California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

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

DATE & TIME: October 29 and 30, 2003

LOCATION: **The Doubletree Hotel and Executive Meeting Center Berkeley Marina**
200 Marina Boulevard
Berkeley, CA 94710

BOARD MEMBERS PRESENT:
John Jones, President
James Acevedo
Richard Benson
Ruth Conroy
Dave Fong
Stanley Goldenberg
Clarence Hiura
Kenneth Schell
John Tilley

BOARD MEMBERS ABSENT:
William Powers
Andrea Zinder

STAFF PRESENT:
Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Dennis Ming, Supervising Inspector
Ron Diedrich, Deputy Attorney General
Joshua Room, Deputy Attorney General
Dana Winterrowd, Department of Consumer Affairs Legal Counsel

Wednesday, October 29, 2003

CALL TO ORDER

President Jones called the meeting to order at 9:05 a.m. on Wednesday, October 29, 2003.

ANNOUNCEMENTS

- **Continuing Education Credits Available for Attending the Board Meeting**

  President Jones stated that continuing education hours could be earned by pharmacists wanting to learn more about the issues and operation of the board by attending this board meeting. A pharmacist may acquire six CE hours once a year by attending one full day of the board's quarterly meetings. (Board members are not eligible for this CE.) A pharmacist must attend the full business day of the board meeting to earn the continuing education credit and no partial credit will be given for attendance at part of a meeting.

- **Introduction of New Board Members**

  President Jones welcomed new board members:

  James E. Acevedo
  Mr. Acevedo has served as the commissioner for the Port of Los Angeles since 2001, and is the owner and president of DCP, Incorporated. He also served as a co-principal of GrapeVine Land Company. Mr. Acevedo previously worked for the Charles Company and served as CEO for the Community and Mission Hospitals of Huntington Park. He was also the assistant regional administrator for Greater El Monte Hospital, Woodruff Hospital, Monterey Park Hospital, Community Hospital of Huntington Park and Mission Hospital of Huntington Park. In 1990, Mr. Acevedo served as director of development at Panorama Hospital. He has been the President of the Neighborhood, Empowerment and Economic Development, Incorporated. He served as a commissioner of the Los Angeles City Fire Commission and the Los Angeles City Board of Zoning Appeals. He is also a board member of the World Trade Center of Los Angeles. Mr. Acevedo earned a Bachelor and Master of Arts degrees from California State University, Los Angeles. Mr. Acevedo is a public member, taking the vacant slot previously held by Caleb Zia.

  Richard Benson
  Mr. Benson has been the president and CEO of the United Food and Commercial Workers Union since 1994 and has served the Union in various leadership positions since 1987. Mr. Benson serves as an executive committee member of the Alameda County Central Labor Counsel. He was appointed by Chief Justice Ronald George to "The Task Force on the Quality of Justice" and also served on the Subcommittee on Alternative Dispute Resolution and the Judicial System. Mr. Benson earned a

Bachelor of Arts degree from Golden Gate University. Mr. Benson is a public member and replaces former board member Robert Elsner.

Ruth M. Conroy
Dr. Conroy has been a pharmacy supervisor at Walgreens since 1996. She was a pharmacy manager at Walgreens from 1985 to 1996. Dr. Conroy serves as an associate professor of Clinical Pharmacy at the University of California, San Francisco. She served as associate professor of clinical pharmacy at the University of the Pacific. She is a board member of the San Francisco Immunization Coalition and Pharmacy Systems Project. Dr. Conroy is a member of the American Pharmacists Association, the California Pharmacists Association and the Pharmacists' Society of San Francisco. Dr. Conroy earned a doctor of pharmacy degree from the University of the Pacific. Dr. Conroy is a professional member and replaces the vacant position previously held by Donald Gubbins.

Kenneth Schell
Dr. Schell has been the clinical operations manager for Kaiser Permanente, San Diego since 1999. From 1997 to 1999, he served as the clinical manager for Owen Healthcare, Incorporated, in the Scripps Health System. He was the critical care pharmacist at the Children's Hospital and Health Center at San Diego and served as a staff pharmacist at the Children's Hospital and Health Care in San Diego from 1985 to 1997. Dr. Schell has also served as the assistant clinical professor at both the Western University School of Pharmacy at Pomona and the University of California at San Francisco, School of Pharmacy. He is a member of the American Society of Hospital Pharmacists, the California Society of Hospital Pharmacists, where he was recognized as Pharmacist of the Year in 2002, the Academy of Managed Care Pharmacists and the Pediatric Pharmacy Group. He has also been recognized as a fellow of the American Society of Health-System Pharmacists and the California Society of Health System Pharmacists. Dr. Schell earned a Bachelor of Arts degree from the University of California, San Diego and a doctor of pharmacy degree from the University of California, San Francisco School of Pharmacy. Mr. Schell is a professional member and fills the board member position previously held by Steve Litsey.

- **Deputy Attorney General**

President Jones announced that Deputy Attorney General Ron Diedrich recently accepted additional duties within the Attorney General's Office and will no longer serve as liaison counsel to the board. President Jones acknowledged Joshua Room from the San Francisco Attorney General's Office as Mr. Diedrich's replacement in this capacity. Both Mr. Diedrich and Mr. Room were in attendance at this meeting.

- **Southern California Fires**

President Jones stated that the board supports victims of the fires currently burning in Southern California and acknowledged the burden and stress placed on the practice of pharmacy in such disaster areas. He added that historically considerable latitude is given to pharmacists assisting in natural disasters to provide refill prescriptions when original prescriptions were lost or burned. He added that board inspectors also recognize the need for flexibility within pharmacy law during natural disasters to assure patients can continue their drug therapy.

- **Charge to Board Members**

President Jones stated that currently there are many issues facing the practice of pharmacy that will provide the board with the opportunity to make a difference in health care policy in California.

Mr. Diedrich welcomed new board members and explained that they are likely to encounter many new contacts from fellow professionals and members of the public concerning issues before the board. He added that professionals with disciplinary action against them may seek advice and it is important to remain circumspect. Mr. Diedrich stated that the primary function of a board member in the area of enforcement is that of judge, and this role precludes board members from engaging in this type of discussion with anyone appearing before the board. He stated that if contacted, board members should politely explain the situation and advise the executive officer or board president of the encounter to assure full disclosure.

President Jones stated that the media may also approach board members and he stated that this is a matter for the executive officers and board officers who can speak in the official capacity of the board. Board members who are approached by the press should notify board staff with the information about the press call so the executive officers can handle the inquiry. President Jones added that if a situation calls for a board member to give an interview, staff typically provide background information to make the interview successful and consistent with board policy.

COMMITTEE REPORTS AND ACTION

Organizational Development Committee

Mr. Tilley, chairperson of the committee, thanked Mr. Goldenberg for his valuable input to resolve the current budget issues before the board. Chairperson Tilley reported on the Organizational Development Committee Meeting of October 9, 2003.

- **Mandatory Ethics Training for Board Members and Designated Staff**

Mr. Tilley stated that board members and designated staff must complete the state-mandated ethics training during 2003.

Mr. Tilley stated that the training can be taken online or via a video tape and will require approximately 1.5 hours to complete. The Web site where the training is located is http://caag.state.ca.us/ethics/index.htm. He asked that completed certificates be sent to Virginia Herold.

- **Budget Update for 2002/03 and 2003/04**

Ms. Herold presented a PowerPoint overview of the state's budget process and the specifics of the board's budget, revenue sources and expenditures. Ms. Herold referred board members and the public to board packet items that comprised the budget report.

- **BUDGET REPORT**

1. 2002/03 Revenue

The board collected $6,047,373 in revenue. In addition, the board obtained $194,500 in cost recovery (which is treated as a reimbursement, not revenue, and is actually an offset against expenditures in the year in which the money is collected).

Licensing fees comprise 90 percent of the board's revenue, and cite and fine contributed 7 percent.

Seventy-three percent of the licensing fees collected are from renewal fees and 27 percent comes from application fees.

Thirty-seven percent of licensing revenue comes from pharmacists' fees, 22 percent comes from pharmacies, and 20 percent comes from pharmacy technicians.

2. 2002/03 Expenditures

The board's expenditures for the year were $6,899,281. The board ended the fiscal year with a surplus of $622,454 in its operating budget (which is 8.4 percent). This includes $326,828 in reimbursements collected during the year from fingerprint fees ($131,829) and from cost recovery ($194,518).

The board had planned to redirect money for AG services to assure it could continue to have access to this essential component which has been under-funded for four years. However, AG services completed the year at $130,000, less than our prior year's expenditures and the amount the board had redirected from other areas of the budget ($1 million).

Personnel services comprise 51 percent of the board's budget, administrative overhead (pro rata and rent) comprises 18 percent, and enforcement costs (AG services, administrative hearings expenses) comprise 14 percent. Travel was 3 percent of the board' budget.

About 67 percent of all staff and resources are for enforcement expenses, 20 percent are for licensing, and 15 percent go to administration (which also includes consumer education expenses).

3. Fund Condition

The board's fund condition is like a savings account, it contains revenue collected by the board, and as reported at board meetings, the amount remaining at the end of a year after revenue has been matched with expenditures. The board is prohibited from operating in a deficit situation. The amount in the board's fund is reported as both a dollar amount and as "months of operating reserve" in the board's fund (savings account). By watching this amount, the board can identify when it needs to seek an increase in funding (i.e., a fee increase) or must decrease expenditures.

Transfer of Board's Reserve and Proposed Fee Increases

Last year the board loaned $6 million from its fund to the state's General Fund. Repayment of this loan is required if the board will enter a deficit situation.

Each year for the past five to seven years have exceeded its revenue generation. This is deliberate, as the board has wanted to reduce the size of its reserve in its fund.

Budget projections done last year forecasted a deficit in May 2004. However, revenue collected last year exceeded projections, and expenditures were $600,000 less than the prior year. Additionally the board collected $400,000 in citation and fine revenue. As such, the board will be able to operate this fiscal year without a deficit in our fund, delaying the need for repayment of our loan.

Projections now are that we will need a repayment of the General Fund loan sometime early in 2005/06.

Currently board fees are at their statutory minimum levels for most programs. The board could generate another $1.3 million in revenue by increasing fees to their statutory maximum, which it has no need to do for more than 1.5 years (should the terms of the General Fund loan be changed and the board NOT be repaid when a deficit looms).

Effect of Budget Reductions on the Board's Budget:

The board's expenditures have been substantially reduced over the last few years:

- 2001/02
  The budget was $7,514,523

- 2002/03
  The initial budget for 2002/03 (in Sept. 2002 when the state's budget was enacted) was $7,481,000
  The board's revised 2002/03 budget (Dec. 2002) was reduced to $7,386,597 (due to the loss of funding for four positions eliminated by the Administration because the positions were vacant).
  Budget cuts reduced the board's expenditures to $6,899,281 less another $326,828 for reimbursement to our budget (fingerprint fees collected and cost recovery payments collected), bringing actual expenditures for the fiscal year to $6,572,583.

- 2003/04
  The initial budget for the year is $7,374,000. We likely will lose $442,500 in Personnel Services from this base.

Dr. Fong asked if the current projections take into account the administration of the NAPLEX in that the board will not need to hold the exam.

Ms. Herold stated that there will be a shift in resource allocation within the board and the board will continue to collect application and exam fees from applicants. She added that it is difficult to predict the number of applicants, however, estimates are that these figures will not change and the board's revenue from the exam should remain the same. The board will continue to administer the California portion of the exam, and will require staff, the Competency Committee and an exam consultant to do this. However it will no longer need to hire proctors or rent exam sites because the exam will be computer administered. She added that these costs over the years have been held to a minimum because the board received free or low cost convention site rental when selecting sites.

Ms. Harris acknowledged supervising inspectors in their efforts to redirect workload and assign inspections because the board was faced with a deficit at the end of the 03/04 fiscal year.

President Jones complimented all board staff on the concentrated efforts to reduce the budget.

Ms. Herold provided an overview of the annual budget cycle:

Ms. Herold stated that seeking any budget augmentation requests for future years in this fiscal climate would not be successful. Budget directions from the Department of Finance required agencies to redirect money from within their programs to meet operational needs and strategic goals. No additional funding for programs or staffing would be provided even for new statutory programs. Agencies have been encouraged to review their operations, statutes, regulations and programs to identify outdated, non-necessary requirements that can be modified or eliminated to reduce expenses.

As such, the board did not seek augmentations for AG services, postage or staffing this year given the Department of Finance's budget instructions.

- **2003/04 State Budget and Deficit Reduction Items**

Ms. Herold stated that since July 1, 2003 (the beginning of the fiscal year), the board has:

Lost six positions vacant on June 30, 2003.

Identified a 12 percent (or $422,518) cut in Personnel Services. Most of this has been linked to the loss of the six positions; additionally $12,000 in board member compensation will be lost, as will all overtime and $9,000 from operating expenses. No staff at the board will need to be laid off to meet the 12 percent reduction. General fund agencies have been required to target a 20 percent reduction in total expenditures during this fiscal year; however, special fund agencies (like the board) have not been required to target the additional 8 percent in budget reductions at this time.

- **Update: Transfer of Board's Reserve**

Ms. Herold stated that last year the board loaned $6 million from its fund to the state's General Fund. Repayment of this loan is required if the board will enter a deficit situation, and before the board could promulgate regulations to increase fees. Staff and the committee are watching the board's fund condition closely, and a report of the board's fund condition is made at every board meeting.

Ms. Herold stated that recent projections indicate that the board will be able to operate this year without a deficit in its fund, delaying the need for repayment of the loan. Projections now are that repayment of the General Fund loan will be needed sometime early in 2005/06, about two years from now.

- **Status Update on the Joint Legislative Sunset Review – Recommendations of the JLSR Committee and Department of Consumer Affairs**

  Chairperson Tilley provided a status report on the recommendations from the Joint Legislative Sunset Review Committee and the Department of Consumer Affairs as part of Sunset review. Chairperson Tilley announced that of the 13 recommendations, 12 have been implemented. He added that the only recommendation that has not been implemented is to have all of the board's committee meetings public. Ms. Harris stated that this committee holds a public meeting once a year during the board's strategic planning session and the board determines whether to hold a public meeting based on the subject matter.

  Dr. Fong commended the executive officers on their significant accomplishment to implement all of the recommendations made by the Joint Legislative Sunset Review Committee.

- **Findings of the Operational Audit of the Board by the Department of Consumer Affairs, Internal Audits Office**

  Ms. Herold stated that the Department of Consumer Affairs' Internal Audits Office released its operational audit of the board in March 2003. This audit started October 1, 2002, and was completed in February 2003. The audit looked at the board's internal controls, compliance with all state requirements, the licensing of pharmacists and technicians, enforcement matters and cashiering. The department typically audits every agency undergoing sunset review. The Organizational Development Committee has been tracking these four recommendations to review board progress. Ms. Herold referred board members to the board's recent 180-day status report after the audit. Progress reports to the department on the board's actions to incorporate these changes are required at six months and at one year after the audit. The board has made significant progress in addressing the four issues identified by the auditors.

- **Personnel Update**

  Ms. Herold stated that all vacant positions on June 30th were eliminated. The board lost the following positions:

  - Three inspectors
    one new position established for the compounding program,
    one inspector position vacated from the promotion of Dennis Ming to a supervising inspector,
    one "technical" position that was reclassified from an analyst position to an inspector position to allow for reclassifying one of the new supervising inspectors – which when filled as a the supervising inspector position by the promotion of a board inspector, left an inspector position vacant.
  - One associate analyst (licensing of sites, created by the retirement of Sandi

Moeckley at the beginning of 2003),

- One office technician (licensing of sites, created by the promotion of Suelynn Yee for licensing compounding pharmacies),
- One office technician (receptionist).

In 2002/03 the board lost four additional positions due to the state's hiring freeze and the board's inability to obtain freeze waivers to fill the positions within six months:

- One office technician (receptionist)
- One office technician (complaint handling)
- One associate analyst (newsletter editor)
- One associate analyst (public outreach)

Ms. Herold stated that over slightly more than one year, the board has lost 10 positions from its (once) total staff of approximately 60, a 17 percent reduction, which is difficult for a small agency such as the board's to absorb.

Ms. Herold stated that the board's strategic plan is used to prioritize board workload. Workload once performed by these staff have been redirected to others, modified in its requirements or has been discontinued.

- **Public Comments**

President Jones stated that it is the board's goal to provide as much information on the Web site as possible. The board is planning to redesign its Web site because of the importance it places on the distribution of information and the ready access for the public.

Steve Gray, representing Kaiser Permanente, referred to one finding by DCA's Internal Auditors to destroy drugs and he stated that many in the pharmacy profession are confused as to the correct method. He added that several groups are working with the Department of Health Services in an effort to clarify the rules and he encouraged the board to participate. He suggested that this issue be addressed as a future agenda item for the Enforcement and Public Education and Communication Committees.

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Chairperson Schell reported on the meeting of October 9, 2003.

- **Emergency Contraception Fact Sheet**

  Chairperson Schell reported that in 2002, legislation took effect that allows pharmacists to provide emergency contraception to patients if they complete specific education, have a protocol with a physician and provide patient counseling. The law also requires the board to provide a fact sheet for the public on emergency contraception that includes (1) indications for use, (2) the appropriate method for using the drug, (3) the need for medical follow-up, and (4) other appropriate information. The board is required to develop this fact sheet in consultation with the California Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association and other health care organizations.

  Since January 2002, the board has made available an emergency contraception fact sheet produced by Pharmacy Access Partnership in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacists Association and the California Department of Health Services. The board has printed this fact sheet in its newsletter and has it available for downloading from the Web site.

  This fact sheet states that EC is effective if taken within 72 hours of unprotected sex. Recent research indicates that EC may be effective if initiated within five days. Additionally a popular form of EC is now provided in one dose, where as the fact sheet describes two doses. According to Pharmacy Access Partnership, more than 700 pharmacists in California operate under protocols with physicians with different timing and dosing information that now reflect community standards, and differ from information on this fact sheet.

  As such the proponents of EC have suggested that the fact sheet needs revision. Additionally some proponents have suggested a fact sheet using a 6^{th}-7^{th} grade reading level instead of the current 10^{th} grade level.

  Ms. Herold stated that a new draft of the fact sheet has been provided to the board for approval. Additionally SB 490 (Alpert, Chapter 651) and SB 545 (Speier, Chapter 652) made modifications to the requirements for pharmacists providing EC, although these statutory changes do not affect the fact sheet.

  Ms. Herold stated that currently the American College of Obstetricians and Gynecologists (ACOG) and the California Medical Association do not agree with a change to the five-day period to initiate treatment and dosing changes from that reported on the current fact sheet until the topic is reviewed during 2004. This dissent was not known to the committee at the time it made the recommendation to proceed with a new fact sheet on October 9.

  Jane Boggess, representing the Pharmacy Access Partnership, stated that they sponsored SB 1169 that created authority for pharmacist initiation of emergency contraception. She stated that this year they sponsored SB 490 that authorizes the board and the California Medical Board to create a statewide protocol. She added that in California, there are 700 new

protocols that permit pharmacists to initiate up to five days and also permits pharmacists to provide a single dose of Plan B.

Ms. Boggess stated that Plan B is a product used by 95 percent of pharmacists. She added that the proposed fact sheet brings the reading level down so everyone can understand it and it is consistent with the reading level of materials published by the Department of Health Services. The proposed fact sheet addresses the dosing issue by eliminating the information on dosing and basically instructs patients to either talk to their pharmacist or to a physician about dosing. She added that from a public policy perspective, this compromise position is in the interest of women in California.

She stated that funding is available to publish the new fact sheet in seven languages if it is completed before January 1.

MOTION: Approve a new fact sheet that, under California law, must be provided to patients receiving emergency contraception directly from pharmacists, reflecting a lower reading level in phrasing, and changes in dosing and in time to initiate treatment.

SUPPORT: 8 OPPOSE: 0

- **Board of Pharmacy Web Site Redesign**

Chairperson Schell stated that the board's budget for educational materials is very limited. The board has established partnerships with CPhA and CSHP to assist in the printing and mailing of board materials. Additionally, the board intends to use its Web site as an ever-increasing avenue for communication with licensees and the public.

Chairperson Schell stated that the board's Web page needs to be redesigned. The current Web page was created by a staff person in 1998, and now is dated. The Governor's Office several years ago directed that all state agencies to redesign their Web pages so they resemble the Governor's Web site. The board lacked the staff expertise to do this redesign, so this project is overdue.

Chairperson Schell stated that during a brainstorming session at the last meeting, the Communication and Public Education Committee suggested that the board sponsor a contest among pharmacy school students to create a new Web page design. The winner could be featured in a future board newsletter, and perhaps on the Web site itself.

David Smith recommended that the board use a professional to help design its Web site or seek assistance from the universities.

MOTION: Sponsor a Web page design contest among pharmacy students to redesign the board's Web Page. The winner would be acknowledged in a future board newsletter.

SUPPORT: 8 OPPOSE: 0

- **Public Outreach and Licensee Education Activity**

  Dr. Schell referred the board members to the many public outreach activities performed by staff and board members since July 1. Several of these public fairs have attracted more than two thousand attendees each.

- ***The Script***

  Dr. Schell stated that the board has published its second newsletter of 2003, the October issue of The Script. This newsletter is being mailed to the California pharmacies. The California Pharmacists Association's Education Foundation will print and mail copies to all California pharmacists. Dr. Schell acknowledged CPhA for this collaborative project.

- ***Health Notes***

  Dr. Schell stated that the board will revise the "Pain Management" issue of *Health Notes* in 2004. There have been a number of changes in pain management since the issue was first published in 1996, and California will have new requirements for prescribing and dispensing controlled drugs between 2004 and 2005.

LICENSING COMMITTEE

Chairperson Hiura reported on the Licensing Committee Meeting held September 10, 2003.

- **Implementation of NAPLEX and the California Multi-State Pharmacy Jurisprudence Exam (CPJE) – Proposed Regulation Change to California Code of Regulations (CCR), Title 16, Section 1719-1728**

  Chairperson Hiura stated that SB 361 (Figueroa) is the legislative vehicle for the Board of Pharmacy's sunset extension and contains statutory recommendations approved by the Joint Legislative Sunset Review Committee. Governor Davis signed SB 361, which authorizes the board to implement the North American Pharmacist Licensure Examination (NAPLEX) and develop the California-specific examination (called the California Multistate Jurisprudence Examination – California MPJE). To do this, the board must modify its regulations as recommended by the Licensing Committee.

- **Implementation of NAPLEX and California MPJE**

  SB 361 allows an applicant who has passed the NAPLEX and the California MPJE on or after January 1, 2004, to have completed the examination requirement needed to be licensed as a pharmacist. The bill requires the board when developing the California MPJE to include all of the following:

  - examination items to demonstrate the candidate's proficiency in patient communication skills
  - aspects of contemporary standards of practice for pharmacists in California including, but not limited to, the provision of pharmacist care and the application of clinical knowledge to typical pharmacy practice situations that are not evaluated by the NAPLEX

  Chairperson Hiura stated that this bill also requires the board to work with the department's Office of Examination Resources or with an equivalent organization to develop the state jurisprudence examination to ensure that applicants for licensure are evaluated on their knowledge of applicable state laws and regulations.

  Tracy Ferrel, Ph.D., Chief, Department of Consumer Affairs, Office of Examination Resources, reported on the transition to the NAPLEX and California MPJE.

  Dr. Ferrel stated that the focus of the board's activities have been to develop a content outline for the California MPJE that encompasses areas identified in California's job analysis that are not covered by the NAPLEX, and that contain items on patient communication and California law which are specifically required by SB 361.

  The board's Competency Committee completed the development of the California MPJE's content outline during an August meeting, and Dr. Ferrel discussed the new content outline. She noted that there was substantial overlap between the content outline for NAPLEX and for California's prior pharmacist examination. The California MPJE will be comprised of 75 graded items and 15 pretest items (non-graded items that will not be identified to candidates as non-graded items).

  Chairperson Hiura stated that an applicant for licensure in California must qualify for eligibility to take the exams according to existing requirements (be 18 years of age, be a graduate of a school of pharmacy, etc.). Once determined by the board as qualified to take the exams, the applicant will contact the exam administrator to schedule the exams. If a candidate wishes to qualify to take the NAPLEX in another state he or she may do so by applying for licensure as a pharmacist to that state board of pharmacy and then having the NAPLEX score (if taken after January 1, 2004) transferred to California. However, to take the California MPJE, only California can qualify the applicant to take this exam. There will be some modifications to California's examination application process and forms. These changes are necessary to streamline the process and make it more efficient for the applicant, the board and the schools.

Chairperson Hiura stated that staff have been working with the NABP on the transition to NAPLEX and the California MPJE. There have been ongoing discussions with the NABP and the Office of Examination Resources on the best approach to implement the computerized component of the California MPJE.

Current law (Business and Professions Code sec. 4200.1) requires an applicant who fails to pass the pharmacist licensure examination after four attempts to complete a minimum of 16 semester units of pharmacy coursework before he or she can take the licensure examination for a fifth time. While it appears that this law still applies; clarification has been sought from the board's staff counsel. For example, would this provision apply if an applicant who has failed the prior pharmacist licensure examination four times be eligible in California to take the NAPLEX and the California MPJE after January 1, 2004, without completing the education.

Chairperson Hiura stated that counsel will be working on this language and if the board approves this action item, then this language will be also be included in the regulatory notice.

Ms. Harris provided an overview of the proposed changes:

- 1719 – The primary change in this section is the requirement that an applicant for the examination must complete the required 1,500 hours for licensure before being qualified to take the examination (currently this is 1,000 hours). This is proposed to streamline the application process in recognition of a substantially reduced time for examination results to be provided to candidates once computerized examination administration is implemented.
- 1720 – Changes are technical except that a foreign graduate applicant must take the pharmacist licensure examination within one year of application instead of the five-year period allowed now.
- 1720.1 – Graduates of foreign pharmacy schools who apply to take the California pharmacist licensure examination must be certified by the Foreign Pharmacy Graduate Examination Committee instead of simply passing the committee's FPGEE examination. This certification will streamline the board's application process for foreign graduates. This certification will provide the board with the graduate's transcripts, which the current process does not. Also, the certification process entails passing the TSE consistent with the board's current regulatory requirement.
- 1721- An applicant engages in dishonest conduct during an examination would not be allowed to take the next examination for two years (currently this is one year), must surrender his or her intern card (currently required) and add that he or she cannot be issued a pharmacy technician permit.
- 1723.1 – Proposed technical changes to existing language.
- 1724 – Would NAPLEX and California MPJE scores be communicated to applicants as pass/fail. This regulation change is consistent with the guidance

provided by the Office of Examination Resources. The board currently establishes its passing score by a criterion-referenced method. The process for establishing the pass score for California's MPJE will not change from current practice.

- 1727 – Proposed technical changes to existing language.
- 1728 - Sections (c) and (d) were moved to section 1719.

One significant change proposed is that an applicant would be required to complete the 1,500-hour requirement for his/her internship at the time of application for the pharmacist licensure examination. At the committee meeting, Chairperson Hiura stated that schools were concerned that this change might negatively impact those students who will graduate in 2004. While this change would not delay a successful applicant's ability to become licensed, it was suggested that this change not be implemented until after July 1, 2004. However, based on the timeframe for implementing regulations changes, even if adopted by the board at the January meeting, it would take a minimum of six months to promulgate the rulemaking so it would not affect the 2004 graduates.

Dr. Ferrell provided a detailed explanation of proposed changes to section 1724. She stated that the change to eliminate specific mention of "a scaled score of 75" as passing would not change how the board actually sets the pass score, it just remove a pass score in the regulation. A licensing examination determines whether a candidate is competent to practice, not whether the candidate performs better or worse than others who take the exam. The written examination measures the knowledge and skills required in practice, and represents a standard of performance that subject matter experts agree is the minimum acceptable level for licensing in the profession.

To establish pass/fail standards for each version of the examination, a criterion-referenced passing score methodology is used. The intent of this methodology is to differentiate between a qualified and unqualified licensure candidate. The passing score is based on minimum competence criterion that is defined in terms of the actual behaviors that qualified pharmacists would perform if they possessed the knowledge necessary to perform job activities.

During a criterion-referenced passing score procedure, a panel of licensed pharmacists also consider other factors that would contribute to minimum acceptable competence such as prerequisite qualifications (e.g., education, training and experience); the difficulty of the issues addressed in each multiple-choice item; and public health and safety issues. By adopting a criterion-referenced passing score, the board applies minimum competence standards to all licensure candidates. Because each examination version varies in difficulty, an important advantage of this methodology allows for the passing score to be lower for a more difficult examination and raised for a less difficult examination, providing safeguards to both the candidate and consumer.

MOTION: Licensing Committee: Approve the proposed regulation change to CCR, Title 16, Sections 1719-1728, to implement the North American Pharmacist Licensure Examination (NAPLEX) and the California

Multi-State Pharmacy Jurisprudence (MPJE) examination.

SUPPORT: 8 OPPOSE: 0

- **Proposed Regulation Change to CCR, Section 1749, 1793-1793.7 to Implement Changes to the Pharmacy Technician Program as a Result of SB 361 (Figueroa) (Chapter 539, Statutes of 2003)**

Chairperson Hiura reported that SB 361 also includes statutory changes to the pharmacy technician program that were recommendations from the board's Pharmacy Manpower Task Force. These changes included the requirement that an applicant for registration as a pharmacy technician has obtained an associate's degree in pharmacy technology. This was changed from an associate arts degree in a field of study directly related to the duties performed by a pharmacy technician. Certification by the Pharmacy Technician Certification Board was added as a qualifying method and the experience provision as a clerk typist was eliminated. Also, the statute was clarified to allow a graduate from a pharmacy school recognized by the board to be eligible for registration instead of requiring that an applicant be eligible for the board's pharmacist licensure examination.

Ms. Harris stated that the proposed regulation amendments are consistent with the provisions of SB 361 and include technical clean up of the language that has not occurred since the original adoption in 1991. There is a great deal of repetition in the regulations of statutory requirements. The changes are:

1749 – Moves the technician fees to the same code section containing all other board application and licensing fees.
1793 - Technical changes.
1793.1 – Moves (g) to 1793.7 and eliminates (h) which is duplicative of existing law.
1793.2 – Duplicative of existing statute.
1793.3 – No change. Proposed changes are being considered by the Legislative/Regulatory Committee.
1793.4 – Eliminates clerk typist experience as a qualification consistent with SB 361 changes.
1793.5 – Duplicative of existing statute.
1793.6 – Amendment removes the specificity of the theoretical and practical aspects of the 240 hours of training.
1793.7 – Removes the duplicative sections of statute and adds (g) from 1793.1.

MOTION: Licensing Committee: Approve proposed regulation changes to California Code of Regulations, Title 16, Section 1749, and 1793-1793.7 to implement the changes to the pharmacy technician program as a result of SB 361.

The board discussed various aspects of these proposed changes.

SUPPORT: 8 OPPOSE: 0

- **Proposed Statutory Changes to the Wholesale Licensure Requirements**

  Chairperson Hiura reported that during the Licensing Committee Meeting on September 10, staff provided the Licensing Committee with proposed changes to the wholesale statutes.

  Ms. Harris added that the changes are primarily technical in nature with a few exceptions. The intent is to make the law easier to read and understand. However, there are a couple of substantive changes. The first one is the deletion of current subdivision (b) of 4160. This elimination would require all nonresident wholesalers to be licensed in California. Under current law, if an out-of-state wholesaler distributes dangerous drugs through a California-licensed wholesaler, the board does not require that the out-of-state wholesaler be licensed with the board. The second substantive change requires an exemptee-in-charge for all nonresident wholesalers. This requirement is consistent with requirements for in-state wholesalers.

  MOTION: Licensing Committee: Approve the proposed statutory revisions to the wholesale licensure requirements.

  SUPPORT: 8 OPPOSE: 0

- **Proposed Statutory Changes to Site License Requirements – Prohibition of Location in Personal Residence and Issuance to a Specific Location**

  Chairperson Hiura reported that the Licensing Committee considered a legislative proposal to add Business and Professions Code section 4107. This provision would prohibit any board-licensed facility from being located in a personal residence. Currently there is no such prohibition and it is problematic in that some wholesale facilities are located in the owner's home. Subdivision (b) would prohibit the board from issuing more than one site permit to one premises address.

  MOTION: Licensing Committee: To move forward with the proposed statutory changes that would clarify the licensure requirements for facilities.

  SUPPORT: 8 OPPOSE: 0

- **Issuance of Pharmacy Permits to Limited Liability Companies (LLCs)**

  Chairperson Hiura reported since the Licensing Committee meeting, staff has identified a new licensing issue that he asked be brought directly to the board.

Ms. Harris explained that that Business and Professions Code section 4201 authorizes the board to issue permits for a pharmacy, wholesaler, and veterinary food-animal drug retailer to several types of legal entities, including partnerships, corporations, or other unincorporated associations. This section was amended in 1994 to include limited liability companies (LLCs), and states information which an LLC must include in a permit application. As such, the original interpretation or reading of this section thought that express authority was given for a LLC to operate a pharmacy or other licensed pharmaceutical "business." However, the board's legal counsel researched the issue and concluded that a LLC is ineligible for any license or permit issued by the board because a license for professional services cannot be issued to a LLC. This analysis was provided to board in March 1998.

In October 1998, the board's counsel issued a recommendation that the board may want to consider proposed legislation, which would authorize the board to issue "site" permits to a LLC. He based this recommendation on the fact that current law already authorized the board to issue "site" permits to corporations, which have the same liability shields as a LLC, and that the proposed legislation would not adversely affect consumer protection.

The board accepted the recommendation and tried to sponsor legislation; however, it was met with opposition and an author was never obtained. Therefore, the legislation was never advanced.

In 2000, the Court of Appeals issued a decision that gave guidance as to the interpretation of what constitutes "professional services" in a clear and precise manner. Based on that case, the Legal Office of the Department of Consumer Affairs gave direction as to what licenses are professional versus business, occupation, or vocational, and the department had legal argument that agencies may issue licenses to LLCs by applying the criteria from this case. Essentially the criterion is whether any education or experience is required before an agency will issue a license.

Although no education or experience is required to issue a pharmacy license, the license does require a qualifier. The qualifier is a professional licensee who is legally responsible for the professional acts of the business entity, a licensed pharmacist who is a pharmacist-in-charge. Staff counsel concluded that a pharmacy license is more of a business and profession hybrid license and therefore, the law continued to be unclear.

The board determined that pharmacies are licensed for the primary purpose of "delivering pharmacist's professional services" and therefore, would not meet the criteria of a business license. At its October 2000 meeting, the board took the position that unless legislation is pursued to clarify the law, the board should not license a LLC as a pharmacy.

Because the board had received numerous applications with LLCs in the pharmacy ownership structure, staff requested additional clarification from counsel regarding LLCs owning a pharmacy. The board's counsel concluded in a new written opinion shared with the board at

this meeting that recent developments and refinements of California law indicate that LLCs are persons eligible to apply for licenses to conduct pharmacies.

This conclusion is contrary to the board's current position. Therefore, it is requested that the board consider this new legal analysis and determine if it wants to take action to allow a LLC to own a pharmacy.

MOTION: Establish policy changes based on a legal analysis provided by staff counsel to authorize a limited liability company to own a pharmacy.

M/S/C: TILLEY/GOLDENBERG

SUPPORT: 8 OPPOSE: 0

- **Approval Process for Security Printers of Controlled Substance Prescription Documents Pursuant to SB 151 (Burton), Chapter 406, Statutes of 2003)**

Chairperson Hiura stated that SB 151 requires the Board of Pharmacy and Department of Justice (DOJ) to approve security printers prior to the production of secure prescription forms for controlled substances. This will require the coordination of security printer approval between the board and the Department of Justice (DOJ).

Ms. Harris added that staff will be working with the DOJ to determine details of how their processes and board processes will interact.

The board's proposed procedures will require that security printers seeking the board's approval will be required to complete an application form. In addition to the standard questions and criminal background check, the applicant will be required to submit policies and procedures for verifying the identity of the prescriber ordering controlled substance prescription forms, and the policies and procedures for verifying the delivery of controlled substance prescription forms to prescribers.

Once the board approves an application, a copy of the file and a letter from the board will be sent to DOJ for review. If the DOJ approves or fails to take action within 30 days, then the security printer application is approved and a letter is generated to the applicant indicating approval.

Once the final approval is issued, the name and contact information of the approved security printer will be added to the master list maintained on the board's website. If the DOJ rejects the applicant, then DOJ will send a denial letter. The DOJ will also notify the board of the denial and the grounds for the denial. If the Board of Pharmacy denies an application, then the board will send the denial letter.

The legislation provides the following as grounds for denying an application: (1) The applicant has been convicted of a crime. (2) The applicant committed any act involving dishonesty, fraud, or deceit with the intent to substantially benefit himself, herself, or another, or substantially injure another. (3) The applicant committed any act that would constitute a violation of this division. (4) The applicant knowingly made a false statement of fact required to be revealed in the application to produce controlled substance prescription forms. (5) The Board of Pharmacy or Department of Justice determines that the applicant failed to demonstrate adequate security procedures relating to the production and distribution of controlled substance prescription forms. (6) The Board of Pharmacy or Department of Justice determines that the applicant has submitted an incomplete application.

The procedures and forms will be in place in January, and information about being qualified as a printer will be on the board's Web site and published in the next newsletter.

- **Update on the Implementation of the Injectable Sterile Compounding Program for Pharmacies**

  Chairperson Hiura gave an update on the implementation of the injectable sterile compounding program for pharmacies that went into effect July 1, 2003.

  Mr. Ming reported that 200 applications were received and 150 licenses were issued.

- **Report from the Ad Hoc Committee on Pharmaceutical Benefit Managers (PBM) Regulation – Recommendation to the Board of Pharmacy that it not take any action to regulate PBMs**

  Chairperson Hiura stated that at its January 2003 meeting, the board created the Ad Hoc Committee on PBM Regulation. This committee is comprised of the board's public members and is functioning under the auspices of the Licensing Committee. The first meeting was held March 4, 2003, and the second meeting June 4th. Board Member Dave Fong facilitated both meetings and both were well attended. The third meeting was held September 11th and was facilitated by Licensing Committee Chairperson Hiura.

  The purpose of this committee is to determine the need to regulate PBMs in order to protect the public. If the committee determines that PBMs are harming the public and need to be regulated to prevent the harm, then the committee's charge is to determine the regulatory framework.

  In order to answer this question, the committee requested that all interested parties, which included the proponents and opponents of PBM regulation, to complete a sunrise questionnaire and submit it by September 1, 2003. This questionnaire is designed to assist proponents of new state boards or new categories of licensed professionals to collect and organize information that is necessary for an objective evaluation. It is intended to determine the merits of governmental regulation to demonstrate the need that licensure and

regulation is necessary to protect the public. The questions were to be used as a guide to the committee in making its recommendation regarding regulation.

Dr. Hiura reported that only one completed questionnaire was received. Several PBM organizations participated in the completion of this questionnaire. The committee also received a letter from the Academy of Managed Care Pharmacy (AMCP) and information from the National Community Pharmacists Association (NCPA). The NCPA provided a brief overview of PBM legislation introduced this year in other states. All the documents were available on the board's website and at the meeting.

At the request of the board, staff identified for this meeting possible elements of PBM regulation in California. Staff prepared a memorandum that used elements from three principal documents [NCPA Model Law on PBMs, NAIC Draft Model Law on Formulary Development, and a recently enacted Maine statute that imposes disclosure requirements on PBMs]. In addition, the testimony and comment provided at the prior committee and board meetings were used to form the regulatory elements.

Part of the analysis noted that existing model statutes are difficult to apply to California for multiple reasons. For example, California is unique in establishing a separate state agency (the Department of Managed Healthcare) for regulating health maintenance organizations (HMOs). Health benefits provided by HMOs are subject to a detailed statutory scheme of regulation (the Knox-Keene Act), which is more extensive than that in other states.

The committee was charged to answer the threshold question of whether the regulation of PBMs is necessary to protect the public, which should have been addressed by the responses to the sunrise questionnaire.

Chairperson Hiura stated that the Ad Hoc Committee was unable to recommend to the board any action that the board should take to license or regulate PBMs. The board will continue to monitor the activities of PBMs for a potential role for the board in the future.

He added that Board Member Bill Powers, who was unable to attend this board meeting, asked to have his comments entered into the minutes of the board meeting.

Memo to: Members of the California Board of Pharmacy
From: Ad Hoc Committee on Pharmacy Benefit Managers (PBMs). Bill Powers and Andrea Zinder

Date: October 22, 2003

The Board of Pharmacy established the ad hoc committee composed of public members of the board to determine if PBMs should be regulated by the board of another state agency. This action was taken at the request of several organizations.

The ad hoc committee held three hearings and heard extensive testimony on both sides of the issue. The committee was also presented with a good deal of written material on both sides of the issue. The PBMs who testified believed that they were already regulated, although indirectly, through the Department of Managed Health Care and the Department of Insurance. The ad hoc committee also heard testimony from several groups who felt that PBMs should be regulated because they have become integral players in the health care system.

At the last hearing the ad hoc committee was unable to recommend to the board any action that the board should take relative to licensing or regulating PBMs. However, that is not to say that we do not have serious concerns about some of the activities of PBMs, which may be questionable at best or a conflict of interest at worst. Other states are making efforts to regulate PBMs and while the ad hoc committee did not come up with any recommendations for the board to consider, we believe that other state agencies should consider what their roles might be. We also believe that the Board of Pharmacy should continue to monitor the activities of PBMs to see if there is a role for the board in the future.

- **Competency Committee Report**

Chairperson Hiura stated that it was reported to the Licensing Committee that the Pass/Fail letters for the June 2003 examination were mailed to the candidates on Friday, August 15, 2003. However, during the regrading of the essay examinations for this exam, it was discovered that some examination booklets had been incorrectly reassembled for machine scanning and scoring.

Accordingly, a complete review was conducted of every essay examination of all 1,160 candidates who passed the multiple-choice section of the examination and whose essay booklets were graded. This quality control process identified those candidates whose essay booklets were not collated correctly, where one page was incorrectly assembled. Based upon this finding, all scoring decisions were reviewed. This review resulted in reconsideration of the passing point for the essay portion of the examination.

On October 10, 2003, the board sent letters to the 1,160 candidates who passed the multi-choice choice section informing them of the incident and notifying those candidates that passed as a result of the re-score. The pass rate for this examination was 56.5%.

Enforcement Committee

- **Importation of Drugs from Canada**

Mr. Goldenberg provided comments on the growing trend for the public to obtain prescription drugs from Canada. He stated that federal law allows for the re-importation of drugs if the

Secretary of Health and Human Services (HHS) certifies the safety of the system. The Secretary of HHS has never certified the safety of a re-importation system.

Prescription drugs are expensive. The US is the last industrialized country without price controls on drugs. As such, most international drug companies develop and introduce drugs for the US first in order to gain the most favorable return on their investment.

Because prescription prices are high in the US and less costly in the rest of the world (where there are price controls), there is a great incentive by American consumers to obtain necessary drugs from other nations. Due to similarities of regulatory systems and common language, many feel safe about importing prescription drugs from Canada and the number of people doing so rapidly growing. Importation from Mexico and other countries via cross border forays and the Internet are also an issue, but the Canadian system is considered to be safer and is therefore preferred.

For Americans, the savings on a prescription from Canada ranges from 20-80 percent. Although obtaining prescriptions from Canada is illegal, the federal Food and Drug Administration (FDA) and US Customs have expressed that they will not intercept shipments or prosecute individual Americans seeking to buy their prescriptions this way.

As a result, the FDA and state Boards of Pharmacy are confronted with new entities that are "storefronts" for Canadian pharmacies. These entities act as brokers for prescriptions between the consumer and the Canadian pharmacies. They often locate near senior centers and communities and aggressively advertise. These storefronts require no training, no pharmacy license and little expense to set up their business. There is question as to whether or not they are subject to Board of Pharmacy regulation because they do not operate as a traditional pharmacy.

The Enforcement Committee and the Board of Pharmacy have been discussing importation of prescription drugs from Canada through these storefront operations at each meeting since April. Senator Alarcon requested an Attorney General Opinion, to which the FDA provided a response as to the federal requirements. The board has produced a consumer booklet on dealing with the high cost of buying prescriptions. It describes discount programs, use of generics, manufacturer assistance programs and deals with the risks of shopping over the Internet or acquiring drugs from other countries. There has been action by other state boards of pharmacy and the FDA against these storefront operations. This board has stated its concern both with patient safety and access to affordable prescriptions. There is concern with the risks inherent to consumers using a system not regulated in the US.

Mr. Goldenberg stated that the board must focus on the security of these drugs to protect consumers and added that the board should not ignore the issue.

Chairperson Jones stated that although there are no easy answers, the board must consider all the issues. He added that a recent study revealed that 88 percent of sample drugs being shipped to consumers in the U.S. were not FDA approved for use in the United States.

Chairperson Jones stated that the issue is to assure affordable and safe prescription drugs. He suggested a board-sponsored summit where these issues could be discussed. This summit would need to be of low cost to the state.

Mr. Goldenberg stated that the board must continue its discussion regarding the importation of drugs from Canada and will take testimony from the public at this summit. He added that the board has not received any consumer complaints regarding re-imported drugs; however, it has received numerous complaints from businesses and licensees against these storefront entities for unfair business practices and using a pharmacy-related sign.

The board considered the issue of holding a summit before the April board meeting.

Dr. Schell stated that this issue might be outside of the board's jurisdiction and he expressed concern that it might create a false sense of expectation between the diverse groups and opinions on this subject. He asked if the board would identify issues and opportunities to create safe medications for consumers received from outside of California.

Chairperson Jones stated that the purpose of the summit would be to invite many interested parties to gather information and then present this information. He added that at the very least, the board should advise consumers of the dangers and pitfalls involved in purchasing drugs from out of California.

Bruce Young, representing the California Retailers Association (CRA), stated that the CRA supports the proposed summit and added that perhaps a system could be developed to facilitate the distribution of imported or re-imported drugs. He added that the board should act to protect the profession of pharmacy and the name of a pharmacy from Canadian pharmacies hanging pharmacy signs, causing consumers to be mislead into thinking that these pharmacies are legitimate.

John Berger stated that many consumers pay a high cost for their prescriptions drugs and he suggested that the board not act to cut them off from their needed prescriptions. He stated that manufactures in this country charge excessively high prices for prescription drugs, and the board should address this issue instead.

Robert LeWinter stated that he is a senior citizen, a licensed pharmacist and the ex director of pharmacy at UCLA Medical Center, retired from the University of California after 25 years. He stated that as part of his health plan, he receives mail order prescriptions from a pharmacy in Pittsburg, PA, where patients who request counseling wait a considerable amount of time and are screened by three or four people before they talk to a pharmacist. He added that he

does not view poor patients structure as any different from purchasing prescriptions from Canada.

Mr. LeWinter stated the board could protect the integrity of drug supplies by requiring wholesalers and pharmacies to purchase their drugs directly from manufacturers. He also suggested that the board regulate this practice so a pharmacist is available to counsel patients.

Fred Mayer, representing Pharmacists Planning Services, Inc., strongly urged the board to take action to shut down the storefront pharmacies before people are injured. He stated these storefronts are illegal and are being shut down in other states. Alternatively, allow licensed pharmacies to import Canadian drugs. This would be facilitated if the drugs sold had a pedigree, tracing ownership from manufacturer to patient.

MOTION: Hold a summit before the April board meeting to discuss importation of prescription drugs from Canada and access to safe prescription medications with the intent to invite leaders of the medical, pharmaceutical, academic, regulatory and senior communities for a roundtable discussion on the issues of drug safety, the proliferation of Canadian pharmacy storefronts and consumer access to affordable drugs.

M/S/C: TILLEY/HIURA

SUPPORT: 8 OPPOSE: 0

- **Prohibition of Pharmacy-Related Signs on Non-Pharmacy Businesses or Buildings**

Mr. Goldenberg stated that at the September 17 meeting, the Enforcement Committee reviewed Business and Professions Code section 4343 in response to the Governor's directive all agencies to evaluate mandates to determine if each is necessary in light of the state's fiscal condition.

Business and Professions Code section 4343 establishes a prohibition on the use of signage that includes words such as "pharmacy," "drugstore," "apothecary," or words of similar import unless the premise is a licensed pharmacy. Although the board has never received a consumer complaint regarding the use of pharmacy-related signage, the law is enforced when the use of such signage may be misleading to the public. The board has been requested to enforce this provision against storefront facilities that assist consumers in obtaining prescription medications from Canada. It was discussed that the use of pharmacy-related signage in this instance is not confusing to the consumer.

The origin of this prohibition was in 1905 when a general regulation of pharmacists was established. It brought existing "pharmacies" by whatever name under the board's regulatory authority. It was an inclusive statute designed to assert the board's jurisdiction over existing

businesses. While over the years the law has been changed, the intent of this section has remained constant.

The committee concluded that the law did serve a useful purpose and should be retained.

The board has few options when enforcing the law because it is non-licensed entities that violate this provision. Usually the only option is to refer the matter to the local district attorney to file a criminal complaint or to seek voluntary compliance.

President Jones stated that the Enforcement Committee-proposed summit would also gather information regarding this.

Bruce Young, representing the California Retailers Association, suggested that since the board has this provision, it should use it and shut down these storefronts that are now in violation of the law.

- **Proposals Regarding Wholesale Drug Transactions**

  President Jones provided an overview of the committee's proposals to increase regulation of wholesalers. He stated that at the July Enforcement Committee meeting, Supervising Inspector Judi Nurse gave an overview regarding bid contract diversion of drugs in California. Pharmacies purchase "bid contract" drugs at special prices and then, through a common ownership, transfer the drugs to their wholesale facilities to be resold to other wholesalers. Often there is no record for these drug transactions. The drugs are resold several times through many wholesalers and many states in largely undocumented transactions that are impossible to trace. This "gray market" system has enabled counterfeiting. Unscrupulous companies can turn one shipment of injectable medications into many by watering down the drugs and reproducing the packaging.

  The issue of bid contract diversion and the proliferation of counterfeit drugs have caused the committee to propose regulations to ensure the integrity of California's drug distribution system.

  The committee discussed proposed regulations for wholesalers at its July meeting and comments were made that the regulations would impede legitimate business transactions and modifications were suggested. Others stated that the federal PDMA allows for intra-company sales, which may be contrary to the regulations proposed. While the board had been using Nevada as its model for the regulatory framework, others suggested that the committee might want to review Florida's legislation. This new legislation identifies a list of drugs that requires due diligence in authenticating prior transactions based on pedigrees.

  At the July meeting, President Jones requested interested parties to submit proposed language to address the concerns that were discussed; however, no language was submitted. Therefore, staff prepared a new regulatory proposal to address wholesale and pharmacy transactions for the September meeting. In addition, a legislative proposal was prepared for citation and fine

authority for wholesale violations. The legislative proposal would establish monetary sanctions to deter economic motivations that create the law violations. While the board can pursue cases administratively for these same violations, usually by the time any formal action is pursued, the wholesaler permit is cancelled and the board has no authority over the non-licensed owners.

At the September committee meeting, there was considerable discussion regarding the burden that the new proposed regulations would place on wholesalers. Currently, drugs are not tracked by lot numbers and it would be unreasonable to limit the sale or transfer of a drug to three times prior to being furnished to the final consumer. The committee asked staff to provide documentation about the magnitude of the problem for presentation at its next meeting in December before making a recommendation to the board.

- **Recommendations from the Joint Task Force on Prescriber Dispensing**

Mr. Goldenberg stated that the Medical Board of California (MBC) and the Board of Pharmacy held a joint task force meeting on the issue of prescriber dispensing. He stated that he and Board President Jones represented the board. The meeting was held on May 27, 2003, and the task force reached consensus on the following: (1) Under current law, an individual prescriber can own his/her own prescription stock and dispense this to his or her own patients as specified. This practice should be allowed to continue with the goal of strengthening and educating prescribers regarding the record keeping requirements; (2) A medical group should be able to dispense prescription medications pursuant to a special permit issued by the Board of Pharmacy and specified conditions that require one physician from the medical group to be responsible and accountable for the security of the prescription medications, record keeping requirements, and a consultant pharmacist reviews the dispensing process; (3) Establish the authority for a pharmacy to place an automated dispensing device in a prescriber's office; and (4) Provide for joint oversight by the appropriate licensing agencies.

The task force agreed that staff from the two boards would work together to draft language for each board to consider as a possible joint legislative proposal for 2004. Draft language was developed and the Medical Board task force members provided comments on the draft. The language was reworked to address their comments. The proposal would require a special clinic license for these group practices, which would have a fiscal impact to the board.

Ms. Harris stated that following the task force meeting, interested parties expressed concern that they had just received the proposed language and did not have sufficient time to review it and provide comment. There was also discussion that consensus was not reached on this issue contrary to the statement made by the task force. The Enforcement Committee agreed to discuss this issue at its December meeting so that the interested parties had sufficient time to review the proposal.

Ms. Harris stated that the Medical Board would take the same language to its board meeting in December. She added that the proposal allows for a group of physicians or prescribers to

dispense from a common stock if they have obtained a special permit from the Board of Pharmacy. If this type of legislation was introduced, this program would represent a major fiscal impact to the Board of Pharmacy. The board will need to consider this issue as well. Ms. Harris stated that this issue would be agendized for the December Enforcement Committee meeting.

Dr. Fong stated that this issue must be on a level playing field. He added that he does not feel that this is consistent with the requirements placed on pharmacies, for example requesting patient consultation or quality assurance. Additionally, prescribers should be able to sell the prescription medication they have prescribed.

Deputy Attorney General Joshua Room clarified that the only issue changing under this proposal is group practice physician prescribing. Individual physician prescribing will remain the same under current law that is not subject to pharmacy requirement.

- **Implementation of Enforcement Provisions from SB 361**

  Mr. Goldenberg stated that SB 361 (Figueroa) is the legislative vehicle for the Board of Pharmacy's sunset extension and contains statutory recommendations approved by the Joint Legislative Sunset Review Committee. The following compliance provisions were recommendations from the board and included in SB 361. They will be added to California Pharmacy Law effective January 1, 2004.

  - **Section 4083 – Order of Correction**
    Will allow an inspector to issue an order of correction to a licensee directing the licensee to comply with the Pharmacy Law within 30 days by submitting a corrective action plan to the inspector, or the licensee can contest the order of correction to the executive office for an office conference. If an office conference is not requested, compliance with the order will not constitute an admission of the violation noted in the order of correction and the order of correction is not considered a public record for purposes of disclosure. The licensee must maintain on the pharmacy premises a copy of the order of correction and corrective action plan for at least three years from the date the order was issued.

  - **Section 4315 – Letter of Admonishment**
    Will authorize the executive officer to issue a letter of admonishment to a licensee for failure to comply with Pharmacy law, directing the licensee to come into compliance within 30 days by submitting a corrective action plan to the executive officer documenting compliance, or the licensee can contest the letter of admonishment to the executive officer for an office conference. If an office conference is not requested, compliance with the letter of admonishment will constitute an admission of the violation noted in the letter of admonishment. The licensee must maintain on the pharmacy premises a copy of the letter of admonishment and corrective action plan for at least three years from the date the

letter was issued. The letter of admonishment will be considered a public record for purposes of disclosure.

- **Section 4314 – Issuance of Citations**

  Will allow the board to issue an order of abatement that would require a person or entity to whom a citation has been issued to demonstrate how future compliance with the Pharmacy Law will be accomplished and provides that such demonstration may include, but not be limited to, submission of a corrective action plan, as well as requiring the completion of up to six hours of continuing education courses in subject matter specified in the order of abatement.

Mr. Tilley stated that as a pharmacy owner, if a storefront opens within a block from his pharmacy, does he have the power to shut down the pharmacy?

Deputy Attorney General Joshua Room stated that anyone could bring a lawsuit under Business and Professions Code section 17200 for this violation of federal law regarding importing and unfair business practices.

- **Implementation of SB 151**

  Mr. Goldenberg stated that Senate Bill 151 (Burton) repeals the triplicate prescription requirement for Schedule II controlled substance prescriptions and replaces it with a tamper-resistant prescription form that may be obtained only from board-approved printers. This new form will be required for all controlled substance prescriptions after a one-year phase-in period. The bill also will require pharmacies to report Schedule III controlled substance prescriptions to the CURES system.

  Because of the expansive nature of the changes required by SB 151, the new requirements will be phased in over a 12-month period. The following is a calendar outlining when the most significant elements of the bill become effective.

  January 1, 2004

  - The board and the Department of Justice (department) may approve security printers to produce the new controlled substance prescription forms.
  - Mail order pharmacies may apply the prescription requirements of the state in which the patient resides when filling prescriptions.
  - Controlled substance prescriptions (Schedules II-V) are valid for six-months.
  - All pharmacies must report Schedule II controlled substance prescriptions to the Department in a time and manner of the department's choosing.
  - Schedule III-IV controlled substance prescriptions must be signed and dated by the prescriber.
  - Controlled substance prescription forms may be acquired from approved security printers and used to prescribe from for Schedule III-IV drugs.

- Requires controlled substance prescription forms to have the following features:
  (1) Latent "void" protection so that if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.
  (2) Watermark with the text "California Security Prescription" printed on the back of the prescription.
  (3) Chemical void protection that prevents alteration by chemical washing.
  (4) Feature printed in thermo-chromic ink (the ink changes color when exposed to heat).
  (5) Feature using micro printing (the text becomes a line if the prescription is copied or scanned).
  (6) Description of the security features included on each prescription form.
  (7) Quantity check off boxes printed on the form in the following quantities: 1-24, 25-49, 50-74, 75-100, 101-150, 151 and over.
  (8) Either of the following statements:
    (a) "Prescription is void if more than one controlled substance prescription is written per blank" or,
    (b) Contain a space for the prescriber to specify the number of drugs prescribed on the prescription and a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."
  (9) The preprinted name, category of licensure, license number, and federal controlled substance registration number of the prescribing practitioner.
  (10) A check box indicating the prescriber's order not to substitute.
  (11) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

July 1, 2004

- The department may no longer produce or distribute triplicate prescription forms.
- Triplicate prescription forms may be used to prescribe Schedule II controlled substances.
- Prescribers may now use the new controlled substance prescription forms for Schedule II controlled substance prescriptions.
- Oral and electronic orders for Schedule II controlled substance prescriptions for patients in skilled nursing facilities, intermediate care facilities, home health care programs, and hospice programs are permitted. Such orders must be reduced to hard copy form and signed by the pharmacist on a form of the pharmacy's design.
- Prescribers dispensing Schedule II controlled substances must report those prescriptions to the CURES system.

January 1, 2005

- Triplicate prescription forms are no longer valid.

- All written controlled substance prescriptions (oral and fax orders for Schedules III-V are still permitted) must be on controlled substance prescription forms.
- 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.

Mr. Goldenberg recognized the effort to get all the stakeholders to participate and the success for the board.

Ms. Harris stated that because of the complexity of the law, the board encourages questions or clarification issues be brought to the board. The board wants to assure that as many questions as possible can be addressed up front regarding implementation.

Ms. Harris stated that the board will post approved security printers on its Web site so prescribers will know where to go to order the prescription forms.

- **Report on Enforcement Actions**
  President Jones acknowledged Board of Pharmacy inspectors who have made great progress in the turn-around time for consumer complaints and also have kept up with routine inspection of pharmacies. He added that this is very difficult during this time when the board has lost positions. He commended all staff for their efforts.

APPROVAL OF MINUTES

Full Board Minutes
(July 21 and 22, 2003)

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

MOTION: Approve the July 21 and 22, 2003, Board Meeting Minutes

M/S/C: HIURA/TILLEY

SUPPORT: 7 OPPOSE: 0

ACKNOWLEDGMENTS

President Jones acknowledged former Board Member Don Gubbins who was in the audience and thanked him for his service on the board over the last several years. President Jones presented him with a clock, courtesy of the board members.

President Jones acknowledged Ron Diedrich as former deputy attorney general liaison for the Board of Pharmacy. President Jones also presented him with a clock in appreciation of his service to the Board of Pharmacy.

LEGISLATION AND REGULATION COMMITTEE

Dr. Fong stated that he would report on the committee meeting held September 11, 2003, in Chairperson Andrea Zinder's absence.

Awaiting Notice

Section 1707.5 – Hospital Pharmacy Central Fill
Dr. Fong stated that the committee recommends altering the draft language for authorizing hospital central fill pharmacies to permit either a community pharmacy or a hospital pharmacy to perform central fill functions.

The board approved initiation of a rulemaking to authorize hospitals to perform central fill functions for other hospital pharmacies. However, the draft presented for the informational hearing in October required that a hospital pharmacy perform the central fill function. Based on comments received at the informational hearing, the committee recommended that the language be altered to permit either a community or a hospital pharmacy to perform central fill function for a hospital pharmacy. The change will provide greater flexibility in designing central fill functions and will free valuable hospital space by permitting central fill functions to be located outside the hospital.

MOTION: Legislation and Regulation Committee: Alter the draft language for authorizing hospital central fill pharmacies to permit either a community pharmacy or a hospital pharmacy to perform the central fill function, and release for the initial 45-day comment period.

SUPPORT: 8 OPPOSE: 0

- **Sections 1717.2 and 1717.4 – Electronic Prescriptions and Records**

Dr. Fong noted that this regulation will make needed changes to board regulations to conform to changes in patient privacy laws. The October meeting was the informational hearing on the matter.

Whereas, the board approved a rulemaking to conform existing regulations on common electronic files to California law relating to confidential medical information, the draft of language presented at the informational hearing has not previously been presented to the board.

MOTION: Legislation and Regulation Committee: Alter the draft language regarding common electronic prescription files to require pharmacies utilizing common electronic files to adopt policies ensuring that confidential medical information is disclosed appropriately, and release for the initial 45-day comment period.

SUPPORT: 8 OPPOSE: 0

- **Section 100 Rulemaking**

The 2003 legislative session has produced two bills making widespread changes to Pharmacy Law that will result in the need for updating many existing board regulations. The Section 100 process is an abbreviated rulemaking procedure that allows relatively easy technical updates to existing regulations without the formal public notice and adoption requirements needed for most regulations.

Dr. Fong stated that this Section 100 process allows the board to make easy technical updates to existing regulations.

MOTION: Legislation and Regulation Committee: Direct staff to review existing regulations and submit a Section 100 rulemaking to conform existing regulations with legislative changes in the 2003 session.

SUPPORT: 8 OPPOSE: 0

- **Proposed Item for 2004 Omnibus Bill – Identification of the Prescriber**

Existing law (Business and Professions Code 4076) requires the name of both the supervising physician and the name of the practitioner ordering a drug under protocol to be on the label attached to a dispensed prescription. This practice results in both pharmacies and patients contacting the supervising physician who typically has never seen the patient instead of contacting the practitioner ordering the drug and who has seen the patient. Eliminating the physician's name from the label will eliminate this confusion.

The proposal also adds a pharmacist operating under protocol to Section 4076. Pharmacists have authority to initiate and adjust drug therapy under protocol in a manner similar to that of these other practitioners and adding pharmacists to these provisions recognizes that authority.

MOTION: Legislation and Regulation Committee: The board sponsor a provision in the 2004 omnibus bill to eliminate the requirement that the supervising physician's name be on the label of a prescription issued under protocol by a nurse practitioner, nurse midwife, pharmacist, or physician assistant.

SUPPORT: 8 OPPOSE: 0

- **Proposed Item for 2004 Omnibus Bill**

  Existing law (Business and Professions Code 4059.5) requires the pharmacist-in-charge, if on duty, or a designated pharmacist to sign for the receipt of any delivery of dangerous drugs or dangerous devices. The board reviewed a proposed change that would free the pharmacist-in-charge from this responsibility and allow the activity to be performed by any pharmacist. The draft text also includes changes to existing law permitting the after hours delivery of drugs to a secure location, a provision that the board approved at its July 2003 meeting.

  MOTION: Legislation and Regulation Committee: That the board sponsor a provision in the 2004 omnibus bill to permit any pharmacist on duty to sign for the receipt of dangerous drugs or dangerous devices.

  SUPPORT: 8 OPPOSE: 0

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

  Dr. Fong stated that this regulation will permit a pharmacist to serve as pharmacist-in-charge at two locations.

  The board has already approved initiating this rulemaking and the committee conducted an informational hearing on draft language on September 11, 2003. The board received many comments from interested parties on the draft. Specifically, the committee directed staff to submit a new draft that establishes some reasonable restriction on a geographic separation between two pharmacies with the same pharmacist-in-charge and that more clearly establish the central role of the pharmacist-in-charge. The draft includes a 50-mile restriction and clarifies that the pharmacist-in-charge must have actual control of pharmacy operations. The language also recasts the language allowing the designation of an interim pharmacist-in-charge per the discussion at the informational hearing. The committee wanted to submit the new draft and the central question of permitting a pharmacist to serve as PIC at two pharmacies for board discussion.

  MOTION: Legislation and Regulation Committee: That the Board of Pharmacy approve the new draft language permitting a pharmacist to serve as pharmacist-in-charge at two pharmacies and release it for the initial 45-day comment period.

  SUPPORT: 8 OPPOSE: 0

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

  This regulation will establish guidelines for the compounding of sterile drug products.

The board approved the proposed sterile compounding standards at its April 2003 meeting with changes that required a 15-day comment period. Subsequent to that meeting the Office of Administrative Law determined that the board must ratify the final version of the regulation again after the close of a 15-day comment period. There is no opposition to the proposed regulations at this time.

MOTION: Legislation and Regulation Committee: Adopt amendments to 16 CCR, Section 1751 et seq. – Sterile Compounding, as proposed.

SUPPORT: 8 OPPOSE: 0

Section 1793.3 – "Clerk-Typist" Ratio

Dr. Fong stated that this regulation would eliminate the clerk/typist ratio. He added that an informational hearing has been held. Action on this proposal would be deferred until the January 2004 Board Meeting to accommodate staff workload and ongoing negotiations regarding a statutory revision to pharmacy staff ratios for non-pharmacist staff.

Dr. Fong stated that there has been considerable activity on the part of stakeholders wanting to remove ratios altogether. Instead to establish legislative parameters allowing flexibility so a pharmacy and the pharmacist-in-charge could determine the appropriate staffing requirements based on a particular type of business.

Bruce Young, representing the California Retailers Association, stated they have been working with the UFCW and CPhA, and currently there is no consensus. In December these three groups will try to recommend a solution.

President Jones asked if the parties were looking at this from the perspective of easing the workload of the dispensing pharmacist.

Mr. Young stated that this is his position but others refer to NAPLEX. He stated that some businesses may want to have more clerk typists. He added that this issue should clearly be up to the pharmacist.

Mr. Young stated that the principal concern is that if the pharmacist agrees to the additional staff, he or she does not want to risk jeopardizing his or her license if a mistake is made by one of those others.

Dr. Fong stated that the Legislation and Regulation Committee hopes that the stakeholders reach an agreement on this issue.

Steve Gray, representing the CPhA, stated that this is on the CPhA's agenda for a future meeting to discuss. However, part of the concern is something that can be addressed by the Enforcement Committee. There is a lot of confusion among pharmacists-in-charge about how

much they are held responsible for things that occur when they are not on duty. He suggested that the Enforcement Committee develop a policy statement that could address the issue.

Recently Approved Regulation

Section 1775 et seq. – Citation and Fine
This regulation designates the executive officer as the issuing authority for citations and fines. The regulation also consolidates and recasts existing board regulations relating to citations and fines. The regulation was approved by the Office of Administrative Law on September 11, 2003, and the effective date is October 11, 2003.

Regulations Awaiting Notice

Dr. Fong noted that the board has a number of other regulations awaiting notice besides those voted on earlier during this meeting.

- **Section 1711 – Patient Notification**
  This regulation will modify the patient notification provisions of the board's quality assurance regulation to require notification to the patient if the drug was actually taken or if the error resulted in a clinically significant delay in therapy. This regulation is awaiting formal notice.

- **Section 1715 – Pharmacy Self Assessment**
  This regulation will update the pharmacy self-assessment form to reflect the recent changes in pharmacy law. An informational hearing required.

- **Section 1717.4 – Authentication of Electronic Prescriptions**
  This regulation will require pharmacists to authenticate electronic prescriptions. This regulation is awaiting formal notice.

2003 Legislation

Senate Bill 361 (Figueroa)

This bill is the board's sunset review legislation. The bill contains the recommendations from the Joint Legislative Sunset Review Committee that require statutory changes including to:

- Adopt NAPLEX and the California MPJE.
- Add two public members to the board.
- Permit non-pharmacists to be board inspectors.
- Revise pharmacy technician qualifications.

The bill also contains the board's omnibus items for 2003.

The bill was signed by the Governor on September 25, 2003. The bill was amended to require periodic evaluation of the NAPLEX and designates three of the pharmacist seats on the board as follows:

- A pharmacist who is a union member.
- A chain community pharmacy representative (more than 75 stores).
- An independent community pharmacy representative (four or fewer stores).

Status of Bills with a Board Position

AB 261 (Maddox)

This bill would increase penalties for operating a "backroom pharmacy." The board has a support position on the bill, which died in committee.

AB 746 (Matthews)

This bill would require the board to revoke a license after a second conviction for Medi-Cal fraud. The board has a support position on this bill and which is currently before Senate Rules Committee.

AB 1363 (Berg)

This bill would establish requirements for needle exchange programs. The board has a support position on this two-year bill.

AB 1460 (Nation)

This bill would permit pharmacists to perform CLIA-waived tests to monitor drug therapy. The board has a support position on this bill, which is a two-year bill.

SB 151 (Burton)

This bill eliminates the triplicate requirement for Schedule II prescriptions, and requires a tamper-resistant prescribing pad for all controlled substance prescriptions and adds Schedule III drugs to CURES. The board has a support position on this bill which was signed by the Governor (Chapter 406, Statutes of 2003).

SB 175 (Kuehl)

This bill adds veterinary drugs to the definition of dangerous drugs. The board has a support position on this bill which was signed by the Governor (Chapter 250, Statutes of 2003).

SB 393 (Aanestad)

This bill would permit "tech check tech" in hospitals. The board has a support if amended position on this two-year bill.

Teri Miller, representing the California Society of Health-System Pharmacists, asked if the board's position might change now they have incorporated the training requirements

SB 490 (Alpert)

This bill establishes a statewide protocol for pharmacists dispensing emergency contraception that must be approved by this board and the Medical Board. The board has a support position on this bill that was signed by the Governor (Chapter 651, Statutes of 2003).

SB 506 (Sher)

This bill would require the board to track wholesale distribution of antibiotic drugs. The board has an oppose position on this two-year bill.

SB 545 (Speier)

This bill would alter requirements for pharmacists who provide emergency contraception. The board has a neutral position on this bill, which was signed by the Governor (Chapter 652, Statutes of 2003).

SB 774 (Vasconcellos)

This bill would eliminate the prescription requirement for hypodermic needles and syringes. The board has a support position on this bill, which the Governor vetoed.

Bills of Interest

AB 57 (Bates)

This bill would places MDMA into Schedule II and is currently in the Assembly inactive file.

AB 186 (Correa)

This bill makes technical changes to the Pharmacy Law relating to optometrists and was signed by the Governor (Chapter 426, Statutes of 2003).

AB 292 (Yee)

This bill would prohibit minors from acting as interpreters and it is a two-year bill.

AB 521 (Diaz)

This bill would require pharmacists to notify patients of harmful drug interactions and it is a two-year bill.

AB 1196 (Montanez)

This bill permits nurse practitioners to order Schedule II drugs and was signed by the Governor (Chapter 748, Statutes of 2003).

SB 292 (Speier)

This bill requires prescription labels to contain a description of the drug. This bill was signed by the Governor (Chapter 544, Statutes of 2003).

SB 907 (Burton)

This bill establishes licensure of naturopaths and makes them prescribers. This bill was signed by the Governor (Chapter 485, Statutes of 2003).

PUBLIC COMMENT ON MATTERS NOT ON THE AGENDA

A pharmacist recruiter expressed concern with staff for not returning telephone calls and with comments from staff that the board is shorthanded due to staff reductions.

He encouraged the board to get as much information as possible on its Web site and referred to the board's Web site where he identified several problems.

ADJOURNMENT

There being no further business, President Jones adjourned the meeting at 4:22 p.m.

Thursday, October 30, 2003

CLOSED SESSION

The board moved into Closed Session pursuant to Government Code Section 11126 subd. (c)(3) to deliberate upon disciplinary cases and the petition for reinstatement.