



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: **January 19 and 20, 2005**

LOCATION: **Embassy Suites Hotel
Los Angeles International Airport – South
1440 Imperial Avenue
El Segundo, CA 90245**

BOARD MEMBERS

PRESENT:

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

BOARD MEMBERS

ABSENT:

James Acevedo
Richard Benson

STAFF

PRESENT:

Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judith Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Dennis Ming, 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 9:05 a.m. on January 19, 2005.

BOARD PRESIDENT'S REPORT

President Goldenberg stated that in his effort to improve communications with the public and licensees, he asked staff to send 22 letters inviting local organizations and schools of pharmacy to attend this board meeting. He added that the board would continue sending invitations for future board meetings.

President Goldenberg summarized the board's activities and new changes in law.

- **Recent Board of Pharmacy Activities**

October 27-30, 2004 – NABP District 7 and 8 Meetings - President Goldenberg stated that he and Board Members Dave Fong, John Jones and Ruth Conroy and Executive Officer Patricia Harris attended this meeting. This group met to address professionalism, public safety, importation, pharmacy market place, developing trends for wholesalers and included a discussion on how one may predict when a pharmacist is more prone to make prescription errors. President Goldenberg announced that Ms. Harris was nominated to run for District 8 representation to the national executive committee. He added that the decision will be made in May at the annual NABP Meeting.

November 11-14, 2004 – NABP Fall Education Conference – In attendance was Executive Officer Patricia Harris and Deputy Attorney General Joshua Room. Topics included federal and state regulations, importation, pharmacist compounding and Medicare prescription drugs. He added that the national boards expressed considerable interest in California's activities involving tracking and tracing drugs and the pedigree issue.

November 19, 2004 – NABP Task Force on Associate Membership – Assistant Executive Officer Virginia Herold served as an ex-officio member on activities associated with board membership in NABP.

December 2004 – Board Member Dave Fong participated in a task force to develop recommendations to reduce medication errors in the community pharmacy practice.

Board Member Ken Schell participated on a board member panel of the ASHP at a December meeting. He also performed site visits at Loma Linda University.

- **New Laws taking effect January 2005**

President Goldenberg provided an overview of new legislation signed by the Governor relating to the practice of pharmacy that took effect January 2005; a number of statutory changes were made to most board regulatory programs. He added that this was a significantly active time for the board, as will be the next few months as the board implements these proposals.

- **Proposal to Restructure State Government**

President Goldenberg stated that on January 5, 2005, the Governor provided more detail about his proposals to reorganize government. The proposal would abolish 279 board member positions for regulatory boards under the Department of Consumer Affairs, and would dissolve boards under the Department of Consumer Affairs, and into the organizational structure of the department, under the direct authority of the director.

President Goldenberg stated that the reorganization plans are scheduled to take effect on July 1, 2005, but legislation must be introduced to accomplish this change. The Little Hoover Commission will hold public meetings on the proposed reorganization at the end of January. The Little Hoover Commission will make a recommendation on the full proposal towards the end of February. He added that the board would maintain its current activity and involvement until any and all action takes place on the restructuring resulting from legislative action.

COMMITTEE REPORTS AND ACTION

ORGANIZATIONAL DEVELOPMENT COMMITTEE

Chairperson Tilley reported on the December 7, 2004, meeting of the Organizational Development Committee. This meeting was not a public meeting.

- **Discussion on how the Board of Pharmacy can Improve and Facilitate Communication with the Public and Licensees - Recognition Program for Pharmacists Licensed 50 Years or Who Have Retired**

Chairperson Tilley stated that in keeping with Board President Goldenberg's priorities to improve communication between the board and its licensees and with the public, each of the board's committees held a public meeting before the October board meeting with this topic listed as a discussion item.

During the December Organizational Development Committee Meeting, the committee discussed an award of achievement for pharmacists for exemplary service or for long careers

of perhaps 50 years without disciplinary action. These pharmacists would receive a board commendation, public thanks, and have their names published in the board's newsletter.

The parameters for such awards are being developed by the committee, but the committee requests board member and public input during this section of the board meeting. Under consideration are awards for:

- (1) Pharmacists who have 50 years of experience as pharmacists
- (2) Pharmacists who obtain retired pharmacist licenses
- (3) Pharmacists who have performed extraordinary service to the public or profession.

Chairperson Tilley read the following letter that President Goldenberg distributed to board members on how the Board of Pharmacy can improve and facilitate communication with the public and licensees and a recognition program for pharmacists who have been licensed for 50 years or more or have retired:

For acknowledging pharmacists of 50 years – There are approximately 400 individuals in California who have been registered as pharmacists for 50 years or more. If the object is to publicly acknowledge those pharmacists, the board can consider again to publish in *The Script* their names, cities and number of years registered. This was last done in February of 1997. However, the list was subsequently omitted in later years due to lack of space.

This might include an appreciation letter or certificate, similar to the retired pharmacist's certificate from the board to each individual. The letter or certificate, for example, would express the board's gratitude for the pharmacist's years of contribution as such to honor the profession. While a retired pharmacist may request a retired pharmacist certificate, there is a charge of \$35. Whereas an appreciation letter or certificate might be sent to this person at no charge.

Another alternative would be to seek legislative acknowledgment of pharmacists with 50 years of practice.

Another option would be to publish their names in *The Script* and send a letter or certificate. Through the years, pharmacists have asked for the license renewal fee to be waived for those who have 50 years or more of registration. He added that other states or California health professions do not waive this renewal fee, but the State of Washington does offer a retired professional license renewal for \$20. He stated that perhaps a reduced fee could be considered if not waived entirely.

Ms. Harris stated that a reduction in licensing fees would require a statutory change.

President Goldenberg stated several states recognize pharmacists with long careers and Missouri reprints the license of the individual on gold paper and “50 Year Recognition” is written across the top. He added that this option could impose a significant cost to the board.

Dr. Schell stated that he supported publishing pharmacist’s names in *The Script* and issuing a certificate.

Dr. Fong suggested that the board consider the cost to administer the program.

M/S/C: POWERS/SCHELL

MOTION: Support recognizing pharmacists who have 50 or more years licensed and staff provides the board with the cost associated with these activities.

SUPPORT: 8 OPPOSE: 0

Chairperson Tilley stated that President Goldenberg also initiated new activities before the October Board Meeting to encourage attendance. Some of these activities included invitations to pharmacy students and local pharmacists’ associations in the Bay Area. He added that this resulted in a noticeable increase in attendance at the October Board Meeting.

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

Chairman Tilley stated that the Governor’s initial proposal to restructure state government was released at the beginning of August. This 2,547-page report developed by the California Performance Review aimed to overhaul 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.

As president Goldenberg stated, the Governor provided more detail about his proposals to reorganize government earlier in January 2005. Most of the proposals initially proposed in the CPR were not mentioned. However, a proposal now advanced by the Governor would abolish 279 board member positions for regulatory boards under the Department of Consumer Affairs, and would dissolve these boards into the organizational structure of the department, under the direct authority of the director.

President Goldenberg welcomed Nancy Hall, Deputy Director of Board Relations, Department of Consumer Affairs.

Ms. Hall thanked the board and recognized Ms. Harris for her efforts in working well with the department.

Ms. Hall explained that the Governor's reorganization plan (GRP) is currently with the Little Hoover Commission that would provide a report to the Legislature. Once the Legislature receives the GRP, the Legislature will vote on either approval or disapproval of the entire plan that would take effect July 1, 2005, if enacted. The Legislature has 60 days to take action.

Mr. Powers expressed concern about the proposed elimination of the Board of Pharmacy. He added that the board has been in existence for over 100 years and he feels that it serves the public well. Ms. Zinder stated that she, too, is opposed to this consolidation that would result in a less-responsive board.

President Goldenberg stated that the board has one more public meeting as well as other public committee meetings before a decision is made. He suggested that the board agendaize this for the next meeting and allow the Legislative process to continue its review.

Dr. Schell asked Ms. Hall to explain the process if this proposal is approved.

Ms. Hall stated that the function of the board would remain intact and whole. She added that the power would be transferred to the Director of Consumer Affairs and staff would report to the director rather than the board. Ms. Hall stated that the goal is to create more efficiency within state government. For example, currently, the board must meet in order to take action, whereas under the proposal, the director would yield authority.

Ms. Hall stated that public meetings would continue to be held subject to the Bagley Keene Act and agendaized 10 days prior to the meeting. The director would appoint an advisory committee. Ms. Hall added that this administration values board members and understands the contribution that all have made to the profession and to consumers. The director would like to see board members transition to the advisory committee if they choose to do so.

Ms. Hall stated that the director met with the executive officers in mid January and conveyed to them that she would like to keep the continuity of the executive officers and hoped that Ms. Harris remains with the department, reporting to the director. Ms. Hall explained that instead of voting on a particular matter, the advisory committee would advise the director of what actions to take.

Ms. Hall stated that under this format the advisory committee could meet specifically on discipline or enforcement, and there could be many advisory committees. The director would hold meetings throughout the state.

Ms. Hall stated that by the April Board Meeting, the department should have more information available on the development of the plan.

Concern was expressed about how the proposal, if enacted, might affect the membership status with the National Boards of Pharmacy since California would no longer be a board and would be the only state within the organization that does not have board status.

Mr. Jones asked how the current discretionary system would differ with the proposed plan.

Ms. Hall stated that the advisory committee would advise the director on a proposed position and an administrative law judge would preside over the hearing.

Deputy Attorney General Joshua Room added that all of the proceedings would be handled by an administrative law judge and action would be adopted or non-adopted by the director. He added that he has not personally interacted with a committee advisory board in a bureau proceeding.

Dr. Fong asked if this proposal would affect existing rulemaking files that are in process.

Ms. Hall stated that current regulation packages in progress should be fine, and would continue through the normal administrative process.

Steve Gray, representing Kaiser Permanente and the California Pharmacists Association, stated that he has been involved with the board for many years and he is very concerned about this proposal and what it means. He stated that this proposal to restructure the board is similar to how the Department of Health Services (DHS), is structured and it is difficult to pursue a regulation change from DHS because often it isn't a priority with the department.

Dr. Gray stated that this proposal is a disservice to the public and to the profession. He added that he is also concerned that this proposal seems to be on a fast track and by waiting until the April Board Meeting for more information about the proposal, there may not be enough time to form a group to provide additional input.

President Goldenberg stated that the Board of Pharmacy is part of the current Administration. He suggested that individuals wanting to express their concern should do so directly to the Legislature. He added that the board would maintain a supportive role for the protection of consumers and provide as much support to the Administration as possible.

Dan Wills, representing Grandpa's Compounding Pharmacy, expressed concern because he believes the board has been very receptive in helping consumers and the profession, and questioned whether someone else who doesn't know the profession could be as responsive. He referred to a situation in Walnut Creek where three people died resulting from a pharmacy compounding error and the Legislature's initial response was to stop all compounding.

Ms. Hall stated that the board would have sufficient time by waiting until the next board meeting to take action. She added that it is the department's intent to work with the board as they move through the process. Public interest concerns can be resolved through the advisory committees throughout the state and will not be limited to quarterly meeting but could meet more frequently depending on the subject.

President Goldenberg encouraged public participation in the evaluation of this proposal.

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

Chairperson Tilley stated that at the board's October Meeting, the board heard from a unified group of California pharmacy students from California's six schools who were 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 that the board examine its policies in this area, and submitted an unsigned petition form requesting restricted access to residence addresses of students. The students specifically requested that the board allow an address for interns to be either the attended school or place of practice.

For over a year, the board has made available on its Web site the address of record of pharmacists, pharmacist interns, pharmacy technicians and exemptees.

Whereas the petition was submitted by student interns in California schools of pharmacy, there are two other groups who hold intern licenses – (1) out of state pharmacists and pharmacy school graduates from outside California who are working in California as they gain practice experience to take the examination, and (2) foreign graduates who are earning the 1,500 hours of experience they need to take the pharmacist licensure examinations.

The committee considered several options:

1. Educate students to use a PO box as their addresses of record or a work address (and caution them about using a residence address).
2. Remove the addresses of interns from the Web site, because typically these individuals do not have work addresses that are permanent.
3. Work with the schools to allow the use of a school address for the address of record for their interns.

The committee recommended that the board take no new action at this time, but to add information currently contained in the Change of Address article in the board's newsletter on the intern application instructions. This would respond to the interns' request to use an alternate address.

Testimony from Marshal Abdulliah from the University of Southern California, Jerrod Mills from the University of the Pacific and Daniel Zlott from U.C. San Francisco

Mr. Abdulliah referred to the three options that the committee considered and stated that there is a waiting list at the post office for a post office box and the cost can range from \$3 - \$300. Most schools do not have the ability to handle mailing access for students.

He added that the only option that would work is to have intern addresses removed from the board's Web site.

Mr. Zlott stated that during a Regional Meeting of the American Pharmacists Association, a student from Western University requested that all students' addresses be removed from the board's Web site because one student was actually visited at home by one of her patients. And, with the many cases of violence concerning contraception issues, this causes concern.

Mr. Abdulliah stated that students distributed petitions at all six of the schools of pharmacy in California and they were not distributed to the board because they hoped that the board would make a decision without them. He added that there were 2,000 signatures on the petition that included concerns about privacy rights of individuals licensed by the California Board of Pharmacy. The students came to the consensus that it is inappropriate to provide personal information about licensees through the board's Web site. The goal of this proposal is to restrict patient access to licensees by simply having their address of record removed from the board's Web site.

Dr. Fong asked for clarification on the policy for publishing licensees' address of record on the board's Web site.

Ms. Harris stated that a policy decision was made because the board does not have the resources to respond to requests for addresses. Many other boards in the department put licensees addresses of record on line. Ms. Harris clarified that as a Public Records Act matter, if the board receives a written request for a licensee's address, the board must respond.

Dr. Schell suggested that the board receive a legal opinion and agendaize this item for the next board meeting.

President Goldenberg requested that the students provide any additional information at least 30 days prior to the April Board Meeting.

MSC: JONES/POWERS

MOTION: That the Board of Pharmacy seek an opinion from its council regarding the requirements of posting the address of record for licensees and consider whether the board can treat a certain group of licensees differently than all other groups of licensees.

SUPPORT: 8 OPPOSE: 0

- **Quarterly Status Report on Committee Strategic Objectives for 2004/05**

Chairperson Tilley stated that typically during the April Board Meeting, the board updates and revises its strategic plan for the next fiscal year that will start on July 1.

In 2003, a major revision of the board's strategic plan was undertaken that substantially restructured the plan. At the time of the revision (which actually was initiated in 2002 and completed in 2003), the board's intent was to make minor updating changes to the strategic plan in 2004 and undertake a major revision in 2005. This was consistent with the direction provided by the board's strategic planning consultant, that generally strategic plans should endure for more than one year in their scope and vision, and should be focused on three to five years.

The committee determined that the current strategic plan is strong and effective for managing and overseeing board activities, and does not require a major overhaul at this time. As such, the committee recommends that at the next quarterly meeting of each committee, an agenda item be established to review the portion of the plan related to the committee. During the discussion, each committee can identify recommended changes, and bring the recommendations to the April Board Meeting for adoption.

There were no additional comments.

- **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: \$5,762,673***

- 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 collected \$218,637 in fines, and \$96,749 in cost recovery as of January 2005.

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

- The board's maximum expenditure authority for the year is \$7.36 million, although several budget adjustments dealing with workers compensation costs and employee benefits are under discussion. Personnel is the largest expenditure: \$3,686,301 or 50 percent of the board's budget.

- ***Board Fund Condition***

During this fiscal year, the board is projected to spend \$1,597,327 more than it will collect as revenue. Any difference between revenue and expenditures will come from the board's fund.

The board's fund condition projects a declining balance over the next three years.

- 2004-05: The board is projected to end this fiscal year with a reserve of 4.7 months of expenditures.
- 2005-06: The reserve decreases to 1.3 months at the end of the year.
- 2006-07: A deficit of 2.4 months is projected.

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

The Governor's 2005-06 proposed budget would repay \$3.2 million of the money borrowed in 2001 (\$200,000 is interest).

2. Relocation of the Department of Consumer Affairs

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 eight miles north of the board's current location in North Natomas. The board will occupy the original Arco Arena, where the rent is less. The expected move date is November 2005. 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.

• Personnel Update and Report

Since the October board meeting, the board has hired Rosario Navarro as a second cashier. The board also hired Jan Perez, the new legislative coordinator, who began working for the board on January 10.

The board is seeking to fill three positions:

- An inspector position
- Two receptionists (temporary positions)

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 board has requested that the Department of Consumer Affairs conduct a new civil service examination for this classification. The final filing date of applications for this examination is February 18. This recruitment is announced in the board's January newsletter.

The board itself has two public board member positions vacant; these positions were created January 1, 2004, and are Governor appointments.

The board has one inspector on parental leave.

- **Presentation and Request from the Department of Justice for Increased Funding for CURES**

Chairperson Tilley stated that the committee did not make a recommendation to the board on this agenda item.

Chairperson Tilley stated that in 2002-03, in response to the board's omnibus legislation in 2001 to extend CURES, certain regulatory boards (Pharmacy, Medical Board, Nursing Board, Dental Board, Osteopathic Board) were tapped to fund CURES data collection costs because the state's General Fund could not support it. This requirement was added to the Health and Safety Code; specifically:

11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II and Schedule III controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, **contingent upon the availability of adequate funds** from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II and Schedule III controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

(b) The reporting of Schedule III controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III controlled substance prescriptions to CURES.

In 2002/03, the board funded \$68,000 for CURES data collection and analysis contracts. The board's budget was augmented by \$68,000 to fund this expense.

Last year (2003/04), staff learned that the DOJ was seeking \$92,000 from the board to fund CURES based on an allocation determined by the Department of Finance. One of the contracts for data collection services from an outside vendor was cancelled about this time and the DOJ brought the data analysis function into their operations. Moreover, since the additional \$24,000 the board was to pay would not be adjusted by the Department of Finance in the board's annual budget, the board would have had to redirect money from existing programs to fund this DOJ expense (instead of having it come directly from the board's fund). Staff did not authorize payment of the additional funding for CURES, and instead paid \$68,000 for support of CURES last year. Staff suggested that the DOJ appear before the board to request this funding, which the DOJ declined.

This year (2004/05) the DOJ has again advised the board that the board's share of expenses will be \$92,000, according to the allocation formula developed by the Department of Finance. Board staff has advised the DOJ that it will need to send representatives to a board meeting to seek this funding. The Department of Finance did approve the board's share at \$92,000, but only provided for funding of \$68,000. (Of the \$48,000 in increased CURES costs charged to regulatory boards for CURES between 2002/03 to 2003/04 (and carried on into 2004/05), the Department of Finance determined that the board's share should be 50 percent of the increased costs.)

The board has long been a supporter of CURES. In the early 1990s, the board funded \$240,000 for a feasibility study report to evaluate automating this system. Between 1996-2001, the board paid almost \$1.05 million to establish and fund the data collection activities. In 2002/03 until the present, the board has continued annual funding at \$68,000. To date, the board has paid \$1.5 million to fund CURES, greatly exceeding the funding provided by any other agency.

Cathy Ellis, manager of the CURES program from the Narcotic Enforcement Division of the Attorney General's Office, appeared to request this additional funding. With her was Jerry Hunter, Chief of Enforcement.

Ms. Ellis stated that in January 2002, for six months, the Department of Justice redirected resources to fund the program. At that point, the department asked the Department of Finance to establish a reimbursement program from the boards using the CURES system.

In July 1, 2002, the Department of Finance established the percentages that the various boards would be required to submit for reimbursement of CURES. This amounted to \$249,000. In 2003-04, the reimbursement needed increased from \$245,000 to \$296,000.

Ms. Ellis stated that reimbursement from the board is needed for maintenance cost of the system.

Ms. Ellis stated that in the CURES annual report that ongoing funds to maintain CURES and ensure system upgrades would be handled through the use of remaining funds from the CURES initial budget allotment from the Board of Pharmacy, the BCP process and increasing fees for continued drug funding from regulatory boards in DCA.

Ms. Ellis stated that during fiscal year 2003/2004, the Department of Justice did not receive any reimbursement from the board until March or April, after 9 months into the year. The DOJ has continued to fund CURES, irrespective of whether it was reimbursed.

Mr. Tilley asked if there is a ceiling limit on what the board will be asked to contribute for this system.

Ms. Ellis responded that a Department of Finance letter identifies the cost increase from \$245,000 to \$298,000. She stated that she hopes that there will not be further increases. She added that she is actively trying to eliminate some of the contract vendors and some of the costs because they are getting astronomical.

Ms. Herold stated that when the board sponsored the CURES continuation bill that eliminated the sunset date, funding was a concern. She added that the General Fund did not have the money to allocate to the program. In the interest of preserving CURES as a long-standing program, the board at the time agreed to support a proportional share of the cost. That year the cost was \$68,000 and an appropriation was made to the board's budget that year.

Ms. Herold stated that last year, the cost of the program increased and a cost overrun had to be allocated among the boards. The Department of Finance chose to divide the allocations up among the boards and the Board of Pharmacy received 50 percent of the increase, which the board thought was unfair. One year ago the Department of Justice was invited to attend the April Board Meeting. She stated that a long-term contract is an important solution. She added that the problem is that the Department of Finance made a cost allocation towards the cost of CURES that the board was not advised of or funded for. She added that the board would need to approve the increase of \$24,000 to fund CURES because this is not a routine budget expenditure.

The board expressed concern that there is no cap on fund increases and suggested that the board evaluate the value of the CURES program and the data obtained from this system.

Mr. Jones asked if the board has benefited from the CURES program from an enforcement perspective.

Supervising Inspector Judi Nurse stated that the board has been working with the program for a number of years and it does provide significant benefit in efforts to control diversion and resultant abuse of Schedule II controlled substances.

Ms. Ellis stated that the Department of Justice negotiated the current contract with Atlantis Associates at the current level and it is under a multi-year contract so additional increases are not expected. It is anticipated that when the current contract expires, the Department of Justice will no longer need the services of the vendor and can run the program within the department.

Ms. Herold stated that the statutory language requiring Schedule IIIs to be reported to CURES specifically exempts having those costs divided among the regulatory boards.

Under the current year budget, the board is only budgeted \$68,000 to fund CURES so the board would have to find additional money within the current year budget for the increase.

Ms. Ellis stated that overall the Department of Justice and the boards are benefiting from this program. She added that the department has recently submitted a grant proposal for an additional \$350,000 for enhancing the CURES program that would allow doctors and pharmacists to request specific information.

Ms. Harris stated that the goal was also to establish an education program for physicians and pharmacists.

M/S/C: JONES/HIURA

MOTION: Approve payment to the Department of Justice of an additional \$24,000 to fund CURES. The board's annual expense for CURES for 2004/05 will be \$92,000; which means the board must redirect the \$24,000 for other program areas. The board will also evaluate the benefits of CURES.

SUPPORT: 8 OPPOSE: 0

- **Proposal to Grant Pharmacy Technicians Continuing Education Credit for Attending Board of Pharmacy Meetings**

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

In early December, the board learned of a pharmacy technician who had attended the October board meeting in part in hopes of earning CE. The board's policy was developed only for pharmacists, so this technician was denied CE credit.

Pharmacy technicians who are certified by the Pharmacy Technician Certification Board must earn 20 hours of CE every two years, one hour of which must be in pharmacy law.

MOTION: That the Board of Pharmacy provide six hours of CE to pharmacy technicians who attend Board of Pharmacy meetings. A technician would be limited to the award of units to six hours per year for attendance at one full day of a board meeting.

M/S/C: JONES/SHELL

SUPPORT: 8 OPPOSE: 0

- **Recognition of Dr. RoseAnn Jankowski**

Dr. Schell recognized Dr. Jankowski for her outstanding work as chairperson for the Competency Committee since 2001 and expressed appreciation for her work on the committee since 1994. Dr. Jankowski is a clinical coordinator of Anaheim Memorial Medical Center. Dr. Schell presented Dr. Jankowski with a plaque that read:

The California State Board of Pharmacy recognizes and commends you for more than nine years of service on the board's Competency Committee, the last three years of service you have served as chairperson. Your significant contributions and assessing the qualifications of those seeking licensure as pharmacists has ensured that quality pharmacist's care is provided to California patients. Moreover, your leadership has enabled the board to redesign and implement a new formulation structure for pharmacists. Your efforts are greatly appreciated.

Dr. Jankowski thanked the board. She stated that Dr. Frances Wong is the new chairperson to the Competency Committee and she is an associate professor of clinical pharmacy at the USC School of Pharmacy. Her practice site is at USC University Hospital where she is a clinical pharmacist in the Medical and Cardiac Intensive Care Unit. Dr. Wong has served on the Competency Committee since 1998.

- **Approval of Minutes
(October 20 and 21, 2004)**

President Goldenberg asked if there were any corrections to the minutes. There were none.

MOTION: Approve the minutes of the October 20 and 21, 2004, Board Meeting.

M/S/C: POWERS/SCHELL

SUPPORT: 8 OPPOSE: 0

LICENSING COMMITTEE

- **Proposed Legislation to Define Compounding, Anticipatory Compounding and Contracting with Another Pharmacy to Compound Pursuant to a Prescription and Proposed Regulations to Establish the Requirements for General Compounding.**

Chairperson Conroy stated that the Board of Pharmacy initially formed the Workgroup on Compounding to respond to a request from the Department of Health Services, Food and Drug Branch to identify the criteria that could be used to determine when a compounding pharmacy should be considered a manufacturer. The goal was to work with the compounding profession to

respond to this request as well as identify and address “gaps” in pharmacy law related to pharmacy compounding. At each workgroup meeting, there were over 30 participants who provided valuable input into the process.

Chairperson Conroy reported that Dr. Schell chaired the workgroup and during the September meeting a concept draft to regulate general compounding by pharmacies was presented and discussed. Based on the discussion and the comments that were provided, proposed statutory and regulatory amendments were drafted for the workgroup’s review. The Workgroup on Compounding met on December 1st (prior to the Licensing Committee meeting) for final review and discussion of the proposal.

The proposal included a recommendation for the Licensing Committee to consider a definition of compounding, which currently is not defined in pharmacy law. It requires a pharmacist to have a professional relationship with both the prescriber and the patient. The proposal also addressed the issues of central fill (where a pharmacy may contract with another pharmacy to compound non-sterile drug products pursuant to a prescription), record keeping requirements, labeling, quality assurance requirements for the compounding process and the compounded drug product, and requirements for facilities and equipment. The proposal specified that the chemicals, drug products and components must be used and stored according to official United States Pharmacopoeia compendia specifications.

During the September workgroup meeting, there was considerable discussion regarding the relative roles of the Board of Pharmacy, the federal Food and Drug Administration and its California counterpart(s). One of the initial requests from DHS was for the board to identify the criteria it uses to determine when a compounding pharmacy would be considered a manufacturer. While one of the workgroup subcommittees updated the list of factors that the board developed many years ago, board counsel explained that the proposed “factors” for distinguishing compounding from manufacturing would at best be considered “guidelines,” and as such, do not have the force of law. Absent adoption by regulation, they may also be underground regulations.

Dr. Schell stated that the Board of Pharmacy’s priority mandate is to protect the public and this mandate extends to the compounding of prescription drugs. The compounding requirements proposed would guarantee that those pharmacies that compound prescription drugs meet specific standards to assure patient safety.

On January 7, 2005, the board received comments from the FDA regarding the draft of the general compounding proposal. It is FDA’s position that it generally does not sanction compounding drugs for third parties to resell to individual patients. Consistent with this position, it is FDA’s belief that pharmacies normally should compound their own products. FDA likely would not exercise enforcement discretion towards a pharmacy that compounds drugs to be re-sold by other pharmacies, unless there is a specific need for this arrangement. In such cases, FDA stated that it would expect the compounding pharmacy to document patient-specific need for the compounded product.

Dr. Schell reported that the task force was a very diverse group and although no one received the exact outcome they wanted, the result was a mutually agreed upon consensus of what was important for the protection of patients in California. He encouraged the board's approval of this proposal.

President Goldenberg thanked Dr. Schell for his efforts in chairing the Task Force on Compounding.

Dan Wills, representing Grandpa's Compounding Pharmacy, also thanked Dr. Schell for keeping the task force on track and moving forward. He suggested the following changes to the proposal:

1. 4019.5 – (a) Adding the following: “A patient or caregiver who changes the dosage form flavor or delivery system for purposes of drug therapy compliance shall not be deemed to be compounding.”
2. 4123 (f) 1 – Removing the last portion that states “provided the drug is not compounded prior to the receipt of the prescription.” He added that it is safer to make batches, test the batch, and then dispense.
3. 4123 (a) – Reconsidering this section: Does the board believe compounding OTCs is dangerous and needs to be regulated.
4. 1735 (b) – Change to ”Quality” to mean that drug product is free of unhealthy levels of contaminants.
5. 1735 (b)(3) – Remove the one year for topical and change to a three-month supply.
6. 1735(2)(b) – Add and/or.
7. 1735(2)(c) – He suggested a change to make the provision more understandable concerning using grocery items.

Chairperson Conroy stated that the language is very restrictive and would prevent pharmacists from conducting minor compounding.

Supervising Inspector Ming stated that the concept in developing compounding regulations and statutes was to standardize the process of compounding drug products. He added that during inspections of compounding pharmacies, he has found that there are many variances in the practice. Where some pharmacies are very thorough, others need a lot of guidance. He stated that the regulation should direct the compounding process in a consistent manner.

Steve Gray, representing Kaiser Permanente, expressed concern about the proposed changes to the definition of a pharmacy in section 4037, because it would require all medical offices to apply for a pharmacy license. This would result in physicians prescribing, administering and preparing prescriptions without the benefit of licensed pharmacists.

Dr. Gray suggested that the definition include the following: “a pharmacy is an area, place, or premise licensed by the board.” He added that the board should leave to regulations what should or should not be licensed by the board as a pharmacy.

Mr. Gray stated that there is concern about not allowing anticipatory compounding especially for pharmacies that are compounding on behalf of a licensed facility such as a hospital or a surgical center licensed by the Department of Health Services. He added that some hospitals in California do not have pharmacies but contract with pharmacies for compounded products. He added that currently section 4052 does not allow pharmacists to compound products for prescriber's office use. He suggested that section 4052 be modified to state: "for prescriber's office use or use in licensed facilities." Then, the regulation describing prescriber's office use would not be problematic because it would allow compounding to continue. He suggested that these changes be made before language is introduced because the definition of a pharmacy is vital.

Bill Blair, Pharmacy Director of McGuff Compounding Pharmacy, expressed concern about the elimination of section 1716.1 because this section allows pharmacies to compound for prescriber's office use.

Ms. Harris clarified that section 4052 still allows compounding for prescriber office use.

MOTION: Licensing Committee: That the Board of Pharmacy approve the proposed legislation to define compounding, anticipatory compounding and contracting with another pharmacy to compound pursuant to a prescription and proposed regulations to establish the requirements for general compounding.

SUPPORT: 0 OPPOSE: 8

MOTION: That the Board of Pharmacy approve a legislative proposal to define general compounding, anticipatory compounding and contractual arrangements for compounding services as proposed, except removing section 4037 from the proposal.

M/S/C: JONES/POWERS

SUPPORT: 8 OPPOSE: 0

- **Board Approval of a New School of Pharmacy at the Palm Beach Atlantic University**

Chairperson Conroy stated that the board received an intern pharmacist application from a student at the School of Pharmacy at the Palm Beach Atlantic University. This application was received after the Licensing Committee agenda was publicly noticed and therefore, could not be considered by the committee. The ACPE has granted the school candidate status in 2002 and reaffirmed this status last year.

Pre-candidate status is the lowest of the ACPE provisional accreditations, and students who graduate from such a school would not be eligible for pharmacist licensure in most states. The ACPE states that pre-candidate schools have the concepts of an acceptable ACPE program committed to paper, but the program components have not yet been fully implemented.

“Candidate Status” is the next provisional level of ACPE accreditation, which would allow graduates from such a school to become licensed pharmacists. In order to be fully ACPE accredited, the school must have graduated one class of students, among other conditions.

Internship is an integral part of the pharmacy education of students. This obviously creates a problem for students in such new programs where state licensing agencies look for ACPE accreditation as a means to assure the students are receiving particular (and approved) educational coursework as a condition of issuing an intern license.

In the past the board has granted approval of schools with candidate status. The board has a pending regulation change to amend section 1719 that defines “recognized schools of pharmacy” as a school of pharmacy accredited, or granted candidate status, by the Accreditation Counsel for Pharmacy Education or otherwise recognized by the board. Recognition of the School of Pharmacy at the Palm Beach Atlantic University is consistent with the pending regulation change.

MOTION: That the Board of Pharmacy consider the approval of the School of Pharmacy at the Palm Beach Atlantic University.

M/S/C: TILLEY/SHELL

SUPPORT: 8 OPPOSE: 0

- **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 was provided with a background document that gave an overview on the many issues and questions that the board has received regarding pharmacists care and the practice of pharmacy for California patients. The purpose of the document was to provide a foundation to begin discussion on how the board should address many issues that do not fit the traditional statutory definition of pharmacy practice and the independent practice of pharmacists as health care providers. The committee agreed to address these issues through its committee meetings in 2005.

President Goldenberg stated that the board’s focus is to enable the practice of pharmacy to California residents through a variety of mechanisms and the board should develop guidelines to enable this process. More information will be developed and discussed at future Licensing Committee Meetings.

- **Implementation of AB 2628 (Chapter 887, Statutes of 2004) Regarding the Licensure of Wholesalers and Nonresident Wholesalers**

Chairperson Conroy stated that Governor Schwarzenegger signed Assembly Bill 2682, on September 29, 2004. This bill makes changes to several Business and Professions Code sections specific to the licensing requirements for wholesalers located outside of California who ship, mail or deliver dangerous drugs or devices into California. Because of the significant changes, the requirements will be phased in over the next two years. The following is a brief description of these changes:

- B & P 4043 – Changes the name of a wholesaler shipping drugs into California from an out-of-state distributor to a nonresident wholesaler. This change is effective January 1, 2006.
- B & P 4161 – Requires any out-of-state distributor who ships, mails, or delivers dangerous drugs or devices into California to be licensed with the board. Previously any business that shipped into California to another California licensed wholesaler was exempt from obtaining a California license. This changed is effective January 1, 2005. Effective January 1, 2006, B & P 4161 is again amended to change the name from out-of-state distributor to nonresident wholesaler and to change the title of “exemptee-in-charge” to “designated representative-in-charge.”
- B & P 4162.5 – Requires an applicant for licensure or renewal to submit a surety bond of \$100,000 for each nonresident wholesaler site licensed or to be licensed. The board may accept a surety of bond of \$25,000 if the annual gross receipts of the previous tax year, as a nonresident wholesale is \$10,000,000 or less. This section takes effect January 1, 2006.

To facilitate the implementation of these changes, board staff has reviewed and revised the wholesaler application forms, requirements and processes for both the wholesaler and nonresident wholesalers and the new forms are available on the board’s Web site.

- **Competency Committee Report - Implementation of NAPLEX and the CPJE, Job Analysis, Committee Restructure, Release of Examination Results**

Chairperson Conroy stated that the Board of Pharmacy transitioned to the new examination structure in January 2004 and began administering the California Pharmacist Jurisprudence Exam (CPJE) in March 2004. As of December 31, 2004, the board had received over 2,600 applications to take the California license examinations, and since June 2004, 1,299 applicants have been licensed as pharmacists. The most recent pass rate for the CPJE is 85 percent.

Ms. Herold stated that the board has worked with its exam consultant to begin releasing the exam results twice a year at the April and October Board Meetings.

- **Recognition of Robert Toomajian, Former Board Member/Board President of the Board of Pharmacy**

President Goldenberg welcomed Robert Toomajian to the board meeting.

- **Report to the California Legislature on the Effect of Requiring Remedial Education for Candidates who Fail the Pharmacist Licensure Examination Four Times**

Since 1999, candidates for the California pharmacist licensure examination who fail the examination four or more times, are required to take 16 units of education in pharmacy in a school approved by the ACPE or by the board before they can retake the examinations. This provision was initially set to end on January 1, 2005; however SB 1913 (Chapter 695, Statutes of 2004) extended this date until January 1, 2008.

The board sponsored the provision to remove a number of applicants from the licensure examination who had repeatedly failed the examination – in fact, there were several applicants who had taken the examination more than 25 times. A major concern was that these individuals were taking the examination only to memorize questions that could be provided to preparation course providers.

The provision itself was modeled after a similar provision enacted for the dental examination.

When the provision was enacted in 1997, the board was also mandated to provide a report to the Legislature before December 31, 2004. The board reviewed a copy of this report to the legislature prepared by staff.

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

- **Request to Develop *Health Notes* on Disaster Response by Pharmacies**

Chairperson Zinder reported on the January 5, 2005, public meeting of the Communication and Public Education Committee.

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

Dr. Jankowski thanked the board and stated that she is the clinical pharmacy coordinator of Anaheim Memorial Medical Center. She presented the board with an outline and an educational objective regarding the monograph and stated that if the publication meets the board's approval, she would find a provider for continuing education credit for the publication.

Dr. Jankowski stated that the purpose of the publication is to focus on disaster preparedness and communicate information to pharmacists that will help Californians in the event of disaster. She will coordinate efforts without a fee and has developed a list of articles and authors. The authors would not be paid for their articles but would receive attribution as authors in the monograph.

Chairperson Zinder stated that the committee saw value in the development of this monograph. Dr. Jankowski stated that once the articles are written, federal money would be sought to pay for publication costs and expand distribution.

President Goldenberg stated that during disasters it is often difficult to gather all of the necessary information and equipment needed, and he agreed that the issue is timely.

Steve Gray, representing Kaiser Permanente, referred to the Northridge Earthquake and the lessons learned by this and issues health care providers should have been prepared for but were not. He added that a disaster that strikes one community actively affects all surrounding communities and pharmacists should anticipate how they could help patients get their medications.

Dr. Fong added that Maria Shriver is planning outreach on earthquake preparedness within the next few months and this would also provide pharmacists with an opportunity to determine their role during a disaster.

MOTION: Communication and Public Education Committee: Develop a *Health Notes* issue on Pharmacy Disaster Response to Declared Disaster Area.

SUPPORT: 8 OPPOSE: 0

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

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

A prototype format for a series of fact sheets has been developed and the first three fact sheets have been prepared -- "Cut Your Drug Costs," "Generic Drugs," and "Is Your Medicine in the News?" The fact sheets contain general information on the topic, but then contain questions consumers can discuss with their pharmacists on making wise decisions in the subject area.

Chairperson Zinder stated that the fact sheets would be distributed by the board and the Center for Consumer Self Care as a joint effort with both agencies' logos and addresses on the fact sheet. The design is simple with blue and black ink that will photocopy well and can also be downloaded from the Internet.

The goal is to develop three fact sheets per quarter. The committee will explore translating the fact sheets into different languages in the near future. After one year and 12 fact sheets, the Communication and Public Education Committee and the Center for Consumer Self Care will reevaluate the project.

All the fact sheets will address consumer issues involving questions to “Ask a pharmacist” about, so that consumers can make informed decisions.

The board reviewed the fact sheets and suggested a new title for one of them.

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

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

Meetings are held monthly. 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 FDA and National Consumer League have participated via phone and in attendance.

The first integrated project has been will be an education campaign for practitioners and patients on antibiotic use, misuse and overuse. The title of the series is “Preserve a Treasure.” The FDA has produced these materials, but has not been able to distribute them widely.

Between November 2004 and February 2005, the partnership agencies are promoting these materials in their quarterly newsletters to licensees and/or on their Web sites. Consumer materials will be distributed at public education fairs, and hopefully by practitioners in their offices or pharmacies (via download of material from the Internet). The board will publish the poster in its January 2005 newsletter, and provide links to obtain the consumer brochure on the board’s Web site.

An evaluation of these efforts will occur after February.

The next integrated campaign is planned for May 2005, which is seniors’ month. Generic drugs will be the focus of this next effort.

- **Update Report on *The Script***

Chairperson Zinder stated that the January issue of *The Script* has been printed and is being mailed to pharmacies. This is a large issue and will focus on new legislation and regulation requirements, providing a summary by code section of what is new. To save publication space, the board's Web site contains the text of every modified code section, so that interested individuals can quickly access the changed sections of Pharmacy Law.

The forthcoming issue of *The Script* will again be published and mailed to pharmacists by the CPhA's Pharmacy Foundation of California.

- **Update Report on the *Health Notes***

Health Notes is a monograph, produced by the board that contains up-to-date drug therapy guidelines for a specific subject area. Because *Health Notes* is produced by the board, it conveys the board's belief of current drug treatment in a particular area. Pharmacists can earn continuing education credit by completing a test published at the back of the monograph. Thus the board provides information and actually is sponsoring CE in an area of importance to the board. Seven issues have been produced since 1996, no issues were published in 2004.

Three issues are under development:

1. Pain Management

The board's staff is still working to complete this new issue on pain management, which should be published sometime by mid-year 2005. Prominent pain management authors have written the articles, and board staff and Board Member Schell are coordinating the issue. 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.

2. Smoking Cessation

At the April 2004 Board Meeting, the board agreed to work with the UCSF School of Pharmacy to develop a *Health Notes* on smoking cessation. The UCSF was seeking funding for this issue since the board cannot provide the \$40,000 to \$50,000 cost of development. However, the School of Pharmacy has not yet found a sponsor, and the staff who would be working on this are focusing their efforts on establishing the Center for Consumer Self Care. This project is inactive at this time.

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

At the April 2004 Board Meeting, the board voted to become a cosponsor with the UCSF School of Pharmacy to produce a monograph on Atrial Fibrillation (A-Fib). Funding for this issue was being sought from a drug manufacturer. Again, the UCSF School of Pharmacy has

disbanded this project at the current time to focus its efforts on the Center for Consumer Self Care. This project is now inactive.

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

Chairperson Zinder announced 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. Refinements to the Web site will occur in the future.

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

Last year the board was asked to collaborate on a study being done by the Center for Health Improvement assessing patient consultation requirements and their impact on older Californians aged 65 or older. 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 pharmacist consultation process for patients aged 65:

- 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 Communication and Public Education Committee asked that the director of the study or another person designated by CHI attend the October Board Meeting to discuss the survey with the board. However, a scheduling conflict prevented this appearance. The CHI has requested the opportunity to attend the April Board Meeting to make this presentation so that it will minimize travel expenses for this nonprofit, Sacramento-based program. The committee agreed to this request.

The survey of 1000 pharmacists has been completed and the results are being tabulated. The CHI will next discuss the survey results with several focus groups of seniors, pharmacists and physicians in the coming weeks.

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

Chairperson Zinder commended the board for its vigorous outreach program that provides 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.

To educate licensees, the board also has a Power Point presentation on the board (containing key board policies and pharmacy law) that 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 are well received by the individuals present.

Since the beginning of 2004, the board has also provided presentations on 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 October Board Meeting, board members and staff have:

- presented 4 public presentations about the board to group of licensees
 - provided 6 public presentations about the new controlled substances to licensees, prescribers and law enforcement officers.
 - staffed 4 public booths at consumer fairs
- **Announcement: Creation of *Consumer Reports* Web site for Ranking “Best Buy” Prescription Medications**

Consumers Union, publisher of *Consumer Reports*, recently activated a Web site that will compare the cost, effectiveness and safety of a given class of drugs, so that patients and prescribers can make the best comparative choice of prescription medication for a specific condition.

At this time, Consumers Union has developed this comparative information on three classes of drugs: drugs for lowering cholesterol, drugs for treating heartburn, ulcer and acid reflux disease, and drugs for treating arthritis and pain. The Web site is: www.CRBestBuyDrugs.org.

Mr. Tilley asked if the board’s mission is to assure that consumers get the best price for prescription drugs.

President Goldenberg stated that he did not feel that the board could separate affordability and accessibility to health care and it isn’t the board’s intent to drive business out of California.

Mr. Jones suggested that pharmacists provide patients with other options if they cannot afford their medications.

Dr. Schell agreed that the intent is to assure that patients maintain their drug therapy and if cost is an issue, pharmacists should provide patients with other options.

Mr. Cronin stated that if a pharmacy is not compensated for advising patients to seek low cost options for drug purchases then they are not likely to offer options.

Lisa Johnson, pharmacist, stated that one of the most common problems patients face is that the prescription drug the doctor ordered is not covered by their insurance plan.

Mr. Powers stated that he would much rather do business with a local pharmacist but affordability is often an issue when purchasing drugs that a physician has prescribed. Therefore he must seek alternatives where the drugs cost less. He added that true solution to the problem is in Washington D.C.

ENFORCEMENT COMMITTEE

- **Request from Safeway Inc. for a waiver of CCR, Title 16, Sec. 1717(e) to use an Automated Dispensing Device for Refill Prescriptions**

Chairperson Powers stated that Safeway Inc. requested a waiver of 1717(e) to install and utilize a self-service dispensing unit, such as the Asters ScriptCenter, at its various Safeway and/or Vons pharmacies in California.

Board Member Dave Fong recused himself from this discussion.

Chairperson Powers stated that according to Safeway, 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 store 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 at his or her convenience. New prescriptions, or those prescriptions requiring consultation, would not be available through these units.

Prescriptions would be filled by a pharmacist and placed into the units either by a pharmacist or pharmacy personnel, under the supervision of a pharmacist. As medications are placed into the units, security measures are used to ensure accurate dispensing. The pharmacy is responsible for all medications dispensed from this unit.

At its October meeting, the Board of Pharmacy granted a similar waiver to Longs Drug Stores to use an automated dispensing device.

Ms. Harris stated that the board has a proposed amendment to repeal CCR, title 16, section 1717(e) and to add CCR, title 16, section 1713 that would provide the authority to use drop boxes for prescriptions and automated dispensing devices to pick-up refill prescriptions. This regulation is awaiting notice.

The waiver granted to Longs Drug Stores permits the use of an automated dispensing device that allows a patient to access his/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 during a presentation to the Enforcement Committee, Ron Bingaman, R.Ph., Corporate Pharmacy Director for Safeway Inc. reported that Longs had placed an automated dispensing unit in one of its pharmacies.

Mr. Tilley stated that he is opposed of dispensing machines that he feels will ultimately replace pharmacists.

Cookie Quandt, representing Longs Drugs, Inc., explained that if patients need assistance after the pharmacy is closed, a telephone number is provided on the dispensing unit that connects to a 24-hour pharmacy. She added that the unit is only used for refill prescriptions and a patient must sign up for the service. Patients access the unit with a specific pin number. She added that over 500 patients have signed up to participate in this service.

Dr. Quandt stated that the refill prescription is processed the same way it is in the pharmacy so the pharmacist can intervene with the patient if necessary.

President Goldenberg asked what options patients have if they forget their pin number to access the dispensing unit.

Dr. Quandt responded that a hint button is provided on the dispensing unit that prompts patients to remember their password and allows them to reset their password. If this fails, a 1-800 number is available to call for assistance.

Chairperson Powers expressed concern that the board has many unanswered questions and he stated that he does not support this proposal at this time.

Bill Holmes, president and CEO, Safeway Inc., referred to a dispensing unit in Salt Lake City from a company called Advanced Pharmacy Technology that operates similarly to this system

and has been in operation for over two years. He suggested that the board seek information from this pharmacy to establish a better understanding of the system.

John Cronin, representing the California Pharmacists Association, stated that he observed a dispensing unit operation at a Del Mar pharmacy and added that the technology is available but the board should move slowly to better assess safety and convenience issues.

Mr. Cronin stated that the board may want to consider requesting a service plan from pharmacies that want to use this system that details how the pharmacist would utilize his or her time to benefit the patient. He added that the biggest fear is that these dispensing machines will be used to cut labor costs, reduce pharmacy business hours and essentially move the pharmacist out of the dispensing process.

Lisa Johnson, pharmacist, asked if controlled drugs are dispensed from these units and she expressed concern that other family members might have access to the pen number and the drugs. She asked what precautions are in place to avoid this type of situation. She added that as a pharmacist, she could often assess a problem situation just from the interaction between patients.

Joshua Room, Deputy Attorney General, responded that security measures are included in the unit including a camera that photographs each patient when he or she picks up the prescription. Also, a credit card is required to purchase the prescription.

Dr. Jim Roche, representing Advanced Pharmacy Solutions, expressed concern with the language and the proximity of the dispensing unit to the pharmacy and said that this may take on the appearance of an ATM in a parking lot or at the airport. He expressed concern about off-site pharmacies delivering to a non-regulated area and refrigerated items being stored in the dispensing unit. He asked how board inspectors would respond to this and the parameters they would use to verify the correct use of the machine.

Mr. Jones stated that the board discussed this issue at its last meeting and should there be inadvertent disclosure of information or if the machine does not perform as it is designed to, the pharmacy is at risk for a disciplinary action. Mr. Jones added that he would like to see unbiased studies that indicate how the dispensing unit improves convenience to consumers but this would be difficult when the owners of the pharmacy or the machines are conducting the studies. He added that just because the board may grant a waiver does not mean that the pharmacy is not responsible if an error occurs.

Mr. Bingaman stated that Safeway is requesting the waiver and would like to work with the board so proper regulations can be created. Perhaps this could include an opt in clause inviting patients to provide input regarding their experience using the unit.

MOTION: That the Board of Pharmacy approve the request from Safeway Inc. for a waiver of 1717(e) to install and use a self-service dispensing unit for

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

M/S/C: HIURA/JONES

SUPPORT: 4 OPPOSE: 3

- **Request from Advanced Pharmacy Solutions for waiver of CCR, title 16, sec. 1717(e) to Allow the Delivery of Prescription Medications to a Licensed Home Health Agency.**

Chairperson Powers stated that Advanced Pharmacy Solutions requested a waiver of section 1717(e) so that they may deliver Synagis to licensed home health agencies for administration at a patient's residence. It was suggested that the board's counsel review the basic interpretation of 1717(e) in that the regulation does allow for the delivery to a licensed home health agency.

The Enforcement Committee recommended that the Board of Pharmacy support this waiver and suggested that a representative from Advanced Pharmacy Solutions attend the board meeting.

A representative from Advanced Pharmacy Solutions, stated that on October 25, the Department of Health Services issued a policy statement establishing parameters for reimbursement for dispensing Synagis. Synagis is a heat labile, life-sustaining injection to prevent respiratory cynival virus (RSV) in certain compromised infants. It requires a professional nurse to reconstitute the medication within a few hours of the administration time. Advanced Pharmacy Solutions is proposing to deliver patient specific prescriptions directly to the licensed home health agency (HHA) as authorized in the DHS Policy Statement. Advanced Pharmacy Solutions currently has more than 465 fragile infants that they intend to begin filling prescriptions for in this manner.

After some discussion, the board expressed that this is a narrow exception only for Synagis.

MOTION: Enforcement Committee: That the Board of Pharmacy approve the request from Advanced Pharmacy Solutions for waiver of CCR, title

16, sec. 1717(e) to allow the delivery of Synagis to a licensed home health agency.

SUPPORT: 8 OPPOSE: 0

- **Proposed Amendments to Business and Professions Code section 4104 to Require Mandatory Reporting of Impaired Licensed Individuals.**

Chairperson Powers stated that Supervising Inspector Joan Coyne presented a request to amend Business and Professions Code section 4104 to mandate all pharmacies to report to the board a licensed individual who is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy. Current law requires that a pharmacy have in place procedures to protect the public when a licensed individual is known to be chemically, mentally or physically impaired to the extent it affects his or ability to practice pharmacy. The law also authorizes the board to adopt regulations that establish requirements for reporting to the board the conduct or incidents described in the law. Currently there is no regulation that requires a pharmacy to report impaired licensees to the board.

Supervising Inspector Coyne reported that as the supervisor of the Pharmacist Recovery Program (PRP)/Probation team, she oversees investigations of licensees that self-use drugs and alcohol.

She stated that a substantial number of incidents of theft and self-use of drugs, improper use of alcohol and obvious mental impairment by practicing pharmacists were never reported to the board. In many instances the discovery was made while the pharmacist was at work filling and dispensing prescriptions for patients. It was only after additional incidents with subsequent employers or an arrest was the impaired pharmacist or technician brought to the attention of the board.

Many times the pharmacy merely requested the resignation of the individual or terminated him/her from employment. And in some cases, the pharmacy would seek restitution for the stolen drugs in cash or a signed promissory note, followed by termination that allowed the pharmacist or technician to practice elsewhere. Usually the board didn't become aware of an impaired licensee until a serious prescription error was made or, a patient, co-worker or conscientious employer at a new work location reported the impaired licensee. It was also discovered through subsequent board investigations that many individuals had lost previous jobs because of chemical, mental or physical impairment affected their practice. She added that her review showed 22 cases where subsequent investigations would probably not have materialized had a prior employing pharmacy been required to report an employee whose practice was affected.

The committee recommended that the board approve the proposed requirement to mandate reporting of impaired licensees. Deputy Attorney General Joshua Room refined the proposal.

Mr. Jones stated that the responsibility should remain with the pharmacy rather than add an extra burden on the pharmacist-in-charge to act as detective in gathering facts.

Mr. Cronin, representing the California Pharmacists Association, agreed that the requirement to report should be placed on the pharmacy. He asked how the board would address the issue of a pharmacist employee who does not report an incident to an employer and asked if the pharmacist would be disciplined.

Joshua Room stated that a duty to report to the board is being placed solely on the pharmacy and what occurs between the pharmacy and pharmacists would be dealt with separately based on the specific facts of the case.

Steve Gray, representing Kaiser Permanente, expressed concern that the language may provide immunity and confuse the pharmacist. He added that unlicensed personnel in the pharmacy may also have substance abuse problems and should be reported. Dr. Gray added that the DEA already has a regulation requiring every registrant to put every employee that has access to controlled substances on notice in writing that they are required by law to report any diversion or suspected diversion to the permit holder of the registrant.

Mr. Room stated that it is difficult at this point to know what the board would do concerning unlicensed individuals who are impaired because the board has no jurisdiction over them. He added that this proposal is more about discovering impaired licensed individuals and initiate board's action against them.

Dr. Coyne added that even though the DEA has a requirement, it does not cover alcohol, which is a big factor.

MOTION: Enforcement Committee: That the Board of Pharmacy approve the proposed statutory changes to Business and Professions Code section 4104 to require mandatory reporting by pharmacies of impaired licensed individuals.

SUPPORT: 8 OPPOSE: 0

- **Implementation of SB 151 (Chapter 406, Statutes of 2003) – Requirements for Controlled Substance Prescriptions – Effective January 1, 2005 and Proposed Legislation to Amend the Health and Safety Code Relating to Application Process and Criminal Background Check for Security Printers, Security Printer Vendor Identification, Check-off Box to Identify Prescriber, Prohibition Against a Prescriber from Ordering Security Forms Pending a Criminal Action and Approval of Security Printers by Department of Justice Only (Removal of Board of Pharmacy)**

Chairperson Powers stated that over the last year, the Board of Pharmacy has been educating California health practitioners about changes to the prescribing and dispensing requirements for Schedule II controlled substances. The board has been working to educate pharmacists and prescribers on the new requirements and has been coordinating efforts with the Bureau of Narcotics Enforcement (BNE), the Medical Board of California, other prescribing boards and the professional associations. Since January 2004, the board has provided over 30 presentations on SB 151 that have included telephone conference calls that have involved large number of individuals.

Starting January 1, 2005, written prescriptions for all controlled substances must be on tamper-resistant security prescription forms that have been printed by a state-approved printer and must contain specific elements. There is no specific format, size or color for the security prescription forms.

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.

A summary of the changes that take effect January 1, 2005 are:

- Triplicate prescription forms are no longer valid.
- All written controlled substance prescriptions must be on the new controlled substance prescription forms printed by an “approved” printer (oral and fax orders for Schedules III-V are still permitted).
- Pharmacies must report Schedule III controlled substance prescription information to the CURES system.
- Prescribers dispensing Schedule 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). (This exemption doesn’t apply to Schedule III prescriptions.)

To further aid in the implementation of the new controlled substance laws, the board has prepared a series of articles that will appear in the January newsletter and on the board’s Web site.

Meanwhile, the Department of Justice (DOJ) is proposing some amendments and additional provisions to make technical changes to the prescribing and dispensing of controlled substances.

The proposed amendments would:

- Make DOJ solely responsible for approving security printers (instead of sharing this responsibility with the Board of Pharmacy).

- DOJ would solely perform criminal background checks of applicants.
- Additional individuals at the printers would undergo criminal background checks.
- The Board of Pharmacy and DOJ could examine books and records of any applicant or visit and inspect the business.
- The Superior Court could order a prescriber not to order or obtain or use any additional prescription forms during a pending criminal action based on the request of the law enforcement agency bringing the criminal action.
- The approved security printers would be required to print security prescriptions forms with a vendor identification code issued by DOJ.
- The security prescription form would be required to have a check box by the name of each prescriber to be checked to identify the prescriber issuing the prescription when there are multiple prescribers on one security prescription form.

DOJ is requesting that the Board of Pharmacy support these proposed changes. Staff recommends that the board support them and that the Board of Pharmacy no longer approve security printers. The board absorbed this workload initially to assist with the transition from the triplicate prescription form to the new tamper-resistant forms printed by “approved” printers. It is no longer necessary that both the Board of Pharmacy and DOJ approve the printer. It should be the sole responsibility of DOJ.

Ms. Harris stated that the legislation to clean up the controlled substance law would be a work in progress as it moves through the legislature. She added that staff recommends support of the changes that the DOJ has recommended.

MOTION: Enforcement Committee: That the Board of Pharmacy support the changes as proposed by the Department of Justice to the Health and Safety Code related to the new security prescription forms and the proposal from board staff that the Board of Pharmacy no longer approve security printers.

SUPPORT: 8 OPPOSE: 0

- **Discussion on Importation of Prescription Drugs**

Chairperson Powers stated on December 21, 2004, the United States Department of Health and Human Services (HHS) released its report of the Task Force on Drug Importation. Pursuant to the Medicare Prescription Drug Improvement and Modernization Act of 2003, which was signed by President Bush in December 2003, the secretary of HHS was directed to conduct a study that would examine whether and under what circumstances drug importation could be conducted safely. The discussion continues about drug importation and there is legislation pending in the California Legislature.

The Enforcement Committee reviewed SB 19 that was introduced by Senator Ortiz on December 6, 2004. The purpose of the bill is to establish the California Rx Program, to be

administered by the Department of Health Services. The bill would authorize the department to negotiate drug rebate agreements with drug manufacturers to provide for program drug discounts. The bill would authorize any licensed pharmacy or drug manufacturer to provide services under this program. The bill also establishes eligibility criteria and application procedures for California residents to participate in the program.

The bill would also require the Department of Consumer Affairs to implement, as part of the California Rx Program, a Prescription Drug Resource Center Web site to educate California consumers about options for lowering their prescription drug costs. The Web site would include information about public and private drug coverage and drug discount programs that are available to California seniors and other consumers and tips for cutting costs on medications, including guidance concerning generic drugs.

In addition, the Web site shall include information about ordering prescription drugs from Canada and other countries. The Web site is to include a list of pharmacies that the Board of Pharmacy has determined meet pharmacy management practices required of pharmacies licensed to operate in California and the United States and a list of medications that can be ordered through the Web site from licensed pharmacies in Canada and other countries.

Chairperson Powers stated that the committee was also provided with a press release issued by the federal FDA regarding action it took against a company for the importation of prescription drugs into the U.S.

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

Chairperson Powers noted that the committee reviewed a number of items related to enactment of SB 1307 (Figueroa) that was sponsored by the Board of Pharmacy. 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 will monitor the implementation of this legislation. One area of close oversight will be 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 maintain the pedigree 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.

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.

McKesson reported that EPCglobal, a non-profit organization, has developed broad industry standards for the use of electronic product codes (EPC) in global commerce. 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.

T3Ci, is an application software company that provides drug counterfeit, diversion detection and electronic drug pedigree for the pharmaceutical market. They demonstrated their technology solution for the electronic pedigree at the December 15 Enforcement Committee Meeting. This presentation was for informational purposes only. Currently, they are pilot testing their system with various manufacturers.

Cardinal Health has requested that the Board of Pharmacy consider an exemption from the registration and licensure process for out-of-state distributors that solely provide intra-company transactions of dangerous drugs and dangerous devices into California. It is their position that such an exemption is warranted because it is practical while retaining the safeguards that the board is trying to achieve.

They argue that the Board of Pharmacy has jurisdiction over the transaction and affected parties at issue. The in-state wholesaler, which receives the shipment from the related out-of-state wholesaler, is licensed with the board. The board has the ability to bring an enforcement action against the in-state wholesaler for any transgressions, which may result from an inappropriate shipment into California by the related out-of-state wholesaler. This would include any action that the board may take against the in-state entity's corporate parent. Third, all transactions would be traceable and readily accounted for given the relationships of the entities involved.

It was presented that these intra-company transactions for which Cardinal was requesting an exemption would only take place when there was a temporary shortage of a drug and the in-state licensed wholesaler was unable to fill the order. Staff counsel commented that the Board of Pharmacy doesn't have the authority to provide an exemption to the licensure requirement.

Such an exemption would require a statutory change. Cardinal stated that it was their position that under the proposed change that takes effective January 1, 2005, an inter-company transfer would not constitute a transaction at wholesale. Counsel advised Cardinal to submit their request and legal analysis in writing for board review and consideration.

Pharmacist-in-Charge Certification Program at the College of Pharmacy, Western University of Health Sciences

Jesse Martinez, Executive Director of External Affairs and Development, and Sam Shimomura, Associate Dean Professional and Student Affairs, at the College of Pharmacy, Western University of Health Sciences presented an overview of a course of study in the skills required to become a pharmacist-in-charge (PIC) in California. It will be a 12-week advanced elective course in their curriculum this year. Both the community pharmacy practitioner track and the community pharmacy management track with an emphasis in independent pharmacy ownership will include training in the requirements to serve as a PIC.

In addition, Western plans to develop a 15-hour “certificate” course designed to prepare a licensed pharmacist in the knowledge, skills and requirements to serve in a PIC position. They plan to offer the “certificate” program to all interested licensed pharmacists in convenient sites in southern and northern California starting in the second quarter of 2005.

The vision for the PIC “certificate” CE program is a format that includes an experiential component with workshop discussions and lectures presented by experts with “real world” experience. The faculty will include attorneys, pharmacy managers, industrial security representatives, medical waste disposal experts and faculty from the WesternU College of Pharmacy. They also asked for participation from the Board of Pharmacy. They requested that a board member or inspector with expertise in community and hospital outpatient pharmacy self-assessment process participate in the training program. The final format that would include a board representative is open at this time. The core content of the PIC certificate program would be in the areas of compliance with the board’s self-assessment form.

The Enforcement Committee agreed that the PIC certificate program was an excellent idea and expressed a willingness to participate in the development of such a program. One concern was the commitment of board resources to actively participate in the training program. However, Supervising Inspector Robert Ratcliff agreed to work with WesternU College of Pharmacy to determine the best way the board can support their efforts.

Chairperson Powers stated that the Enforcement Committee was very supported of the recommendation for this proposed program and although the board could offer only a limited amount of support, Supervising Inspector Robert Ratcliff has agreed to help in some capacity to develop this program.

Dr. Shimorura stated that WesternU would incorporate this program curriculum with about 40 students and develop a 15-hour certificate program for pharmacists who are already practicing. He added that it is anticipated that this will be up and running by June 2005.

- **New Statutory Changes Effective January 1, 2005**

Chairperson Powers stated that the Enforcement Committee was provided with an overview of the new statutory changes that became effective January 1, 2005. These changes will be in the board's January newsletter.

LEGISLATION AND REGULATION COMMITTEE

Chairperson Jones reported that the Legislation and Regulation Committee has not met since the last board meeting.

Ms. Herold introduced Jan Perez who was hired by the board as the new legislative coordinator replacing Paul Riches. Ms. Perez previously worked at the Department of Forestry.

Regulations Approved

- **Protocol for Furnishing Emergency Contraception: Adopt California Code of Regulations, title 16, section 1746.**

Chairperson Jones stated that this regulation adopts the board's protocol for the dispensing of emergency contraception by pharmacists. The Office of Administrative Law approved this rulemaking in late October, and this regulation took effect December 2, 2004. Information about this regulation is on the board's Web site and will be discussed in the board's forthcoming newsletter, *The Script*.

Pending Regulations -- Awaiting Notice and Board Action

- **Proposed amendments to California Code of Regulations, Title 16 – Repeal of Section 1717(3) and to Adopt Section 1713 – Authority to Use Drop Boxes for Prescriptions and Automated Dispensing Devices to Pick-Up Refill Medications**

Chairperson Jones stated that at the October 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, this regulation has not been noticed.

- **Pending Regulations -- Action to Adopt the Modified Regulations to Title 16, California Code of Regulations**

Chairperson Jones stated that on November 12, 2004, the board published the required public notice and other documents seeking comments on an omnibus group of more than 15 regulations.

Two comments were submitted in response to the proposed rulemaking during the 45-day comment period. Both changes are nonsubstantive, technical modifications to section 1745.

No public hearing has been requested for this omnibus package of regulation changes. As such, the board may take action on any or all of the regulations listed below during this portion of the board meeting.

Staff also suggested several amendments to the regulations to sections 1720.1, 1732.05(b)(7), and to remove section 1715.5 from this rulemaking.

Chairperson Jones stated any changes adopted by the board that differ from the initially noticed language will be released for a 15-day comment period, as required by the Administrative Procedure Act. The board will then compile and submit the rulemaking to the director of the Department of Consumer Affairs for review.

Chairperson Jones then led the board through a section-by-section review of the rulemaking for action by the board.

a) Adopt Amendments to Section 1706.1 --Abandonment of Application Files

§1706.2. Abandonment of Application Files.

(a) An applicant for a ~~permit~~ license to conduct a pharmacy, ~~non-resident pharmacy, sterile injectable compounding pharmacy manufacturer, wholesaler, supplier, out-of-state distributor, or clinic, medical device retailer or warehouse of a medical device retailer~~ who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his, her or its file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements ~~which are~~ in effect at the time of reapplication.

(b) An applicant for ~~a~~ pharmacy technician license registration who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.

(c) An applicant who fails to pay the fee for licensure as a pharmacist required by subdivision (f) of section 1749 of this Division within 12 months after being notified by the board of his or her eligibility be deemed to have abandoned the application and must file a new application and be in compliance with the requirements in effect at the time of reapplication.

(d) An applicant to take the pharmacist licensure examinations who fails to take the

examinations within 12 months of being deemed eligible, shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements in effect at the time of reapplication.

Note:

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

MOTION: Adopt specified amendments to CCR, title 16, sec. 1706.1 –
Abandonment of Application of Files.

M/S/C: POWERS/SCHELL

SUPPORT: 8 OPPOSE: 0

b) Adopt Section 1712 – Use of Pharmacist Identifiers

§1712. Use of Pharmacist Identifiers.

(a) Any requirement in this division for a pharmacist to initial or sign a prescription record or prescription label can be satisfied by recording the identity of the reviewing pharmacist in a computer system by a secure means. The computer used to record the reviewing pharmacist's identity shall not permit such a record to be altered after it is made.

(b) The record of the reviewing pharmacist's identity made in a computer system pursuant to subdivision (a) of this section shall be immediately retrievable in the pharmacy.

Note:

Authority cited: sections 4005, Business and Professions Code. Reference: sections 4005 and 4115, Business and Professions Code.

MOTION: Adopt CCR, title 16, sec. 1712 – Use of Pharmacist Identifiers.

M/S/C: POWERS/TILLEY

SUPPORT: 8 OPPOSE: 0

c) Adopt Amendments to Section 1715 – Self Assessment of a Pharmacy by the Pharmacist-in-Charge

§1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.

(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be

performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new pharmacy permit has been issued, or

(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.

(c) The components of this assessment shall be on Form 17M-13 17I-29 (Rev 1/01) entitled “Community Pharmacy & Hospital Outpatient Pharmacy ~~and Practice~~ Self-Assessment ~~(Including Hospital Pharmacy That Dispenses Prescriptions)~~” or Form 17M-14 17I-30 (Rev 1/01) entitled “Hospital ~~Inpatient~~ Pharmacy ~~and Practice~~ Self-Assessment” which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations, ~~regarding: facility condition and security, drug stock, posting of certificates and notices, pharmacist in charge obligations, intern pharmacist activities, pharmacy technician activities, general pharmacy practice, corresponding responsibility for filling controlled substances provisions, prescription requirements, prescription labeling and dispensing, refill authorization, prescription transfers, confidentiality of prescriptions, record keeping requirements for all dangerous drugs, record keeping requirements for controlled substances, automated dispensing devices, repackaging for use by the pharmacy, compounding unapproved drugs for future use or prescriber office use, electronic transmission of prescriptions.~~

(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.

Authority cited: §section 4005, Business and Professions Code. Reference: §sections 4021, 4022, 4029, 4030, 4037, 4038, 4040, 4050, 4052, 4070, 4081, 4101, 4105, 4113, 4115, 4119, ~~4133~~, 4305, 4330, 4332 and 4333, Business and Professions Code.

MOTION: Adopt amendments to CCR, title 16, sec. 1715 – Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.

M/S/C: POWERS/TILLEY

SUPPORT: 8 OPPOSE: 0

d) Proposed Repeal of Section 1715.5 - Implementation of Electronic Monitoring of Schedule II Prescriptions.

Ms. Herold stated that at the request of the board’s supervising inspectors, the following repeal of section 1715.5 is being recommended to be withdrawn from this rulemaking until definitive requirements for pharmacies to submit CURES data as directed by the Department of Justice and the board are added to the Health and Safety Code. She added

that this is an important program for the board and the board is currently enforcing this provision.

§1715.5. Implementation of Electronic Monitoring of Schedule II Prescriptions.

The collection of information authorized by Health and Safety Code section 11165 shall be provided as follows:

(a) For each prescription for a Schedule II controlled substance, the dispensing pharmacy shall provide the following information: the full name and address of the patient; the gender and date of birth of the patient; the DEA (Drug Enforcement Administration) number of the prescriber; the triplicate prescription number; the pharmacy prescription number; the pharmacy license number; the NDC (National Drug Code) number and the quantity of the controlled substance; the ICD-9 (diagnosis code), if available; the date of issue of the prescription, the date of dispensing of the prescription, and the state medical license number of any prescriber using the DEA number of a government exempt facility.

(b) The above information shall be provided in the following format:

(1) For each pharmacy with the capacity to do so, by on-line transmission at least every 30 days and no later than the 18th calendar day of the month following the month in which the prescription is dispensed.

(2) For each pharmacy which does not have the capacity to transmit the information on-line, on a three and one-half inch diskette in a ASCII format or one-half inch nine track magnetic 1600 BPI tape or any other medium approved by the Board of Pharmacy, which diskette, tape or medium shall be mailed or delivered to a location specified by The Board of Pharmacy, at least every 30 days and no later than the 18th calendar day of the month following the month in which the prescription is dispensed.

(3) For each pharmacy without the capacity to comply with either subsection (b)(1) or (2), the original triplicate shall be transmitted to the Department of Justice by the end of the month in which the prescription was filled.

For each pharmacy which submits hard copy pursuant to this subdivision and which pharmacy averages more than 25 triplicate prescriptions per month in any six months, the Board of Pharmacy or its designee may thereafter require that pharmacy to comply with subsections (b)(1) and (2).

(4) As to a prescription which is partially filled or dispensed, the period for compliance with subsections (1), (2), or (3) shall be measured from the earlier of the following dates and times: the prescription is either (1) completely dispensed or (2) can no longer be dispensed.

(c) Every pharmacy which has made a submission as required by this section by July 18, 1998, shall receive a reduction of \$75 on its next renewal fee for licensure of the pharmacy by the board. Every pharmacy shall be in compliance with this section and Health and Safety Code section 11165 by September 18, 1998.

Note:

Authority cited: Sections 4005, Business and Professions Code. Reference: Sections 11164 and 11165, Health and Safety Code.

There was no motion to make any change or repeal this section. The section will be removed from the rulemaking.

e) **Adoption of Amendments to Section 1717 – Pharmacy Practice**

§1717. Pharmaceutical Pharmacy Practice.

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.

Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:

- (1) a patient med pak is reused only for the same patient;
- (2) no more than a one-month supply is dispensed at one time; and
- (3) each patient med pak bears an auxiliary label which reads, “store in a cool, dry place.”

(b) In addition to the requirements of ~~Business and Professions Code~~ Section 4040 4036, ~~Business and Professions Code~~, the following information shall be maintained for each prescription on file and shall be readily retrievable:

- (1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist ~~preceptor~~ before they are dispensed.
- (2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and
- (3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
- (4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing.

Chart orders as defined in ~~§~~section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.

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

(e) No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

However, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the

patient receives health care services. The Board may in its sole discretion waive this application of the regulation for good cause shown.

(f) A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, section 1306.26.

Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of section 1716 of this Division. Information maintained by each pharmacy shall at least include:

- (1) Identification of pharmacist(s) transferring information;
 - (2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;
 - (3) Original date and last dispensing date;
 - (4) Number of refills and date originally authorized;
 - (5) Number of refills remaining but not dispensed;
 - (6) Number of refills transferred.
- (g) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Note:

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

MOTION: Adopt specified amendments to CCR, title 16, sec. 1717 – Pharmacy Practice.

M/S/C: POWERS/TILLEY

SUPPORT: 8 OPPOSE: 0

f) Adoption of Amendments to Section 1719 – Recognized Schools of Pharmacy

Article 3. Licentiatees in Pharmacy Pharmacist Candidates

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

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

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

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

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

Note:

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

MOTION: Adopt specified amendments to CCR, title 16, sec. 1719 – Recognized Schools of Pharmacy.

M/S/C: POWERS/TILLEY

SUPPORT: 8 OPPOSE: 0

g) Adoption of Amendments to Section 1720 – Application for Pharmacist Examination and Licensure

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

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

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

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

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

~~(e) An applicant for examination who does not take the examination within one year of the date the applicant is determined by the board to be eligible to take the examination shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements which are in effect at the time of reapplication.~~

Note:

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

MOTION: Adopt specified amendments to CCR, Title 16, section 1720.

POWERS/CONROY

SUPPORT: 8 OPPOSE: 0

h) Adoption of Amendments to section 1720.1 – Graduates of Foreign Pharmacy Schools

Ms. Herold stated that staff suggested two changes to this section.

1. Correct the name of the FPGEC to Foreign Pharmacy Graduate Equivalency Committee.
2. Restore a requirement formerly in section 1719(c) to require foreign graduates who became FPGEC certified before 1996 to meet the Test of Spoken English requirements currently required of all foreign graduates. The FPGEC did not require a score of 50 on the TSE until 1998.

§1720.1. Graduates of Foreign Pharmacy Schools.

Graduates of foreign pharmacy schools who have been certified by the Foreign Pharmacy Graduate ~~Examination~~ Equivalency Committee shall be deemed by the board to have satisfied the requirements of paragraphs (3) and (4) of Business and Professions Code Section 4200(a). Candidates who have been certified by the Foreign Pharmacy Graduate Equivalency Committee before January 1, 1998, must also provide the board with a score on the Test of Spoken English of least 50. For candidates who took the Test of Spoken English before June 30, 1995, a score of at least 220 must be achieved.

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

~~Pharmacy Equivalency Examination administered by the National Association of Boards of Pharmacy.~~

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

Note:

Authority cited: ~~S~~ection 4005, Business and Professions Code. Reference: ~~Section~~ sections 851 and 4200, Business and Professions Code.

MOTION: Adopt specified amendments to CCR, title 16, sec. 1720.1 – Graduates of Foreign Pharmacy Schools. The regulation will be released for 15-day comment. Delegate to the Executive Officer the ability to review comments and submit the rulemaking unless adverse comments are received.

M/S/C: POWERS/SCHELL

SUPPORT 7 OPPOSE: 0

i) **Adopt Amendments to Section 1725 – Acceptable Pharmacy Coursework of Examination Candidates with Four Failed Attempts**

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

(a) Coursework that meets the requirements of section 4200.1 of the Business and Professions Code is any pharmacy coursework offered by a pharmacy recognized school of pharmacy. ~~approved by the American Council on Pharmaceutical Education or recognized by the board.~~

(b) A final examination must be a part of the course of study.

(c) When a candidate applies for reexamination after four failed attempts, he or she shall furnish evidence of successful completion of at least 16 semester units or the equivalent of pharmacy coursework. Evidence of successful completion must be posted on a transcript from the pharmacy school sent directly to the board.

Note:

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

MOTION: Adopt specified amendments to CCR, title 16, sec. 1725 – Acceptable Pharmacy Coursework for Examination Candidates with Four Failed Attempts

M/S/C: POWERS/SCHELL

SUPPORT: 7 OPPOSE: 0

j) Adopt Amendments to Section 1726 – Supervision of Intern Pharmacists

§1726. Preceptor– Supervision of Intern Pharmacists.

(a) ~~The pharmacist supervising an intern pharmacist shall be responsible for all professional activities performed by the intern under his or her supervision. A preceptor is a pharmacist registered in any state whose license is not revoked, suspended or on probation in any state in which he or she is now or has been registered.~~

(b) ~~The preceptor pharmacist supervising an intern pharmacist shall supervise the intern's activities to provide the experience necessary to make for the intern pharmacist to become proficient in the practice of pharmacy. provision of pharmaceutical services.~~

(c) ~~The preceptor shall be responsible for all professional activities performed by the intern under his or her supervision.~~

Note:

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

MOTION: Adopt specified amendments to CCR, title 16, sec. 1726 – Supervision of Intern Pharmacists.

M/S/C: POWERS/TILEY

SUPPORT: 7 OPPOSE: 0

k) Adopt Amendments to Repeal Section 1727 – Intern Pharmacist

§1727. Intern Pharmacist.

(a) ~~An intern pharmacist is a person who holds a valid intern card.~~

(b) ~~An intern card shall be issued for a period of:~~

(1) ~~One to five years for the person who is currently enrolled in a school of pharmacy recognized by the Board.~~

(2) ~~One year to a person who is a graduate of a school of pharmacy recognized by the Board.~~

(3) ~~One year to a foreign graduate who has met educational requirements described in Business and Professions Code Section 4200.~~

~~(4) One year to an out of state licentiate who is awaiting the administration of the next licensure examination.~~

~~(c) Registration as an intern may be renewed or extended at the sole discretion of the Board for:~~

~~(1) Persons who have not completed experience requirements.~~

~~(2) Persons who have completed experience requirements but have not taken or passed the licensure examination. Intern cards shall not be extended or renewed for a person who failed the licensure examination three or more times.~~

~~(d) An intern shall notify the Board within 30 days of any change of address. An intern shall return his or her intern card, by registered mail, within thirty (30) days of a change of eligibility status.~~

~~(e) An intern pharmacist may perform all functions of a pharmacist at the discretion and under the supervision of a preceptor in accordance with Business and Professions Code Section 4114.~~

Note:

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

MOTION: Repeal CCR, title 16, sec. 1726 – Intern Pharmacist.

M/S/C: POWERS/CONROY

SUPPORT: 7 OPPOSE: 0

I) Adopt Amendments to Section 1728 – Requirements for Examination

§1728. Intern Experience—Requirements for Examination. Licensure.

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

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

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

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

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

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

~~(2) Patient medication profiles;~~

~~(3) Prescription preparation;~~

~~(4) Consultation;~~

~~(5) Record keeping;~~

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

~~(7) Drug information.~~

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

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

(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:

(1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:

(A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.

(B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.

(C) Experience in both community pharmacy and institutional pharmacy practice settings.

(D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

(2) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.

(3) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code section 144.

(4) A signed copy of the examination security acknowledgment.

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

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

Note:

Authority cited: ~~Sections 851, and 4005 and 4114~~, Business and Professions Code.

Reference: ~~Sections 144, 851, 4114 and 4200~~, Business and Professions Code.

MOTION: Adopt specified amendments to CCR, title 16, sec. 1728 – Requirements for Examination.

M/S/C: POWERS/CONROY

SUPPORT: 8 OPPOSE: 0

m) **Adopt Amendments to Section 1732-1732.7 – Continuing Education**

Ms. Herold noted that a technical amendment is proposed by staff to correct a grammatical problem in section 1732.05(b)(7), which is indicated below in double underscore, and double strikeout.

§1732. Definitions.

As used in this article:

- (a) ~~An accreditation~~ “Accreditation agency” means is an organization which evaluates and accredits providers of continuing ~~pharmaceutical~~ education for pharmacists, ~~monitors the quality of their educational activities, and audits continuing education coursework.~~
- (b) ~~The American Council on Pharmaceutical Education (ACPE) is the national accrediting agency for providers of continuing pharmaceutical education.~~
- (c) ~~The Accreditation Evaluation Service is the continuing education provider and coursework review component of the California Pharmacists Association.~~
- (d) ~~A recognized provider is anyone whose qualifications as a continuing education provider have been approved by an accreditation agency approved by the Board.~~
- (e) ~~An hour consists of~~ “Hour” means at least 50 minutes of contact time.
- (c) “Provider” means a person who has been accredited by an approved accreditation agency or accredited by the board to provide a specific continuing education course.

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~section 4232, Business and Professions Code.

§1732.05. Accreditation Agencies for Continuing Education.

- (a) The following organizations are approved ~~by the Board as continuing education and accreditation agencies:~~
 - (1) ~~The Accreditation Council for Pharmacy Education. American Council on Pharmaceutical Education~~
 - (2) ~~The Pharmacy Foundation of California. Accreditation Evaluation Service of the California Pharmacists Association~~
- (b) ~~Upon written application to the Board, any other organization will be approved by the board if:~~ Accreditation agencies shall:
 - (1) ~~the organization submits a plan demonstrating that it has the capacity to evaluate~~ Evaluate each continuing education provider seeking accreditation in accordance with the provider’s ability to comply with the requirements of section 1732.1 of this Division.

~~(A) Topics and subject matter shall be pertinent to the practice of pharmacy as specified in section 4232 of the Business and Professions Code and section 1732.1(c) of the California Code of Regulations.~~

~~(B) Each continuing education course shall have written educational goals and specific learning objectives which are measurable and which serve as a basis for an evaluation of the program's effectiveness.~~

~~(C) Speakers shall be competent in the subject matter and shall be qualified by education, training and/or experience.~~

~~(D) Each continuing education course shall have a syllabus which provides a general outline of the course. The syllabus shall contain at a minimum, the instructional objectives for each course and a summary containing the main points for each topic.~~

~~(E) When an approved provider works with others on the development, distribution and/or presentation of continuing education programs (joint sponsorship), there shall be procedures to identify and document the functions of each participating party.~~

~~(F) Promotional materials shall meet the requirements specified in section 1732.3(d) of the California Code of Regulations. Advertisements shall also include at least the following:~~

- ~~1. the educational goals and specific learning objectives of the program.~~
- ~~2. the nature of the targeted audiences that may best benefit from participation in the program.~~
- ~~3. the speakers and their credentials.~~

~~(G) An evaluation mechanism shall be used. The mechanism shall allow all participants to assess their achievement in accordance with the program's learning objectives. Self-evaluation mechanisms may include, but are not limited to, pre and post-testing, pre-testing along with group discussion and critique of answers, patient case study discussions and problem solving exercises.~~

~~The provider shall also develop a mechanism for each participant to evaluate the continuing education course.~~

~~(H) Where the method of educational delivery does not translate into contact hours, such as home study programs and other mediated instructional approaches, there shall be procedures for the determination of hours of credit for courses. Procedures used to determine the amount of time required for participants to successfully complete the program shall be documented and defensible. Acceptable procedures include:~~

- ~~1. assessing the amount of time the activity would require if it were delivered in a more formal and structured live program format; or,~~
- ~~2. pilot testing the activity with a group of pharmacists who are representative of the target audience and ascertaining the mean average length of time for completion for only those participants who successfully complete the program; or,~~
- ~~3. determination by an advisory panel, consisting of individuals qualified by experience and training in the development and administration of continuing education.~~

~~(I) The provider shall be required to maintain records of each enrollee's participation in continuing education programs.~~

- ~~1. For live programs, acceptable documentation of participation includes attendance rosters, sign-in sheets, completed program evaluation forms, or signed verification forms.~~
- ~~2. For home study and other mediated instructional approaches acceptable documentation of participation includes:~~

- a. use of a post-testing procedure in which a pre-established proficiency level is established and certificates are awarded only upon attainment of the pre-specified minimum proficiency level;
- b. in the case of study groups, the successful completion of the program may be attested to by all participants; or
- e. completion and submission, by the individual participant, of a written evaluation or critique of both the program and its applicability to the participant's practice of pharmacy. The evaluation shall be of sufficient length and detail to demonstrate successful completion of the program and a reasoned consideration of its applicability to the participant's professional practice.
- (2) ~~The organization agrees to perform the following:~~(A) Maintain a list of the name and address names and addresses of the persons designated as person responsible for the provider's C.E. continuing education program. The accreditation agency shall require that any change in the ~~designated~~ responsible person's identity shall be reported to the accreditation agency within 15 days of the effective date of the ~~of such~~ change.
- ~~(B) Notify the Board of~~
- (3) Provide the board with the names, addresses and responsible party of each provider, upon request.
- ~~(C)~~
- (4) Respond to complaints from the board ~~Board~~, providers or from ~~California~~ pharmacists concerning activities of any of its ~~approved~~ accredited providers or their coursework.
- ~~(D)~~
- (5) Review at least a ten percent (10%) sample of coursework, as determined by the Board, but not less than one course per year offered by each provider approved accredited by the agency for compliance with the agency's requirements and requirements of the board Board and, on request, report the findings of such reviews to the board Board.
- ~~(E)~~
- (6) Take such action as is necessary to assure that the continuing education coursework offered by its providers meets the continuing education requirements of the board ~~Board~~; and
- ~~(F)~~
- (7) Verify the attendance of licentiates completion at of a specific continuing education course by an individual pharmacist presentations upon request of the board ~~this article~~ the Board.
- (c) Substantial failure of an approved accreditation agency to evaluate continuing education providers as set forth in subdivision (b)(1) or to perform in accordance with the terms of its agreement as described in (b)(2) shall constitute cause for revocation of its approval as an accreditation agency by the board Board.

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~section 4232, Business and Professions Code.

§1732.1. Requirements for Recognized Accredited Providers.

~~(a) Anyone seeking to provide continuing education courses as a recognized provider for California pharmacists shall apply to a Board approved accreditation agency for recognition as a provider prior to offering any such courses. No person shall provide continuing pharmacy education without being accredited by an approved accreditation agency or having the course accredited by the board pursuant to section 1732.2 of this Division.~~

~~(b) Providers shall ensure that each continuing education course complies with the requirements of section 1732.3 of this Division.~~

~~Upon satisfactory completion of the accreditation requirements of the accreditation agency and receipt of written approval therefrom, a continuing education provider may represent itself as a California recognized provider of continuing education material for pharmacists.~~

~~(c) The provider is responsible for assuring the educational quality of its coursework. Coursework shall be relevant to the practice of pharmacy and shall be related (1) to the scientific knowledge or technical skills required for the practice of pharmacy, or (2) to direct and/or indirect patient care, or (3) to the specific management and operation of a pharmacy practice. All continuing education coursework shall be:~~

~~(1) accurate and timely;~~

~~(2) presented in an orderly fashion conducive to the learning process;~~

~~(3) complete and objective, and not reflecting predominantly the commercial views of the provider or of anyone giving financial assistance to the provider;~~

~~(4) specifically applicable and pertinent to the practice of pharmacy; and~~

~~(5) based on stated educational goals and objectives.~~

~~(d) All providers~~

~~(c) Providers shall furnish certificates of completion statements of credit to all participants that complete a continuing education course. enrollees. The certificate statement of credit shall contain the name of the enrollee, name and number of the provider, title of the course, number of completed hours, date of completion, expiration date of the coursework, course number, if applicable and the name of the accrediting agency.~~

~~(e)~~

~~(d) Each recognized provider shall notify the accreditation agency, on forms approved by the board, within at least 15 days in advance of the first time each new C-E. continuing education course is offered or presented.~~

~~(f) All providers~~

~~(e) Providers shall maintain records of attendance at or completion of their continuing education courses programs for four (4) years.~~

~~(f) Providers shall include the following information in promotional materials regarding continuing education courses:~~

~~(1) Provider's name.~~

~~(2) The number of hours awarded for completion of the course~~

~~(3) The course's date of expiration~~

~~(4) The provider number assigned by the accreditation agency.~~

~~(5) The name of the provider's accrediting agency.~~

~~(6) The learning objectives of the program.~~

~~(7) The nature of the targeted audiences that may best benefit from participation in the program.~~

(8) The speakers and their credentials.

(g) Providers shall have written procedures for determining the credit hours awarded for the completion of continuing education courses.

Note:

Authority cited: ~~S~~ection 4005, Business and Professions Code. Reference: ~~S~~ection 4232, Business and Professions Code.

§1732.2. Coursework from Non-Recognized Providers. Board Accredited Continuing Education.

~~(a) Non-recognized providers or pharmacists~~ Individuals may petition the Board board to allow continuing education credit for specific coursework which is not offered by a recognized provider but meets the standards of Section 1732.3. relevance to pharmacy practice and educational quality, as set forth in subdivision (c) of section 1732.1.

(b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.

Note:

Authority cited: ~~S~~ection 4005, Business and Professions Code. Reference: ~~S~~ection 4232, Business and Professions Code.

§1732.3. Coursework Approval for Providers. Requirements for Continuing Education Courses

~~(a) Unless denied by the accreditation agency upon audit, all coursework offered by California recognized providers is considered as approved in California. may be used to satisfy the continuing education required by section 1732.5 of this Division.~~

~~(b) On a random basis established by the Board or in response to complaints about a particular provider or requests by the board Board, the accreditation agency shall review selected coursework. Within 15 days of receipt of written notification, the provider shall submit to the accreditation agency all material deemed necessary by the Committee to review the course. The material shall be forwarded to a reviewer to judge the quality of the program on the basis of factors established by the accreditation agency in addition to the requirements of this section. those defining relevance to pharmacy practice and educational quality stated in Section 1732.1(c).~~

~~(c) A recognized provider's coursework shall be valid for up to three years following the initial presentation provided that the information is still current.~~

~~(d) A recognized provider's advertisements for approved coursework shall clearly indicate the provider's name, the coursework's number of hours, date of expiration, the provider number assigned by the accreditation agency and the name of the accrediting agency.~~

(d) Continuing education courses shall comply with the following:

- (1) Courses shall have specific, measurable learning objectives which serve as a basis for an evaluation of the program's effectiveness.
- (2) Speakers, or those developing the content of the course, shall be competent in the subject matter and shall be qualified by education, training and/or experience.
- (3) Courses shall have a syllabus which provides a general outline of the course. The syllabus shall contain at a minimum, the learning objectives for each course and a summary containing the main points for each topic.
- (4) Courses shall include a mechanism that allows all participants to assess their achievement in accordance with the program's learning objectives.
- (e) (1) Continuing education courses shall be relevant to the practice of pharmacy as provided in this section and in section 4232 of the Business and Professions Code and related to one or more of the following:
 - (A) The scientific knowledge or technical skills required for the practice of pharmacy.
 - (B) Direct and/or indirect patient care.
 - (C) The management and operation of a pharmacy practice.
- (2) Continuing education courses shall not reflect the commercial views of the provider or of any person giving financial assistance to the provider.

Note:

Authority cited: ~~S~~sections 4005, ~~4206~~ and 4232, Business and Professions Code. Reference: ~~S~~section 4232, Business and Professions Code.

§1732.4. Provider Audit Requirements.

Upon written request from the accreditation agency, relating to an audit of continuing education course ~~coursework~~, each ~~recognized~~ provider shall submit such materials as are required by the accreditation agency.

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~section 4232, Business and Professions Code.

§1732.5. Renewal Requirements for Pharmacist.

(a) Except as provided in ~~S~~section 4234 of the Business and Professions Code and ~~S~~section 1732.6 of this ~~Article~~ ~~Division~~, each applicant for renewal of a pharmacist license shall submit ~~with the application for renewal~~ proof satisfactory to the ~~board~~ Board ~~that, that the applicant has completed 30 hours of continuing education in the prior 24 months. subsequent to the last renewal thereof, he or she has completed 30 hours of approved continuing education.~~

(b) All pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course. ~~the program.~~

Note:

Authority cited: ~~S~~section 4005, Business and Professions Code. Reference: ~~S~~sections 4231 and 4232, Business and Professions Code.

§1732.6. Exemptions.

Pharmacists may seek exemption from the continuing education requirements for licensure renewal on the grounds of emergency or hardship by applying to the ~~board~~ Board in writing, ~~on a form provided for that purpose,~~ setting forth the reasons why such exemption should be granted. Exemptions may be granted for such reasons as illness or full-time enrollment in a health professional school.

Note:

Authority cited: ~~§~~section 4005, Business and Professions Code. Reference: ~~§~~section 4234, Business and Professions Code.

§1732.7. Complaint Mechanism.

A provider may request reconsideration of any adverse action taken against the provider or its coursework by an accreditation agency. Following such reconsideration, the provider may request review of the accreditation agency's decision by the ~~board.~~ full Board of Pharmacy.

Note:

Authority cited: ~~§~~section 4005, Business and Professions Code. Reference: ~~§~~section 4232, Business and Professions Code.

MOTION: Adopt specified amendments to CCR, title 16, sec. 1732 – 1732.7 – Continuing Education.

M/S/C: POWERS/SCHELL

SUPPORT: 8 OPPOSE: 0

n) Adopt Amendments to Section 1745 – Partial Filling of Schedule II Prescriptions

Ms. Herold stated that the board received two written comments suggesting changes to this section. Both were added to the proposed changes. The specific recommended changes were to subdivisions (c) and (c)(2).

§1745. Partial Filling of Schedule II Prescriptions.

(a) A prescription for a Schedule II controlled substance (as defined in Health and Safety Code ~~§~~section 11055) may be partially filled, as defined in paragraph (b), if:

(1) The prescription is for an inpatient of a skilled nursing facility as defined in Health and Safety Code ~~§~~section 1250; or

(2) The prescription is for a terminally ill patient. “Terminally ill” as used herein means a patient for whom a licensed physician and surgeon has made and documented a diagnosis of illness or disease that will result in death.

(b) A “partially filled” prescription is a prescription from which only a portion of the amount for which the prescription is written is filled at any one time; provided that regardless of how many times the prescription is partially filled, the total amount dispensed shall not exceed that written on the face of the prescription.

(c) When partially filling a prescription pursuant to subsection (a), all of the following conditions must be met:

(1) The prescription must be tendered and at least partially filled within ~~fourteen~~ 60 days following the date of issue;

(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form and on the original ~~triplicate~~ prescription, also recording the initials of the pharmacist dispensing the prescription;

(3) No portion of the prescription is dispensed more than 60 ~~30~~ days from the date of issuance of the prescription; and

~~(4) The original triplicate prescription is forwarded to the Department of Justice in conformity with Health and Safety Code section 11164(a) at the end of the month in which the prescription has been completely filled or in which the prescription has been canceled by death of the patient or otherwise, whichever comes first.~~

(d) A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II, if the pharmacist is unable to supply the full quantity ordered by the prescriber. The pharmacist shall make a notation of the quantity supplied on the face of the written prescription. The remaining portion of the prescription may be filled within 72 hours of the first partial filling. If the remaining portion is not filled within the 72-hour period, the pharmacist shall notify the prescriber. The pharmacist may not supply the drug after 72 hour period has expired without a new prescription.

Note:

Authority cited: ~~§~~section 4005, Business and Professions Code. Reference: ~~§~~section 4301, Business and Professions Code; and ~~§~~sections 11055, 11153, 11154, ~~11164~~, 11166, 11200, Health and Safety Code.

Supervising Inspector Ratcliff referred to subsection (c) (1) and stated that controlled substance prescriptions in California are valid for 6 months not 60 days. He added that the prescription must be tendered and partially filled within 6 months.

Steven Gray, representing Kaiser Permanente, stated that this might have been referenced from federal law.

Dr. Gray asked if a patient has a prescription for a 60-day supply of Schedule II drug and the insurance covers only a 30-day supply could the pharmacist fill the prescription. He added that there is confusion about what the inspectors are telling pharmacies.

Chairperson Jones suggested that Dr. Gray bring this before the Enforcement Committee for further review and consideration by the committee as well as inspector staff.

Ms. Herold stated that federal law allows for fractionation of a prescription for those who are terminally ill or in a skilled nursing facility as a means to reduce the amount of drugs on hand.

She added that subsection (d) provides the opportunity to finish filling a prescription within 72 hours if a pharmacy lacks enough of a drug to fill the entire order.

MOTION: Adopt specified amendments to CCR, title 16, sec. 1745 – Partial Filling of Schedule II prescriptions.

M/S/C: POWERS/SCHELL

SUPPORT: 8 OPPOSE: 0

o) Adopt Amendments to Section 1749 – Fee Schedule

§1749. Fee Schedule.

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

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

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

(c) The fee for the issuance of a pharmacy technician license shall be fifty dollars (\$50). The fee for the biennial renewal of a pharmacy technician license shall be fifty dollars (\$50). The penalty for failure to renew a pharmacy technician license is twenty-five dollars (\$25).

(d) The fee for application and examination as a pharmacist is one hundred fifty-five dollars (\$155).

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

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

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

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

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

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

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

- (2) For the issuance or renewal of an original certificate for an application approved by the board the fee is one hundred ten dollars (\$110). The penalty for failure to renew is fifty-five dollars (\$55).
- (k) The fee for the issuance or renewal of a license as an out-of-state ~~distributor manufacturer or wholesaler~~ is five hundred fifty dollars (\$550). The penalty for failure to renew is one hundred fifty dollars (\$150).
- (l) The fee for ~~registration as an intern pharmacist~~ license or extension of the registration is sixty-five dollars (\$65). The fee for transfer of intern hours or verification of licensure to another state is ten dollars (\$10).
- (m) ~~The fee for the reissuance of any permit, license, certificate or renewal thereof, which has been lost, or destroyed or must be reissued because of name change, is thirty dollars (\$30).~~ The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is sixty dollars (\$60).
- (n) ~~The fee for registration and annual renewal of providers of continuing education is one hundred dollars (\$100). The penalty for failure to renew is fifty dollars (\$50).~~
- (o) The fee for evaluation of continuing education courses for accreditation is forty dollars (\$40) for each hour of accreditation requested.
- (p) ~~The fee for evaluation of an application submitted by a graduate of a foreign college of pharmacy or college of pharmacy not recognized by the board is one hundred sixty five dollars (\$165).~~
- (q) (o) The fee for the issuance of a clinic license ~~permit~~ is three hundred forty dollars (\$340). The fee for the annual renewal of a clinic license ~~said permit~~ is one hundred seventy-five dollars (\$175). The penalty for failure to renew is eighty-seven dollars and fifty cents (\$87.50).
- (r) ~~The fee for the issuance of a permit for a warehouse of a medical device retailer is one hundred seventy dollars (\$170). The fee for the annual renewal of said permit is eighty-seven dollars and fifty cents (\$87.50). The penalty for failure to renew is forty three dollars and seventy five cents (\$43.75).~~

Note:

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

MOTION: Adopt specified amendments to CCR, title 16, sec. 1749 – Fee Schedule.

M/S/C: POWERS/FONG

SUPPORT: 8 OPPOSE: 0

p) Repeal Section 1750 – Fee Schedule, Health and Safety Code

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

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

Note:

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

Article 8. ~~Rules of Professional Conduct~~ Prohibitions and Discipline

MOTION: Repeal CCR title 16, sec. 1750 – Fee Schedule – Health and Safety Code

M/S/C: TILLEY/POWERS

SUPPORT: 8 OPPOSE: 0

Legislation Report and Action

• **Board-Sponsored Legislation**

Chairperson Jones stated that at the October Board Meeting, the board approved a number of legislative proposals for sponsorship. The Senate Business and Professions Committee will sponsor an omnibus bill that will contain these proposals. Also, Assembly Member Negrete McLeod will author the proposed compounding provisions developed during the Compounding Subcommittee meetings.

• **Pending or Introduced Legislation Related to the Practice of Pharmacy**

Chairperson Jones stated that the Legislative Session began December 6.

The board was provided with legislative proposals that were introduced that affect the board, patients or the practice of pharmacy. At the April Board Meeting analyses of these and other bills will be provided to the board so that the board may take action on these proposals.

NEW BUSINESS/AGENDA ITEMS FOR FUTURE MEETINGS

A comment from someone the audience requested streamlining the renewal process by offering an online renewal and mailing renewal notices on a post-card rather than sending a letter.

Ms. Harris stated that the board is moving in the direction of such a streamlining process. Currently, the California State Employment Development Department mails renewal notices

to licensees; however, because of budget constraints, notices are mailed later than they used to be. This delay causes an additional workload at the board with more calls and letters as licensees attempt to have their licenses renewed before the expiration date. The board has requested that EDD print license renewal notices earlier. She suggested that licensees mail their application and fee in as soon as the renewal notices are received to avoid a delay in getting a new license before that license expires.

Dr. Fong asked the board to address the issue of scanning prescriptions and other related documents as a method retaining a copy for the pharmacy and move away from the record keeping requirements.

Ms. Harris asked Dr. Fong to present this information to the Legislation and Regulation Committee for review.

- **Compounding**

Dan Wells asked the board to address some of the compounding issues that he felt were not handled during Compounding Committee Workgroup Meetings.

President Goldenberg stated that this would be addressed in the Legislation and Regulation Committee.

- **Intern License**

Sam Shimomura, representing Western University, stated that foreign graduate students are having difficulty getting their intern licenses from the Board of Pharmacy without a social security card.

Ms. Herold explained that Western University has admitted foreign graduates into their second year pharmacy school class and as a condition to being a student, an intern card is needed in order to perform clinical rotations. However, the board is precluded from issuing an intern card to anyone who does not have a social security card. Because these students do not have jobs, they are unable to get a social security card, yet they are already in the country with a student visa. These students meet all of the requirements for an intern card except having a social security number. She added that unfortunately, the board does not have the ability to issue an intern permit without a social security number, but a letter from the board that a foreign individual has completed all requirements for an intern license except for a social security number has been sufficient for the Social Security Administration to issue a number.

CLOSED SESSION

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

The board also move into Closed Session to confer with Legal Counsel pursuant to Government Code section 11126(e) regarding the following pending litigation: Doumit v Board of Pharmacy, Sacramento Superior Court Case #98A504499.

ADJOURNMENT

There being no further business, President Goldenberg adjourned the meeting at 4:25 p.m.

Thursday, January 20, 2005

The board held three petition hearings to consider early termination of probation for John Grasela and Medical Arts Pharmacy and petitions for reinstatement for Kenton Crowley and Sarkis Festekdjian.

CLOSED SESSION

The board moved into Closed Session pursuant to Government Code section 11126(c)(3) to deliberate upon disciplinary cases and the petitions for reinstatement and early termination of probation for these individuals listed above.

ADJOURNMENT

There being no further business, President Goldenberg adjourned the board meeting at 12:30 p.m.