issue of drug importation were provided in the board packet.

- **Legibility of Prescriptions**

At the July Board meeting, Pharmacist Jim Colucci requested that the board consider a future agenda item to require all prescriptions be printed, typed, or computer generated to improve legibility and prevent prescription errors. During the discussion, the board was reminded of

previous legislation that required the Medical Board of California to perform a study on e-prescribing.

The legislation was AB1589 (Chapter 464, Statutes of 2001), which required the Medical Board to consult with the Board of Pharmacy and commission a study to evaluate the electronic transmission of prescriptions by physicians and surgeons and report its results to the Legislature on or before January 1, 2003. The bill specified that the Medical Board's report include recommendations on whether the electronic transmission of prescriptions should be encouraged, methods to encourage physicians and surgeons and other specified persons to use this method to transmit prescriptions, and to identify systems to protect the privacy of patients, including the issuance of a digital certification. AB 1589 did not appropriate funds for the Medical Board to conduct the study.

In 2001, Medical Board staff consulted with Paul Riches, Legislation Coordinator for the Board of Pharmacy, who suggested that the Medical Board review a November 2001, California Health Care Foundation Report titled, E-Prescribing. The Medical Board reviewed the report, adopted it as meeting the requirements of AB 1589, and submitted the report to the Legislature.

It was also reported to the committee that current legislation, Senate Concurrent Resolution (SCR) 49 (Speier 2005) was signed by the Governor, which will create a panel to study the causes of medication errors and recommend changes in the health care system to reduce errors associated with the delivery of prescription and over-the-counter medication to consumers. The resolution requires the panel to convene by October 1, 2005, and to submit to the Assembly Committee on Health and the Senate Committee on Health a preliminary report by March 1, 2006, and a final report by June 1, 2006.

The committee agreed that Pharmacist Colucci's request transcends the practices of many health professionals and the issue of prescription legibility and its impact on patient safety, prevention of prescription errors and e-prescribing as a solution should be considered by the SCR 49 panel.

- **Clarification from the DEA of Existing Requirements Under the Controlled Substances Act for Prescribing Schedule II Controlled Substances**

  On January 18, 2005, the Drug Enforcement Administration (DEA) published in the Federal Register a Solicitation of Comments on the subject of dispensing controlled substances for the treatment of pain. Most of the comments that the agency received sought clarification on the legal requirements governing the prescribing of Schedule II controlled substances by physicians. On August 26, 2005, the DEA reiterated its principles under the Controlled Substances Act and DEA regulations. The following is a summary of the notice:

- DEA stands firm that the act of a physician writing multiple prescriptions for a Schedule II drug on the same day with instructions to fill on a future date is the same thing as writing a refill which conflicts with the provision of CSA that provides "No prescription for a controlled substance in schedule II may be refilled."

- DEA clarified that the Interim Policy did not mean that patients who have been receiving prescriptions for Schedule II medications for several years for the treatment of severe pain or attention deficit hyperactivity disorder were required to see the physician each month in order to get another prescription. Physicians that properly determine there is a legitimate medical purpose and acting in their usual course of professional practice can determine whether a patient for whom they are prescribing a Schedule II must be seen in person each time a prescription is issued or whether seeing the patient less frequently is consistent with sound medical practice and appropriately safeguards against diversion and misuse.

- If a physician decides to issue the Schedule II prescription without seeing the patient, the physician can mail the prescription to the patient or to the pharmacy to be filled. Alternatively, the physician can fax a Schedule II prescription to the pharmacy but the pharmacy must have the original signed prescription before dispensing the drug to the patient.

- The DEA and CSA regulations contain no specific limit on the number of days worth of Schedule II controlled substance that a physician may authorize per prescription. However, any state limitations in place would apply.

The DEA plans to complete its review of comments submitted last January and plans to issue a new Federal Register document. The board has taken the lead from Medical Board of California on this issue. In its April 2005 *Action Report* publication, the Medical Board of California (MBC) caution physicians regarding DEA's interim policy statement on prescribing Schedule II controlled substances. The interim policy statement prohibits physicians from issuing multiple prescriptions for Schedule II controlled substances on the same day to the same patient with instructions for the pharmacy to fill some of the prescription on a specific date in the future.

In its April 2005 newsletter, MBC stated that unless DEA changes its position, physicians must see their patients each time a prescription for a Schedule II drug is written. However, MBC provided clarification in its July newsletter that stated the term "see" has implied to some that patients must be seen "face to face" each time and this was not the board's intent. It is MBC's position that the amount prescribed and period for follow-up is not dictated by the DEA, and is subject to the standard of care. MBC provided the following statement as guidance and clarity to physicians who prescribe Schedule II controlled substances to their patients:

When prescribing Schedule II controlled substances to patients, the length of time and quantity of each Schedule II prescription should be based on the needs of each patient and must be within the standards of responsible prescribing.

- **New Labeling Requirements – Physical Description of the Dispensed Medication**

On January 1, 2006, new information must be added to labels on prescription containers dispensed from outpatient pharmacies. This requirement is the physical description of the dispensed medication, including its color, shape and any identification code that appears on the tablets or capsules. Exceptions to this labeling requirement are:

- Prescriptions dispensed by a veterinarian;
- Dispensed medications for which no physical description exists in any commercially available database;
- New drugs for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file; and
- When a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to section 1250 of the Health and Safety Code (e.g., acute care hospital, skilled nursing facility, and correctional treatment center) and the prescription drug is administered to a patient by a licensed certified nurse-midwife, nurse practitioner, physician assistant or pharmacist who is acting within his or her scope of practice.

This requirement is in Business and Professions Code section 4076(a)(11)(A).

- **Implementation of SB 1307 (Chapter 857, Statutes of 2004) Relating to Regulation of Wholesalers**

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

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

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

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

The board has been participating in the Uniform Drug Pedigree meetings. This is a group of participants that represents manufacturers, wholesalers, and regulators. The purpose of these meetings is to provide a cooperative effort to develop uniform standards and regulations regarding electronic pedigrees. Through the board's participation with this group and others, a list of questions and answers are being developed that will be shared at the next enforcement committee meeting in December.

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

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

Chairperson Powers stated that the Enforcement Committee felt that extending the deadline at this time is premature and instead suggested that they work with the industry that produces this technology to try and resolve the issues and find out where the gaps are. He added that this legislation is important and these drugs need to be tracked to protect consumers.

Dr. Fong stated that he supports SB 1307. He added that the board needs to gage how these companies are progressing to reach compliance with the new regulation. He expressed concern that providers are not ready to comply.

Ms. Harris stated that this will be a general topic for discussion at the December Enforcement Committee Meeting and Supervising Inspector Nurse will develop a question and answer sheet for compliance.

NEW BUSINESS

William Marcus suggested that the board develop guidelines on what questions a pharmacist can ask when there are objections to filling prescriptions. Also, he suggested that the board consider regulations that address the issue of minors acting as interpreters for patients with language barriers. Mr. Marcus also suggested provisions for global emergencies and alternative settings and how pharmacists can pre-plan for emergencies.

Mr. Marcus suggested that the board strengthen its strategic plan in specific relation to issuing waivers for kiosks and the priority of patient/pharmacist contact.

ADJOURNMENT

There being no further business, President Goldenberg adjourned the meeting at 4:41 p.m.

Wednesday, October 26, 2005

Closed Session

The board moved into Closed Session pursuant to Government Code section 11125(c)(3) to deliberate upon disciplinary cases and petition for early termination of probation. The board moved into Closed Session to confer with Legal Counsel pursuant to Governor Code Section 11126(e)(2)(A) regarding the following pending litigation: Blackburn v. Board of Pharmacy, California Superior Court, Orange County Case No. 03CC11189.

- **Petition for Early Termination of Probation**
  Samy Saleeb

- **Petition for Reinstatement**
  Bruce Figoten

CLOSED SESSION

The board moved into Closed Session pursuant to Governor Code Section 11126(c)(3) to deliberate upon disciplinary cases, the petitions of early termination of probation and the petition for reinstatement.