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

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

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

DATE & TIME: July 24 and 25, 2002

LOCATION: The Westgate Hotel
1055 Second Ave.
San Diego, CA 92101

BOARD MEMBERS PRESENT:
John Jones, President
Donald Gubbins, Vice President
Caleb Zia, Treasurer
Dave Fong – July 24, 2002 only
Stanley Goldenberg
Clarence Hiura
Steve Litsey
John Tilley
Andrea Zinder

BOARD MEMBERS ABSENT: William Powers

STAFF PRESENT:
Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Ron Diedrich, Deputy Attorney General
Dana Winterrowd, Department Legal Counsel

Wednesday, July 24, 2002

CLOSED SESSION

The board moved in closed session pursuant to Governor Code Section 111126(a) regarding personnel matters to perform the evaluation of the executive officer. The board moved into closed session pursuant to Government Code Section 11126(c)(3) to deliberate upon one disciplinary case.

CALL TO ORDER

President Jones called the meeting to order at 9:45 a.m. on Wednesday, April 24, 2002.

ANNOUNCEMENTS

President Jones announced that this was his first board meeting as board president.

President Jones welcomed Lynn Morris, Deputy Director of Board Relations, Department of Consumer Affairs, who was in the audience.

President Jones acknowledged former public member and board president Robert Elsner who attended the meeting. Mr. Elsner was presented with an inscribed clock in appreciation of his service to the board.

COMMITTEE REPORTS AND ACTION

COMMUNICATIONS AND PUBLIC EDUCATION COMMITTEE

Ms. Herold provided the report due to the absence of Chairperson Powers.

Ms. Herold reported that this committee has not met since before the last board meeting because of conflicting schedules among committee members.

Ms. Herold stated that there were a number of budget steps taken in an attempt to close the $24 billion gap in the state's 2002/03 budget. One step was a transfer of $6 million from the board's reserve fund to the state's general fund as a loan. This removes the board's revenue reserve for the next few years.

Ms. Herold reported that another budget item for the deficient 2002/03 budget is the elimination of all vacant positions as of June 30, 2002. If this provision goes into effect the board will lose four positions – two most critical staff for this committee – *The Script* editor, and the public outreach coordinator. If these positions are lost, the board's management will pursue whatever process is required to restore both positions in the future. The loss of these positions would be highly detrimental to the committee's work.

Ms. Herold added that staff is examining options to produce the newsletter or methods to communicate with licensees.

Ms. Herold reported that the board has two more issues of *Health Notes* in progress, "Quality Assurance" which will be mailed in 2-3 weeks and "Geriatrics" which should be ready for mailing by December or January 2003.

Ms. Herold stated that for the 2002/03 budget, the Department of Finance denied the board's request to reprint and mail the *Pharmacy Lawbook* to licensees. The vendor is producing the lawbook independently. Ms. Herold added that the board will assure revised statutory law and regulations and the lawbook's index are posted on the board's website so that individuals can obtain the current version of the law.

Dr. Fong stated that currently there are approximately 6,000 pharmacists in California. He noted that with the complexity of law and regulation changes and pharmacists wanting to do the right thing, it is important that the board develop stronger relations with pharmacists in the community. He suggested that the board and staff be accessible to educate and work with licensees to initiate this activity in various types of group settings to convey changes in the law.

Update on Committee Projects

- **Modify the Goal of the Committee as Modified during the April Strategic Planning Session by the Board**

Ms. Herold stated that the board's current goal is to encourage consumers to discuss their medications with their pharmacists, emphasizing the importance of patients complying with their prescription treatment regimens, and helping pharmacists to become better informed on subjects of importance to the public. Ms. Herold stated that the proposed goal is to provide relevant information to consumers and pharmacists.

Mr. Goldenberg referred to the proposed goal and expressed the need to covey the board's pro-activity in the board's desire to get relevant information to pharmacists.

MOTION: Modify the goal of the committee as proposed during the April strategic planning session by the board; Specifically, modify "Provide relevant information to consumers and pharmacists, "to "proactively provide relevant information to consumers and pharmacists."

M/S/C: ZINDER/TILLEY

SUPPORT: 8 OPPOSE: 0

- **Participate as a Co-Sponsor of Fall 2002 Self-Care Seminar Series**

  Ms. Herold stated that the board has been asked to join with the UCSF Center for Consumer Self Care and the Department of Consumer Affairs to co-sponsor a seminar series of health care topics for the public. President Jones indicated that this ties in with the board's strategic plan and that the board would join this important DCA project as a co-sponsor.

  The first seminar is scheduled for October 2002, followed by others scheduled once a month beginning in January through May 2003. The seminars will be held in Sacramento at the State Capitol and will last 1.5 hours in length either before or after lunch. The topics under consideration for this series are:

  - Facts and Fiction Regarding Alternative Medicine
  - Understanding Direct-to-Consumer Advertising
  - Pain Management and End-of-Life Care
  - Understanding Hope Testing Options
  - Worldwide Implications for Antibiotic Use and Misuse
  - Latest in Smoking Cessation
  - Women's Health Care

  Ms. Herold stated that these are among the most topical of a number of issues to help educate individuals be better aware of their own self care which feeds into the board's public protection mandate to provide consumers with information to care for themselves. She added that this is a very important initiative of the Department of Consumer Affairs Director Kathleen Hamilton.

- **"Notice to Consumers"**

  Ms. Herold reported that at the April 2002 Board Meeting, the board held its regulation hearing to amend California Code of Regulations Section 1707.2 regarding the "Notice to Consumers" that either must be posted in a pharmacy or printed on receipts.

  The text for the revised notice to consumers adds the questions patients need to understand to take their medications optimally, retains information about price information and generic drugs, and the final poster, once complete, will include an 800 number for consumers with inquiries to contact the board.

  Following the April meeting, staff compiled the rulemaking file and submitted it into the required approval process. The Department of Consumer Affairs approved the rulemaking file in June and in early July, the file was submitted to the Office of Administrative Law which has six weeks to review it.

Once the regulation is approved, the board will finalize its "Notice to Consumers" poster and mail these to all California pharmacies, possibly in October. The poster will be translated into additional languages for camera-ready distribution by the pharmacy. Ms. Herold added that the board should have the poster printed by the October board meeting.

Dr. Fong asked if there would be a public service announcement at the time of distribution of the "Notice to Consumers."

Ms. Herold responded that October is "Talk about Prescription Month" which will provide the board with a means to publicize its poster. The board can work with the Department of Consumer Affairs' Press Office to issue a press release without additional resources.

- **Public Outreach**

  Ms. Herold stated that in keeping with Dr. Fong's request for public outreach efforts to the public and the importance of this conveyed by committee chairman Bill Powers, staff attended two public education fairs since the last board meeting:

  - Redding – Area Agencies on Aging
  - San Diego – Scam Jam 2002, by the San Diego Better Business Bureau and co-sponsored by various media (that provided coverage and publicity), about 3,000 people.

  Ms. Herold stated that the next public education event the committee plans to attend is scheduled for October in Sacramento, which is sponsored by the CAUSE Consumer Protection and Public Safety Foundation.

- **Emergency Contraception Fact Sheet**

  Ms. Herold reported that work on the Emergency Contraception Fact Sheet would resume after the board's Sunset Report is finished. In January, SB 1169 took effect to create a "pharmacist's class of drugs," enabling a pharmacist to furnish emergency contraception medication to patients if there is a protocol in place with a prescriber. The patients do not have to be patients of the prescriber with whom the pharmacy has developed the protocol. The law requires any pharmacist providing emergency contraception to provide a fact sheet prepared by the board. At the January meeting, the board approved the temporary use of a fact sheet prepared by the Pharmacy Access Partnership, until the board develops its own fact sheet.

- **Health Notes**

  Ms. Herold reported that there are currently two issues of the *Health Notes* in progress:

  - **"Quality Assurance Programs"**

The board contracted with UCSF to develop this issue, the goal of which is to aid pharmacies in complying with the requirements to establish quality assurance programs for prescription errors.

Final page proofs for this issue are currently being modified and the issue should be printed and distributed shortly.

- **"Geriatrics"**

  UCSF has obtained outside funding to develop this manuscript, which the board will publish and distribute as a *Health Notes*. The publication of this issue will most likely occur in January 2003. The board should receive $75,000 in one-time publishing and mailing costs for this issue in the 2002/03 board budget.

  Ms. Herold stated that staff appreciates the efforts of Board Member Bill Powers who spent considerable time with the Governor's Office and with the Department of Finance to get the board's public education position approved during the 2001/02 fiscal year. It has been extremely frustrating to have a hiring freeze prevent the filling of this position.

LICENSING COMMITTEE

- **Report on the Meeting of June 24, 2002.**

  Chairperson Gubbins reported that the Licensing Committee met on June 24, 2002.

- **Recommendation to Eliminate the Clerk-Typist Ratio**

  Chairperson Gubbins reported that the current regulation specifies that a pharmacist can supervise one clerk-typist (or as stated in the regulation, a non-licensed pharmacy personnel who can type a prescription label and request refill information). The Licensing Committee recommends that the clerk-typist not be counted in the ratio of ancillary personnel that a pharmacist on duty can supervise.

  Chairperson Gubbins added that while the Pharmacy Manpower Task Force did not support this proposed solution because it totally eliminated the clerk-typist ratio and placed no controls on the number of clerk-typists that a pharmacist may be required to supervise in addition to the other ancillary personnel under the pharmacist's supervision, the committee discussed that this regulation is outdated and does not reflect current pharmacy practice.

  At the last board meeting, the Licensing Committee recommended that the ratio of clerk-typists that a pharmacist may supervise be increased. The board approved this

recommendation. However, the Licensing Committee is now recommending the elimination of the ratio altogether.

One of the most significant impacts to the community pharmacist is the clerical processing of insurance claims. And while the clerk-typist classification is not required for insurance processing, it is done "real-time" when the clerk-typist enters the prescription information into the computer. When a problem arises with an insurance claim, the clerk-typist must stop what he or she is doing and resolve it. Because of the limitation of one clerk-typist to one pharmacist, the pharmacist is unable to add clerk-typists to process prescriptions. The pharmacist is pulled away to either resolve the insurance issue or perform the clerical function of processing the prescription.

The committee also agreed that as part of its review of the pharmacy technician program, it would develop language that would give the pharmacist on duty the authority to supervise a specific number of ancillary personnel (interns, pharmacy technicians and pharmacy technician trainees) and to determine what the mix of ancillary personnel would be. The committee discussed that 1 pharmacist to 4 ancillary personnel appeared to be reasonable; however, it agreed that whatever the mix of ancillary personnel that was determined, the pharmacist should only supervise one pharmacy technician trainee.

MOTION: Licensing Committee: Amend California Code of Regulations section 1793.3 to eliminate the ratio on the number of non-licensed pharmacy personnel (clerk-typists) that a pharmacist on duty can supervise.

SUPPORT: 8 OPPOSE: 0

- **Recommendation for Board Sponsorship of Legislation to Allow the Supervision of Two Interns**

Chairperson Gubbins stated that at the last board meeting, the board approved the recommendation that a pharmacist at his or her discretion be authorized to supervise two interns. Legislation is required to implement this action. Therefore, the Licensing Committee is recommending that the board sponsor such legislation.

The Licensing Committee will be reviewing the pharmacy technician program and as part of this review, the committee will be developing language that would give the pharmacist on duty the discretion to determine within a fixed ratio the mix of ancillary personnel (interns, pharmacy technicians and pharmacy technician trainees) that he or she could supervise.

Ms. Zinder suggested that the current motion be held over until the entire issue can be addressed at the September Licensing Committee meeting.

The board discussed the demand for quality sites for interns and whether the two new pharmacy schools would increase the demand.

Mr. Goldenberg stated that the intern program is part of the student's education rather than part of the industry's need to develop efficiency.

Sam Shimomuro, representing Western University of Health Sciences School of Pharmacy, encouraged the board to move quickly on this issue because the two new schools of pharmacy would increase the amount of interns available for pharmacy positions and many out-of-state schools send students to California as well. Also, the accreditations standards have changed to require students to observe during their first year, making third and fourth year students more productive in helping pharmacists.

Mr. Riches stated that the Legislation and Regulation Committee would hold its public meeting in October to consider regulatory proposals for the coming year. If the board makes its decision during the January board meeting, there would be ample opportunity for meeting the legislative deadline for introducing bills. Mr. Riches added that legislative bills would need to be introduced by the end of February.

Mr. Cronin, representing the California Pharmacists Association, suggested that the board address all of the pharmacy support personnel issues at the same time to avoid problems.

Mr. Gubbins stated that the Licensing Committee determined that this issue would be addressed separately.

Mr. Hiura asked Mr. Cronin to submit a letter from the CPhA with suggested legislative action.

Mr. Gray, representing Kaiser Permanente, stated that Kaiser receives inquires from all over the country regarding possible intern positions in California. He added that this action would encourage students and California residents who are obtaining their educations outside of California to return to California. Mr. Gray added that the demand is so great to place interns, that schools are paying institutions to take students and there is competition among them as to how much they will pay.

President Jones requested that Kaiser Permanente send a letter to the board expressing its concern.

Bruce Young, representing the California Retailers Association, informed the board of its working partnership with the USCW to consider legislation that would limit the number of personnel working behind the counter in a pharmacy and leave it to the discretion of the pharmacist to make the decision, with a caveat that the pharmacist cannot be forced into this.

Mr. Young added that they are considering a "one-size fits-all" as a maximum standard and they are planning to work with other groups on establishing this number.

MOTION: Licensing Committee: Sponsor legislation that would authorize a pharmacist at his or her discretion to supervise two interns.

SUPPORT: 7 OPPOSE: 1

- **Request for Waiver of CCR 1717(e) – Delivery of Medications to Non-Pharmacy Locations When the Patient is not Present**

Chairperson Gubbins reported that La Clinica Pediatric Pharmacy is requesting a waiver of CCR section 1717(e) to deliver prescription medications to a clinic, La Clinica Pittsburg.

MOTION: Licensing Committee: Approve the request for waiver of California Code of Regulations section 1717(e) from La Clinica Pediatric Pharmacy.

SUPPORT: 7 ABSTAIN: 1

- **Approval of Committee Goal Statement and Strategic Objectives for 2002/2003**

Chairperson. Gubbins reported that during strategic planning at the April Board Meeting, the Licensing Committee revised its goal statement and updated the strategic objectives based on the actions of the board.

MOTION: Licensing Committee: Approve the committee goal statement and strategic objectives for 2002/2003:

Licensing

Goal

Ensure the professional qualifications of pharmacists and establish the minimum standards for board-licensed facilities.

Implementation Responsibility

Licensing Committee and Staff

	Strategic Objectives	Timeline
1.	Meet performance expectations for processing license applications to note deficiencies within 7 days of receipt, process deficiency documents within 3 days of receipt and issue licenses once deficiencies are corrected within 3 days.	Ongoing
2.	Review the Intern program.	July 2003
3.	Review the Technician Registration Program that will include the use of the Pharmacy Technician Certification Board (PTCB), supervision ratio of all ancillary personnel, and expanded duties that a PTCB registered pharmacy technician may perform.	July 2003
4.	Increase the ratio on the number of clerk-typists that a pharmacist can supervise at his or her discretion.	July 2003
5.	Develop language and pursue a regulation change to allow the central fill of medication orders for inpatient hospital pharmacies.	July 2003
6.	Explore the feasibility of offering the California pharmacist licensure examination more than twice a year.	July 2003
7.	Assist applicants preparing for the California pharmacists licensure examination by developing (or fostering the development of) educational programs and information on how to prepare for the pharmacist exam and by requesting that outside agencies (schools of pharmacy and private educational organizations) develop exam workshops that prepare applicants for the California Pharmacist Exam.	July 2003
8.	Develop statutory language to grant the Board of Pharmacy the authority to grant waivers for innovative, technological and other practices to enhance the practice of pharmacy and patient care that would have oversight by an independent reviewing body during the study.	July 2003
9.	Explore the feasibility and need to regulate Pharmacy Benefit Managers (PBMs)	July 2003

SUPPORT: 8 OPPOSE: 0

- **Application/Licensing Statistics**

  Dr. Fong noted that the chart provided in the board packet indicates that pharmacist-in-charge (PIC) applications are 10 times greater than other application categories during the 01/02 fiscal year, reflecting a high turnover among PICs.

- **Competency Committee Report**

  Report on the June 2002 Examination

  Chairperson Gubbins reported that on June 18 and 19, 2002, the board administered its June 2002 pharmacist licensure examination at the Oakland Marriott Convention Center. There were 1,156 candidates who took the exam. Grading for this exam was conducted in Sacramento on July 17 and 18, 2002.

  Competency Committee Annual Meeting

  The Competency Committee will meet on August 12 and 13, 2002, for its annual meeting. The purpose of the annual meeting is to focus on the long-term goals of the committee and to work on questions for the item bank.

  Mr. Goldenberg stated that he and Dr. Litsey had the opportunity to grade the exam and he encouraged other board members to participate in the process, especially in light of NAPLEX issues.

  Dr.. Litsey also expressed the importance of board participation in grading.

- **Pharmacy Manpower Issues – A Presentation by Kathy Knapp, Ph.D. – Director, Center for Pharmacy Practice Research and Development and Professor of Social and Administrative Sciences – Western University of Health Sciences**

  Chairperson Gubbins introduced Dr. Knapp and reported that she served on the board's Pharmacy Manpower Task Force and was invited to the board meeting to provide an update on pharmacy manpower issues.

  Dr. Knapp reported that in May 2002, during a presentation on the manpower situation to the Orange County Society of Health System Pharmacists, she was asked by Dr. Litsey to provide a similar presentation to the board.

  Dr. Knapp stated that the pharmacist shortage is a national topic. She added that many articles have been written on the subject and media coverage has helped to

inform the public of the shortage and the impact on raising salaries and the increased potential for prescription errors. She acknowledged the California Board of Pharmacy's efforts to address the manpower shortage in California and she encouraged the board to move forward.

Dr. Knapp stated that the 2000 Congressional Report concluded that there was a dynamic shortage of pharmacists that is not likely to improve within the near future. The report concluded that two reasons for the shortage could be identified: one is the growth and use of prescription medications and the other is the new role that pharmacists play.

Dr. Knapp stated that Western University is just beginning to get involved in the new roles that pharmacists are moving into such as into physician office practices, collaborating with physicians in different ways and running clinics. Most of the successful pharmacists in these areas have residency or fellowship training or other significant training beyond their first entry-level degree. However, it is not known how they were trained, how long they were trained, what the essential job requirements are and how the duties match with the education these pharmacists have.

Dr. Knapp stated that the Bureau of Health Professions is a group within the federal Department of Health and Human Services that in the last few years has developed a new supply model to estimate how many pharmacists there are. The last count was completed over ten years ago.

Dr. Knapp commended the efforts of the National Association of Chain Drug Stores for their data about community pharmacy. This represents two thirds of where pharmacists practice.

Dr. Knapp also reported that the American Society of Health System Pharmacists has provided valuable information for understanding the practice of pharmacy from their surveys on hospital and ambulatory care pharmacies.

Dr. Knapp stated demographically one area affecting the practice of pharmacy is created by baby boomers entering retirement and moving to warmer climates, accordingly, pharmacists will need to be involved in helping deliver these seasonal differences regarding their health care needs.

Dr. Knapp stated that in the United States, the population has increased from 268 million to 281 million and at the same time, California's population has increased from 32 million to 34 million.

Dr. Knapp reported that retail prescription growth is to reach 2.8 billion in the year 2000 for the US and 234 million prescriptions in California. She added that

California has relatively low prescriptions per person compared to the national average and compared to a number of other states. Nevertheless, in 1998 and 1999, prescriptions were growing faster in California (10 percent compared to 1 percent population growth). She added that this is one of the reasons for the pharmacist shortage.

Dr. Knapp stated that in order to embrace the hospital sector, it is necessary to look at dollars spent on prescription medication. Medication growth expenditures have grown tremendously year to year and this accounts for much of the medical literature that focuses on the cost of drugs. Also, medications have become more central to health care than they have in the past.

Dr. Knapp reported that the number of pharmacies have increased very slowly over the past. During the 1990s, there was a decline in retail pharmacy outlets that started to swing upward again in 2000 and has continued upward to 2001. However, the number of retail pharmacies in 2000 was actually less than in 1990. During that time there was a great decline in the number of independent pharmacies because they were replaced by larger stores that employ more people.

Dr. Knapp stated that during a classical labor shortage, wages increase and more pharmacists work because of the higher wages and flexibility with work schedules. She added that in the most recent analysis, it has not been established that higher pharmacist wages are driving more technicians into the work force.

Dr. Knapp stated that the Bureau of Labor Statistics data show that pharmacist positions are rising. Pharmacists' income has grown from $65,000 – $70,000 up to $79,000. Technicians have an annual income that is less than the average income for the state; this results in lack of commitment on the job, moving to better positions and creating a high turnover within the workforce.

In 1999 technician salaries were $27,000 – $37,000 on average in California, and the aids were $22,000 – $24,000. Dr. Knapp noted that if pharmacists are expensive, we turn to technicians and as the technicians become more valued within the system, their wages increase.

Dr. Knapp reported that in 1998 when the pharmacist shortage began, there were approximately 20,000 pharmacists in California but there were only 16,770 jobs. As the shortage impacted the workforce and salaries increased, in 1999 and 2000 there were 22,000 pharmacist jobs.

Technicians and aids positions have increased considerably since 1998, from 16,600 in 1998 to 25,000 in 1999-2000. This represents a one-to-one ratio when compared to the number of pharmacists. If the technicians were fully implemented to the limit of the law, we should see more technicians than

pharmacist positions. Dr. Knapp added that the opportunities for technicians are not fully developed.

Dr. Knapp referred to the Pharmacy Manpower Project monthly survey located on the Internet at www.pharmacymanpower.com where data is provided on the difficulty in filling open pharmacist positions. The panel represents about 27 percent of the jobs in the entire nation. Dr. Knapp added that it is moderately difficult (or worse) to fill open positions, and California is notably higher than the national average. Some of the large medical centers have the greatest difficulty because they have different job descriptions for pharmacists with specific skill set needed.

Dr. Knapp stated that pharmacy staff have increased and hospital staff sizes have increased despite all of the problems they face. Currently, 33 percent of the total staff is technicians and that means that there are two pharmacists for every technician. This is secondary evidence of the failure to fully use the opportunities to put technicians to work in pharmacy operations. The ratio could well be 2-1 in the use of technicians.

Dr. Knapp concluded that the pharmacist shortage is a reality, and California remains on the top of the list as the place where it is most difficult to fill positions. She added that the reason California is most hard hit is because pharmacy practice is more advanced and has more specialist type positions to fill.

Dr. Knapp stated that predictable economical consequences are occurring and salaries are increasing both for pharmacists and pharmacist extenders. She added that there would be stiff competition among available pharmacists, particularly for those with advanced training. Dr. Knapp stated that the pharmacist shortage may curtail opportunities to engage in new roles and creative strategies to retain talent and increase productivity are needed.

ENFORCEMENT COMMITTEE

Mr. Goldenberg reported on the Enforcement Committee Meeting of July 3, 2002.

- **Recommendation on Proposed Restitution for Consumers Who Have Been Harmed by a Prescription Error**

Mr. Goldenberg reported that one of the board's strategic objectives is to explore the feasibility of implementing a restitution program for consumers who have been harmed by a prescription error. The proposal was presented as a concept with the understanding that implementation of a restitution program would require legislation.

There was general discussion that it would be very difficult for the board to determine even to a very limited extent ""restitution" or the "recovery of damages" when a patient has been harmed by an error. It was advocated that patients who may have been injured already have a means by which to seek recovery through the civil court system. The civil justice system has the ability to assess liability, causation and damages, areas not within the scope or expertise of the board. It was also cautioned that awarding restitution might conflict with an arbitration clause that some patients have with their health plans. It was the general opinion that the current civil justice system provides patients with the necessary legal remedy to pursue the recovery of damages that may have been the result of a prescription error.

Staff prepared a discussion paper on this issue for the Enforcement Committee. It was suggested that the board could assist consumers in this area by updating its brochures and complaint forms advising consumers about their options if they wish to pursue restitution.

John Cronin, representing the California Pharmacist Association (CPhA), stated that the CPhA supports this recommendation.

MOTION: Enforcement Committee: The Board of Pharmacy not assert itself in the restitution process on behalf of consumers and that the remedy of restitution appropriately belongs within the civil justice process.

SUPPORT: 8 OPPOSE: 0

- **Compliance Guidelines – Electronic Signatures**

Mr. Goldenberg stated that the Enforcement Committee developed compliance guidelines on electronic signatures in response to specific questions that the board has received in this area. He referred members to the guidelines that were provided in the board's packets. The guidelines once approved, will be available on the board's web site, in the next newsletter and provided to the Medical Board of California.

Steve Gray, representing Kaiser Permanente, stated that this is an excellent step for the board to clarify the issue of controlled substances/electronic transmission of prescriptions. Mr. Gray questioned if the pharmacist had to call to verify a prescription every time an electronic prescription is received.

Ms. Harris responded that regardless of whether it is a computer generated prescription or a regular prescription, the pharmacist has the responsibility to know that a prescription is authentic.

Deputy Attorney General Ron Diedrich stated that the language, as written, is an accurate reflection of the law. However, the board might want to consider adding: "A pharmacist has

an affirmative obligation to verify a prescription when appropriate to do so." This will reinforce that there is no obligation to verify every prescription that a pharmacist receives.

Electronic Signatures
Compliance Guidelines

Electronically Transmitted Prescriptions
Computer to Computer – Computer to FAX

California pharmacies can accept computer to fax prescriptions for controlled substances (except for Schedule II prescriptions) and these electronically transmitted prescriptions are not required to be in the handwriting of the physician. However, these prescriptions must contain an electronic signature of the prescriber.

Pharmacies that accept electronically transmitted prescriptions (computer to fax, or computer to computer) must ensure the authenticity, integrity, and non-repudiation ad confidentiality of the document. Authentication means ensuring that the prescriber is the person he or she purports to be. Integrity means ensuring that both the document and the signature have not been altered in the course of the transmission. Non-repudiation means ensuring that a party to the transaction cannot later repudiate it. Moreover, under any circumstance (whether it is a paper or data prescription), a pharmacist has an affirmative obligation to verify a prescription~~.~~ when appropriate to do so.

The pharmacy must also ensure that the prescription was electronically transmitted to the pharmacy of the patient's choice. This may be done a number of ways, including, but not limited to, an affirmative statement on the prescription that the prescriber advised the patient of this right.

While pharmacies may under certain circumstances accept computer generated prescriptions for controlled substances (excluding Schedule II) that are electronically transmitted, Health and Safety Code section 11164, subdivision (b)(1), still requires that prescriptions for controlled substances in Schedules III and IV must "be wholly written in ink or indelible pencil in the handwriting of the prescriber" if they are not electronically transmitted to the pharmacy.

COMPUTER GENERATED PRESCRIPTION FOR NON-CONTROLLED SUBSTANCES

California pharmacies can accept computer-generated paper prescriptions for non-controlled substances that contain the electronic signature of the

prescriber. These are paper prescriptions that are printed at the prescriber's office and given to the patient.

Pharmacies that accept these paper prescriptions that contain the prescriber's electronic signature must ensure the authenticity, integrity, non-repudiation and confidentiality of the document. Authentication means ensuring that the prescriber is the person he or she purports to be. Integrity means ensuring that both the document and the signature have not been altered. Non-repudiation means ensuring that a party to the transaction cannot later repudiate it. Moreover, under any circumstance, a pharmacist has an affirmative obligation to verify a prescription.

The prescriber is also responsible for ensuring the authenticity, integrity, non-repudiation and confidentiality of the printed prescription that contains his or her electronic signature. This includes, but is not limited to, the printing of the prescription document on security paper that voids the prescription document should it be altered or reproduced.

Non-Repudiation

The requirement of non-repudiation is consistent with, and an integral part of, ensuring the security, integrity and confidentiality of a prescription that is transmitted from a computer to a facsimile machine, as well as any of the information contained on that prescription. Moreover, it is consistent with the pharmacist's affirmative obligation to verify a prescription, regardless of how the prescription is transmitted.

It is likely that a different method might be needed to ensure the non-repudiation of a prescription transmitted from computer-to-fax than that needed for one transmitted from computer-to-computer. Depending upon the circumstances, such a method might not necessarily require the high-tech approach needed for computer-to-computer transmissions.

The California Board of Pharmacy does not provide specific directions or technological requirements on how to ensure the authenticity, integrity, non-repudiation and confidentiality of prescriptions. It is up to the involved parties to meet those requirements in whatever way best suits the circumstances in question.

John Cronin, representing the California Pharmacist Association, requested that the board comment for the record on how the guideline would be implemented.

Mr. Jones stated that the board inspectors use the guidelines during routine inspections, investigations and complaints to determine if appropriate activity is being conducted. He

added that there would be opportunity for further discussion by the public and board inspectors on the guidelines during the open meeting of the Enforcement Committee.

Ms. Harris stated that the guidelines would be available on the board's website, in *The Script* and copy provided to the Medical Board.

Mr. Cronin stated that this guideline should not have immediate impact on pharmacies and he suggested that pharmacies have some flexibility in meeting these guidelines.

MOTION: Adopt the compliance guidelines on electronic signatures as stated above.

M/S/C: TILLEY/GUBBINS

SUPPORT: 8 OPPOSE: 0

- **Update on Citation and Fine Process – Recommendation for Requests for Office Conference Requests being Handled by a Supervising Inspector**

Mr. Goldenberg reported that a licensee has 14 calendar days after the service of a citation and fine to request an office conference pursuant to the California Code of Regulations, Title 16, section 1775.4, subdivision (b. The Enforcement Committee is recommending that the board delegate to the supervising inspector the authority to hold these office conferences. The supervising inspector is the appropriate level of review to assess the information that may be provided to contest the citation and fine.

Based on the information provided at the office conference, the supervising inspector may affirm, modify, or dismiss the citation, including any fine levied or order of abatement issued. The person or entity cited does not waive his/her or its request for a hearing to contest a citation by requesting an office conference after which the citation is affirmed. If the citation is dismissed after the office conference, the request for a hearing on the citation will be deemed withdrawn. If the citation, administrative fine or order of abatement is modified, then the citation originally issued is considered withdrawn and a new citation issued.

Prior to the recent amendments to the citation and fine regulations, a board inspector had the authority to issue citations and fines for very specific violations of pharmacy law such as unlicensed activity and violations of the continuing education requirements. California Code of Regulations section 1775.4 provided licensees the ability to contest the citations and fines issued by a board inspector through the office conference process. However, when the regulations were amended, this section of the regulations was not updated to reflect the change in the citation and fine process, i.e., as part of the investigation process, a Citation and Fine Committee (comprised of two board members) issues citations and

fines for violations of pharmacy law and the executive officer may issue citations and fines for unlicensed activity and violations of pharmacy law by non-pharmacy licensees.

Therefore, the authority to request an office conference remains in regulation although an inspector is not issuing the citation and fine. The Enforcement Committee views the office conference as giving the licensee yet another opportunity to respond to the violations and to foster communications during the transition to the new Citation and Fine Committee process.

Mr. Goldenberg stated that the board understands there may be tension during a board inspection of a pharmacy, and the best response to the inspector's inquiries may not be thought of during the inspection. Mr. Goldenberg added that the inspectors are the connection between that pharmacy and the board and they provide a very interactive process with the committee and the public.

Chairperson Jones stated that the office conference is intended to improve the board's ability to get all of the facts that may not have been apparent during the inspection. Mr. Jones added that once an inspector issues a violation, it will then go before the Cite and Fine Committee where there is an opportunity to provide the board with additional information. He added that the only vehicle after that is to appeal and go to hearing but this is an expensive process.

Steve Gray, representing Kaiser Permanente, requested clarification on this recommendation and asked if this occurs after a citation and fine has been issued. Mr. Gray added that Kaiser Permanente supports this recommendation.

Bruce Young, representing California Retailers Association, stated that the cite and fine process appears to eliminate due process and he questioned why the NCC/SCC process was abandoned. He expressed concern that an inspection can occur during a frantic time at the pharmacy and it is hard to recall the details when only a verbal citation is issued and the pharmacy does not receive written notice until six months to a year later.

Mr. Young questioned the office conference process where a supervising inspector, who hires inspectors, makes the decision either for or against the inspector and either for or against his or her own decision. Mr. Young also questioned the absence of a board member during the office conference meetings

Mr. Young stated that the California Retailers Association initially supported the concept of cite and fine but was unaware that "tickets" would be mailed out months after the alleged violation. He added that with the NCC/SCC process, at least there was a forum of appointed board members and not staff making decisions based on their own actions.

Ms. Harris stated that when an inspection becomes an investigation, a "notice of violation" is issued to explain the violations to the licensee along with an explanation to

provide additional information. Ms. Harris added that the process the board has been using is not changing, that citations and fine for pharmacies and pharmacists would be issued by a two-member Citation and Fine Committee. She added that the law allows for the licensee to request an office conference with either a board member, the executive officer or a supervising inspector. The Enforcement Committee is recommending that the supervising inspector be the person to take the additional information during the office conference that will either support or add additional mitigation.

Mr. Diedrich stated that the current process complies with the board's regulations and Business and Professions Code section 125.9. Mr. Diedrich added that the cite and fine process provides even more due process. He noted that it is the board's decision whether a board member is present during an office conference. If a board member is present, he or she would have to be recused from any further consideration of the case if it goes on appeal. He added that as members of the committee, two board members already must recuse themselves from the appeal process and by adding additional board members to the office conference process, this could limit the board's ability to handle future proceedings in a case.

Mr. Diedrich stated that upon consideration of additional information submitted after the investigation, the committee on several occasions has dismissed the citation. He added that the Cite and Fine Committee is able to effectively handle far more cases than it could with the previous NCC/SCC process. Mr. Jones added that the board is reaching its goal of a 90-day turn around time for handling cases.

Mr. Young expressed concern that pharmacists are receiving citation tickets three or four months after a notice of violation has been issued, and the decisions are being made by inspectors who initially issued the citations. He added that at least one board member should be present during the office conference to avoid an administrative decision, even if the board member is disqualified from future deliberations. Mr. Young added that the owner of the pharmacy should also receive notification of the citation.

John Cronin, representing the California Pharmacist Association, agreed and added that he does not feel that the board's responses are adequate to address the concerns of the profession. He added that when cite and fine regulations were amended last year, the board argued that the cite and fine process was needed to effectively force corrections on individuals. Mr. Cronin also expressed concern that return inspections are not made to follow-up on the corrections made in the pharmacy.

Mr. Cronin stated that the cite and fine process gives the board an administrative tool to compel compliance with the law. He added that once pharmacies come into compliance with the law, they should not be cited and fined.

Mr. Cronin stated that the board has not met its 90-day turn around goal and he noted that the complaints he hears are for cases at least six months old and most are nine months

old. He added that what he finds very irritating is that the cite and fine process is completely trashing due process because it does not provide individuals with the opportunity to present their case directly to board members in person.

Mr. Diedrich stated that the board has the ability to determine how it wishes to convene office conferences under the regulation. He added that due process is being followed every step of the way.

Allen Pope, representing Longs Drug Stores, Inc., referred to his suggested revisions to section 1775.

Mr. Pope requests that the owner of the pharmacy also receive a copy of the citation once a notice of violation is issued and that the citation is served within 180 days of the alleged violation.

Mr. Pope referred to subsection (f) and stated that that there would be greater flexibility if inspectors would issue a notice of corrective action when the pharmacy has complied with the correction notice.

Mr. Diedrich stated that the board has a valid regulation in place now that it must comply with. The regulation does not give the board discretion about the office conference; it mandates that it must hold an office conference.

Mr. Goldenberg offered to participate in all office conferences with one supervising inspector.

MOTION: Enforcement Committee: Delegate to the supervising inspector and one board member the authority to hold an office conference pursuant to California Code of Regulations, Title 16, section 1775.4, subdivision (c), when a licensee requests such an office conference in accordance with California Code of Regulations, Title 16, section 1775.4, subdivision (b).

M/S/C: ZIA/LITSEY

SUPPORT: 8 OPPOSE: 0

- **Approval of Committee Goal Statement and Strategic Objectives for 2002/2003**

Mr. Goldenberg stated that during the strategic planning at the April Board Meeting, the Enforcement Committee revised its goal statement and updated the strategic objectives based on the actions of the board.

Mr. Goldenberg stated that a request was made that the Enforcement Committee consider as a strategic objective the implementation of the federal HIPPA requirements and provides guidance to licensees as to potential conflicts between the federal and state privacy requirements. DCA staff counsel recommended that licensees provide this information to the state agency that is coordinating the implementation of HIPPA in California. Also, Committee Chair John Jones advised licensees that as they identify these conflicts and prepare their own internal legal analysis as to whether state or federal law prevails, the committee will review those conclusions to determine if there is agreement or not.

MOTION: Enforcement Committee: Approve the revised goal statement for the Enforcement Committee – "Exercise oversight in all pharmacy activities."

SUPPORT: 8 OPPOSE: 0

- **Comments from the Public:**

President Jones stated that at the next Enforcement Committee Meeting in September, the committee will again offer an opportunity for comments on the cite and fine process.

Steve Gray, representing Kaiser Permanente, commended the committee on the guidelines and he requested clarification of the changes made since the Enforcement Committee Meeting. He expressed concern for privacy issues and requested that the board only review confidential information on site as outlined in the California Confidential Medical Act. He added that the board inspectors are asking for this confidential information that should only be viewed on site.

President Jones requested that Mr. Gray submit his comments in writing.

John Cronin, representing the California Pharmacists Association (CPhA), stated that CPhA is advising those who are dissatisfied with a pharmacy inspection to immediately write down their concerns, their objections and comments and send them to the board so that these comments become part of the inspection/investigation file. He added that other pharmacists would not realize that they should do this and this is a problem. He added that pharmacies also need to know when the case has been resolved and the file has been closed. He added that the NCC/SCC process is still needed because not every problem encountered can be resolved through the cite and fine process.

LEGISLATION AND REGULATION COMMITTEE

Regulation Report and Action

Pending Regulations

Board Approved – Pending Approval by the Administration

Mr. Riches reported that the 45-day public notice documents were filed with the Office of Administrative Law:

- CCR 1717(e) – which would allows for the delivery of medications to a non-pharmacy location where the patient receives health care,
- CCR 1720.4 – which would specify the procedure for foreign trained pharmacists who need an outside reviewer to obtain verifiable transcripts which are necessary to establish eligibility to take the pharmacist licensure examination, and
- CCR 1745 – which would make the partial refill regulation consistent with recent statutory changes to the Schedule II prescription requirements.

- **Adopt Section 1777-1775.5 – Cite and Fine for Violation of the confidentiality of Medical Information Act (CMIA)**

  Ms. Zinder reported that the Department of Consumer Affairs approved the proposed regulations establishing the board's ability to issue citations and fines for patient privacy and Internet dispensing violations. The regulations will be submitted to the Office of Administrative Law once the Department of Finance approves the fiscal impact statement.

- **1707.2 – Notice to Consumers**

  Ms. Zinder reported that this regulation will substantially revise the text of the "Notice to Consumers" required by CCR section 1707.2. The new version contains five questions consumers should understand before taking medication. This rulemaking file was submitted to the Office of Administrative Law on July 9, 2002.

- **Section 100 Changes**

  Ms. Zinder stated that this submission would make technical corrections to existing regulations. Consistent with Assembly Bill 1496, these corrections will include the repeal of sections dealing with medical device retailers and the removal of medical device retailer from any other regulations. This submission has been submitted to the Department of Consumer Affairs for review.

Other Items on the Regulation Calendar for 2002

- **1706.3 – Privacy of Financial Records**

  Ms. Zinder reported that this regulation would specify that financial records submitted to the board as part of a site license application are confidential.

- **1717 (e) – Delivery of Medications**

  Ms. Zinder stated that this regulation would eliminate the need for the board to approve waivers under section 1717(e). This waiver process permits pharmacies to depot/store patient specific drugs for delivery to patients at non-pharmacy location. Instead, the regulation will permit pharmacies to depot drugs at any location where the patient receives heath care services.

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

  Ms. Zinder reported that this rulemaking will make changes to confirm board regulations to Assembly Bill 2240 and require that pharmacists confirm the authenticity of any electronic prescription in which there is an uncertainty or ambiguity. It will also repeal the notice to consumers required by section 1717.2, which has been superseded by amendments to California law that substantially strengthened privacy protections.

- **1751 – Sterile Compounding**

  Ms. Zinder stated that this regulation would establish guidelines for the compounding of sterile drug products. Draft guidelines will be the subject of an information hearing at the April 2002 Board Meeting, and will also be discussed during an informational hearing at this board meeting.

- **1732.05 – Continuing Education**

  Ms. Zinder reported that this regulation would recognize continuing education credits approved by other California health professions licensing boards.

Legislation Report and Action

Board Sponsored Legislation for 2002

Ms. Zinder reported that the board is sponsoring AB 2655 (Mathews) to extend the CURES program and move to a monitoring program like that in Nevada. The bill was amended to permit practitioners to access CURES data for their patients and to permit the Department of Justice to screen CURES data and send practitioners profiles of their patient(s) when a potential pattern of abuse is indicated by the CURES data. The bill passed the Senate Health and Human Services Committee on June 20, 2002. The bill is currently pending in the Senate Appropriations Committee.

The board was notified in April that CURES would be paid for by both the General Fund and various board funds. The Medical Board, Pharmacy Board, Dental Board, and Osteopathic Board will all contribute to pay for CURES. However, during the budget

deliberations in June, the budget conference committee eliminated General Fund support for CURES and transferred the full cost to the relevant boards. This will result in approximately a $70,000 annual cost to the board. The board has been fully supporting the CURES program prior to this legislation with approximate costs of $300,000 per year.

- **SB 2026 (Senate Business and Professions Committee)**

  This is the annual omnibus bill providing technical cleanup of professional licensing acts. The board sponsored provisions conforming state controlled substance schedules with recent changes in federal controlled substance schedules. The board also sponsored a provision repealing an unused statute that permits the licensing of controlled substance warehouses.

New Legislation

Ms. Zinder stated that the committee has reviewed the following new bills, but has no recommendations for positions on any:

- **SB 1386 (Peace) – Information Privacy**

  Ms. Zinder stated that this bill requires immediate disclosure of any security breach of an electronic database containing personal information to individuals with personal information in that database. This disclosure requirement applies to both government and private entities.

- **SB 2019 (Speier) – Student Loans**

  Ms. Zinder stated that this bill permits boards to deny licensure or issue a citation and fine to applicants or licensees who are in default on federally subsidized student loans.

- **SB 2059 (Figueroa) – Complaint Disclosure Policies**

  Ms. Zinder stated that this bill requires professional licensing boards to adopt complaint disclosure policies by regulation.

- **AB 2045 (Matthews) – Pharmacist-In-Charge**

  Dr. Fong stated that Longs met with Assemblywoman Barbara Mathews to discuss simplifying AB 2045. Dr. Fong stated that the most recent language in this bill was too specific regarding the pharmacist-in-charge and micromanaged pharmacies, and he referred to recommendations Longs made to the Legislature to simplify the bill. Dr. Fong stated that according to the author's office, the language was submitted by the board. Dr. Fong asked about the board's intent.

Mr. Riches stated that during the April Board Meeting, the board discussed language for amendments. Issues raised during the board discussion included concerns about PICs using the reporting process as a way to avoid charges against them and concern that the PICs need to faithfully execute their duties.

Dr. Fong read the two provisions submitted from Longs Drug Inc.:

1. The pharmacist in charge did not permit, incur, approve of or …with willful ignorance, any conduct met by another person that violates either federal law or regulation.
2. The pharmacist in charge reported the violation or suspected violation of any state or federal law and regulation pertaining to the practice of pharmacy.

Mr. Riches stated that the sponsors of the bill wanted to create an incentive to provide a safe harbor for PICs who faithfully report suspected violations. He added that the genesis for the bill was that the existing system was perceived to create a disincentive for PICs to report any violations to the board.

Steve Gray, representing Kaiser Permanente, expressed support of the language submitted by Longs and stated that the intent of the bill was to insure that the board considers mitigating factors. He referred to the removal of paragraphs (c) and (d) and stated that the board can only consider the mitigating factor if (c) and (d) are complied with. He added that if the pharmacist-in-charge did not report an incident as soon as reasonably possible, then the board would not be able to consider the other mitigating factors of the case.

Mr. Diedrich stated that the board already has the means to handle this in Business and Professions Code section 4113 (d).

Dr. Fong questioned the need to be this specific in law when the Business and Professions Code provides regulatory authority.

The board took no action on this request.

Ms. Zinder stated that the committee has a refined goal that needs board discussion and approval.

MOTION: Legislation and Regulation Committee: Approve the new strategic goal to advocate legislation and promulgate regulations that advance the vision and the mission of the Board of Pharmacy.

SUPPORT: 8 OPPOSE: 0

- **Proposal to License Benefit Managers (PBMs)**

  Mr. Riches stated that during the January 2002 Board Meeting, John Tilley requested that the Legislation and Regulation Committee consider a proposal drafted by the National Community Pharmacists Association regarding pharmacy benefit managers (PBMs). The Legislation and Regulation Committee discussed this proposal at its April 2002 meeting. During the discussion the committee identified several gaps in its knowledge regarding this proposal and recommended that the proposal be placed on the July agenda for discussion and comment by the board and interested parties.

  Mr. Tilley stated that pending legislation in 13 states would allow boards of pharmacy to regulate PBMs within their states. Mr. Tilley added that this offers consumer protection against prescription errors. He added that mail order pharmacies are not necessarily regulated in the state that they conduct business in and this does not offer consumers recourse in certain cases and in some cases, there is no accountability by the PBMs. He stated that the Board of Pharmacy should have jurisdiction over PBMs.

  Mr. Cronin, representing the California Pharmacists Association (CPhA), stated that the CPhA is not sure if the Board of Pharmacy is the proper authority to regulate PBMs but suggested that the board review this issue.

  Leslie Spahnn, representing Advance PCS and Express Scripts Inc. (PBMs) stated that it would be inappropriate for the State Legislature and the State of California to enact this draft proposal because PBMs do more than dispense drugs. He added that PBMs also administer pay claims, perform drug and prescription utilization review and research drug interactions. He added that many of the PBM activities are already subject to regulation and statutory law in California.

  Jim Gross, representing Merk Medco Managed Care, stated that Merk Medco operates both a Knox-Keene licensed PBM in California and an entity that does not fall under licensure and both must follow the Knox-Keene provisions when contracting with a managed care organization.

  Mr. Gross disagreed with Mr. Cronin about the willingness of the Department of Managed Health Care to get involved in pharmacy disputes because they are aggressive in pursuing such matters and also in assuring that the PBMs are following the procedures of the act.

  Mr. Gross stated that there are already substantial regulations in California in place and he suggested that the board review this issue closely to determine where the problems are and if the law is enforced before determining that more regulation by another agency is warranted.

Steve Gray, representing Kaiser Permanente, stated that the board already has the ability to regulate dispensing of prescriptions to residents of California through non-resident pharmacy license.

MOTION: Approve new strategic activity for the Licensing Committee to consider the feasibility of the need for regulation of Pharmacy Benefit Managers (PBMs).

M/S/C: GOLDENBERG/GUBBINS

SUPPORT: 8 OPPOSE: 0

INFORMATIONAL HEARING – Compounding of Sterile Products (Proposed Amendment to Section 1751 – Regulations for Compounding Sterile Products)

Mr. Riches stated that this is an opportunity for additional public comment on the regulations. Prior hearings were held at the April board meeting and the June meeting of the Licensing Committee for consideration by the board in developing the formal regulation proposal for sterile compounding.

Mr. Riches reported that this draft represents a substantial revision to prior versions of the regulations and that the most substantive change relates to defining risk categories for sterile compounding. The category definitions now take route of administration into account when defining risk categories. This draft also includes a provision directing pharmacists to consider the condition of individual patients when compounding sterile drug products, particularly, whether the compounded drug should be subject to more stringent compounding and evaluation processes if provided to a person with reduced immune system functions.

Mr. Riches stated that these regulations are needed to implement Senate Bill 293 (Chapter 827, Statutes of 2001) requiring pharmacies that compound sterile injectable drug products to be separately licensed by the board and requiring the board to adopt guidelines for sterile compounding. SB 293 requires all pharmacies compounding sterile injectable products to comply with the guidelines adopted by the board.

Mr. Riches stated that the board received a broad range of comments on prior versions of the regulation that included concern that the regulations were overly complex and detailed to a more general request for simplified regulations. Specific issues were raised regarding the testing methodology for sterile filtration for certain types of products and a discussion included structural requirements for clean rooms.

Mr. Riches stated that one of the first considerations was not to regulate this practice out of business because of the important role sterile compounding has within the health care system. He added that this practice saves lives and improves the quality of life for many on a daily basis

but as a consumer protection agency, it is important to assure that this practice occurs in a safe manner.

Mr. Cronin commended Mr. Riches on efforts to incorporate the changes and comments provided. However, he added that the current language establishes a set of standards based on documents produced by entities that did not intend for the guidelines to be incorporated as requirements. He added that another issue is that the board, by adopting this is becoming a standard setting entity and over time, as situations change and as the ASHP standards change, the board will not be in line with these other standards.

Mr. Cronin requested that the board make the guidelines as simple as possible, using the resources available through other organizations. He stated that the board's regulations should allow pharmacies to select the option of choosing whichever voluntary standard (USP or ASHP) works better for them.

Mr. Riches stated if the standards of practice change, the board would have to amend its regulation to reflect the change.

Dr. Gray suggested that the board hold one more workshop or informational hearing. He noted that as written, the outpatient labeling standards would apply to all in-hospital distribution and this would represent a million dollar (or more) remodel in many of the major hospitals in California.

Ms. Herold stated that this regulation must be scheduled for hearing at the October Board Meeting; otherwise the board would not meet the statutory deadline of the July 1, 2003. However, additional comments can be made during the 45-day public comment period and during the regulation hearing.

Mr. Riches stated that the board welcomes all comments by the end of the first week in August.

MOTION: Move forward with a regulation hearing on proposed amendment to Section 1751 – Regulations for Compounding Sterile Products at the October 2002 Board Meeting.

M/S/C: FONG/ZIA

SUPPORT: 8 OPPOSE: 0

ORGANIZATIONAL DEVELOPMENT

ANNOUNCEMENT

Mr. Jones announced the board's committee assignments as follows:

Cite and Fine Committee
Stan Goldenberg (Chair)
John Jones

Communication and Public Education Committee
Bill Powers (Chair)
Caleb Zia

Enforcement Committee
John Jones (Chair)
Stan Goldenberg
Don Gubbins

Legislation and Regulation Committee
Steve Litsey (Chair)
Andrea Zinder

Licensing Committee
Dave Fong (Chair)
Clarence Hiura

Competency Committee
Steve Litsey

Organizational Development Committee
Don Gubbins (chair)
John Tilley

Executive Officer's Report

Personnel Matters

Ms. Harris reported that on October 23, 2001, Governor Davis instituted a state-hiring freeze aimed at reducing state expenditures. The freeze prohibits the hiring, promoting or reinstating of state employees unless specifically approved by the Department of Finance. The freeze requires the board to fill positions solely with other board staff – restricting the board to transfer employees from one position to another. The board is unable to hire new staff unless permitted by the Department of Finance.

The board was granted one freeze waiver to fill an associate analyst position to oversee the CURES program and other Enforcement Program tracking systems. In mid June, the board hired Sue Durst for this position. Ms. Durst formerly worked centrally for the Department of Consumer Affairs, and is knowledgeable about the department's

centralized computer systems and data tracking. She has also prepared a number of departmental reports over the years.

Ms. Harris stated that in response to the deteriorating fiscal estimates of revenue, the Department of Finance states that it will not approve future freeze waivers. Moreover on June 30, 2002, all vacant positions have been targeted for elimination by the Legislature in the state budget for 2002/03. The board currently has four staff vacancies in the Sacramento Office.

If the elimination of all vacant positions occurs, the board will lose two clerical positions and two associate analyst positions (the newsletter editor and the public outreach coordinator). If these positions are lost, the board will seek to have them reinstated as soon as possible.

Ms. Harris reported that the new budget will authorized three new positions (one supervising inspector, one inspector and one application technician) to implement the sterile compounding licensure program and represent a significant achievement since state government is cutting positions, not creating. Without these positions, the board will not be able to implement the new requirements of the sterile compounding program.

Training

Ms. Harris stated that in July all staff was provided training in two modules from the Bullet Proof Manager series of training being taken by all board managers. These modules were improved customer service and dealing with stress. Additionally all staff have completed the required sexual harassment training sponsored by the department.

Budget

Ms. Harris reported that there is no state budget yet from the fiscal year that began July 1, 2002. She added that the state has a huge budget deficit forecast of $24 billion and a number of additional controls and transfers are underway to help reduce the size of the state's expenditures.

Transfer of Board's Reserve

Ms. Harris stated that when the 2002/03 budget is enacted, there is language either in it or in a trailer bill that requires the board to loan $6 million from its fund to the state's General Fund. She added that most agencies with fund reserves have loaned their funds to the state as well. The board will not be able to increase fees to offset the loss of revenue, but the Department of Finance must review the board's fiscal condition to assure it does not have a deficit situation arise once the board's fund is depleted, at which point the loan will be repaid.

Ms. Harris reported that at the board's current revenue and expenditure levels, the board is expected to have had a fund reserve of 16.6 months of operating expenses on June 30, 2002. By June 30, 2003, after the loan, the board is expected to have 4 months of operating expenses left.

The board's annual expenditures greatly exceed its annual revenue with an annual deficit of $2 million in 2001/02 and a projected $2.5 million gap in the current (2002/03) year.

Ms. Harris stated that the board will have tough decisions to make. While the direction is that the board cannot raise fees, if the board does not have a fee increase regulation by July 1, 2003, the board will be in a difficult situation and may have to lay-off staff or reduce the number of enforcement cases that go to the Attorney General's Office. She added that the board's highest expenditures are personnel and Attorney General's legal services cost, but the board also lacks resources in a number of program areas – for example postage.

Ms. Harris stated that currently the board's fees are at minimum levels, and if the board chooses to move forward with a regulation hearing to increase fees, it will have to be held during the January 2003 board meeting. President Jones added that the Organizational Committee would address a plan at the next committee meeting for a possible regulation hearing in January 2003.

Ms. Harris provided the following summary of the board's budget for 2001/02:

1. 2001/02 Budget Year

The 2001/02 fiscal year ended June 30, 2002. Final budget figures for the year will not be available until mid-August.

Projected Revenue: $5,748,872

Revenue is estimated to be comprised of $4,831,760 in licensing fees and $621,000 in interest on the board's contingency reserve fund. The board has also received $246,512 in cost recovery and collected 49,600 in fines through June 30, 2002.

Projected Expenditures: $7,499,355

The board is projected to spend $3.5 million or 46.9 percent of its budget on personnel expenses and benefits; the remainder will be spent on operating expenses.

Fund Condition Estimate: $10,374,103 (or 16.6 months)

Ms. Harris stated that the board had an estimated deficit between its expenditures and revenue of $2 million during the fiscal year.

The board is required by the Business and Professions Code to have a prudent reserve in its fund of one year.

2. **Budget Change Proposals for 2002/03**

Ms. Harris stated that the board has the following augmentations currently in the state budget that will cover the fiscal year that began July 1, 2002:

- Budget realignment to provide funding to budget areas under-funded in prior years (requested: $847,000; approved $247,000 for 2002/03, $172,000 ongoing)

  Specifically:

  - Annual printing needs (Health Notes, The Script, but not the Pharmacy Lawbook)
    Approved: $159,776 (2002/03) - $84,776 (ongoing)
  - Exam site rental
    Approved: $41,600
  - External contractors
    Approved: $28,825
  - Travel
    Approved: $10,800
  - Enforcement Management Reclassification
    Approved: $6,000 to redirect of one inspector position to that of a supervising inspector

The following items have also been added to the pending budget:

- Finance Letter to implement SB 293 (Torlakson and Figueroa): which requires the board to issue a special license to pharmacies that perform sterile compounding, and requires annual inspections
  Approved $309,000 (2002/03) and $272,000 ongoing for one supervising inspector, one inspector, one technician and operating expenses
- Finance Letter (submitted by the Department of Justice) to fund CURES by the Medical Board, Dental Board, Board of Pharmacy and Osteopathic Medical Board) – the board's share is $68,000 annually.
- Finance Letter (submitted by the Department of Consumer Affairs for increased rent) – the board's portion is $25,000 annually.

Ms. Harris reported that the board would have a lean year even with these augmentations because in years past, vacant inspector positions provided salary savings that were redirected to other program areas. Since January 2002, all board inspector positions have been filled. Last year, the board sought status quo funding for the other program areas (printing, postage, AG, temporary help, proctors) which was denied by the Department of Finance, Consequently, the board's budget for many program areas were under-funded and will require cutbacks or reduced levels of use or service unless augmented.

Organizational Development Committee Meeting

Action Items and Report on the Meeting of July 16, 2002

Ms. Harris reported that the Organizational Development Committee met on July 16, 2002, in a teleconferenced meeting.

Approval of Committee Goal Statement and Strategic Objectives for 2002/2003

Ms. Harris stated that at the April Board Meeting, the board created a new vision and mission statement for the board. The board also created values and began a process to restate and refine its goals. During the committee report portion of the board meeting, the board also approved strategic activities for each committee during the 2002/03 fiscal year.

The board plans to substantially modify its strategic plan in a new format. This restructuring will take considerable effort from the Organizational Development Committee and the assistance of a strategic planning consultant to complete the work started in April. Over the next six months this transition will occur during the committee's meetings.

The committee decided to compile the 2002/03 strategic plan so that it contains the new mission and vision approved by the board, but retains the prior plan's structure with the board-approved strategic and ongoing activities for 2002/03.

Meanwhile the Organizational Development Committee will move forward to revise the plan into the new format, so that by April 2003 when the board is ready to refine its goals for 2003/04, the new format will be ready for review and comment.

MOTION: Organizational Development Committee: Add a new strategic goal to the Organizational Development Committee: redesign and reformat the board's strategic plan into a new strategic management plan structure for the 2003/04 fiscal year.

SUPPORT: 8 OPPOSE: 0

Create a new goals statement for the committee: "Achieve the Board's Mission and Goals."

Ms. Harris stated that at the last board meeting, the committee redrafted its goal statement. During the committee meeting on July 17, 2002, the committee modified the statement slightly.

MOTION: Organizational Development Committee: Create a new goal statement for the committee: "Achieve the Board's Mission and Goals."

SUPPORT: 8 OPPOSE: 0

MOTION: Organizational Development Committee: Approve the Board of Pharmacy's Strategic Plan for 2002/03.

SUPPORT: 8 OPPOSE: 0

SUNSET REPORT

Ms. Herold referred to the draft of the Sunset Report sent to board members. She added that this report is due to the Legislature on September 1, 2002. Ms. Herold added that the report is divided into three parts. The first part describes how the board is structured, its achievements and accomplishments over the last five years. The second part of the report contains the responses to a detailed questionnaire prepared by the Joint Legislative Sunset Review Committee. The third part of the report describes how the board implemented recommendations made by the legislative committee resulting from the last sunset review.

Ms. Herold referred the board to a section of the report intended for future action items. Mr. Jones stated that the board needs to review this list of strategic items and determine how it wants to move forward with its resources and energy in the best interest of the public.

Ms. Harris stated that this document is currently a draft that will need comments, edits and approval from the board to move forward. Board members were asked to submit editing comments to the board by August 1.

Ms. Harris acknowledged Ms. Herold, Ms. Cates, Ms. Sodergren, Ms. Durst and Mr. Riches for their efforts on this project.

MOTION: To move forward with the Sunset Report, subject to written comments submitted by the board.

M/S/C: FONG/ZIA

SUPPORT: 8 OPPOSE: 0

APPROVAL OF MINUTES

Full Board of Pharmacy
(April 24-26, 2002)

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

MOTION: Approve the April 24-26, 2002, Board Meeting minutes.

M/S/C: TILLEY/ZINDER

SUPPORT: 8 OPPOSE: 0

PUBLIC COMMENT

John Cronin, representing the California Pharmacist Association, thanked the board for having public meetings of the Enforcement Committee.

ADJOURNMENT

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

Thursday, July 25, 2002

CLOSED SESSION

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