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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 25, 2001

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

BOARD MEMBERS PRESENT:
Steven Litsey, President
John Jones, Vice President
Caleb Zia, Treasurer
Robert Elsner
Stanley Goldenberg
Donald Gubbins
Clarence Hiura
William Powers
Holly Strom
John Tilley
Andrea Zinder

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

CALL TO ORDER

President Litsey called the meeting to order at 8:30 a.m. on Wednesday, July 25, 2001.

CLOSED SESSION

The board moved into Closed Session pursuant to Government Code Section 11126(a) regarding personnel matters to perform the evaluation of the Executive Officer. The board also conferred with legal counsel pursuant to Government Code Section 11126(e) regarding the following pending litigation: Doumit v Board of Pharmacy, Sacramento Superior Court Case #98A504499 and Gonzalez v Board of Pharmacy, Sacramento Superior Court Case #99AS01990.

ANNOUNCEMENTS

President Litsey announced that Governor Davis appointed three new board members to the Board of Pharmacy and he introduced them as follows:

- Stanley Goldenberg, a licensed pharmacist from the Los Angeles area who has specialized in long-term care facilities and skilled nursing facilities since 1972. Mr. Goldenberg serves as the president of Pharmatech LTC, a company that provides research for a nationwide network of skilled nursing facilities and long-term care facilities. Mr. Goldenberg is the founder and president of the Long Term Care Management Council. He served as the president of Advanced Pharmaceutical Services an institutional pharmacy specializing in skilled nursing facilities. Mr. Goldenberg also serves as the president of Osteographix Medical Associates, which provides osteoporosis testing and educational services. He earned a Bachelor of Science degree from the University of Arizona College of Pharmacy.

- Clarence Hiura, also from the Los Angeles area, who has practiced pharmacy for more than 42 years. Dr. Hiura is a former member of the California State Board of Pharmacy, having served from 1979 to 1986. Dr. Hiura was a Clinical Associate Professor at the University of Southern California and is a member of the Los Angeles Pharmacy Task Force. He is the president of the California Pharmacy Association Board, Inc. and vice president of United Pharmacy Network Inc. Dr. Hiura is also a member of the Board of Directors of the East Los Angeles Pharmacist Association and the California Pharmacist Association. He was honorably discharged from the California State National Guard Armed Forces. Dr. Hiura is on the Board of Directors for QSAD, a fund development organization for the USC School of Pharmacy. He is also a lifetime member of the USC Alumni Association. Dr. Hiura earned a doctor of pharmacy degree from the University of Southern California.

- John Tilley, who has practiced pharmacy for 24 years and has owned three Zweber Apothecaries in Downey, California since 1984. He is a past trustee and president of the California Pharmacist Association (CPhA) and president of the California Pharmacists-Political Action Committee. Mr. Tilley is the owner of pharmacies located within 26 Stater Brothers Markets in Southern California. He is also a member of the American Pharmaceutical Association, and serves on the Board of Directors for the American College of Apothecaries. Mr. Tilley also serves on the Executive Committee for the National Community Pharmacists Association (NCPA) where he is in the midst of a 14-year commitment that culminates in the presidency of the NCPA. In 1994, he received CPhA's Bowl of Hygenia Award, an honor presented annually to California pharmacy's community practitioner of the

year. Mr. Tilley has testified before joint sessions of the Senate and House Health subcommittees on prescription coverage for Medicare, and attended meetings at the White House during the health care reform debate in 1994. He earned a Bachelor of Science degree from Whittier College and a Bachelor of Science degree from Idaho State University College of Pharmacy.

President Litsey introduced Ron Diedrich, Deputy Attorney General, Office of the Attorney General, who is filling in for Deputy Attorney General Elena Almanzo.

COMMITTEE REPORTS AND ACTION

PUBLIC EDUCATION AND COMMUNICATIONS COMMITTEE

Chairperson Zia reported that the Public Education and Communications Committee did not meet during this quarter. He added that the committee is awaiting the Governor's action on the budget before planned activities will be initiated regarding the proposed revisions to the "Notice to Consumers" poster for distribution to pharmacies.

Mr. Hiura referred to the language where it states, "At your request, the pharmacy must provide its current price of any medicine without obligation." He asked if there is a time frame indicating how long a pharmacist has to provide this information.

Ms. Harris responded that the law is specific in that, if a patient requests the price of five or more drugs, the pharmacist can require the patient to make a request in writing. She added that pharmacists could charge $1 for each prescription price request. Further, it should be a matter of the pharmacist's best judgment as to the time frame for providing the prices.

Ms. Harris stated that during the next quarter, the graphic artist will work on the "Notice to Consumers" poster and the committee will finalize the text of the regulation. Thereafter, the language will be released for the 45-day public comment period.

LICENSING COMMITTEE

- **Presentation of Audit Findings on the North American Pharmacist Licensure Examination (NAPLEX) and Recommendation to Support its Use in California – Presentation by Norman Hertz, Manager, DCA-Office of Examination Resources and Carmen Catizone, Executive Director, National Association of Boards of Pharmacy**

Chairperson Holly Strom reported that as part of the Board of Pharmacy's strategic plan, the board conducted a review of the board's exam process and also examined the North American Pharmacist Licensure Examination (NAPLEX). She stated that the board completed its job analysis in 1999 and from that analysis, the board developed a revised content outline for California's exam. The June 2001 exam was the first exam to use the new content outline.

Ms. Strom stated that the board had planned to do an extended review of the NAPLEX exam after its next job analysis. However, the NABP does not have immediate plans to do another job analysis in the near future so the board contracted with Dr. Norman Hertz, Director of Office of Examination Resources, Department of Consumer Affairs to examine NAPLEX now. She added that the Office of Examination Resources is a specialized unit within the Department of Consumer Affairs for the professional review and development of professional licensing examinations.

Ms. Strom stated that the board contracted with Dr. Hertz specifically to help the board to conduct

an independent audit of the NAPLEX examination.

Ms. Strom reported that Dr. Hertz assembled a team of psychometric experts to assist him with the review. She referred the board to the biographical sketches of this team of experts. Members of the team include Norman R. Hertz, Kara Schmitt, Barbara Showers and Eric Werner all of whom perform analysis and validation of high stakes occupational exams in each of their home states (Wisconsin, Michigan and Colorado). Ms. Strom stated that she also served on the audit committee as a representative of the board and content expert, to provide content review of this process.

Chairperson Strom introduced Dr. Hertz.

Dr. Hertz stated that he had been asked by the Board of Pharmacy in January 2001 to conduct a psychometric audit of the NAPLEX examination. He added that the team did a site visit to the National Association of Boards of Pharmacy (NABP) in March 2001.

Dr. Hertz stated that this was an independent audit team that functioned independently from the board, the Department of Consumer Affairs and the NABP. The committee knew that the audit results were to be made public.

Dr. Hertz stated that the audit team used an objective standard (Standards for Educational and Psychological Testing) for evaluating the program. He reported that the audit team reviewed the major elements of the NAPLEX program on its job analysis, test development, cut scores, test administration and score reporting.

Dr. Hertz stated that the audit committee concluded that the NAPLEX is a valid measure of competencies, essential for entry-level pharmacist practice.

Ms. Strom stated that in developing the report, the independent auditors made a number of recommendations with regards to the NAPLEX exam. Ms. Strom introduced Carmen Catizone, executive director of the National Association of Boards of Pharmacy.

Mr. Catizone acknowledged Dr. Hertz and the audit committee on the professional learning experience they provided to the NABP.

Ms. Strom stated that on June 28 the Licensing Committee met and made a recommendation that the Board of Pharmacy supports the use of NAPLEX as its examination based on the following conditions:

- NABP commits to performing a job analysis within two years and every five years thereafter, and NABP incorporates California's 1999 job analysis in its next job analysis
- NABP administer a California specific Multi-State Pharmacy Jurisprudence Examination (MPJE) using the NABP computer-based testing program
- The board retains its Competency Committee (subject-matter experts) for the development and maintenance of the MPJE question bank, to write questions for NAPLEX and to participate on the NAPLEX Review Committee (NRC)
- The board retains its own examination consultant for writing questions for the MPJE and NAPLEX examinations
- The NABP agrees to place at least 8 members from the board's Competency Committee on its NAPLEX Review Committee and cut score setting committee
- The NABP responds to the audit recommendations and provides documentation on

integrating these elements into its exam program to the board's Competency Committee for review. The recommendations will be provided to the Licensing Committee

- California uses the "direct processing" option where an applicant submits his/her examination application directly to NABP and NABP sends the examination results directly to the candidate with a copy to the board
- Legislation is passed to authorize the acceptance of the NAPLEX and California's MPJE no earlier than June 1, 2002
- Legislation is passed to authorize the transfer of a pharmacist license from another state based on specified conditions including the passage of the NAPLEX and California's MPJE after June 1, 2002

Ms. Zinder expressed concern about why non-California graduates do worse than California graduates on California's exam. She also asked about how California would develop its MPJE.

Mr. Catizone responded that the board would determine the type of questions that would be included in the examination and the NABP would provide all other services relating to the exam, such as making sure that the questions meet the exam structure criteria. He added that this exam is a computer based multiple-choice examination and he explained that the NABP rules and regulations from all of the states, including California, are combined to develop a common examination. California then designates questions that are applicable to California. For California candidates, the computer only selects those questions that apply to California law.

Ms. Strom stated that she has served on the Competency Committee since she began serving on the board in 1993. She added that during the audit, she examined the content of both exam programs and found that the two job analyses to be almost identical. One advantage of the NAPLEX is that this exam is available basically anytime a candidate wants to take the exam.

Mr. Elsner expressed concern about testing the communications skills of pharmacists on a written exam.

Mr. Catizone stated that many boards of pharmacy have expressed concern with the communication ability of pharmacists and consequently the NABP is reviewing several proposals from different states that would require the Test of Spoken English as a requirement for licensure.

Mr. Catizone explained the basic educational standard of a professional degree from an ACPE accredited school. He stated that the NABP conducted a national study of all pharmacists. The study was conducted by the NABP, the American Association of Colleges of Pharmacy, the American Pharmaceutical Association and the American Society of Hospital Pharmacists. This study looked at the type of tasks performed by pharmacists and how often they were performed (this provided a very standard job analysis). To address public health issues, they looked at the tasks a pharmacist must perform correctly at the entry level to avoid harming patients. He added that this is how the standard was set for the NAPLEX exam.

Ms. Strom stated that the NABP's exam review committee determines if a question is used on the exam once the content experts write the questions. She added that immediately, the board's content experts will be placed on that exam review committee and on the committee that determines the cut score.

Ms. Strom reminded the board that the license transfer agreement will not allow for reciprocity and that the board would place requirements on those wishing to practice in California. She referred to sample legislation that would require everyone graduating from an accredited

pharmacy school prior to June 1999, to take the NAPLEX exam starting in June 2002.

Dr. Hertz responded that in high stakes occupational licensing, there is a need to verify that a person has acquired the skills and competence through the educational and experience requirements. He added that a licensing examination does not guarantee that a person will be successful as a pharmacist or as any other professional. He stated that a licensure exam only measures minimum competency and it is not an employment exam.

Mr. Catizone stated that the candidate pool passes the NAPLEX in the range of 89–92 percent.

Mr. Powers asked how using the NABP's exam would benefit consumers.

Bruce Young, California Retailers Association, responded that it would attract more pharmacists. He added that one area where consumers will see value is that it will give California pharmacies a chance to attract good students from other areas of the country.

John Cronin, California Pharmacists Association, stated that CPhA endorses and encourages the Board of Pharmacy to become a full member of the NABP, which requires the use of the NAPLEX. However, the CPhA will oppose any type of licensure of pharmacists without an individual examination given by the Board of Pharmacy. He added that the CPhA opposes reciprocity. He noted that the CPhA's policy is to support a test of communication skills for pharmacists to ensure that consumers in California will have the necessary information to properly take their medications.

Dr. Hertz stated that it is not possible to assess communication skills in an examination, instead these skills are measured through education and internship.

Shane Gusman, attorney with the law office of Barry Broad, representing the United Food and Commercial Workers, stated that they have serious concerns regarding this proposal. He stated that the Pharmacy Manpower Task Force has not completed its work yet and there is also legislation pending that would increase the pharmacy technician ratio. He stated that the board should wait before acting at this time.

John Perez, United Food Commercial Workers (UFCW), responded to Mr. Powers' concern for consumers. He stated that the study was not responsive to the question of whether the test adequately reflects the job analysis in California. He added that the study does not directly compare the NAPLEX exam to California's exam. He added that they would hope that this move toward NAPLEX would increase manpower in California. He added that they are mindful that there are barriers in place for persons to become licensed in California and barriers that the board has within its discretion the ability to license.

Mr. Perez stated that the UFCW made the following suggestions:
1) To suggest a new act to increase the number of times per year that the test is given from two times to continuous testing;
2) To evaluate the predicted value of the essay exam to determine if it measures the appropriate information;
3) Candidates that fail one section of the exam, have the ability to take the portion they failed.

Mr. Catizone stated that he has not seen evidence to support the claim that California's practice standards are different than other states. He added that the issue of standards and passing rates continue to be intertwined incorrectly. Further, statements have been made that the use of the NAPLEX exam in California would lower the pharmacist's standards in California. He cautioned

the board against accepting a characterization that the NAPLEX would lower the standards in California because it impugns NABP and the 49 other states that use the exam.

Mr. Perez clarified that he has not seen studies that assure that the NABP exam does not lower standards.

Dr. Hertz stated that it is not possible to design a study to ascertain the negative in a study.

Ms. Zinder stated that this recommendation is premature and added that the Pharmacy Manpower Task Force is addressing these issues. She noted that communication skills are a real issue and whether or not consumers are getting adequate consultation. She added that she felt the board is rushing through with this based on the recent audit, without fully looking at its own testing program. She also stated that error rates and disciplinary actions from other states would need to be examined as well.

MOTION: Supports the use of NAPLEX as the board's examination based on the following conditions including an implementation of a psychometric audit on a regular basis.

- NABP commits to performing a job analysis within two years and every five years thereafter, and NABP incorporates California's 1999 job analysis in its next job analysis
- The board retains its Competency Committee (subject-matter experts) for the development and maintenance of the MPJE question bank, to write questions for NAPLEX and to participate on the NAPLEX Review Committee (NRC)
- The board retains its own examination consultant for writing questions for writing questions for the MPJE and NAPLEX examinations
- The NABP agrees to place at least 8 members from the board's Competency Committee on its NAPLEX Review Committee and cut score setting committee
- The NABP responds to the audit recommendations and provides documentation to the board's Competency Committee for the Competency Committee's review and recommendation to the Licensing Committee
- California uses the "direct processing option" where an applicant submits his/her examination application directly to NABP and NABP sends the examination results directly to the candidate
- Legislation is passed to authorize the transfer of a pharmacist license from another state based on specified conditions including the passage of the NAPLEX and California's MPJE after June 1, 2002
- Legislation is passed to adjust the application fee for pharmacist licensure accordingly

SUPPORT: 7 OPPOSE: 2 ABSTAIN 1

- **Requests for Waiver of CCR 1717(e) – Delivery of Filled Prescriptions to Clinics**

Chairperson Strom stated that the Licensing Committee reviewed requests for waivers of California Code of Regulations section 1717(e), and placed additional requirements on each of them, and they have complied or agreed to comply.

MOTION: Approve the requests for waiver of CCR 1717(e) – Delivery of Filled Prescriptions to five specific clinics

1. San Ysidro Health Center
2. Yosemite Medical Clinic
3. Community Clinic Association of Los Angeles County
4. Marshall Hospital
5. AIDS Healthcare Foundation ("AHF")

SUPPORT: 10 OPPOSE: 0

Chairperson Strom referred to the Licensing Committee meeting minutes of June 28, 2001, and asked if there were any questions or comments. There were none.

LUNCH RECESS

COMMITTEE REPORTS AND ACTION - Continued

ENFORCEMENT COMMITTEE REPORT

Chairperson Jones acknowledged the Enforcement Committee's achievements. He acknowledged Darlene Fujimoto's long-standing and dedicated efforts on the committee.

Mr. Jones reported that over the last year, the board's enforcement staff have a huge reduction in the backlog of complaints. He added that the board's time frame for handling these cases has been reduced from as long as two years to less than 6 months and the board is now nearing towards a 90-day turn around on complaint investigations and mediations. He commended board staff on a job well done to resolve these cases more quickly.

Mr. Jones reported that effective July 1, the board began routine inspections. To date, 180 inspections have occurred resulting in the opening of 10 new cases. During routine inspections, the inspectors educate and make recommendations for improved pharmacy practice; at least 30 percent of their time will be used to conduct after-hour inspections.

- **Request to Amend CCR 1717.3 – Preprinted, Multiple Check off Prescription Blanks for Hospital Inpatient Pharmacies**

Mr. Jones reported that since the board adopted amendments to CCR 1717.3, another request was received to allow inpatient hospital pharmacies to add controlled substances to the list of drugs on preprinted prescription blanks. The preprinted forms would be used for discharge medications that would be filled by community pharmacies.

Mr. Jones added that the Enforcement Team recommended that the board not amend the regulation as requested. Currently, law requires prescriptions for Schedule III and IV controlled substances to be in the handwriting of the prescriber (Health and Safety Code section 11164(b)(1)). If the prescriber wanted to write a prescription for Schedule III and IV drugs, he/she could do so by writing the order on the preprinted form.

Steve Gray, Kaiser Permanente, stated that Kaiser was the origin of the recent amendment to the regulation to allow multiple check-off prescriptions for non-controlled substances. He added that errors could be prevented with preprinted prescription forms.

He agreed that the board should not proceed with the new proposal because it would be a violation of the law.

MOTION: Not to amend California Code of Regulation section 1717.3.

SUPPORT: 10 OPPOSE: 0

- **Request to Restore Routine Inspections of Pharmacies with Emphasis on Education and Prevention of Violations**

Mr. Jones stated that the board has restored its inspection program beginning July 1, 2001. While the Enforcement Team agrees that routine inspections are important, California pharmacy law does not mandate the inspection of pharmacies. He added that the board has been successful in reducing case investigation time down to six-month aging of cases by July 1, and the goal for September 1 is to get down to 90 days. Accordingly, because the backlog of cases has been resolved, board inspectors will then have more time for routine inspections.

It was suggested that the training of board inspectors on pharmacy law be improved to avoid misinterpretations and misapplications. Mr. Jones responded that it is the Enforcement Team's goal to do this. He added that inspectors are often asked for legal advice, which they cannot provide. They are also asked for legal interpretations that are based on hypothetical situations that have a tendency to change if the answer received is not the "right" answer. In these situations, the licensee goes shopping for the "right" answer from other board staff. It is also the board's experience that licensees want an interpretation for which the only interpretation is for the pharmacist to make a decision based on his or her professional judgment. Efforts are being made to develop compliance policies to give licensees consistent legal interpretations such as the one that was adopted by the board on "Expiration Dates." The goal is to post these compliance guides on the board's Website and print them in the newsletter so they are widely available to the state's pharmacists.

- **Request to Have a Committee of the Board Review All Disciplinary Actions Prior to Filing**

Mr. Jones stated that it is the Enforcement Team's recommendation that the current process is sufficient and does not need to change. This is evident by the sustained number of filings at the Attorney General's Office. During the investigation, the board's pharmacist-inspectors report all mitigation as part of the investigation process. This is especially important when balanced against the evidence showing the serious nature of the violation. The presentation of the evidence and mitigation allows management to make an informed decision as to the appropriate disposition of the case. The inspector submits the case to the supervising inspector for review and recommended action. The case is then referred to the Executive Officer with a recommendation from the supervising inspector for final action. When an investigation is referred to the Attorney Generals' Office, the deputy attorney general also evaluates the case to determine if there is evidence to support the allegation and the filing of an accusation.

Mr. Jones stated that when every accusation is served, the Attorney General's Office includes a document indicating that settlement discussions are available. Moreover, every deputy attorney general in the Licensing Section is willing to receive any credible information or documentation that might bear on the validity or strength of the case and forwards that information to the board's staff in connection with any suggestion for settlement of the case.

With the expanded cite and fine authority; marginal cases that otherwise could be referred to the Attorney General's Office will instead be referred to the Northern or Southern Compliance

Committees because a lower level of discipline can be achieved without filing an accusation.

- **Request to Provide Documentation to Support Any Claim for Cost Recovery Pursuant to Business and Professions Code section 125.3**

  Mr. Jones stated that statutory and case law uphold the right of the board to recover reasonable investigative and prosecution costs, including charges by the Office of the Attorney General, in a disciplinary processing (including by settlement). Neither the board nor the Office of the Attorney General produces every underlying detail or document for cost. The Office of the Attorney General has stated that statutory or case law do not require such detail.

  The board provides a certification as required by law. If additional documentation is requested, the board will provide a breakdown of the costs.

- **Request that Standard Terms for Discipline Not be Used**

  Mr. Jones reported that the board has identified the "standard" terms and conditions of probation that it wants imposed on all probationers. These standards have been refined over the years through its experience of monitoring probationers. The use of standardized language ensures certainty and consistency, including the intent and meaning of particular probationary conditions. This lessens the possibility of unfair or arbitrary treatment of any individual. Each instance of discipline is tailored for the individual cases. This is achieved by the actual discipline, whether it is revocation, suspension or probation. It is the probation terms and conditions that are "standard" and specialized conditions are identified in the disciplinary guidelines as "optional" conditions of probation.

  Mr. Cronin, California Pharmacists Association, asked how much of the time inspectors are spending on inspections.

  Supervising Robert Ratcliff responded that the Compliance Team's main focus is to do the compliance inspection. He added that each inspector has been assigned a given number of inspections to be performed for the month. Inspectors complete the inspections and their caseload as well. In addition, the inspectors have been asked to perform 30 percent of their inspections in non-traditional work hours. He added that it is up to the inspector to decide how much time to dedicate to inspections but during the course of a month it presently amounts to 78 percent of the inspectors' work time.

  Mr. Cronin stated that the CPhA is disappointed with the committee's recommendation because they had provided comments on the Disciplinary Guidelines. He asked about the type of input the committee solicited from organizations that provided comments. Mr. Jones responded the board held a public meeting specifically to receive input from individuals.

  Mr. Cronin stated that they did not have the opportunity to respond in advance of the enforcement Team meeting. He complained about the lack of consistent information received on laws and regulations from different inspectors. He suggested that the board facilitate discussions with professional organizations for their interpretations of pharmacy law.

  Mr. Jones stated that the board did convene a special meeting to allow comments on cases that had gone through the disciplinary process. Ms. Powell reported that during the meeting there was a very in depth discussion with Carlo Michelloti (California Pharmacists Association), Ron Russo (Attorney General's Office) and others.

Mr. Cronin responded that they never had the opportunity to address the issues the way that CPhA wanted to present them.

Mr. Jones stated that there was an open invitation to bring issues before the committee that the committee could review without conflict. He added that it is his intention to assure a fair process.

Mr. Cronin stated that inspectors are not learning some of the very basic things about pharmacy law. He added that another issue deals with violation notices and providing the information needed and then getting this removed from the record. He added that he has made several requests from supervising inspectors and inspectors and has not received a response.

Ms. Harris stated that the board would review the request.

Mr. Cronin stated that the professional organizations want to work with the board to resolve these problems and they have offered to talk to the board.

Mr. Jones stated that the board's public meetings are held specifically to solicit public comment and the board will continue to provide these opportunities, which are now set for twice a year.

Mr. Cronin acknowledged that the board is moving in the right direction with efforts to handle enforcement cases within 60 days and doing routine inspections.

Mr. Goldenberg asked how new inspectors are trained.

Supervising Inspector Ratcliff explained that new inspectors attend a 2-3 week training class in Sacramento, moving from desk to desk in the office to receive an overview of the licensure and enforcement processes. Part of the training process focuses on reading and researching items in the lawbook. He added that new inspectors are slowly transitioned in the field where they spend six weeks working side by side with another inspector working on complaint investigations and routine inspections. New inspectors work then with a supervising inspector to determine if they are ready to work on their own. Inspectors are encouraged to contact the team leader or the supervising inspector with questions or advice. Mr. Ratcliff added that clarification guidelines are communicated to all inspectors via e-mail to clarify the law.

Cookie Quandt, Longs Drugs, acknowledged the board's training efforts for inspectors. She stated that Longs has also received incorrect information from inspectors dealing with pre-fill prescriptions and getting advice that the date the prescription was authorized has to be on the prescription label. She added that this issue was discussed many years ago and new inspectors need to be brought up to date. She added that another issue dealt with triplicate prescriptions when pharmacists were advised to write the diagnosis on each triplicate prescription.

Ms. Harris explained that as guidelines for clarification are addressed, they would be published as guidelines and presented on the Website and communicated to inspectors.

Ms. Quandt referred to policy guidelines regarding expiration dates and the ambiguities that leave no room for the pharmacist's professional judgment.

Ms. Harris stated that the guidelines direct pharmacists to use their professional judgement. She stated that if there are ambiguities in the guidelines, they should be directed to the board.

Mr. Cronin referred to the Pharmacist Recovery Program and the issue of substance abuse by health care professionals. He added that the California Pharmacists Association has requested that

the board review the current program and evaluate the need for reform. He introduced Grant Vincent, retired dentist, Kent Howard, practicing dentist and member of the dental board's diversion evaluation committee, Kevin McCauley, physician, and Kenton Crawley, PharmD.

Dr. Crawley, PharmD., talked about his experience as a pharmacist who lost his license because he self administered Demerol, leading to an overdose. He added that as a felon, he is now a recovering addict with almost three years of sobriety. He added that he would like to give back to the profession, his experience having lived through the rehabilitation process. He stated that he would like to share with the board alternatives to what he feels is a punitive disciplinary model. Dr. Crawley stated that in a letter he wrote to the California Pharmacists Association, he described four points as follows:

1. Licensees currently encounter a punitive action usually from the California State Board of Pharmacy
2. A criminal pathway is a natural and predictable consequence of this course of action.
3. Very little rehabilitation guidance occurs from the Board of Pharmacy and the Mental Health Network (MHN) (formerly OHS).
4. There is a complete absence of peer substance abusers involved in decision making of his treatment plan and for his rehabilitation.

Kevin McCauley, physician, discussed the absence of advocacy on addiction. He stated that it is now know that addiction fits the disease models and that the preventive risk management viewpoint should eventually take over from the reactive punitive viewpoint. He added that this protects the investment of the professional, as well as protects consumers.

Kent Howard, dentist, stated that he has worked with recovering dentists and staff for approximately 10 years. He added that the American Medical Association and the American Dental Association have recognized chemical dependency as a disease and treating it as such.

Grant Vincent, retired dentist, stated that he became sober 17 years ago and worked on a committee in efforts to change behavior in others and he stressed the benefit he has had in helping others.

Mr. Cronin stated that they are asking the board to place this issue on the agenda for the next board meeting and to evaluate what other boards are doing.

Mr. Jones stated that to move in this direction would require legislative action. He asked if the CPhA would sponsor such legislation.

Mr. Cronin responded they they have not examined the issue but they are willing to discuss and review it.

Mr. Elsner acknowledged the speakers and suggested that the board agendize the item for discussion at the next board meeting.

Ms. Harris explained that the board has legislation that was passed in 1985 where the board uses one central contract with MNH. She added that the board does monitor the program, participates with PRP and develops the treatment contracts. The board has a pharmacist recovery team that monitors probationers as well as reviews the contracts and makes recommendations.

Ms. Harris stated that pharmacists could access the program without the board's knowledge. This

usually is the result of an ongoing investigation. She added that when the board completes an investigation, it determines whether a pharmacist should go through the diversion program or not. She added that diversion offset costs. In criminal offenses, the recovery program is a term of probation. She added that it is a public safety issue when a disciplined pharmacist continues to have access to drugs.

LEGISLATION AND REGULATION COMMITTEE

Regulation Report and Action

Board Approved – Pending Administrative Approval

- **Quality Assurance Program (Adopt Section 1711) – Proposed Amendments Based on Comments Received during 15-day Comment Period**

  Chairperson Andrea Zinder reported that in May, the Quality Assurance Program regulation, as adopted by the board at the April 2001, board meeting, was published. In response to that notice, the board received four comments on the proposed quality assurance regulation. She added that the Legislation and Regulation Committee suggests further revisions to the regulation in response to the comments received.

  Ms. Harris referred to four comments that were received from Albertson's that were handed out during the board meeting.

  Paul Riches, Legislative Analyst, referred to the proposed additions to the language and explained why the changes were made. He referred to subdivision (a) where a change was suggested to clarify the intent of the mission of the Quality Assurance Program.

  Mr. Riches referred to the changes in paragraph (c) where it states "Each quality assurance program shall be … "described" was changed to "manage." He added that this change provided a clearer statement to reflect the board's direction for pharmacies regarding their quality assurance programs and the role of the policy and procedures and guiding those programs. He referred to the policies and procedures and that they are available in an immediately retrievable form.

  Mr. Riches referred to the next change in subdivision (c) where it addresses the review and revision of the program prior to renewal. The board received comments about this, particularly from the chain drug stores where they renew their license on different schedules. He added that because the review process may not coincide with the timing of license renewal and because it is an unenforceable mandate, the committee recommends its removal. He added that quality assurance program policies need to be revised periodically, consistent with good practice.

  Mr. Riches referred to the change in the next sentence in subdivision (c). This was the result of a comment that vast majority of prescription errors are discovered by patients. This language was added to clarify the process for patient notification.

  Mr. Riches referred to the changes made to subsection (e) under the numbered items. These changes are simply refinements in the language to increase clarity. He referred to the last paragraph in subsection (e) regarding notification to pharmacy personal regarding the outcome of quality assurance reviews. He added that an issue was raised that this might impact other personnel actions that arise out of error and may interfere with other pending personnel matters. The language was changes to avoid this problem but still require pharmacies to make an effort to get this information from the quality review process to the pharmacy personnel.

Mr. Riches referred to the changes in subdivision (f) regarding retrievable records. Documents need to be available in the pharmacy as stated above but if it is more efficient to maintain electronic copies, this should be allowed.

Ms. Powell referred to subsections (f) and (g) and stated that it is not clear enough that if errors are found from the quality assurance program, that the board cannot use this information against them. She added that this could present a conflict because it would keep the quality assurance program from subject to discovery, (civil or otherwise), if the board initiated a disciplinary case that would become a public record. She recommended that the regulation be clear to every board member, exactly what the extent of the shield is as far as the information being in the quality assurance program.

Ms. Powell expressed concern because the regulations make it clear that the board would not take action if errors are found in the quality assurance program, and the board finds information that requires disciplinary action.

Mr. Powers agreed.

Mr. Jones stated that if this is a no-fault system, then it becomes a board policy issue as to what the inspectors will do if errors are found. He added that otherwise, errors will not be reported and it was not the board's intention to create a document that hinders reporting of errors.

Mr. Powers expressed reservations about the program because pharmacists would not report something that may incriminate them.

Mr. Elsner reminded the board that the board initiated this proposal because it was not intended to be self-incriminating and not a means to punish those that were trying to self-assess and correct their shortcomings. He added that if the board is going to change its commitment, which is the commitment that everyone agreed with, the board is going back on that commitment. He suggested that the board not view this as a punitive endeavor.

Mr. Riches stated that the research that this effort was based on is clear in terms of how you deal with quality assurance and error reporting. He added that a blame-free system is the only way to effectively implement this type of quality assurance process. Otherwise, it generates a system of non-reports and a system of non-learning. It is an unusual position, in many ways, for consumer protection and a represents a difficult policy choice that the board made since day one.

Ron Diedrich, Deputy Attorney General, stated that according to subsections (f) and (g), it is not a blame free system, and there is uncertainty and some inherent conflict between the two subsections. He referred to the last sentence were it states that the board may review quality assurance records to protect the public health and safety or fraud and this is reinforced in subsection (g) that states "or other proceedings as provided in subdivision (f). He added that the review is not a proceeding, it is a review, and the only proceeding that would be recognized is either administrative action or an unfair business complication action, which is in fact what the last sentence in subsection (f) provides for. He added that the conflict comes in (g) when you provide for the information map in discovery. He added that this is fine, except, if you take a proceeding a allowed in paragraph (g), then all of the information that is not discoverable, becomes public record. Because that is the evidence and the proceeding comes out of a public forum, there is no need for discovery, it is public record. He added that you have not shielded the information, nor have you created a blame-free system within the two paragraphs.

Mr. Riches stated that this would seem to be all the more reason to not use quality assurance records as the basis of disciplinary action.

Ms. Harris stated that if the board did take disciplinary action, it would be based on a consumer complaint or found through an investigation. She added that the board inspectors would be looking for a quality assurance program and this would not preclude the board from taking disciplinary action based on the existence and implementation of a quality assurance program.

Mr. Riches stated that the shield deals with the records and the quality assurance program. It is not a shield from the prescription records and dispensing records for patients. You would not want to take the pharmacies self-examination and use it against them. This will not remove errors from the books but is intended as a self-examination resulting from errors made that will not be used against the pharmacy.

Ms. Harris stated that it is not the board's intent to go on a fishing expedition to find prescription errors.

Mr. Diedrich raised two issues; 1) Underlying information from an improper source does not apply to administrative litigation, 2) If you did not use the information for a disciplinary action initially and instead took the information from another source, the fact still exists that the quality assurance records are there. He added that he did not know if they could be shielded from this type of action because it would run afoul with discovery proceedings in Government Code 11476 for discovery and litigation.

Mr. Riches stated that possibly language needs to be crafted on the discovery provision to tighten it up so that it is consistent with the policy direction the board has given. He added that it was the board's policy to implement a quality assurance system, largely based on principles discussed in the Institute of Medicine report. Those principles include having a blame free reporting system that would allow pharmacies to learn from their mistakes and not be punished by their effort to learn from their mistakes.

Ms. Strom stated that as a policy direction for the board, the concept of blame-free environment is one that encourages reporting, not a blame-full environment, which prevents reporting.

Mr. Riches stated that part of the board's enforcement obligation is that pharmacies will have the shield and will have the opportunity to get self-examination without punishment. He added that inspectors will review the quality assurance programs and will not file an accusation based on the information in the files because this would void the purpose of the program.

Ms. Powell referred to subdivision (f) where it states that the board may review quality assurance records. She added that in statute, it is made clear that the board's has authority to investigate any incidence that is found in a quality assurance program. Within the regulation, it is not clear what the board's public policy decision is and how far it goes.

Ms. Strom asked for further clarification on the time frame as to when a pharmacy would have to comply with having a program in place, if an undetected error occurred in the past.

Ms. Harris stated once the investigation started, the pharmacy would be required to present documentation and provide the board with a review.

Mr. Riches stated that the process is triggered by the discovery of the error.

Ms. Harris stated that the board has very rarely filed an accusation on prescription errors, and that these types of cases go before the Northern and Southern Compliance Committees or an office conference.

Mr. Diedrich stated that the regulations may have problems getting through the Office of Administrative Law because Business and Profession Code section 4125 (d) states that the privilege shall not prevent review of a pharmacy's quality assurance program and records maintained as part of that system by the board, as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the pharmacy. He stated that this is mandatory language in the statute that says that you shall not prevent access in order to take disciplinary action and if you take a no-fault position in your regulation, you may be running afoul of your statute authority for peer review records.

Mr. Riches asked if the board was at the point of pursuing a disciplinary action, that's not an issue of board inspector going into a pharmacy and looking at their program.

Mr. Diedrich responded that it might be.

Mr. Riches asked what is in the statute that tells the board they have to pursue a disciplinary action?

Mr. Diedrich responded that there is nothing in the statute that states the board has to take a disciplinary action. He added that clearly, the issue of taking a disciplinary action is a discretionary act but what it does say is that you cannot preclude the board from taking a disciplinary action. If you attempt to put in place regulation that makes it de facto blame-free (you can't take that information and use it) which (f) and (g) suggest, that's different from saying you have to. What you can't say is you are precluded from using information just from a peer review document and use that as the basis for disciplinary action. Once you do this, it becomes public record and you run a foul of subsection (g) about no disclosure.

Mr. Riches stated that the statute allows the board discretion to take disciplinary action when it sees fit, and the fact that the board has made a decision in its regulation, in this particular case, most likely they aren't going to, that's a consistency problem?

Mr. Diedrich responded that coupled with the way the statute is worded that says the privilege "shall not prevent. It says you cannot do anything to prevent it. If you put in an automatic blame free system, then you are in fact preventing it and that runs a foul of B&PC 4125 (d).

Mr. Riches stated that on the one hand, the board has discretion to pursue disciplinary action, but when the board, using that discretion, decides not to take disciplinary action it becomes a consistency problem?

Mr. Diedrich stated that yes because it is not discretion if by regulation you say, "cannot" in every circumstance. You have to allow the board to continue to have discretion because once you put into place regulation that blanketly prohibits. He added that the intent articulated here. You are.

Mr. Riches stated that the quality assurance record is not the prescription record, they are not protected under statute or regulation available under the board's authority. If the board pursued a disciplinary action for medication error, that would be the grounds for which the board would do this.

Mr. Diedrich suggested that if you mandate the non-use and it is not in the regulation but is the

board's intent, it is the opposite of what the intent was. In paragraph the board can review the documents and that they can use them as necessary to protect the public health and safety. In paragraph (g) you say the proceeding to implement (f).

Mr. Jones asked counsel for recommendations. He added that the blame free environment has huge public policy implications. The board is here for consumer protection and if it can reduce errors in pharmacy practice by this process, it protects many consumers.

Ms. Powell stated that the board does not need to repeat the statute within the regulation. She suggested that the board remove the last sentence in subdivision (f) and remove all of subdivision (g).

Mr. Gubbins stated that he has supported the idea of quality assurance but his fear is that the board will end up with language that is unintentionally not what the board has decided. He referred to subdivision (e) where it states "A written record of the quality assurance review shall be retained in the pharmacy in an immediately retrievable form." He added that the word "immediate" is a problem. He asked if this could be changed.

Ms. Powell suggested the use of the word "readily".

Mr. Riches stated that one concern raised was the documentation requirement and the form in which they are maintained. The general standard for readily retrievable and is 72 hours. Concern was expressed for pharmacies that may create their quality assurance review between the time when the inspector arrives in the pharmacy and the 72-hour time frame.

Mr. Elsner expressed concern that the regulation needs amendments. He added that Mr. Mazzoni made a proposal at the last meeting that was not adopted by the board. He felt that it should be reviewed in redrafting this. That the self-assessment form alone shall not be the impedance for a disciplinary action. He stressed the importance of honoring the commitments that the board has made on this.

Ms. Strom referred to the routine inspections. She asked if the language states "readily available" that it must be a record that remains in the store. Everyone's name will be on this document. She expressed concern that this would provide the inspector with a name in which to issue a citation.

Mr. Riches stated that the very clear discussions with the Enforcement Team indicated that this would not occur. And, the very clear direction from the board is that the board is not going to pursue disciplinary action against pharmacists based on information found in the review documents. The fact that the information is there does not mean that the board has to pursue disciplinary action.

Ms. Powell asked if the board needs the quality assurance records to prove the pharmacy is not reporting.

Mr. Riches stated that if the board receives a complaint and investigates a pharmacy and the reporting was not done, the basis for that disciplinary action is failure to do the quality review process.

Ms. Powell stated that you would need to show the records to show that they can do it.

Mr. Tilley expressed concern that the board is becoming a more punitive board. He added that anything that is written down could be used against the pharmacist.

Mr. Jones referred to documents stored in the computer that can be printed out and he asked if this is an adequate measure to satisfy requirements. He added that he wants to assure that this regulation would not be made more burdensome.

Mr. Ratcliff stated that when a reported medication error is reported, inspectors will inspect the pharmacy and if this is the first time the pharmacy is aware of the issue, the inspector would ask to see the QAP. The pharmacy will initiate the QA program and investigate the error. If the pharmacy does not have a QAP in place, the inspector will issue a correction, probably a violation notice, then figure out the error. The complaint form indicates whom they talked to in the pharmacy.

Ms. Herold stated that at the last board meeting during the regulation hearing, a motion was made by Mr. Mazzoni that the board add into subsection (h) the evidence of information in the QAP shall not be used as the sole probable cause of initiating an investigation. She added that the board might want to reconsider reinserting this language to provide for the integrity of this regulation and to safeguard the board's principals in adopting the regulations and moving forward with the statute in the first place.

Ms. Strom responded to Mr. Tilley's concern that the regulations seem punitive. She referred to the Northern and Southern Compliance meetings where many of the errors that occur, are handled very sloppy. She added that if these errors were handled in a complete and proper manner, it would not have come before the board. She added that in many cases, the pharmacists are not even aware of what quality assurance review is. By making the requirement that they have such a program, at least there will be some minimum level of understanding of what occurred and how to correct the problem in the future.

Mr. Hiura stated that it is his intention, as well as other pharmacists, when filling prescription to not make any errors. He added that most pharmacists do not realize that an error occurred and too much time may have gone by before the error is found.

Ms. Harris stated that the language will go out for 15-day comment period, then on to the department and then to OAL. She added that the board has a mandate to adopt the regulation by September 1, 2001.

Mr. Gubbins suggested an amendment to the language to reflect the requirement of "written" documentation to "electronic" documentation.

Mr. Jones stated that when an error is found, the pharmacy needs to do something about it. And, not only does the pharmacy need to produce this documentation in electronic format, they also need to produce it on the spot as a written document. He added that this is the best risk management that the pharmacy's can do for themselves.

Ms. Powell recommended removing the language that is already in statute (subdivision (f), last sentence) and remove all of subsection (g), this would allow the board to still have the quality assurance program in place and to move forward. Also, change "written record" to "record." She suggested that in the mean time, interested parties can work on the regulation moving forward.

MOTION: To delete the last sentence of subsection (f)

M/S/C: ZINDER/JONES

SUPPORT: 10 OPPOSE: 0

MOTION: To remove the word “written” in the first sentence

M/S/C: ZINDER/JONES

SUPPORT: 10 OPPOSE: 0

MOTION: To remove the term “immediately retrievable” to “readily retrievable” in subsection (e)

M/S/C: GUBBINS/TILLEY

SUPPORT: 8 OPPOSE: 1 ABSTAIN: 1

Mr. Powers expressed concern and urged a no vote because the document should be immediately available.

Steve Gray suggested that the board keep the word “immediate” because if you don’t have the record immediately then an inspector would ask the pharmacist to mail it and then it is an issue of reviewing patient records on site.

Bruce Young stated that the language is somewhat conflicting with the ability to store off-site records. The details were explained and he asked that the language be clarified as to the exact meaning of the term “immediately retrievable.”

Mr. Riches clarified that the language should read that the records shall be “immediately retrievable” in the pharmacy.

Steve Gray, Kaiser Permanente, suggested that the board reconsider adding subsection (g). He stated that the important part of (g) was the second sentence. The first part of (g) is admittedly a repeat of statutory language. The second sentence of (g) is a clarification of the board’s intent and the statutory language was recommended in previous hearings and submissions to the board. He added that it has been a problem where they do not have access to the documents but we will subpoena the people to come in and they can tell us what went on in the quality assurance committee and in the committee’s that reviewed the records. He recommended that (g) be kept without the first sentence and keep the first sentence.

Mr. Gray referred to subsection (a) to regulation 1716. He stated that he is not recommending a change but there are problems with section 1716. He added that there will be more problems as it applies to this when the statute change goes into effect at the first of the year and gives the pharmacist the ability to change the dosage form and the directions for use. He added that there are also some things in the Pharmacy Practice Act where pharmacists can make changes that were under policies and procedures. He suggested that the board leave it described in 1716 and ask the Legislation and Regulation Committee to engage at a future date, a review of 1716 to update it according to current law. He added that this is specifically in response to Senator Figueroa’s office which is off track, that refers to an error as any deviation that was not allowed by law which is what we intended and 1716 is very narrowly stated as from the prescriber. There are deviations allowed that do not have to be agreed to by the prescriber.

Ms. Harris stated that the end of subsection (b) addresses this issue by stating "or any variation allowed by law."

Mr. Young acknowledged Mr. Elsner's comments about the faith and spirit that these were adopted and he added that they supported legislation. He added that he is actually one who argued strongly that discretion should be left to the board. He added that now, because the statutory language becomes a problem, he now believes that they should be cautious, not only with the NABP language and be more succinct in legislation because they tend to get misinterpreted by staff who may see this as an enforcement tool.

Mr. Young referred to comments made by Bill Powers that self-reporting does not work. He added that it does not work if there is a disciplinary tool attached. He added that the Governor said in signing that there are already existing programs in place. He added that his office responded to the Governor's office that this is a productive tool. Now, as they hear the word "timely basis" and "not necessarily" and do not see those things in writing, it really feeds the suspicion about the purpose of this. He stated that he wanted to clarify subsection (a) that each pharmacy shall establish or participate in an established quality assurance program. He asked if this was intended so that a chain has one established program. Or, if independent, decides to adopt another program. He asked if the language would suffice.

Mr. Young referred to the last part of (c) and their concerns regarding "medication error threatens a patient's well being." He added that they believe that this language is so vague that it will ultimately have to be litigated to define what is well being. He added that it is overly broad and not specific and besides, there is already an obligation for pharmacists in their professional duty to notify patients if they believe there is a problem in filling the prescription. He added that the words "well being" add a specter of unknown and would be followed by costly and lengthy litigation. He suggested the language be changed or amended so case law does not have to be used to determine a patient's well being.

Mr. Riches referred to Mr. Gray's issues and stated that this is once again following through on the board's policy directive to create a system that makes pharmacists and pharmacies comfortable engaging in their own self-evaluation.

Mr. Diedrich stated that a regulation can only clarify or implement statutory authority and section 4125 does not provide statutory authority. He added that section 4125 refers to records. He did not believe that the board has the statutory authority through the regulatory process of precluding somebody from pursuing their civil rights in litigation from issuing subpoenas to testify.

Cookie Quandt referred to subsection (a) and the last part of the sentence where it reads "an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors." She questioned whether "quality pharmacy service" is pertinent in this particular regulation and this particular sentence. She suggested that the board determine cause and prevent future errors. She added that this is the intent of this regulation and it does not deal with quality pharmacy service.

Ms. Quandt also suggested that rather than have the one statement in (f) be moved to section (e) and state that and shall be retained in the pharmacy for one year.

Ms. Quandt also suggested the following statement in (e) be chanced to: "The pharmacy shall inform pharmacy personnel of changes made as a result of the quality assurance

review." She added the board has already discussed above in (4) the recommended changes to pharmacy policy, procedure, systems, or processes …She added that it is redundant to name them again.

MOTION: Recommendation to amend the language in subsection (c) to remove "well being" and to "notify the patient".

M/S/C: POWERS/ELSNER

SUPPORT: 10 OPPOSE: 0

President Litsey concluded this hearing.

Recently Approved

Informational Hearing – Cite and Fine

Proposed adoption of Cite and Fine Regulations for Violation of the Confidentiality of Medical Information Act (CMIA) and Internet Pharmacies for Violation of Business and Profession Code Section 4067

Mr. Riches referred to the draft regulation to establish a cite and fine system for violations of the Confidentiality of Medical Information Act and for violations related to dispensing on the Internet based on SB 19, passed last year and signed by the Governor. He added that the authority and the nature of these citation and fine systems are such, that they do not operate under the board's general cite and fine authority. He added that the Administrative Procedures Act requires rulemaking agencies to conduct information hearings prior to noticing rules for formal action.

Ms. Harris referred to corrections to section 1778.3 – Contested Citations and 1777.5 and stated that the appeal process is one that would go to the Attorney General's office because the cite and fine for these violations would be issued by a committee of the board. The appeal process would not go to office conferences as it does when it is issued by the Executive Officer.

Mr.Gray expressed concern for pharmacists filling a prescription from the Internet without knowing whether or not it was based on a good faith examination as required under the Medical Practice Act and would therefore face a citation and fine. He added that the Medical Practice Act is not clear and there is a lot of controversy as to what constitute a good faith examination. He asked how is a pharmacists would know and added that it will require considerable education. Also, there is confusion as to what is an Internet prescription versus an electronically transmitted prescription. He referred to issues with Intranet.

Ms. Powell referred to definitions that distinguish.

Mr. Riches stated if the pharmacy is licensed in California as a non-resident pharmacy, it couldn't dispense a prescription to a patient in California without a good faith prior examination.

Mr. Gray stated that there needs to be a lot of education regarding this issue or run the risk of shutting down a very valuable practice of treating patients in California.

Mr. Jones stated that telemedicine is advancing at such a rate, an exam can be completed over the phone lines and a good faith examination can occur without being in the state.

Mr. Riches stated that care needs to be taken and he referred to the fact that the Medical Board has chosen not to exercise its authority to establish telemedicine practice in California. He added that when you start treating and diagnosing patients from out-of-state by electronic means, a constellation of legal issues are raised.

Mr. Cronin suggested an amendment to section 1778.1 to include mitigation factors, whether or not the Medical Board has gone after the physician for not provided a good faith prior examination.

Mr. Cronin stated that the second issue deals with confidentiality. He added that there are federal regulations dealing with confidentiality that are similar. He added that there would be conflict and a major issue to inform pharmacists about what they can and cannot do. He suggested that the board work with the associations to define this for pharmacists.

Mr. Litsey concluded the information hearing.

LEGISLATION AND REGULATION COMMITTEE

Legislation Report

- **Introduced Legislation Relating to the Practice of Pharmacy**

Chairperson Andrea Zinder reported on the recommendations made by the Legislation and Regulation Committee.

SB 633 (Sher) – Mercury Thermometers

Chairperson Zinder stated that this bill requires any seller of mercury fever thermometers to be licensed by the board as a hypodermic needle or syringe handler, in addition to any other license they may hold (Public Resources Code 15026). Further, it requires the seller of mercury fever thermometers to provide the consumer with written instructions concerning careful handling to avoid breakage and proper cleanup should breakage occur (Public Resources Code 15026). This bill also requires the Board of Pharmacy to enforce this requirement. (Public Resources Code 15026).

Ms. Zinder stated that the Legislation and Regulation Committee recommends that the board adopt an oppose unless amended position on Senate Bill 633. The bill should be amended to remove the responsibility to enforce the law governing the sale of mercury fever thermometers from the board.

MOTION: Legislative Committee: Oppose SB 633 (Sher) unless amended.

SUPPORT: 8 OPPOSE: 0 ABSTAIN: 1

SB 1169 (Alpert) – Emergency Contraception

Ms. Zinder stated that this bill permits pharmacists to initiate a drug regimen based on a protocol for patients in outpatient care settings on emergency contraception.

MOTION: Legislative Committee: Support SB 1169 (Albert)

SUPPORT: 8 OPPOSE: 0 ABSTAIN: 1

AB 586 (Nation) – Laboratory Testing

Ms. Zinder stated that this highly technical bill could eliminate the ability of pharmacists to perform moderate clinical laboratory tests. Also, the bill requires pharmacists to perform waived clinical laboratory tests under the supervision of a laboratory director. She added that this bill permits pharmacists to perform skin puncture related to a clinical laboratory test.

Peter Kellison, California Pharmacists Association, encouraged the board to review this bill further before taking an oppose position.

The board agreed to work with the sponsors of the bill and the California Pharmacists Association to reach an administrative resolution with the Department of Health Services, which is the origin of an interpretation that led to the introduction of this bill.

Mr. Riches explained that the bill limits the authority of pharmacists to perform certain tasks and it changes the circumstances under which those tasks can be performed.

Mr. Kellison stated that recent amendments address the moderate complexity so there is no perception of a restriction of existing authority with regard to tests. He added that this bill tries to provide clarity between three very conflicting and confusing sections of law. He added that CPhA has legal opinions from the Department of Health Services and Legislative Counsel Bureau basically siding against the current authority that is perceived to be granted to pharmacists to perform skin puncture waived moderate complexity tests that in their opinion requires the bill to move forward. He added that they are very committed to working with the board to try and seek an administrative remedy that would not undermine the pharmacists' scope of practice.

Mr. Riches stated that the latest amendments to this bill addressed the board's principal concern that was the rescission of the ability to do moderate complexity tests.

MOTION: Support AB 586 (Nation) as amended

M/S/C: POWERS/TILLEY

SUPPORT: 9 OPPOSE: 0

Legislative Proposal – Sterile Compounding

Ms. Zinder referred to draft legislation that would increase the requirements for pharmacies that engage in sterile compounding. This proposal was developed in pursuant to a request from Senator Liz Figueroa (D-Fremont) and Senator Tom Torlakson (D-Antioch). The senators were responding to a recent case in Walnut Creek where contaminated drugs compounded in a pharmacy led to the deaths of three patients and the hospitalization of many others.

Mr. Riches stated that board staff has met with stakeholders and worked with the senators. The language is the initial draft from the board. He added that the bill is currently scheduled for hearing on August 21 in the Assembly Health Committee. He added that there is a lot of agreement about the need to address this issue.

Mr. Gray from Kaiser Permanente stated that they would submit their recommendation for amendments. He expressed concern that this proposal might overly address the problem and interferes with other valuable patient care issues.

MOTION: Legislation Committee – Sponsor the introduction and passage of legislation increasing standards for pharmacies engaged in sterile compounding.

SUPPORT: 9 OPPOSE: 0

Proposed strategic and ongoing objectives of the Legislation and Regulation Committee as Part of the Board's Strategic Plan.

President Litsey referred to the board's strategic plan and noted that the strategic goals of the Legislation and Regulation Committee had not been adopted.

MOTION: Accept the proposed strategic and ongoing objectives of the Legislation and Regulation Committee as part of the board's strategic plan.

SUPPORT: 8 OPPOSE: 1

ORGANIZATIONAL DEVELOPMENT COMMITTEE

Executive Officer's Report

The Communication Team Committee Report

Vickie Betker, representing the Communications Team, explained that the Communications Team is comprised of elected board staff consisting of two inspectors, two analysts and two clerical staff. She added that the team's mission is:

> To respectively promote effective communications between all Board of Pharmacy staff. To improve the performance of the organization as a whole and to work together as a team.

Ms. Betker stated that to reach these goals, the TCT facilitates staff meetings that include a recognition program for board employees. Recognition is acknowledged for length of service and accomplishments.

Ms. Betker reported on the June team building exercises that included a trip to a baseball game and an all staff picnic. The picnic provided staff with the opportunity to interact and get to know each other better.

Ms. Strom stated that board staff independently raised money for these events. She encouraged board member participation and donations in this effort.

President's Report

- **Committee Appointments**

President Litsey announced the following committee appointments:

Organizational Development Committee:	Robert Elsner, Chairperson John Tilley
Licensing Committee:	Holly Strom, Chairperson

	Donald Gubbins
Enforcement Committee:	John Jones, Chairperson Stanley Goldenberg
Legislation & Regulation Committee:	Steve Litsey, Chairperson Andrea Zinder
Public Education & Communications Committee:	William Powers, Chairperson Clarence Hiura
Competency Committee:	Holly Strom Clarence Hiura
Northern Compliance Committee:	Donald W. Gubbins, Chairperson Stanley Goldenberg Robert Elsner William Powers (training)
Southern Compliance Committee:	John Jones, Chairperson Steve Litsey John Tilley Clarence Hiura (training) Caleb Zia Andrea Zinder Holly Strom

President Litsey stated that Holly Strom and Don Gubbins will remain on the Licensing Committee.

President Litsey stated that even though members are assigned to each of the Northern and Southern Compliance Committees, the board will ask back-up participation as well, because of the many cases the board anticipates.

- **Final Adoption of Strategic Plan 2001/2002**

  President Litsey stated that at the April Board Meeting, the board approved the strategic goals of all committees except those of the Legislation and Regulation Committee (which had not yet developed its proposed list of strategic goals for the year). During the July Board Meeting, the board has the opportunity to select strategic goals for the committee for the year.

  He commented that the board's environmental scan has also been changed to reflect comments made by the board during the April meeting.

  Mr. Powers referred to the patient privacy issue. He added that there are several bills pending in the state legislature on patient privacy issues that have generated a lot of heat especially from the banks and insurance companies. He referred to AB 773 and asked the board to review this bill for a role that the board may be concerned about. He expressed concern about personal information that is obtained by any institution that is not approved by the customer or patients themselves. He added that this is especially relevant in terms of medical information that may be released.

Ms. Harris stated that this could be referred to the Legislation and Regulation Committee.

MOTION: Approve the Board of Pharmacy's Strategic Plan for 2001/02

SUPPORT: 9 OPPOSE: 0

- **Strategic Planning for 2002**

Ms. Harris stated that because there are three new board members, it was recommended that the board revise the 2002 Strategic Plan and hire a facilitator on April 26, 2002, to thoroughly go through the process.

MOTION: Perform a major revision to the board's strategic plan for 2002-03; add one day (April 26) to the board's April 2002 board meeting currently scheduled for April 24 and 25, 2002 in Sacramento.

SUPPORT: 9 OPPOSE: 0

2001 Budget Update

- **Attorney General's Office Augmentation Request**

Ms. Herold reported that the board received its Attorney General augment and it amounted to approximately one-third of the amount the board needed.

She reported that in May 2001, the board received a $143,000 legislative augmentation to its 2000/01 budget to permit increased spending for legal services from the Attorney General's Office for the year. The board was initially funded for $555,000 in such expenses, but had spent all this in late January, and had projected nearly $1 million in AG legal expenditures for the year.

She added that this augmentation, which was approved very late in 2000/01, was necessary because the board had overspent its AG budget for the third time in three years. Forecasting this as a potential problem one year ago, (in August 2000), the board submitted a budget change proposal to augment its 2000/01 budget for the Attorney General's Office. The Department of Finance denied the budget change proposal.

The board had projected a significant deficiency of about $400,000 more than the board's AG budget for the 2000/01. As a result, an augmentation (another budget change proposal) was submitted in early February 2001 for $430,000 to allow the board to continue to purchase legal services through June 2001.

In the end, the Department of Finance approved only a $143,000 deficiency augmentation request in April 2001, but also directed the board to cut expenditures. The board did so, in part by holding work on some AG cases, canceling a computer order, and postponing publication of *Health Notes* and *The Script* until the next fiscal year (which started July 1). The resulting adjustments provided the board with AG funding of $900,000.

Final budget figures for the year will be available in August, and will be provided during the October Board Meeting.

Ms. Strom stated that the Department of Finance's denial of the Attorney General's augment is

beyond belief. She expressed great concern for this in light of auditor general report that stated the board was not working its cases. So, now when many of the cases are ready to go to the AG's office, the board is unable to do this because of this denial and lack of funds.

Ms. Herold stated that the board was successful in getting an augmentation request for this fiscal year of an additional $540,000 that will allow the board to handle the cases that are already over at the AG's Office. She added that the board is aggressively managing cases and the intent is to have not only to have the investigations done in the vicinity of 90 days but to have the AG work the cases in no longer than six months. After this year, the board looses the supplemental funding and gets only $135,000 for an additional AG augment. She added that during the last three years, the board has spent over $300,000 more. To prevent future shortages, a budget change proposal for supplemental AG funding for 2002/03 is planned, which if approved would result in the board's AG budget being $855,000 per year.

Executive Officer's Report

- **Sacramento Office Staff**

Ms. Harris reported that Debbie Anderson, currently a staff analyst with the board, has been transferred to the board exam coordinator and rulemaking coordinator (regulations) position. She added that Ms. Anderson has been the board's budget analyst for four years, and in May, began working on the June pharmacist exam.

Susan Cappello, recently the board's citation and fine analyst, has transferred to another analyst position at the board where she will manage cases referred to the Attorney General's Office.

Genie Mitsuhara, who processed pharmacy technician and intern applications for the board left in late April. Her office technician position has been filled by Angelique Poindexter, who started with the board July 2. Ms. Poindexter comes from the Employment Development Department.

To ease the heavy workload that cannot be completed with existing staff, the board has hired two-part-time employees in non-permanent positions. Denise Wong will assist the board with processing exemptee applications and Adriana Yanez has been hired to assist the receptionist and with assembling and mailing applications.

Betty Thorson, a retired annuitant with the board, who prior to her retirement processed mail votes for the board, resigned at the end of June after more than five years with the board. Ms. Thorson most recently assisted the board by processing exemptee applications for medical device retailers and drug wholesalers.

Kim DeLong, who processes mail votes, has been promoted to a management services technician. She will continue to perform her current and additional, more complex, duties in her upgraded position.

Brenda Cartwright, who processes pharmacy applications, has been promoted to a staff services analyst and will perform more complex duties in her new position still dealing with the licensing of pharmacies and other premises.

In May, the board received resignations from two relatively new inspectors—Tim Black and Julie Hutchinson. Dr. Black worked for the board for 11 months and returned to community pharmacy. Dr. Hutchison worked for the board for just over six months.

The board has hired two new inspectors who started on May 31.

Ralph Orlandella, from Sacramento, who formerly worked in both community and hospital settings.

Rick Iknoian, from Fresno, who formerly worked principally in hospital settings.

Inspector William Wislosky has ended his second career with the board as a retired annuitant, and after working for the board for more than 25 years as an inspector.

The board currently has three inspector vacancies, and 19 pharmacists working for it.

BUDGET REPORT

Ms. Harris referred to the budget estimates and stated that the budget figures for the year will be available in August 2001.

Ms. Harris reported that the fund condition is $10,232,244 and according to an estimate prepared by the department in April, the board was projected to have 21.4 months of operation expenses remaining in its fund on June 30,2001.

Ms. Harris reported that the 2001/02 fiscal year started July 1, 2001. She added that it is expected that the budget for this year will be similar to last year's budget, except for the augmentations below.

- **Budget Change Proposals for 2002/03 or Future Years**

Ms. Harris stated that at the last board meeting, the board authorized staff to develop budget change proposals in the following areas (most of the proposals are resubmissions of budget change proposals denied by the Department of Finance in 2001/02, but which are still needed for effective board operations).

- Communication and Publication: one associate analyst to oversee the public education program, coordinate public information fairs and respond to press inquiries (1 staff position, $87,000)
- Organizational Development:
    1. budget realignment (needed for 2001/02 and ongoing years) to provide funding to budget areas under-funded in prior years, but which were funded from salary savings from unfilled inspector positions (estimated: $400,000)
    2. management reorganization: to establish two additional supervising inspectors, one chief of enforcement, and one attendance supervisor for the office who will also handle recruitment for vacant positions (4 staff positions, $420,000)
- Enforcement: two analysts and one clerical person for the Complaint Unit to process complaints timely and monitor the status of complaints and investigation cases (3staff positions, $217,000)
- Licensing:
    1. one technician to aid in the licensing of applicants for pharmacy technicians, interns, foreign graduates and pharmacists ($67,000)
    2. one technician to process pharmacist-in-charge applications and follow up on changes in permit indicated on renewal applications ($67,000).

APPROVAL OF MINUTES

Full Board Minutes – April 25 and 26, 2001

MOTION: Approve the minutes.

M/S/C: STROM/ZINDER

SUPPORT: 8 OPPOSE: 0 ABSTAIN: 1

Northern Compliance Committee Minutes – May 16, 2001

President Litsey stated that the minutes were provided as information.

Southern Compliance Committee Minutes – April 11, 2001

President Litsey stated that the minutes were provided as information.

Southern Compliance Committee Minutes – May 30, 2001

President Litsey stated that the minutes were provided as information.

NEW BUSINESS/AGENDA ITEMS FOR FUTURE MEETINGS

Mr. Powers stated that President Bush submitted a proposal for prescription drug coverage. He added that, as a representative of senior organizations, the proposal is meaningless in terms of the savings it promotes and it is actually burdensome to the pharmaceutical area because pharmacists will have to comply. He requested that staff investigate this proposal and bring back information so a recommendation can be made to the pharmacist's organizations that are against this proposal.

Mr. Cronin stated that he would like to reiterate his objection to the SCC and NCC minutes that relate all of the accusations but none of the mitigating factors, or the conversations during the meetings.

Ms. Powell stated that the board has gone over this issue. She added that they are minutes, not transcripts.

ADJOURNMENT

President Litsey adjourned the meeting at 5:40 p.m.