

Memorandum

To: Board Members

Date: July 13, 2005

From: Organizational Development Committee

Subject: Committee Actions and Update of the Meeting of July 13, 2005

The Organizational Development Committee met on July 13, 2005, in a non-public meeting. A summary of this meeting is provided below: no separate minutes will be prepared for this meeting.

Board President Stan Goldenberg chaired the meeting, which was also attended by Executive Officer Patricia Harris and Assistant Executive Officer Virginia Herold.

For Discussion

Item 1: Recommended Board Meeting dates for 2006

Already Scheduled:

October 25 & 26, 2005 San Francisco/Oakland

Proposed:

January 24 & 25, 2006 Orange County (CPhA Outlook is scheduled for February 16-19 in Palm Springs)

April 26 & 27, 2006 Sacramento (Easter is April 16, 2006; NABP's annual meeting is April 8 – 12, 2006 in San Francisco).

July 19 & 20, 2006 San Diego

October 25 & 26, 2006 San Francisco/Oakland (CSHP Seminar is scheduled for October 12- 15, in Sacramento)

Item 2: Department of Justice Will Need Additional Board Funding for CURES

At the January 2005 Board Meeting and at the request of the Department of Justice, the board agreed to redirect an additional \$24,000 to fund CURES for

2004-05 for a total funding level of \$92,000.

We recently learned that for 2005-06, the Department of Justice again seeks \$92,000 from the board for funding for CURES for 2005-06. The Department of Consumer Affairs recommends that the board approve the contract for this amount.

Meanwhile we will work to resolve the situation so that this does not become a future problem. Following the January board meeting, staff worked with the Department of Consumer Affairs' Budget Office to draft an amendment to Health and Safety Code section 11165 that would link any future increase in funding for CURES to an appropriation increase for the board.

However, this amendment has not been amended into SB 734 (Torlakson), a legislative proposal advanced by the Department of Justice to modify provisions for security printers for controlled substances prescription forms.

If SB 734 does not incorporate this amendment, the board can seek to include the provision in next year's omnibus bill.

For Information

Item 3: Request from California Pharmacy Students Regarding the Availability of Intern Addresses of Record Online

Since the board's October 2004 meeting, the board has had discussions with a group of California pharmacy students who are concerned about their addresses of record being available online. In the case of the students, this address of record is most often their residence address, and the students expressed great concern about their safety from this information being available online.

The students requested the board to examine its policies in this area, and requested that their address of record be removed from the board's Web site. At the April Board Meeting, in accordance with a legal opinion from Departmental Counsel Dana Winterrowd, the board agreed to promulgate a regulation excluding pharmacist interns from having their addresses of record posted on the board's Web site.

At the July 2005 Board Meeting, the board will hold an informational meeting on proposed language to exclude the address of record of intern pharmacists on the board's Web site. The Legislation and Regulation Committee will oversee this hearing.

Item 4: Subcommittee on Part D of the Prescription Drug Benefit Plans

At the April Board Meeting, the board moved forward with President Goldenberg's suggestion to form a board task force about Part D of the new Medicare and Medicaid provisions. This subcommittee of the Communication and Public Education Committee held its first meeting on July 7th. A number of knowledgeable parties shared information.

Item 5: Award CE for attending Board and Committee Meetings

The committee discussed the awarding of 2 hours for attending public committee meetings.

Currently the board awards 6 hours of CE to individuals who attend the full business day of a board meeting. Only 6 units can be earned per year.

The is currently considering that 2 hours of CE be awarded to individuals who attend full committee meetings. A maximum of 4 hours annually could be earned from attending committee meetings.

The committee will further discuss this item at the next committee meeting and may bring the final proposal to the full board in October.

Item 6: Partner with the CPhA in Developing a Joint Web Site for Data Collection

The CPhA is interested in exploring with the board development of a joint Web site where information could be more readily exchanged, for example, online renewal, email addresses, release of exam scores.

Staff is currently exploring this proposal with the department's Information Technology Office. More information should be available at the next committee meeting.

Item 7: 2005-06 Strategic Plan

The board's 2005-06 Strategic Plan has been updated, as approved at the last board meeting.

Item 8: *Board Member Procedure Manual*

The *Board Member Procedure Manual* has been updated as approved at the

last board meeting.

Item 9: Recognition of Pharmacists who have been licensed as pharmacists for 50 years.

At the board's July 2004 meeting, President Goldenberg stated that one of the priorities for his term is to improve the communication of the board with its licensees and with the public. One item under discussion is an award of achievement to pharmacists for exemplary service or for long careers without disciplinary action.

At the January meeting, the board discussed parameters for an award for those who have been licensed for 50 years as pharmacists. The board will send out these awards with a congratulatory letter in the next week.

Each quarter, board staff will identify those with 50 years of licensure as a pharmacist. These individuals will be mailed the award certificate and a congratulatory letter. Then, the list of those with such achievements will be presented to the board publicly, printed in *The Script*, and posted on the board's Web site. Additionally, each individual will be invited to attend a board meeting when the meeting is held in the pharmacist's regional area.

Approximately 486 pharmacists were in the first group for recognition.

Still on the committee's list of discussion items is whether another recognition program for pharmacists and pharmacies could be developed. At the April 2005 Board Meeting, Lorie Rice of the Medical Board stated that that board acknowledges one practitioner and one practice site each year for superior accomplishment.

President Goldenberg suggested that the committee work to develop a board recognition program for preceptors who spend extraordinary effort to develop the skills of future pharmacists. This proposal will be discussed more fully at the next committee meeting.

Item 10: Budget Update and Report:

The new fiscal year started July 1, 2005. A state budget for the year was signed by the Governor on July 11.

The board's 2005-06 budget is nearly the same budget as the board had for 2004-05, with one major exception – the board received repayment of \$3 million for the new fiscal year. This repayment is for the \$6 million loaned to offset the state budget crises four years ago.

(1.) 2004/05 and Future Year Budgets

Final budget figures for this year will be available in mid-August, thus the figures reported below are estimates.

▪ **Revenue Projected: \$6,042,113**

The board's revenue for the year is expected to be comprised of \$5,346,813 in licensing fees and \$97,474 in interest. The revenue estimate projected from fees is conservative and traditionally is about 10 percent less than actual revenue will be.

The board has also collected \$428,404 in fines, and \$169,422 in cost recovery as of June 30, 2005.

▪ **Expenditures Projected: \$7,990,998**

The board's maximum expenditure authority for the year is \$7.99 million. Personnel is the largest expenditure: \$3,994,568 or 50 percent of the board's budget.

In the Governor's 2004-05 budget, the board received additional funding in response to skyrocketing worker's compensation costs, increased hourly rates for legal services at the Attorney General's Office, and higher employee compensation, bringing the total expenditure authority to \$7.99 million.

Our actual expenditures will be less than this amount. The board estimates that we will end the year with expenditures approximately 5 percent less than this (\$7,590,000).

(2.) Board Fund Condition

During this fiscal year, the board is projected to spend nearly \$2 million more than it will collect as revenue. The difference between revenue collected and the amount spent (or expenditures) will come from the board's fund (the board's "savings account").

The board's fund condition displays the amount of savings remaining at the end of each year, after adjustments are made for projected revenue and expenditures. A fund condition prepared several months ago is provided in Attachment 1 (in other words, the figures will not match directly with the more recent figures reported above).

The board's fund condition is adequate for the present time. Additionally, the board will receive \$3,227,000 next fiscal year as partial repayment of the \$6

million transferred to the General Fund several years ago. The \$227,000 is interest.

The board's fund condition projected over the next three years is:

- 2004-05: The board is projected to end this fiscal year with a reserve of 4.1 months of annual expenses.
- 2005-06: The reserve is estimated at 5.3 months (after repayment of the \$3.2 million).
- 2006-07: A reserve of 1.4 months is projected. Repayment of the remaining \$3 million appears to be needed before the end of this fiscal year).

(3.) *Relocation of the Department of Consumer Affairs*

The board will be relocating to a new office location about 8 miles north of our current location (about half-way between our office and the airport), in an area known as North Natomas.

The expected move date is December 2005 or January 2006. The new building's owner has promised to pay for the purchase and installation of new systems furniture as well as utilities and janitorial service for the half of the new lease (the lease is 15 years).

The board's office space will be reduced to about 80 percent of its current space, and will no longer include a conference room within the board's suite. The board will also have wholly new phone numbers as well.

(4) *Board Member Reimbursement and Travel*

Attachment 2 displays board expenditures for board member reimbursement and travel for the current fiscal years.

ITEM 11: Personnel Update and Report

Office Technician Yolanda Powell has accepted a promotion with another agency and will be leaving the board around July 15. Ms. Powell has worked on the pharmacist examination desk and more recently on processing pharmacy technician applications. The board has begun recruitment for this position.

Inspector Cindy Drogichen-Rich resigned in mid June; she had been on parental leave for the last year. The board now has three inspector vacancies.

The board has recruited for the inspector positions, but could not find applicants with the qualifications needed by the board. Instead, in June, the board secured development of a new civil service hiring list for the inspector classification. Job interviews with these qualified applicants will be conducted in August.

John Tilley's term as a board member ended June 1, 2005, after Mr. Tilley served one year of Grace. A celebration for Mr. Tilley is planned for a future board meeting since he is unable to attend the July Board Meeting.

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.



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

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

BOARD OF PHARMACY COMMITTEE ASSIGNMENTS

2005

Communication and Public Education Committee

Andrea Zinder (chair)
Richard Benson
William Powers
Kenneth Schell

Subcommittee on Medicare Drug Benefit Plans

Stanley Goldenberg (Chair)
William Powers
John Jones

Organizational Development

Stanley Goldenberg (Chair)
Ruth Conroy

Enforcement Committee

William Powers (chair)
Marian Balay
David Fong
Stanley Goldenberg

Legislation and Regulation Committee

John Jones (chair)
David Fong
Kenneth Schell
Andrea Zinder

Licensing Committee

Ruth Conroy (chair)
Richard Benson
John Jones
Clarence Hiura

Competency Committee

Kenneth Schell

Attachment 1

Board of Pharmacy's Fund Condition

0767 - State Board of Pharmacy Analysis of Fund Condition

(Dollars in Thousands)

	ACTUAL 2003-04	2004-05	2005-06	2006-07
BEGINNING BALANCE	\$ 4,402	\$ 4,874	\$ 2,757	\$ 3,544
Prior Year Adjustment	\$ 385	\$ -	\$ -	\$ -
Adjusted Beginning Balance	\$ 4,787	\$ 4,874	\$ 2,757	\$ 3,544
REVENUES AND TRANSFERS				
Revenues:				
125600 Other regulatory fees (REVISED)	\$ 917	\$ 250	\$ 250	\$ 250
125700 Other regulatory licenses and permits	\$ 1,486	\$ 1,418	\$ 1,291	\$ 1,291
125800 Renewal fees	\$ 4,086	\$ 3,838	\$ 3,928	\$ 3,928
125900 Delinquent fees	\$ 69	\$ 60	\$ 58	\$ 58
131700 Misc. revenue from local agencies	\$ 7	\$ -	\$ -	\$ -
141200 Sales of documents	\$ 9	\$ -	\$ -	\$ -
142500 Miscellaneous services to the public	\$ -	\$ -	\$ -	\$ -
150300 Income from surplus money investments	\$ 70	\$ 57	\$ 15	\$ 19
150500 Interest Income From Interfund Loans	\$ -	\$ -	\$ 227	\$ -
160400 Sale of fixed assets	\$ -	\$ -	\$ -	\$ -
161000 Escheat of unclaimed checks and warrants	\$ 4	\$ -	\$ -	\$ -
161400 Miscellaneous revenues	\$ 3	\$ -	\$ -	\$ -
Totals, Revenues	\$ 6,651	\$ 5,623	\$ 5,769	\$ 5,546
Transfers from Other Funds	\$ -	\$ -	\$ 3,000	\$ -
Transfers to Other Funds				
T00001 GF loan per Item 1490-011-0767, BA of 2002	\$ -	\$ -	\$ -	\$ -
Totals, Revenues and Transfers	\$ 6,651	\$ 5,623	\$ 8,769	\$ 5,546
Totals, Resources	\$ 11,438	\$ 10,497	\$ 11,526	\$ 9,090
EXPENDITURES				
Disbursements:				
1110 Program Expenditures (State Operations)	\$ 6,564	\$ 7,740	\$ 7,982	\$ 8,142
9670 Equity Claims / Board of Control (State Operations)	\$ -	\$ -	\$ -	\$ -
Total Disbursements	\$ 6,564	\$ 7,740	\$ 7,982	\$ 8,142
FUND BALANCE				
Reserve for economic uncertainties	\$ 4,874	\$ 2,757	\$ 3,544	\$ 948
Months in Reserve	7.6	4.1	5.2	1.4

NOTES:

- A. ASSUMES WORKLOAD AND REVENUE PROJECTIONS ARE REALIZED
- B. EXPENDITURE GROWTH PROJECTED AT 2% BEGINNING FY 2006-07

Attachment 2

*Board of Pharmacy Expenditures
for Board Member Reimbursement
and Travel*

Chart 1
Board Member Reimbursement and Expenses
2004/05

Board Member	Hours		Travel	
	Meeting	Other	Expense	Airfare
James E. Acevedo	8	0	\$0.00	\$0.00
Marian Balay	16	26	\$518.08	\$195.90
Richard L. Benson	18	33	\$263.49	\$0.00
Ruth M. Conroy	76	49	\$2,755.73	\$1,776.60
David J. Fong	79	32	\$1,391.99	\$501.80
Stanley Goldenberg	108	54	\$1,575.73	\$759.00
Clarence Hiura	79	66	\$1,567.44	\$1,033.40
John D. Jones	75	23	\$1,605.79	\$663.80
William Powers	63	18	\$366.70	\$532.80
Kenneth H. Schell	48	0	\$1,160.79	\$894.80
John Tilley	48	20	\$0.00	\$95.60
Andrea Zinder	63	14	\$941.12	\$669.00
Total	680	333	\$12,146.86	\$7,122.70

Board member expenses paid from July 1, 2004 to June 30, 2005

Board of Pharmacy
2004-05 Strategic Plan
Fourth Quarterly Status Report

Strategic Goals
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, 2005.
Measure:	Percentage approved for identified program needs
Tasks:	<p>1. Review workload and resources to streamline operations, target backlogs and maximize services.</p> <p><i>Oct. 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:</i></p> <ul style="list-style-type: none"> - 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. <p><i>Jan. 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.</i></p> <ul style="list-style-type: none"> - 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

Oct. 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.

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 2005-07 fiscal year.

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.

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

	<p>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.</p> <p>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.</p> <p>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</p> <p>October 2004: Full budget report provided to board on fund condition, revenue, expenditures, and mandatory budget reductions.</p> <p>January 2004: Full budget report provided to board on fund condition, revenue and expenditures.</p> <p>April 2005: Full budget report provided to board on fund condition, revenue and expenditures.</p> <p>July 2005: Full budget report provided to the board on fund condition revenue and expenditures.</p>
Objective 5.2:	Maintain 100 percent staffing of all board positions.
Measure:	Percentage staffing of board positions
Tasks:	<ol style="list-style-type: none"> 1. Continue active recruitment of pharmacists for inspector positions. <p>July 2003: Three vacant inspector positions lost due to executive order mandating elimination of any position vacant on June 30, 2003</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>April 2004: One inspector on parental leave. Freeze waiver for one vacant inspector position undergoing review by the Department of Finance.</p> <p>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.</p>

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.

September 2004: 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.

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.

	<p><i>July 2005: One office technician resigns to accept a promotion at another agency. Recruitment begins to fill this position.</i></p> <p>2. Perform annual performance and training assessments of all staff. <i>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.</i> <i>December 2004: All licensing staff and most inspectors have annual assessments. The remaining assessments will be conducted in the next few months.</i></p>
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
Tasks:	<p>1. Perform a feasibility study to establish the board's own computer system to track licensees and enforcement activities. <i>July 2003: Department of Finance issues budget instructions stating all computer installation projects and proposals are postponed due to budget crisis.</i></p> <p>2. Continue to work with the Department on the development and implementation of the Professional Licensing and Enforcement Management System (PLEMS). <i>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.</i> <i>May 2004: Board prepares parameters to join DCA's applicant tracking system to eventually enable online renewals in the future.</i> <i>April 2005: Board in first tier of agencies implementing applicant tracking. Implementation is still at least one year away.</i> <i>June 2005: Staff meet 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.</i> <i>July 2005: Board 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.</i></p> <p>3. CURES <i>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</i></p>

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.

4. 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

5. 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.

6. 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.

7. Provide equipment to facilitate performance of board duties

Computer Equipment:

June 2004: New computers ordered for inspectors.

October 2004: New laptop computers are imaged and provided to board inspectors.

February 2005: Desktop computers ordered for office staff.

Communication Systems with Field Staff

June 2004: new integrated communication systems ordered to allow access of e-mail from field.

September 2004: Board receives handheld communications devices that combine the ability to send and review e-mail, function as telephones and pagers for all board inspectors. This will improve communications with these field staff regardless even when they are away from their home offices.

October 2004: Inspector staff receive and are trained to use new equipment.

June 2005: new desk top computers received. Once images for the software are completed, the computers will be replaced throughout the board's office

General Equipment

June 2004: Provision of postage system in inspectors' home office to eliminate the need for frequent trips to the post office.

	<i>June 2005: Use of Garmins provided to inspectors to facilitate better directions to locations statewide.</i>
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
Tasks:	<p>1. Continue the Communication Team to improve communication among staff and host quarterly staff meetings.</p> <p><i>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.</i></p> <p><i>Sept. 2003: TCT conducts mail-ballot election to replace vacancy of one analyst on the TCT</i></p> <p><i>October 2003: to reduce travel expenses, quarterly staff meetings are converted to biannual meetings (July and December), as such no TCT quarterly meeting held.</i></p> <p><i>December 2003: TCT hosts staff meeting and team building activities for all board staff. Board members provide Christmas lunch to staff.</i></p> <p><i>March 2004: LA-based inspector staff attend Enforcement Team Meeting in Burbank.</i></p> <p><i>May 2004: Inspectors hold inspector workshop in Fresno</i></p> <p><i>June 2004: TCT hosts staff meeting and annual staff picnic</i> <i>Sacramento-based inspector staff join other Sacramento staff to attend Enforcement Team Meeting</i></p> <p><i>September 2004: LA-based inspector staff attend Enforcement Team Meeting in Burbank</i></p> <p><i>October 2004: Team meetings of each inspector team occur in Sacramento during time of new equipment exchange</i></p> <p><i>December 2004: TCT hosts staff meeting. Board members provide a Holiday lunch for staff.</i></p> <p><i>June 2005: TCT hosts staff meeting and annual staff picnic.</i></p> <p>2. Continue Enforcement Team meetings with board members and enforcement staff.</p> <p><i>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.</i></p> <p><i>Sept. 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.</i></p> <p><i>Dec. 2004: Enforcement Committee and Enforcement Team meetings held with all board enforcement staff.</i></p>

	<p><i>March 2004: LA-based Enforcement Staff meet in Los Angeles as part of Enforcement Team Meeting.</i></p> <p><i>June 2004: Enforcement team meeting in Sacramento. Los Angeles inspectors not present</i></p> <p><i>September 2004: LA-based Enforcement Staff meet in Los Angeles as part of Enforcement Team Meeting.</i></p> <p><i>December 2004: Enforcement Team Meeting in Sacramento.</i></p> <p><i>March 2005: Southern California inspectors meet as Enforcement Team in Burbank in conjunction with Enforcement Committee Meeting.</i></p> <p><i>June 2005: Enforcement team meeting in Sacramento with all enforcement staff statewide.</i></p> <p>3. Convene inspector meetings to develop standardized investigation and inspection processes and earn continuing education.</p> <p><i>July 2003: inspector meeting held in conjunction with Enforcement Team meeting.</i></p> <p><i>Sept. 2003: Inspector meeting held in Northern and Southern CA. Topics include development of new procedures, case presentation and review, and workload discussions.</i></p> <p><i>Dec. 2003: inspector meeting held with all inspectors. Computer modifications incorporated onto all inspectors' computers.</i></p> <p><i>March 2004: Inspector meeting planned for late May to focus on improving investigation reports.</i></p> <p><i>May 2004: Inspectors hold four-day inspector workshop in Fresno to provide training and discussion of investigations.</i></p> <p><i>June 2004: Inspectors have one-day inspector meeting as part of semi-annual meetings.</i></p> <p><i>August 2004: Compliance team inspectors meet to identify and assign inspection locations through June 2005</i></p> <p><i>October 2004: All inspector teams meet during reassignment of equipment</i></p> <p><i>December 2004: All inspectors trained in new Pharmacy Law provisions for 2005.</i></p> <p><i>March 2005: Drug diversion inspector team undergoes training for inspecting wholesaler facilities.</i></p> <p><i>June 2005: All inspectors attend inspectors meeting that focuses on new activity reporting system and use of Garmins for directions.</i></p>
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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
Tasks:	<p>1. Attend outreach programs.</p> <p><i>September 2003: President Jones attends NABP's District VII and VIII meeting</i></p> <p><i>October 2003: Board participates in CSHP's Annual Seminar in Sacramento</i></p> <p><i>November 2003: Board participates in development of Emergency Contraception Protocol for pharmacists, as required by SB 490 (Alpert, Chapter 651, Statutes of 2003)</i></p> <p><i>December 2003: Staff attend USC Seminar in Balancing the Rx Cost/Benefit Equation</i></p> <p><i>January 2004: Board participates in CPhA's Outlook 2004</i></p> <p><i>March 2004: Board convenes Workgroup on Pharmacy Compounding task force to determine parameters for distinguishing between compounding and manufacturing</i></p> <p><i>April 2004: Board members attend NABP's annual meeting.</i></p> <p><i>June 2004: Board participates in public policy discussion regarding importation of Canadian drugs hosted by the Pharmacy Foundation of California.</i></p> <p><i>Board holds second meeting of Workgroup on Pharmacy Compounding to determine parameters for distinguishing between compounding and manufacturing.</i></p> <p><i>September 2004: Board holds third meeting of Workgroup on Pharmacy Compounding to determine parameters for distinguishing between compounding and manufacturing.</i></p> <p><i>October 2004: Executive Officer attends Clearinghouse on Licensure and Enforcement Regulator (CLEAR) in Kansas City, she provides a presentation on doing more with less.</i></p> <p><i>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.</i></p> <p><i>December 2004: Board holds fourth and final meeting of Workgroup on Pharmacy Compounding to determine parameters for compounding pharmacies.</i></p> <p><i>January 2005: Staff begin participation with the NABP on implementing radio frequency identification technology.</i></p> <p><i>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.</i></p> <p><i>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.</i></p> <p><i>July 2005: Board convenes Subcommittee on Medicare Prescription</i></p>

Drug Plans to discuss the coming changes in prescription drug coverage for Medicare- and Medicaid-covered



California State Board of Pharmacy

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

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

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

DATE: April 27 and 28, 2005

LOCATION: Department of Consumer Affairs
400 R Street, 1st Floor Hearing Room
Sacramento, CA 95814

BOARD MEMBERS

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

BOARD MEMBERS

ABSENT: Dave Fong – Until 10:00 a.m. on April 27

STAFF

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

CALL TO ORDER

President Goldenberg called the meeting to order at 8:40 a.m. on April 27, 2005.

BOARD PRESIDENT'S REPORT

- **Introductions**

President Goldenberg introduced from the Department of Consumer Affairs Charlene Zettel, director, Sherry Mehl, chief deputy director and Nancy Hall, deputy director, Board Relations, from the Department of Consumer Affairs.

Director Zettel welcomed everyone and thanked the students who were in attendance for their participation in the state government process.

Director Zettel also thanked board members for their contribution and willingness to serve on the Board of Pharmacy.

Director Zettel welcomed Marian Balay, who was appointed to the Board of Pharmacy as a public member on March 24, by Governor Schwarzenegger. She congratulated Stanley Goldenberg on his reappointment to the board on April 20, 2005. She commended Mr. Goldenberg for his willingness to serve a second term. Director Zettel presided over the official swearing in for Ms. Balay and President Goldenberg.

President Goldenberg also recognized Lori Rice, representing UCSF and the California Medical Board, who was in attendance. President Goldenberg welcomed Don Gubbins, former board member and board president in attendance and Page Talley, representing the Long Term Care Management of the CPhA, who was also in attendance.

President Goldenberg asked board staff in attendance to stand and introduce themselves.

President Goldenberg recognized Virginia Herold, assistant executive officer, for her dedication during her career over the last 25 years and especially for her dedication and commitment to the Board of Pharmacy during the last 15 years. He invited everyone to join the board for cake to celebrate the occasion during the break.

Ms. Harris acknowledged Ms. Herold's accomplishments and dedication and her contributions to the success of the board during the last 15 years. She thanked her for being a good friend and colleague.

Ms. Herold thanked the board, Ms. Harris and staff for the acknowledgment.

Fred T. Mahaffey Award

President Goldenberg announced that the board won the Fred T. Mahaffey award presented by the National Association of Boards of Pharmacy in recognition for demonstrating a significant accomplishment in protecting the public. The board's ground breaking legislation to require an electronic pedigree from the manufacturer of drugs to the pharmacy that dispenses them. This will be a strong deterrent to prevent counterfeit drugs from entering California's market. He added that the board also won this award in 2003 for implementation of the quality assurance program to evaluate prescription errors and in 1997 for the consumer outreach program.

- **Efforts to Increase Public Participation at Board Meetings**

President Goldenberg stated that the board has participated in the Pharmacy Leadership Council and has begun discussions with the Medical Board and Lori Rice. He added that the board plans to invite the Dental Board and the Nursing Board to future board meetings.

President Goldenberg announced that Chairperson Andrea Zinder will schedule a roundtable discussion with all interested parties at the next Communication and Public Education Committee Meeting in efforts to create a safe and informed environment for seniors covered by the Medicare Modernization Act. He encouraged the board, the committee and staff to meet this challenge in a timely fashion and to have information presented to the board at the July Meeting in San Diego.

The subcommittee will gather information and disperse it to members of the Board of Pharmacy, seniors, pharmacists and other boards. President Goldenberg stated that he and Mr. Powers would co-chair this committee.

COMMITTEE REPORTS AND ACTION

Organizational Development Committee

Chairperson Tilley congratulated Ms. Herold on 25 years of state service and thanked her for assistance she provides to him as he chairs the Organizational Development Committee.

Chairperson Tilley reported on April 12, Meeting of the Organizational Development Committee.

- **Request from California Pharmacy Students Regarding the Availability of Intern Addresses of Record Online**

Chairperson Tilley reported that at the board's October Meeting, the board heard from a group of California pharmacy students who were concerned about their addresses of record being available online. Most often their residence address is used and the students expressed great concern about their safety with this information available online.

The students requested that the board examine its policies in this area and they submitted a petition requesting restricted access to residence addresses of these students. The students specifically requested that the board allow an address for interns that is “the address of either the attended school or place of practice.”

At the January 2005 Board Meeting, the students again attended to participate in the discussion about alternatives to having their addresses online. During this discussion, the students specifically requested that their addresses of record be removed from the board’s Web site.

Chairperson Tilley stated that during the board’s discussion at the January meeting, the board requested a legal opinion about whether the board could exempt interns’ addresses of record from the Web site.

Board Counsel Dana Winterrowd prepared this legal opinion that concludes that:

1. Licensees’ addresses of record are public records that can be disclosed by the board.
2. The board may post addresses online on its Web site.
3. The board cannot withhold posting one group of licensees’ addresses online unless it promulgates a regulation to treat that group differently.

Chairperson Tilley stated that the committee discussed the opinion, but declined to recommend that the board promulgate a regulation to exempt intern addresses from posting on the Web site. Instead, the committee considered several options offered to the students previously (using a PO box, using a group PO box, using the school’s address). The committee also asked staff to augment the information already provided to intern applicants notifying them that their address of record is public, and to provide several options they can select as alternatives to listing their home address. These alternatives would be to use a PO address, use a work address, join with other students to obtain a group PO address, use the address of the student association at the intern’s schools of pharmacy,

This information will be provided to schools and placed on the board’s Web site as well.

The committee also recommended that the student associations aid the board in publicizing these options to interns for use as the address of record.

Jarrod Mills, representing interns at the University of the Pacific, expressed disappointment that all of the options that were presented were not helpful and he did not feel that any progress was made in resolution of the problem since the January 2005 Board Meeting.

Steve Gray, representing the California Pharmacists Association, requested that the board proceed with a promulgation of a regulation change. He added that there is no value in publishing student addresses when a licensed pharmacist must approve the work of an intern.

Chairperson Powers requested that Dr. Gray present a recommendation to the board. Dr. Gray responded that he does not have authorization from the Board of Trustees of the California Pharmacists Association but will seek authority at the next meeting.

Ms. Herold stated that the board is required to hold an informational hearing on new regulations and she anticipated that this could be placed on the agenda for the July Board Meeting. The board would notice the regulation for 45-days and take actions in October. After the October Board Meeting the board would compile a rulemaking. The Department of Consumer Affairs has 30 calendar days to review the rulemaking file and the Office of Administrative Law has six weeks. She added that the earliest that this regulation could be in place is approximately one year.

MOTION: That the Board of Pharmacy move forward with regulation to remove the requirement of posting intern's address of record on the Board of Pharmacy's Web site.

M/S/C: POWERS/SHELL

SUPPORT: 9 OPPOSE: 0

- **Formation of Subcommittee to Develop Public Information on Educational Materials on Medicare Drug Benefit Part D**

Chairperson Tilley stated that as mentioned earlier by President Goldenberg, at the April Organizational Development Committee Meeting, President Goldenberg suggested the formation of a board task force to develop informational materials about Part D of the new Medicare and Medicaid regulations. The new prescription drug benefits that will take effect January 1, 2006, are a significant change in prescription benefits. The board needs to develop materials or assist in the distribution of information to the public and licensees.

Mr. Powers referred to the new regulations and stated that it represents a significant downgrade of service to Medicare and Medicaid patients and he encouraged the board to assure that information is provided to them. He added that a proposal to reduce the Medicaid budget is pending before Congress which will create an even greater hardship for these patients. He stated that the board should be concerned about these cuts to Medicaid because it will affect prescription drugs.

President Goldenberg encouraged all board members to keep abreast of the changes. He added that the board is charged with public protection, and this is a significant development in the delivery of prescription drugs.

- **Proposed Updates to the Strategic Plan for 2005-06**

Chairperson Tilley stated that each year during the April Board Meeting, the board updates its strategic plan for the next fiscal year that will start on July 1. The committee believes the current strategic plan is strong and effective for managing and overseeing board activities, and the plan does not require a major overhaul at this time.

Chairperson Tilley stated that the committee did suggest modifications to the front portion of the plan to update it since its creation in 2002 and 2003. These modifications were provided to the board in their materials.

Chairperson Tilley stated that the committee recommends that next year the board conduct a major restructuring of its strategic plan.

MOTION: Organizational Development Committee: That the Board of Pharmacy revise and approve its strategic plan for 2005-06 and conduct a major restructuring of its strategic plan next year.

SUPPORT: 9 OPPOSE: 0

- **Proposed Revisions to the *Board Member Procedure Manual***

Chairperson Tilley stated that the committee developed proposed revisions to the *Board Member Procedure Manual*. This manual was developed about eight years ago to assist board members as a reference for their roles as Board of Pharmacy members.

MOTION: Organizational Development Committee: That the Board of Pharmacy approve the update of the Board Member Procedure Manual.

SUPPORT: 9 OPPOSE: 0

- **Recognition of Pharmacists who have been licensed as pharmacists for 50 years.**

Chairperson Tilley stated that at the board's July 2004 meeting, President Goldenberg stated that one of the priorities for his term is to improve the communication of the board with its licensees and with the public. One item under discussion is an award of achievement to pharmacists for exemplary service or for long careers without disciplinary action.

At the January meeting, the board discussed parameters for an award for those who have been licensed for 50 years as pharmacists. Chairperson Tilley showed a copy of the award

certificate. The award will be mailed to the licensee along with a congratulatory letter from the board's president.

Each quarter, board staff will identify those with 50 years of licensure as a pharmacist. These individuals will be mailed the award certificate and a congratulatory letter. Then, the list of those with such achievements will be presented to the board publicly, printed in *The Script*, and posted on the board's Web site. Additionally, each individual will be invited to attend a board meeting when the meeting is held in the pharmacist's regional area.

Approximately 450 pharmacists will be in the first group for recognition, which will begin at the July Board Meeting.

President Goldenberg encouraged recognized pharmacists to attend future board meetings so they could be personally congratulated.

Lori Rice, representing the California Medical Board, stated that she was invited to attend the board meeting to speak on issues also relating to the Medical Board. She added that two years ago the Medical Board established a recognition program for outstanding physicians with service in the community and each year one medical practice and one physician is recognized for making significant contributions.

- **Proposal to Restructure State Government and its Proposal for the Board of Pharmacy**

Chairperson Tilley stated that the Governor's initial proposal to restructure state government was released at the beginning of August 2004. This report was a 2,547-page report, developed by the California Performance Review, a group of 275 individuals charged to develop an overhaul of state government into a more logical and less costly organization. The CPR stated that the full reorganization would achieve \$32 billion in savings over five years. Public hearings were held to collect information from the public.

On January 5, 2005, the Governor provided more detail about his proposals to reorganize government. Most of the proposals initially proposed in the CPR were not addressed. However, a proposal advanced by the Governor would have abolished 279 board member positions for regulatory boards under the Department of Consumer Affairs, and would have dissolved these boards into the organizational structure of the department, under the direct authority of the director.

The board discussed this plan at its January Board Meeting. Following the January Board Meeting, the Little Hoover Commission held public hearings on the Governor's proposal to restructure government by eliminating the boards in the Department of Consumer Affairs and consolidating their functions and staffs into the department. Public hearings were held on January 25 and 27, 2005.

On February 17, 2005, before the commission issued its recommendations, the Governor withdrew this proposal. The Governor may resubmit this proposal in the future.

- **Budget Update and Report:**

- 1. 2004/05 and Future Year Budgets**

The state's fiscal year runs from July 1, 2004 through June 30, 2005.

- **Revenue Projected: \$5,945,702**

The board's revenue for the year is expected to be comprised of \$5,346,813 in licensing fees and \$97,474 in interest. The revenue estimate projected from fees is conservative and traditionally is about 10 percent less than actual revenue will be.

The board has also collected \$369,018 in fines, and \$132,397 in cost recovery as of March 18, 2005.

- **Expenditures Projected: \$7,990,998**

The board's maximum expenditure authority for the year is \$7.99 million. Personnel is the largest expenditure: \$3,994,568 or 50 percent of the board's budget.

In the Governor's 2005-06 budget, the board received additional funding in response to skyrocketing worker's compensation costs, increased hourly rates for legal services at the Attorney General's Office, and higher employee compensation, bringing the total expenditure authority to \$7.99 million.

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

As discussed at prior meetings, the board's loss of 10 positions over the last three years has created a number of difficulties for the board. One of the greatest hurdles the board faces is responding to telephone inquiries. The board lost both of its receptionist positions. This is a key function since the board receives over 160,000 calls annually. In the last few months, the board has hired another temporary part-time individual, so it now has two part-time, temporary employees who are board receptionists. However, all staff are assigned to take turns at answering the telephones in the absence of one or both of these part-time staff.

The board will seek to make the receptionist positions again permanent through a future budget change proposal. In the interim, the board will redirect funding from other authorized expenditures to assure the ongoing employment of these staff.

2. Board Fund Condition

During this fiscal year, the board is projected to spend nearly \$2 million more than it will collect as revenue. The difference between revenue collected and the amount spent will come from the board's fund.

The board's fund condition displays the amount of savings remaining at the end of each year, after adjustments are made for projected revenue and expenditures.

The board's fund condition is adequate for the present time. Additionally, the board will receive \$3,227,000 next fiscal year as partial repayment of the \$6 million transferred to the General Fund several years ago. The \$227,000 is interest.

The board's fund condition projected over the next three years is:

- 2004-05: The board is projected to end this fiscal year with a reserve of 4.1 months of annual expenses.
- 2005-06: The reserve is estimated at 5.3 months (after repayment of the \$3.2 million).
- 2006-07: A reserve of 1.4 months is projected (repayment of the remaining \$3 million appears to be needed before the end of this fiscal year).

3. CURES Support by Board – Additional Board Funding

At the January 2005 Board Meeting and at the request of the Department of Justice, the board agreed to redirect an additional \$24,000 to fund CURES for 2004-05 for a total funding level of \$92,000.

During the discussion, the board asked for a more permanent resolution to potential future costs increases for this program.

Staff worked with the Department of Consumer Affairs' Budget Office to draft an amendment to Health and Safety Code section 11165 that would link any future increase in funding for CURES to an appropriation increase for the board. The proposed amendment has been referred to the Legislation and Regulation Committee for action.

4. Relocation of the Department of Consumer Affairs

Chairperson Tilley stated that the board would relocate to a new office at the end of the year. The lease for the building housing the main portion of the Department of Consumer Affairs, including the Sacramento office of this board, ended in November 2004.

Lease negotiations conducted by the Department of General Services will result in the relocation of the department to a new location about 8 miles north of the current location in the North Natomas area. The board will actually occupy a portion of the original Arco Arena, where the rent is less than in the current location. The expected move date is now

December 2005 or January 2006. The new building's owner has promised to pay for the purchase and installation of new systems furniture as well as utilities and janitorial service.

The board's office space will be reduced to about 80 percent of its current space, and will no longer include a conference room within the board's suite. The board will also have new phone numbers to go with its new address as well.

5. *Equipment Purchases*

The board is currently seeking to replace all office desktop computers.

The board is also purchasing electronic mapping devices for inspectors. The extensive statewide travel inspectors undertake makes it difficult for inspectors to obtain accurate and timely travel directions to all sites they inspect.

- **Personnel Update and Report**

Chairperson Tilley stated that Inspector Soriya Ly resigned in March and the board now has two inspector vacancies.

The board has recruited for the inspector position, but cannot find an applicant with the qualifications needed by the board. Instead, the board will need to create a new list of eligible pharmacist candidates. The new civil service examination for this classification will be held in mid-May. Once the list is available, the board intends to hire two inspectors.

The board also has one inspector on parental leave.

Communication and Public Education Committee

Chairperson Zinder reported on Communication and Public Education Committee of March 22.

Presentation by the Center for Health Improvement: Results of its Study the Impact of Patient Consultation Requirements on Older Californians

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

The two-year study's goal is to improve the pharmacist consultation process for patients aged 65 plus:

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

The board has been a strong supporter of pharmacist to patient consultation over the years, and this is a key area reviewed by board inspectors during all compliance inspections.

Chairperson Zinder stated that the committee asked the CHI to make a presentation about the study to the board.

Chairperson Zinder introduced Patricia Powers, CHI director, and Gregg Shibata who provided an overview of this project to the board.

The survey of 1000 pharmacists has been completed and the results are being tabulated. The CHI is currently discussing the survey results with several focus groups of seniors, pharmacists and physicians.

Dr. Schell asked whether patient consultation would improve patient outcomes.

Ms. Powers responded that they are unable to measure outcomes. She added the survey reveals the percentage of the pharmacists who state they adhere to the mandated requirements is high.

Mr. Powers asked about the intent of the survey.

Ms. Powers stated that there is a lot of discussion on the changing role of the pharmacists and the purpose of study is to look at the current role and improve on it.

President Goldenberg recommended reading a study by the American Society of Consultant Pharmacists called the Fleetwood Project as it addresses seniors.

Lorie Rice, representing the UCSF, stated that this study is interesting because it addresses the complication requirements in California. She added that the number of instances should be documented and a determination made of the reason why complications occur. Ms. Rice added that the timing of consultation should also be considered because many patients do not have questions initially when their prescription is filled but instead have questions after they begin taking the medication.

The board thanked Ms. Powers and Mr. Shibata for coming to this meeting. The CHI was invited back to present the results of the study once it is completed.

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

Chairperson Zinder stated that one year ago, the board approved a proposal by the committee to integrate pharmacy students into public outreach activities. This project is being coordinated by the UCSF Center for Consumer Self Care under the direction of R. William Soller, Ph.D.

The project has pharmacy students develop one-page fact sheets on diverse health care topics. The board will work with Dr. Soller to develop these fact sheets, using pharmacy students from UCSF and UCSD. The project began in the late fall of 2004.

All the fact sheets will address consumer issues involving questions to "Ask a Pharmacist" about, so that consumers can make informed decisions. The fact sheets will contain general information on the topic, but then contain questions consumers can discuss with their pharmacists on making wise decisions in the subject area.

A prototype format for a series of fact sheets has been developed and the first five fact sheets prepared:

- Lower Your Drug Costs
- Is Your Medicine in the News?
- Generics
- Antibiotics – A National Treasure
- Did You Know Good Oral Health Means Good Overall Health?

The board and the Center for Consumer Self Care are distributing the fact sheets. As a joint effort, both agencies have their logos and addresses on the fact sheet, which is a simple design with blue and black ink. An important element of the fact sheet's design is that it photocopies well. Many fact sheets will be downloaded from individuals' computers or copied from the colored copies, so the black and white appearance/presentation of the fact sheet is important to the success of the public outreach program.

The goal is to develop three fact sheets per quarter. The committee is exploring translating the fact sheets into different languages in the near future. After one year, the Communication and Public Education Committee and the Center for Consumer Self Care will reevaluate the project.

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

Chairperson Zinder stated that at the July board meeting, the board voted to become a founding member of 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.

Monthly meetings have occurred since September 2004. Membership on the committee includes representation from the CSHP, CMA, Medical Board of California, UCSF, FDA, CPhA, Board of Registered Nursing, and the Department of Consumer Affairs.

The function of the group is to develop or disseminate integrated public information campaigns on priority health topics identified by the partnership members.

The first integrated project was an education campaign for practitioners and patients on antibiotic use, misuse and overuse. Between November 2004 and February 2005, the partnership agencies promoted these materials in their quarterly newsletters to licensees and on their Web sites. Consumer materials were distributed at public education fairs, and could be distributed by practitioners in their offices or pharmacies (via download of material from the Internet). Both the Medical Board and the Board of Pharmacy board published the practitioner alert poster in their winter newsletters.

The next integrated campaign is planned for May 2005, which is seniors' month. Generic drugs will be the focus of this effort. In this regard, various materials from the FDA and the board's new consumer fact sheet will be among the materials promoted.

In the future (October or November 2005) the partnership is considering continued emphasis on generic drugs or early detection tests for cancer. October is Talk About Prescriptions Month.

- **Status of *The Script***

Chairperson Zinder reported that the board's newsletter, *The Script*, was printed and mailed to California pharmacies in early February. This issue focused on the many new law changes taking effect in January 2005.

To save publication space, the board developed a special section of the board's Web site to list the actual text of every modified code section. By accessing this section of the board's Web site, interested individuals can quickly access the changed sections of Pharmacy Law (http://www.pharmacy.ca.gov/laws_regs/new_laws.pdf).

The Pharmacy Foundation of California will again mail the January 2005 issue to California pharmacists in the next few weeks.

In March, the board will begin development of the next issue. Publication is planned for July 2005.

A pharmacist in the audience referred to the disciplinary actions that were once published in *The Script* and felt that this is a deterrent effect to the profession.

- **Status of *Health Notes***

Chairperson Zinder stated that two issues of *Health Notes* are under development:

- 1. Pain Management Issue:**

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

Prominent pain management authors have written the articles, and Board Member Schell has edited the articles. The CSHP is seeking funding for production and mailing costs. Depending on how many grants the CSHP obtains for this issue, the board hopes to spend \$0 on this issue.

Work on the manuscript for this issue will be completed this summer.

- 2. Pharmacy Emergency Response to Patients in a Declared Disaster Area:**

At the January 2005 Board Meeting, the board approved the development of a pharmacist emergency response *Health Notes* for the board.

RoseAnn Jankowski, former chair of the board's Competency Committee, is coordinating this issue. A list of articles and educational objectives for this issue were provided to the board for review. Completion of this manuscript is scheduled for mid summer 2005.

- **Redesign of the Board's Web site**

Chairperson Zinder stated that on December 22, the board's redesigned Web site was activated. The new format fits the mandated style of design of the Governor's Office. The goal is to have all state Web sites look similar.

However, several additional changes will be made to the Web site in the next few weeks as the new configuration is a little more difficult for some of staff to use.

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

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

The board's Power Point presentation on the board (containing key board policies and pharmacy law) is a continuing education course, typically provided by a board member and a supervising inspector. Questions and answers typically result in a presentation of more than two hours, and these presentations usually are well received by the individuals present.

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

Since the January Board Meeting, board members and staff have:

- presented 9 public presentations about the board and new pharmacy laws
- provided 5 public presentations about the new controlled substances dispensing and prescribing requirements
- staffed 2 public booths at consumer fairs and 1 information booth for 2 days at the CPhA Annual Meeting

President Goldenberg welcomed Raffi Simonian, former Board Member and Board President, who arrived to attend the board meeting.

Ms. Harris stated that the board's supervising inspectors saw a presentation by Target in February regarding the new prescription vials used for patients. She demonstrated to the board the features that include a color-coded indicator to distinguish which person in a household the medication is for, large typed information on the prescription bottle, and a patient information card inside the label. She added that larger typed patient information sheets would also be distributed at the time the prescription is dispensed.

ENFORCEMENT COMMITTEE

Chairperson Powers reported on the Enforcement Committee Meeting on March 9 in Burbank. He stated that due to the cancellation of flights to the Burbank airport that morning due to fog, he and a number of other individuals were unable to attend the meeting. Because the Enforcement Committee did not have a quorum, staff counsel advised that an official meeting of the Enforcement Committee could not be held.

- **Letter from Jeffrey A. Moss, Attorney for the Pharmacy Defense Fund Related to the Waiver of California Code of Regulations, title 16, sec. 1717(e) – Use of an Automated Dispensing Device**

Chairperson Powers referred to a letter from Attorney Moss representing the Pharmacy Defense Fund (PDF). According to the letter, the PDF has requested that Mr. Moss investigate the issues related to the board's approval of the temporary waiver that it issued to

Longs Drug Stores for use of an automated dispensing device. In his letter, Mr. Moss provides a list of comments regarding the PDF's concerns with the waiver and the use of these machines.

Chairperson Powers stated that subsequent to the board receiving a letter from Mr. Moss, Mr. Moss also filed a lawsuit on the same issue. The board's legal counsel advised the board not to discuss the matter.

- **Update from Longs Drug Stores Regarding the Use of an Automated Dispensing Device (Patient Delivery Units) in its Pharmacies**

At its October meeting, the Board of Pharmacy granted to Longs Drug Stores a request for a waiver of 1717(e) to install and use a self-service dispensing unit, such as the Asters ScriptCenter, at various Longs Drug Stores in California. At its January meeting, the board granted a similar waiver to Safeway, Inc., to install and use these same units at its Safeway and Vons pharmacies.

The board granted the waivers to permit the use of an automated dispensing device that allows a patient to access his or her filled prescriptions under the following specified conditions:

- The automated dispensing device is used for refill prescriptions only.
- It is the patient's choice to use the automated dispensing device.
- The device is located in reasonable proximity to the licensed pharmacy premises.
- The device is secure from access and removal by unauthorized individuals.
- The pharmacy provides a means for the patient to obtain a consultation with a pharmacist if requested by the patient.
- The pharmacy is responsible for the prescriptions stored in the device.
- A pharmacist is not to use the device to dispense refilled prescriptions if the pharmacist determines that the patient requires counseling pursuant to CCR, title 16, sec. 1707.2(a)(2).

Chairperson Powers stated that at previous meetings, John Cronin, Senior Vice-President for the California Pharmacists Association (CPhA), raised concerns about the effect that granting these waivers will have on the interactions between pharmacists and consumers. He discussed the philosophical question of technology in pharmacies and the impact that these devices will have on consumers and the role pharmacists play in monitoring ongoing drug therapies. In his letter dated April 12, 2005, Dr. Cronin is recommending that as part of the waiver process, the board require the pharmacy to submit a "pharmacy services plan" that would include a clear description of how the requested waiver would facilitate the provision of pharmacist care and improve patient care in the pharmacy. CPhA is suggesting that the plan should also include a description of how the requesting pharmacy will monitor and measure attainment of the plan goals. It may also include a description of the anticipated impact on business operations, hours of operation and staffing. Compliance with the plan would be monitored by periodic

inspections and failure to comply with the proposed pharmacy services plan would be basis for withdrawal of the waivers, or other action by the board.

Chairperson Powers reported that Supervising Inspector Dennis Ming inspected Long's Drugs #247 in Del Mar, California and the inspection revealed compliance in regards to limitation on only refill medications not requiring consultation in the machine, notice to provide consultation, security and patient choice. And the pharmacy staff appeared to be well trained in using the ScriptCenter.

Orriette Quandt, PharmD, with Longs Drug Stores, presented a PowerPoint demonstration of the Longs ScripCenter Patient Delivery System.

Dr. Quandt stated that the purpose of the presentation was to address questions and concerns about patient delivery units that were raised in the media and in letters to the board. She described the patient delivery system location, how Longs is monitoring and auditing the unit, privacy and security features, training and quantification of when patients are using the unit. She added that so far, over 600 patients have signed up to use the system and 1550 prescriptions have been provided from the machine.

- **Request from University of San Diego (UCSD) Medical Center for a waiver of 1717(e) to install and use a self-service dispensing unit for refill prescriptions at its hospital outpatient pharmacy**

Chairperson Powers stated the Board of Pharmacy has received a request from the UCSD for a waiver of California Code of Regulations section 1717(e) to install and use a self-service dispensing unit at its hospital outpatient pharmacy.

Chairperson Powers stated that because the Enforcement Committee did not have a quorum at the last meeting, the committee did not make a recommendation on this agenda item.

Raffi Simonian, representing UCSD Medical Center, thanked the board and stated that the Medical Center, in an effort to improve patients' access to pharmacy services and therefore improve their compliance with their prescribed drug regime, respectfully requests a waiver to allow the installation and implementation of ScriptCenter, a self service prescription delivery unit manufactured by Asteres.

Dr. Simonian stated that in conjunction with this waiver, the UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences (SSPPS) is developing a formal study on the impact of this technology to pharmacy and patients. He added that a waiver is needed to proceed with providing periodic reports and an end report at the conclusion of the study.

Dr. Simonian introduced Jan Hurst, Assistant Professor, UCSD, as the principal investigator on the research project and the Associate Dean.

Dr. Simonian stated that the Asters ScriptCenter is an automated, self-contained instrument that allows patients to access their filled prescriptions. The intent is to install the units in close proximity to the pharmacy area. To improve patient convenience and therapeutic compliance, a patient may access the units during pharmacy hours or during those times when the main facility is open, but the pharmacy is closed.

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

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

President Goldenberg asked how this project would be funded.

Dr. Simonian responded that the UCSD would seek funding from foundations.

Dr. Hiura asked how long it would take to issue a report.

Dr. Simonian responded that significant progress should be made within six months from the start of the project. UCSD would prepare quarterly reports for the study which would last 18 to 24 months.

Dr. Schell asked if any patients would be excluded from the research study.

Charles Daniels, Pharmacist-In-Charge, UCSD Medical Center, stated that patients would be excluded from the research study if they take five or more medications and 12 or more doses per day. Dr. Daniels added that the intent is to build on the literature already developed.

Chairperson Powers asked if the study would also include an economic impact. Dr. Daniels stated that this would be considered.

Dr. Simonian responded that this particular pharmacy fills approximately 400 prescriptions daily. The study would include assessment of long-term patient satisfaction and wait times.

John Cronin, representing the California Pharmacists Association, stated that although the CPhA is not opposed to the waiver request, there is concern about the consultation aspect and how this would be provided. Dr. Cronin stated that the system should only be available after the pharmacy is closed. He cautioned against calling the unit a dispensing device because patient care compliance is not considered. He added that the technology is valuable but patient care must be considered first.

Chairperson Powers recommended that Dr. Cronin provide his comments in writing for the next Enforcement Committee Meeting.

Dr. Fong stated that there are many layers to the practice of pharmacy such as regulations and staff initiative and everyone is trying to achieve the best practice. He cautioned against getting hung-up on these issues that stand in the way of progress. He added that improvement of total care should be the objective and if this dispensing machine can dispense medication when the store is closed it will achieve this objective.

Mr. Jones reminded the board and the audience that even if the board grants a waiver, the pharmacy is still responsible for any errors that may occur in the pharmacy.

UCSD is seeking a waiver to initiate the study but will return with a more detailed study plan in the future.

MOTION: Approve the request from University of San Diego Medical Center for a waiver of California Code of Regulations, title 16, section 1717(e) to use an automated dispensing device for refill prescriptions at its outpatient pharmacy in conformity with components in the board's proposed regulation, and in conjunction with the development of a formal study on the impact of this technology to pharmacy and to patients.

M/S/C: SCHELL/CONROY

SUPPORT: 6 OPPOSE: 4

- **Request from White Cross Drug Store for a waiver of California Code of Regulations, title 16, section 1717(e) to use an Automated Dispensing Device for Refill Prescriptions**

Chairperson Powers stated that White Cross Drug Store is requesting a waiver of California Code of Regulations section 1717(e) to install and use a self-service dispensing unit (the ddn, APM Automated Product Machine) in its pharmacy.

Dr. William Holmes, representing the ddn, Corp., stated that Bassam Massaad, Pharmacy Manager of White Cross Drug Store, could not attend the board meeting because his pharmacy was too busy and he could not take the time off from work. Mr. Homes gave a presentation to the board on the ddn, APM system.

Dr. Holmes stated that the APM technology is three years old and was approved by the Utah State Board of Pharmacy for use in a pharmacy there. The dispensing unit was installed in March 2002, and remains in service today.

Dr. Fong asked if the unit is in use anywhere else in the United States. Dr. Holmes stated that it was not.

President Goldenberg asked if there were any plans to conduct a study.

Dr. Holmes stated that the ddn, Corp. would offer the dispensing unit to be included in the study and also conduct their own study to analyze customer reaction to the dispensing unit.

Mr. Jones stated that it is the pharmacist-in-charge or the pharmacy owner needs to personally appear before the board to request a waiver and answer questions from the board. He suggested that Mr. Massaad appear at the next meeting to request the waiver.

MOTION: That the Board of Pharmacy delay action on a waiver request from the White Cross Drug Store until the next board meeting so the pharmacy owner can formally request a waiver of California Code of Regulations, title 16, section 1717(e) to use an automated dispensing device for refill prescriptions.

M/S/C: POWERS/JONES

SUPPORT: 10 OPPOSE: 0

- **Discussion on the Importation of Prescription Drugs**

Chairperson Powers stated that 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.

This year, Governor Schwarzenegger is sponsoring SB 19 "California Rx," which is in response to his last year's veto of SB 1149 (Ortiz, 2004). In his veto message, the Governor stated, "A top priority of my Administration is to provide access to affordable prescription drugs. However, importing drugs from Canada or assisting residents in their efforts to do so would violate federal law and could expose the State to civil, criminal and tort liability. In an effort to bring significant price reductions to California's most at-risk consumers, my Administration put forward California Rx that seeks to provide real assistance to these Californians."

- **Information Regarding the Prescribing Authority for Naturopathic Doctors**

Chairperson Powers referred to a legal opinion from staff counsel Dana Winterrowd regarding the prescribing authority for naturopathic doctors. An article appeared in the board's January 2005 newsletter regarding the authority of Naturopathic Doctors to prescribe; however, since the article appeared, the board has been working with the Bureau of Naturopathic Medicine to further clarify this authority.

- **Implementation of SB 151 (Chapter 406, Statutes of 2003) – Requirements for Controlled Substance Prescriptions Became Effective January 1, 2005**

- Chairperson Powers stated that as of January 1, 2005, written prescriptions for all controlled substances must be on tamper-resistant security prescription forms that have been printed by a board-approved printer and must contain specific elements. Oral and fax orders for Schedules III-V are still permitted.

If a pharmacist has questions concerning the validity of the prescription, the board is advising that the prescription should be treated like any other questionable prescription – call the prescriber to verify the prescription. If the form does not contain the proper features, it may indicate that a board-approved printer did not print it. Such prescriptions should be reported to the BNE at (916) 319-9062.

Other new changes are:

- Pharmacies must report Schedule III controlled substance prescription information to the CURES system.
- Prescribers dispensing Schedule II and III controlled substances must report those prescriptions to the CURES system.
- The exemption for Schedule II prescriptions for the terminally ill remains in effect (H&S Code 11159.2), meaning that a security prescription form is not needed for these prescriptions. (This exemption doesn't apply to Schedule III prescriptions.)

To further aid in the implementation of the new controlled substance laws, a series of articles appeared in the board's January newsletter and is available on the board's Web site.

A frequent question asked is what should a pharmacy do if it receives a Schedule II-V prescription that is not on a security form. The board's direction to pharmacies is to treat these prescriptions as "oral" prescriptions and for the pharmacist to initial and date under Health and Safety Code 11164(b)(1). The pharmacist should always use his or her professional judgment when filling the prescription, contact the prescriber to verify if necessary and to advise the prescriber that for future written prescriptions, security forms are required.

Clarification also has been recently provided regarding the filling of prescriptions by California pharmacies for prescriptions that are written by prescribers from another state.

Health and Safety Code section 11164.1 provides that a California pharmacy may fill a prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state if the prescription conforms with the requirements for controlled substances in the state in which the controlled substance was prescribed, and the prescriptions for Schedule II and Schedule III controlled substances dispensed must be reported to CURES.

Pharmacies may dispense prescriptions for Schedule III, Schedule IV and Schedule V for out-of-state prescribers pursuant to Business and Professions Code section 4005 and CCR, title 16, section 1717. This means that the prescriber must be authorized to prescribe Schedules III-V in that state and the prescription must be either faxed or an oral order. Otherwise, the prescription must be on California's security prescription form.

The direction that board inspectors are giving to pharmacists is to take care of the patient. It is not the board's position that pharmacists be the "forms police." It is the responsibility of the prescriber to have the correct legal forms. Board members and supervising inspectors continue to provide extensive outreach presentations on this new law change.

- **Implementation of SB 1159 (Chapter 608, Statutes of 2004) – Disease Prevention Demonstration Project**

With the recent enactment of Senate Bill 1159, (Vasconcellos, Chapter 608), local cities and counties can now authorize the establishment of the Disease Prevention Demonstration Project (DPDP), allowing pharmacies to sell syringes without requiring a doctor's prescription. The new legislation stipulates that the California Department of Health Services (DHS) must convene an uncompensated Evaluation Advisory Panel and, in coordination with this panel, design and implement a comprehensive evaluation that will assess the impact that SB 1159 has on HIV and HCV risk behaviors as well as the health and well-being of surrounding communities and stakeholders.

SB 1159 requires that DHS evaluate the effects of allowing licensed pharmacists to furnish or sell a limited number of hypodermic needles or syringes without prescription, and provide a report to the Governor and the Legislature on or before January 15, 2010.

The report shall include the effect of nonprescription hypodermic needle or syringe sale on: 1) hypodermic needle or syringe sharing practices among those who inject illegal drugs; 2) rates of disease infection caused by hypodermic needle or syringe sharing; 3) needle stick injuries to law enforcement officers and waste management employees; 4) drug crime or other crime in the vicinity of pharmacies; 5) safe or unsafe discard of used hypodermic needles or syringes; and 6) rates of injection of illegal drugs.

Chairperson Powers stated that he and President Goldenberg are the Board of Pharmacy representatives and the first meeting was held March 29th.

Chairperson Powers stated that it appears from the panel's first meeting that implementation of this legislation involves many factors such as: pharmacy participation, local city or county approval of the project, the disposal of hypodermic needles, and local law enforcement. Board participation on this advisory committee will provide the opportunity to be knowledgeable about the implementation and provide outreach to licensees and to the public. He added that these meetings would provide a better understanding for everyone involved. To date, nine counties and/or cities have approved participation in the demonstration project. The next meeting is scheduled for June 7.

- **Recognition of Claudia Foutz, CSHP, Executive Director**

President Goldenberg welcomed Claudia Foutz who is the newly appointed executive director of the California Society of Health-System Pharmacists. He added that Ms. Foutz was also a former executive officer with the Board of Pharmacy.

- **Recognition of Eric Luedeke, Center for Public Interest Law**

President Goldenberg welcomed Mr. Luedeke to the board meeting. Mr. Luedeke is a student representative for the Center for Public Interest Law.

President Goldenberg stated that Collette Galvez, Staff Attorney for the Center for Public Interest Law, has accepted a position with the Office of the Attorney General's Office. President Goldenberg acknowledged Ms. Galvez's efforts and contributions to the board on behalf of the Center for Public Interest Law.

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

Last year, the Board of Pharmacy sponsored SB 1307 (Figueroa, Chapter 857). 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.

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. The pedigree must contain information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by a wholesaler, until final sale to a pharmacy or other person furnishing, administering, or dispensing the drug.

The pedigree must contain all of the following information: (1) the source of the dangerous drug, including the name, state license number, including California license number if

available, and principal address of the source (2) the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers (3) the business name, address, and if appropriate, the state license number, including a California license number if available, each owner of the dangerous drug and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug (4) a certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.

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

EPCglobal, a non-profit organization, has developed broad industry standards for the use of electronic product codes (EPC) in global commerce. An EPC is a simple "license plate" that uniquely identifies objects (items, cases, pallets) in the supply chain. Multiple committees within EPCglobal are currently working to develop standards and fully examine both the feasibility and the ramifications of implementing EPCs to support the use of RFID with pharmaceutical products. EPCs can securely store information about a specific product in a tag that is affixed by the manufacturer. With the development of global standards and the utilization of RFID technology, EPCs will provide for immediate, automatic, and accurate identification of any pharmaceutical item in the supply chain and will enable the industry to track a product's distribution history, which constitutes an e-pedigree. The industry goal is to develop EPC standards by the summer of 2005, with the expectation of meeting the FDA's requirements for recommended time frame for implementation of electronic track and track technology by late 2007.

Meanwhile, the National Association of Boards of Pharmacy (NABP) announced in November that it is exploring the creation of a clearinghouse of pedigree data. To facilitate the collection and maintenance of electronic pedigree information, NABP stated that it would establish a task force of state regulators, manufacturers, wholesalers, pharmacies, government regulators, and information technology experts to explore the feasibility of creating a clearinghouse for relevant information to establish an electronic pedigree. The task force will work with EPCglobal to create the necessary standards for the development of e-pedigree software. It is the intent of NABP to act as an honest broker to facilitate the creation of policies and business rules for the exchange of information among trading partners.

In January, Executive Officer Harris participated on the National Association of Boards of Pharmacy (NABP) Task Force to Develop Recommendations for Electronic Pedigree Requirements that were convened via teleconference call. The task force recommended the electronic pedigree data elements. Staff has also participated in two other NABP wholesale

distributor regulatory meetings in January and February. In addition, staff has been involved in two telephone conference calls with Accenture. This company has been serving as the project manager for a group of trading partners in the pharmaceutical industry to explore the use of RFID/EPC technologies. They are currently working with several companies over the next four months to create company specific plans to enable RFID capabilities while facilitating collaboration among the trading partners.

At the December 2004 Enforcement Committee meeting, T3Ci, an application software company that provides drug counterfeit, diversion detection and electronic drug pedigree for the pharmaceutical market demonstrated their technology solution for the electronic pedigree. This presentation was for informational purposes only. Currently, they are pilot testing their system with various manufacturers. It is not the intent of the Board of Pharmacy to support or endorse any specific technological solution for the electronic pedigree requirement.

At this Board Meeting, Benjamin Yee, VP Sales and Marketing, Acerity Corporation, presented its security software program, which is an electronic authentication process. The system employs cryptography techniques in conjunction with RFID forming a multiplayer secure process, which provides numerous advantages and allows versatile applications.

Mr. Yee demonstrated how RFID technology works from a manufacturer through wholesalers to a pharmacy.

LICENSING COMMITTEE

Chairperson Conroy reported on the March 16, 2005 meeting of the Licensing Committee.

- **Development of Proposal for Pharmacist Performing Drug Utilization Review (DUR), Medication Therapy Management (MTM), Pharmacist Call Centers and Central Processing of Prescriptions for California Patients**

Chairperson Conroy stated that at the last Licensing Committee meeting, staff prepared an overview of the many issues and questions that the board has received regarding pharmacist's care and the practice of pharmacy for California patients. The purpose of the document was to provide the foundation to begin the discussion on how the board should address the many issues that do not fit the traditional statutory definition of pharmacy and recognize the independent practice of pharmacists as health care professionals.

The committee agreed to address the various issues through its quarterly meetings and was encouraged to develop a proposal sooner than later as the provisions of the Medicare Modernization Act (MMA) that addresses pharmacists' services within the Medication Therapy Management Programs of the Medicare Act take effect in 2006. The drug benefit in Medicare Part D provides reimbursement for pharmacists to provide medication therapy management (MTM) for Medicare beneficiaries. Examples of MTM services are: patient health status assessments; medication "brown bag" reviews; formulating/adjusting prescription treatment

plans; patient education and training; collaborative drug therapy management; special packaging; refill reminders; and other pharmacy related services.

Based on the discussions at the last Licensing Committee Meeting, staff drafted a proposal from which the committee could begin addressing the many issues. The proposal is a means by which to begin the discussions. For better understanding, the concepts were written as statutory changes. The proposal:

- Updates the definition of a pharmacist.
- Revises the definition of a pharmacy to include an “intake/dispensing pharmacy,” a “prescription processing pharmacy,” an “advice/clinical care pharmacy” and “nonresident pharmacy.”
- Acknowledges that pharmacy is an evolving profession that includes more sophisticated and comprehensive patient care activities.
- Updates pharmacy law to accurately reflect pharmacy practice and the functions of a pharmacist.
- Requires that a pharmacist who performs cognitive services for California patients be licensed in California.
- Specifies that a pharmacist who authorizes the initiation of a prescription or performs other cognitive services outside a licensed pharmacy must maintain patient records or other patient-specific information used in those activities and the records must be provided to the board upon request.

Statutory changes were also made to the pharmacist scope of practice sections contained in Business and Professions Code section 4052, which are exclusively technical clean up provisions to improve the clarity of this section.

Other changes updated the definition of a nonresident pharmacy to include prescription review, patient consultation drug utilization review, medication therapy management and other cognitive pharmacy services. Another proposal states that the pharmacist-in-charge of a nonresident pharmacy must be a California licensed pharmacist, another section requires that only a California licensed pharmacist can perform prescription review, consultation, drug utilization review, medication therapy management or other cognitive pharmacy services for California patients.

There is also a change to require a pharmacy to include in its quality assurance program inappropriate provisions of cognitive services such as prescription review, consultation, and drug utilization review or medication therapy management. The board would be given authority to investigate matters related to the performance or provision of cognitive services. The definition of unprofessional conduct for a pharmacist is amended to include those acts or omissions that involve the failure to exercise or implement his or her best professional judgment and/or corresponding responsibility with regard to dispensing or furnishing controlled substances, dangerous drugs or dangerous devices and/or with regard to the provision of cognitive services. It also includes the acts or omissions that involve the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function. For pharmacists that practice outside of a licensed pharmacy premise, unprofessional conduct may

include acts or omissions that involve the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

There was considerable discussion and concern expressed regarding the draft statutory proposal. The greatest concern raised was the requirement that pharmacists practicing outside of California and providing cognitive services to California patients would be required to be licensed pharmacists in California even if these services are being provided under the auspices of a nonresident pharmacy permit. Another concern was the proposed requirement that the pharmacist-in-charge for nonresident pharmacies would possess a California license. These are major deviations from the current regulatory framework for nonresident pharmacies. There were also questions as to the expanded definitions of pharmacy and the need for these types of facilities to be licensed as pharmacies.

This proposal will be the focus of roundtable discussions at future Licensing Committee meetings. It is the committee's goal to have a proposal for action at the October board meeting.

John Cronin, representing the California Pharmacists Association, asked the board to allow enough time to address these significant issues.

- **Competency Committee Report**

- **Pharmacist Licensure Examination**

Chairperson Conroy stated that the Board of Pharmacy transitioned to the new examination structure in January 2004. The board began administering the California Pharmacist Jurisprudence Examination (CPJE) in March 2004. Since February 28, 2005, the board has received 2,778 applications to take the California license exams; 1,341 individuals have become licensed as pharmacists since mid-June 2004 and 2,195 individuals have been made eligible to take the licensure examinations; 1,731 individuals have been verified to the National Association of Boards of Pharmacy (NABP) qualified to take the North American Pharmacist Licensure Examination (NAPLEX) for California (includes score transfers); 1,990 CPJE examinations have been administered and 357 have failed the CPJE examinations. Also, 82 regrades of the CPJE have been performed (resulting in no change in score).

Ms. Herold referred to a report provided to the board on the pass/fail rate, the demographic characteristics and the performance of candidates who have taken the NAPLEX and CPJE, from March 29, 2004 – March 31, 2005.

Ms. Herold stated that the overall pass rate of the exam was 81.5 percent. The overall pass rate for the prior exam format was in the mid 50s. She added that California candidates did significantly better than others on the exam with a pass rate of 94 percent on the CPJE.

The NAPLEX exam had an overall pass rate of 99.3 percent for students from California schools. Other domestic graduates had a pass rate of 77 percent on the CPJE, and 95 percent on the

NAPLEX. Foreign candidates had a pass rate of 66.7 percent on the CPJE and a pass rate of 91.3 on the NAPLEX.

Ms. Herold added that the degree candidates earned higher school candidates attended makes a difference on how they perform on the exam. Candidates with a Pharm.D. Degree had a pass rate of 85 percent on the CPJE. The overall pass rate for those candidates with a B.S. Degree was 68 percent.

Ms. Herold stated that the goal is to provide this statistical report for the April and October Board Meetings.

- **Restructure of the Competency Committee**

Ms. Herold stated that last year the Board of Pharmacy agreed with the recommendation from the Licensing Committee to restructure the Competency Committee. The Competency Committee develops and scores the CPJE. The committee is to be restructured into a two-tier structure – a core committee and a group of item writers. The item writers will develop questions for the examination, and the core committee will select items and refine them for the examination, select cut scores and oversee issues arising from administration of the examination.

Ms. Herold stated that to activate this restructuring, the board needs additional pharmacists to serve as item writers and committee members. The board is now aggressively recruiting individuals for these important duties. She referred to an article in the board's January 2005 newsletter, requesting interested individuals to submit applications. She added that all board members are asked to assist in recruiting for these positions.

The preference for members of both committees would be for pharmacists who are more recent graduates of pharmacy schools instead of long-term practicing pharmacists, although some experienced pharmacists are also needed.

- **Job Analysis**

The Board of Pharmacy is required to perform a job analysis of the pharmacist profession every three to five years, to maintain the validity of the licensure examination. The Department of Consumer Affairs recommends that a job analysis be conducted 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. The board completed its last job analysis in 1999/00.

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 will be tallied by the board's examination consultant and analyzed by the Competency Committee in August. A new content outline should be in place by the end of 2005. 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 will not include tasks tested by NAPLEX; these tasks will be removed via analysis of the NAPLEX content outline.

- **Administration of the CPJE – New Vendor Contract**

Ms. Herold stated that the administration of the CPJE is 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 is not required to go out to bid for separate test administration contracts. However, this master contract ends November 30, 2005.

Currently the Department of Consumer Affairs is 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.

At this time, the tentative RFP release date was April 4th. Review of the responses to the RFP by the evaluation team should be completed by May 4. The new contract should be awarded on June 20, 2005, leaving four months to implement a transition to the new contract before the end of the current contract.

However, delays in this process could impact the ability of applicants to take the CPJE after November 30, 2005. The board's staff is participating in the RFP process and carefully following the timelines to assure there are no administration problems in December.

On a different matter Dr. Fong stated that the problem is that employers plan for candidates to take the exam and it creates a difficult situation for employers whenever there is a delay.

Ms. Herold stated that the quality assurance review must be done periodically to test the exam's validity. When this occurs, the board holds exam results until a number of exams are administered. The exam vendor advises the board when to release scores.

Ms. Harris stated that letters are sent to candidates informing them of the quality assurance review process but the delay is dependent upon the number of candidates taking the exam. If few take it, it takes longer to have the data to perform the review.

- **Petition Process for Intern Hours**

For a number of years, pharmacist interns have been required to earn 1,500 hours of intern experience as a requirement for pharmacist licensure. The only exception was for pharmacists licensed in other states who could meet this requirement by providing evidence of licensure and working as a pharmacist for one year in another state.

Last year's board omnibus bill (SB 1913, Chapter 695) contained provisions that moved key intern requirements from board regulations to statutes. At the January 2005 board meeting, the board approved adoption of a related rulemaking to streamline the requirements for earning intern hours. Several changes were made, including one to eliminate a cap of 250 hours on maximum intern hours earned during the first year of pharmacy school. This regulation should be in effect by July 1, 2005.

The committee declined to continue with the following process.

Since before 1990, the board has had an informal process to allow pharmacists from foreign countries to petition for 600 intern hours for experience they earned in the foreign country as an intern or pharmacist. To petition for the 600 hours, the applicants had to have earned 250 hours of intern experience in California, and provide experience affidavits attesting to their experience in the foreign country. The board used the old intern experience affidavits that list a number of pharmacist duties, and required an estimate of how many hours the applicant spent performing the specific duties in the foreign country.

The core of this evaluation was the assumption that the time spent performing the duties on the experience affidavit in the foreign country (e.g., processing prescriptions) would be the same as when performed in California. There was no other validation for this assessment. Members of the Competency Committee would review these experience petitions. Anyone who worked with the individual from the foreign country could sign the affidavit, although the board preferred that a pharmacist do it. Typically fewer than 10 of these petitions were received annually.

The problem is that the petition process outlined above was an underground regulation, and the board cannot continue with this process unless a regulation is promulgated to permit it. The board took no action to continue this process.

- **Accreditation Council for Pharmacy Education (ACPE) Site Visits**

Ms. Herold stated that over the last few months, the ACPE has visited the new schools of pharmacy at Loma Linda University and the University of California San Diego. Chairperson Conroy participated in the review at the Loma Linda School of Pharmacy, and Board Member Schell participated in the review at UCSD. More recently Board Member Dave Fong participated in the pre-candidate review at the University of Touro.

LEGISLATION AND REGULATION COMMITTEE

Chairperson Jones reported on the April 7, 2005, Legislation and Regulation Committee Meeting.

- **Regulations Undergoing Review**

Chairperson Jones stated that staff published a 15-day notice on February 2, 2005, to make minor changes to the omnibus group of regulations approved by the board at the January 2005 Board Meeting. That notice period ended on February 22, 2005. There were no changes or comments made to this language.

The rulemaking file has been compiled and is now undergoing administrative review. It is anticipated that the regulations will be in place about the time of the July 2005 Board Meeting.

- **Pending Regulations**

Amend CCR Title 16, Section 1717(e) and add section 1713

At the October 2004 Board Meeting, the board moved to regulation hearing proposed regulation changes that will permit the use of drop boxes to drop off prescriptions, and the use of automated dispensing devices to dispense refill medication when the patient has “opted-in” to use this system. At the current time, the regulation has not been noticed.

Legislation Report and Action

Board-Sponsored Legislation

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

Chairperson Jones stated that this bill would define compounding of a prescription drug for the purposes of the Pharmacy Law and would implement standards for pharmacies that compound medications.

Ms. Harris stated that the April 18 version of the bill clarifies that compounding over-the-counter drugs or nonprescription drugs are excluded from the definition of compounding.

Steve Gray, representing Kaiser Permanente, expressed concern that the statute allows pharmacists to compound a reasonable supply of medication for doctor’s office use but does not allow a pharmacist to compound medications for use in a licensed facility. He suggested that the statute be amended to also allow pharmacists to compound a reasonable supply for use in a licensed health care facility like a surgical clinic or not-for-profit clinic that does not have its own pharmacy.

Mr. Powers suggested that staff check with the Department of Health Services to see if they have objections.

MOTION: That the Board of Pharmacy support AB 595 (Negrete McLeod) and that staff contact the Department of Health Services to pursue possible amendments to Business and Professions Code section 4052 that would allow pharmacies to compound medication for prescriber's office use and also for exempt hospitals (without pharmacists) as well as surgical clinics.

M/S/C: POWERS/TILLEY

SUPPORT: 10 OPPOSE: 0

- **SB 1111 (B&P Committee) Omnibus Bill**

Chairperson Jones stated that this omnibus bill includes eight changes the board is proposing for the Business and Professions Code. These proposed changes would be made to:

1. Eliminate the Rules of Professional Conduct (B&P 4005 & 4206)
2. Recast and revise requirements for designated representatives (B&P 4053)
3. Make technical updates to licensing provisions (B&P 4127.5, 4205 & 4400)
4. Recast and revise continuing education requirements (B&P 4231 & 4232)
5. Recast and revise the Pharmacist Recovery Program (B&P 4360-4373)
6. Modify the Pharmacy Technician Program (B&P 4023.5, 4038, 4114, 4115, 4115.5 & 4202)
7. Alter requirements for the letter of admonishment (B&P 4315)
8. Establish reporting requirements for impairment or theft by licensed individuals (B&P 4104)

Jan Perez, Legislative Coordinator, stated that these changes would clean up previous legislation to strengthen the board's ability to provide consumer protection, update the law, or respond to state and national trends in regulating pharmacies and pharmacists. All the proposals are non-controversial.

John Cronin, representing the California Pharmacists Association, stated that the CPhA has identified a couple of issues with the language regarding technicians and the externship and number of hours.

An individual from the audience stated that the requirement for 120 hours of practical experience for pharmacy technician trainees who are enrolled in a technician training school is not sufficient. This number of hours does not begin to give students the hands-on experience needed. She added that only after six weeks do students begin to be able to

perform at the level they should and provide the site a good enough opportunity to see if this is someone they would like to employ. She added that she is in favor of raising the level of experience for technician trainees.

Ms. Harris expressed concern that this could be an issue with labor organizations because and this technician training issue was very controversial and careful negotiations were established to define the standard as it is. She added that pharmacy technician trainees can work in excess of 120 hours at one location but can only receive credit for 120 hours and therefore should be rotated to another location.

Another comment from the audience was related to the impaired pharmacist program and that technicians should be included.

Ms. Harris stated that this would require a major amendment to the bill.

She added that if the board included technicians within the pharmacists recovery program, it would increase program costs greatly. Technicians can participate within the program now but have to pay for the administrative costs for this service on their own.

Lori Rice, representing UCSF, stated initially, the Pharmacist Recovery Program was established to promote treatment without disciplinary action. She felt that this program would also benefit technicians.

Ms. Herold stated that technicians could elect to participate in the Employee Assistance Programs through their employers. She added that traditionally, treatment for pharmacists has been successful because of the investment made in their education and the motivation pharmacists have to retain their careers as pharmacist. She added that in addition to the monthly fees the board pays per participant to the program provider, it would also require additional costs to the board for monitoring technicians in the program.

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy supports the proposed changes to SB 1111 (Committee on Business, Professions and Economic Development)

SUPPORT: 10 OPPOSE: 0

- **AB 497 (Negrete McLeod) Drug Wholesalers and Manufacturers: Licensure Exemption Committee Recommendation: Oppose**

Ms. Perez stated that the Legislation and Regulation Committee recommended an oppose position on the initial version of this bill that would exempt from the licensing requirements of B&P 4161, a nonresident wholesaler that ships, mails, or delivers dangerous drugs or dangerous devices into California to an affiliated or related wholesaler

licensed by the board. This bill reverses provisions enacted last year in board-sponsored bill AB 2682 (Chapter 887, Statutes of 2004).

Parke Terry, representing drug wholesalers, requested that the board restore the exemption from licensure requirements for non-resident wholesalers who ship dangerous drugs and devices into California-licensed wholesalers.

Deputy Attorney General Joshua Room expressed concern about the board's enforcement ability if out-of-state entities are not licensed by the board.

Ms. Perez added that the current version of the bill restores last year's enacted provisions and instead makes non-resident wholesalers subject to a single \$100,000 surety bond requirement as a condition to license or renew the site licensing of all the owner's wholesaler locations.

MOTION: That the Board of Pharmacy change its previous motion on AB 497 (Negrete McLeod) – Drug Wholesalers and Manufacturers from oppose to support

M/S/C: Powers/Tilley

SUPPORT: 10 OPPOSE: 0

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

Chairperson Jones stated that bill is sponsored by the Department of Justice. The author's intent is to make clean-up changes to facilitate the effective operation of CURES, the prescribing and dispensing of controlled substances, and the program duties of the Bureau of Narcotics Enforcement with respect to security printers.

He added that the committee suggested amendments to: 1) Add a provision that would effectively cap board's funding of CURES each year unless the board receives an appropriation augmentation sufficient to cover the additional cost billed by the DOJ. 2) Delete the requirement that the privileges of a practitioner to prescribe controlled substances be printed on the prescription form. (Page 10, lines 10-19). 3) Delete the requirement that a pharmacist must report to the DOJ the method of payment used by a customer when purchasing Schedule II and III drugs.

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy oppose SB 734 unless it is amended to include the three amendments specified.

SUPPORT: 10 OPPOSE: 0

- **Right to Refuse to Fill a Prescription:**

AB 21 (Levine) Pharmacists: Prescriptions, would require a pharmacist to dispense a prescription except in specified limited circumstances. The bill would allow a pharmacist to decline to dispense a medication on ethical, moral, or religious grounds only if he or she has notified his or her employer in writing. The bill would make a violation of its provisions unprofessional conduct, subject to disciplinary action by the board. (B&P 4069)

Mr. Tilley stated that he opposes AB 21 because the pharmacist should not be disciplined or required to dispense a medication on ethics grounds.

The committee recommended no position on this bill, and the board did not take a position at this time.

SB 644 (Ortiz) Dispensing Prescription Drugs And Devices, would require 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)

Lilly Spitz, representing Planned Parenthood, a co-sponsor of SB 644, stated that if a pharmacist refuses to dispense medication due to moral or ethical reasons, the employer must accommodate the patient if possible. However, if no other staff is available to dispense the medication, the pharmacist would have to dispense the medication. She added that a pharmacist's professional judgment should be respected and it is within their authority to refuse to dispense the medication and the pharmacy owner can refuse to stock a certain prescription.

Dr. Gray, representing Kaiser Permanente, stated that SB 644 lacks clarity.

MOTION: The Board of Pharmacy support SB 644 (Ortiz) – Dispensing Prescription Drugs and Devices

M/S/C: POWERS/ZINDER

SUPPORT: 5 OPPOSE: 4

- **AB 283 (Koretz) Pseudoephedrine Retail Sale**

Chairperson Jones stated that this bill would limit access to ephedrine and pseudoephedrine products by requiring 1) the products be placed in a locked cabinet, and 2) a retail employee check the identification of a purchaser and report specified information about purchases to the Department of Justice.

The committee did not recommend, nor did the board take a position on this bill.

- **SB 152 (Speier) Pseudoephedrine**

Chairperson Jones stated that this 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 to produce photo identification; and 4) the purchaser to sign a document with specific information about the transaction. As amended April 18, this bill takes the provisions of the bill out of the Pharmacy Law and places them in the Health and Safety Code. Consequently, the board would not be responsible for enforcement the measure.

MOTION: Legislation and Regulation Committee: Oppose SB 152 (Speier) – Pseudoephedrine as introduced.

SUPPORT: 6 OPPOSE: 3

MOTION: That the Board of Pharmacy take a neutral position on SB 152 (Speier) - Pseudoephedrine, as amended April 18.

M/S/C: POWERS/FONG

SUPPORT: 5 OPPOSE: 4

- **AB 446 (NEGRETE MCLEOD) Settlement Agreements (Gag Clauses)**

Chairperson Jones stated that this bill is intended to close a loophole in current law that allows a practitioner licensed under the auspices of DCA to prohibit a consumer from filing a complaint as part of a settlement of a civil suit.

MOTION: Legislation and Regulation Committee: Support AB 446 (Negrete Mcleod) – Settlement Agreements (Gag Clauses)

SUPPORT: 9 OPPOSE: 0

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

Chairperson Jones stated that this bill permits general acute care hospitals to employ specially trained pharmacy technicians to check the work of other pharmacy technicians for filling floor stock, ward stock, and unit dose cassettes. The bill contains provisions required by the board in the past when granting waivers for studying technicians checking technicians.

Ms. Zinder stated that there is concern that this practice could end up in all practice settings.

Dr. Gray, representing the California Pharmacists Association, stated that CPhA supports this bill.

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy support SB 592 (Aanestad) – Acute Care Hospitals: Inpatient Pharmacy Technician Services.

SUPPORT: 6 OPPOSE: 5

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

Chairperson Jones stated that this bill would have authorized a pharmacist to serve as a laboratory director of a clinical laboratory that provides routine patient assessment procedures, as defined, under specified conditions.

The committee did not recommend, nor did the board take a position on this bill.

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

Chairperson Jones stated that this bill revises the prescription labeling requirement 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, unless the patient, requests that the information be omitted.

Mr. Tilley stated that he opposes this bill because it is a matter of privacy and patients may not want the information on the prescription label.

Comments were made that the bill is confusing and if a pharmacist adds the patient’s condition on the label, the pharmacist could be cited for violation of the code because the pharmacist did not get the expressed permission of the patient to add it to the label. The law already has requirements for what appears on the prescription label.

MOTION: Oppose AB 657 (Karnette) – Pharmacies: Prescription Containers: Labels.

M/S/C: TILLEY/FONG

SUPPORT: 8 OPPOSE: 2

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

Chairperson Jones stated that this bill allows health care professionals to receive non-monetary 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.

Suggested by the committee: Require the prescriber, prior to the electronic transmitting of a prescription, to offer to transmit the prescription to a pharmacy of the patient's choice.

MOTION: Legislation and Regulation Committee: Support if amended AB 225 (Negrete McLeod) – Electronic Prescription Information

SUPPORT: 10 OPPOSE: 0

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

Chairperson Jones stated that this bill is intended to provide clean-up language for AB 2184 (Chapter 342, Statutes of 2004), Automated Dispensing Devises. This language was requested by the Department of Health Services.

Amendment: Add the words “and dosage” to page 3, line 37 to read:

“After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to the drug and dosage as ordered by the prescriber and reviewed by the pharmacist and that is specific to the patient.”

MOTION: Legislation and Regulation Committee: That the Board of Pharmacy support if amended AB 522 (Plescia) – Automated Drug Delivery System.

SUPPORT: 10 OPPOSE: 0

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

Chairperson Jones stated that 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.

MOTION: That the Board of Pharmacy take no position on SB 401 (Ortiz)
Medical information: Pharmacies: Marketing Committee
Recommendation

M/S/C: POWERS/TILLEY

SUPPORT: 10 OPPOSE: 0

- **AB 1485 (Wyland) – Medi-Cal: Providers: Change in Ownership**

Mr. Tilley recommended that the board support this bill and agendize it for the next Legislation and Regulation Committee Meeting.

Other Bills for Consideration

Chairperson Jones stated that the committee recommended no position on the following bills, but would like staff to watch for amendments and report the status of each bill to the next committee meeting.

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

Chairperson Jones stated that this bill would establish the California Drug Safety Watch, which would require the development of a public database of adverse prescription drug reactions.

- **SB 380 (Alquist) Drugs: Adverse Event Reporting**

Chairperson Jones stated that this bill would require a licensed health professional, (a physician and surgeon, dentist, or pharmacist), and a health facility, (a hospital or clinic), to report all suspected serious adverse drug events that are spontaneous or observed in medical practice to the FDA's MedWatch program.

- **AB 72 (Frommer) Clinical Trials**

Chairperson Jones stated that this bill would require pharmaceutical companies to submit to the state the results of all studies on the safety and efficacy of prescription drugs sold in California.

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

Chairperson Jones stated that this bill would establish a state Web site to help patients purchase lower-cost prescription drugs from pharmacies in Canada, Britain and Ireland.

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

Chairperson Jones stated that this bill would establish a hotline that state residents could call for information about state and federal prescription drug discount programs.

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

Chairperson Jones stated that this bill is sponsored by the Governor and would establish the California Rx Program to negotiate for lower price prescription drugs for lower income Californians.

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

Chairperson Jones stated that this bill would establish a prescription drug discount program for low-income state residents

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

Chairperson Jones stated that this bill would place the responsibilities of several state agencies under a new state Office of Pharmaceutical Purchasing to purchase prescription drugs.

- **AB 306 (Baca) Purchasing Pool for Prescription Drugs**

Chairperson Jones stated that this bill would establish a prescription drug purchasing pool that would allow employer health plans and the uninsured to join with state and local governments in the purchase of prescription drugs.

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

Chairperson Jones stated that this bill would require a pharmacy benefits manager to make specified disclosures to its purchasers and prospective purchasers, including specified information about the pharmacy benefit manager's revenues.

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

Chairperson Jones stated that this bill would authorize a county to establish, by local ordinance, a repository and distribution program for purposes of distributing surplus unused medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies.

APPROVAL OF FULL BOARD MINUTES

January 19-20, 2005

President Goldenberg asked if there were any corrections to the board minutes of January 19 and 20, 2005. There were none.

MOTION: Approve the full board minutes of January 19 and 20, 2005.

M/S/C: JONES/TILLEY

SUPPORT: 10 OPPOSE: 0

ELECTION OF OFFICERS

President

Mr. Tilley stated that over this last year, President Goldenberg has demonstrated a great ability in meeting the challenges before the board resulting in professional outcomes. He added that President Goldenberg has worked diligently for California consumers and licensees. Mr. Tilley stated that President Goldenberg is a dedicated, fair minded individual who will do an excellent job if reelected as board president.

MOTION: Nominate Stan Goldenberg to a second term of President of the Board of Pharmacy.

M/S/C: TILLEY/POWERS

SUPPORT: 10 OPPOSE: 0

Vice-President

Ms. Zinder stated that as a public member of the board, Bill Powers has continually demonstrated his depth of knowledge, understanding and incite as Vice President of the Board of Pharmacy.

MOTION: Nominate Bill Powers as Vice-President of the Board of Pharmacy.

M/S/C: ZINDER/TILLEY

SUPPORT: 10 OPPOSE: 0

Treasurer

MOTION: Elect Ken Schell as Treasurer of the Board of Pharmacy

M/S/C: FONG/TILLEY

SUPPORT: 10 OPPOSE: 0

ADJOURNMENT

There being no further business, President Goldenberg adjourned the meeting at 5:45 p.m.