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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: April 25, 2001 -- 1:00 – 3:00 p.m.
April 26, 2001 -- 8:30 a.m. – 3:45 p.m.

LOCATION: Department of Consumer Affairs
400 R Street, Suite 1030
Sacramento, CA 95814

BOARD MEMBERS PRESENT:
Robert Elsner, President
Steven Litsey, Vice President
Caleb Zia – Treasurer – Arrived at 2:30 on April 25
Darlene Fujimoto
Richard Mazzoni
Andrea Zinder – April 26, 2001 only
John Jones
Donald Gubbins
William Powers
Holly Strom

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

CALL TO ORDER

President Elsner called the meeting to order at 1:00 p.m. on Wednesday, April 25, 2001.

ANNOUNCEMENTS

President Elsner announced that it was Board Member Darlene Fujimoto's final board meeting, having served on the Board of Pharmacy for over eight years. He added that this was also Rich Mazzoni's final meeting unless Governor Davis re-appoints him.

President Elsner announced that his and board member Holly Strom's terms expire in June 2001.

COMMITTEE REPORTS AND ACTION

ORGANIZATIONAL DEVELOPMENT

Chairperson Steve Litsey reported on the committee meeting of March 15, 2001. He noted the following items recommended by the committee:

- **Direct 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 this year).**

  Communication and Public Education: one associate analyst to oversee the public education program, coordinate public information fairs and respond to press inquires (1 staff position, $87,000)

  Organizational Development:

  1. budget realignment (needed for 2001/02 and ongoing years) to provide funding to board 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 (3 staff 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).

MOTION: Direct staff to develop a budget change proposal to hire staff as outlined above.

SUPPORT: 7 OPPOSE: 0

- **Approve the strategic plan update for the Organizational Development Committee for 2001/02 (these were all strategic goals for 2000/01):**

1. Pursue budget change proposals to meet identified program needs (July 2002)
2. Reorganize the board management structure to oversee board programs and staff (July 2002)
3. Pursue regulatory changes to require inspectors to file annual conflict of interest statements with the Fair Political Practices Commission (July 2002)
4. Manage the board's financial resources to ensure fiscal viability and program integrity

MOTION: Approve the strategic plan update for the Organizational Development Committee for 2001/02.

SUPPORT: 7 OPPOSE: 0

- **Procedural issue for referral of items to the board's Legislative and Regulation Committee (to be added to the board's strategic plan)**

Mr. Litsey reported that the committee discussed the proper referral process for items to be brought to a committee. Specifically, when does an item undergoing a legislative or regulation change, needs to return to the originating committee for modification (e.g., Enforcement or Licensing) or remain in the purview of the Legislation and Regulation Committee?

Mr. Litsey stated that the committee developed the following language for board consideration:

> No new material is to originate in the Legislation and Regulation Committee and materialize as a regulation or statutory change unless the board has existing policy in the issue area or the concept is submitted to the board for consideration.

Ms. Harris clarified that issues sometimes come before the Legislative and Regulation Committee that should have come from other policy committees. Discussion from board

members indicated that in most cases such policy committees do provide review and comment, and the proposal seems unnecessary or needs further refinement.

MOTION: Refer the language back to the Legislation and Regulation Committee for further consideration.

M/S/C: POWERS/FUJIMOTO

SUPPORT: 7 OPPOSE: 0

Mr. Litsey referred to the board's proposed schedule for 2001 and 2002 board meeting dates.

Mr. Jones requested that the board change the October board meeting from October 17, 18, 2001 to October 15, 16, 2001, as follows.

2001 Meeting Dates:

July 25, 26, 2001	San Diego
October 15, 16, 2001	San Francisco (If possible, start meeting in the afternoon of October 15)

2002 Proposed Meeting Dates

January 23, 24, 2002	Los Angeles (near LAX)
April 24, 26, 2002	Sacramento
July 24, 25, 2002	San Diego
October 23, 24, 2002	San Francisco CSHP Seminar is October 3-6, in Anaheim CPhA's Ed Fair is October 27-29, in Sacramento, NABP's District 7 & 8 Meeting is not yet set.

The board accepted this meeting date schedule.

Executive Officer's Report

- Personnel Changes

Ms. Harris reported that the following board staff has transferred to other state government positions:

> Ruta Arellano, an associate analyst with the board, who coordinated the board's rulemaking processes (regulations) and the pharmacist's licensure exam, left the board at the beginning of March.
>
> Linda Alderman, a special project analyst with the board, who among other duties established the board's website, left at the beginning of March to work for the Cemetery Program.
>
> Candace Raney, a board enforcement analyst, left the board at the end of March.
>
> Genie Mitsuhara, an office technician with the board, accepted a promotion with the Chiropractor Board. Ms. Mitsuhara has been with the board 3.5 hears and will be leaving on April 26.

Ms. Harris reported that training has continued with the six new inspectors hired since November 8.

Ms. Harris noted that the board currently has three inspector vacancies, and 20 pharmacists working for the board. Board interviews for the remaining inspector positions have taken place. The board has made a tentative offer to one individual who expressed interest in the position, and will conduct a second interview with another candidate just before the board meeting. She added that the board is seeking Northern California inspectors for these two positions.

Ms. Harris added that the final filing date for the next inspector civil service exam was April 2001. Interviews for these candidates who rank on the civil service list for inspector are scheduled for the last week in June.

BUDGET REPORT

Ms. Harris reported that the board has overspent its Attorney General budget for the year. The board depleted its AG budget of $550,000 at the end of January. This was not unexpected; the board submitted a budget change proposal in August 2000 to augment its 2000/01 budget for the Attorney General's Office. The Department of Finance denied this request. As a result, the board submitted another deficiency request in February 2001, which is still pending review by the Administration.

Mr. Powers expressed concern and asked what options the board has to resolve the deficiency since the board cannot stop work at the Attorney General's Office.

Ms. Harris explained that one year ago when another deficiency was projected, the board was able to redirect funds from vacant inspector positions to cover the AG deficiency

expenditures after the Department of Finance turned down the board's initial augmentation request. In November 2000 when the budget change proposal for 2000/01 was denied, the board asked the director of Consumer Affairs to intervene. We were assured that this occurred with high level staff within the Department of Finance but the budget change proposal remained denied.

President Elsner commented that at the direction of the Department of Consumer Affairs, the board will need to address its concerns with the department first.

Mr. Powers recommended that the board seek leadership assistance from the department.

Ms. Fujimoto expressed concern that because the board has hired more inspectors, the situation will continue to worsen with less money available and new inspectors generating more cases.

Ms. Harris and Mr. Powers will both contact Director Hamilton and request her assistance and intervention.

- Communication Team Update

Inspector Lin Hokana reported that The Communication Team (TCT) has begun its fourth year at the board. He added that he, Vicki Betker and Pamela Martinez are new members voted onto the TCT at the last staff meeting. He added that terms expired for Sandi Moeckly, Cassandra Kearney and Robert Grimm.

Mr. Hokana reported that the TCT's goal is to improve communications between staff and management, raise the morale in the office and strengthen the Board of Pharmacy's team.

Mr. Hokana reported that the TCT has planned several team-building exercises for staff participation. The team is hosting two events in June; a staff afternoon picnic and a evening River Cats baseball game. He added that the team is involved with various fund raising efforts to cover the cost of these events.

- Strategic Plan Update - - Update to Environmental Scan

Ms. Harris reported that during the March 14, 2001, staff meeting, all board staff participated in a review and update of the board's strategic plan. She added that comments were principally focused on the environmental scan.

Ms. Harris asked the board for comments or suggestions to the Environmental Scan.

Ms. Strom referred to the language in the environmental scan and noted that the figures needed to be updated for 2001/04, specifically: "Yet nearly 50 percent of the 2 billion prescriptions…" should now be closer to 3 billion.

The board directed staff to update the environmental scan for the next meeting

MOTION: To include the Environmental Scan as part of the board's strategic plan provision.

SUPPORT: 8 OPPOSE: 0

CLOSED SESSION

The board moved into Closed Session to deliberate upon disciplinary cases.

The board 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 #99ASO1990.

Board Member Caleb Zia arrived at the board meeting during the closed session discussion.

The meeting recessed at 3:00 p.m.

Thursday, April 26, 2001

CALL TO ORDER

President Elsner called the meeting to order at 8:45 a.m. on Thursday, April 26, 2001.

ANNOUNCEMENTS

President Elsner acknowledged board staff in attendance, each of whom introduced him or herself.

President Elsner announced that this would be Deputy Attorney General Bill Marcus' last board meeting.

Mr. Marcus introduced Elena Almanzo, who will be the board's liaison counsel with the Attorney General's Office. He stated that Ms. Almanzo has been with the Department of Justice for 14 years serving in Los Angeles, the Bay Area and now Sacramento. Mr. Marcus acknowledged Ms. Almanzo as an exceptional attorney. He added that she has taken on the responsibility of representing the office on Internet issues as they pertain to prescribing, dispensing and the National Association of Attorneys General Task Force. Mr. Marcus stated that the board is truly fortunate to have Ms. Almanzo.

Ms. Almanzo thanked the board for the opportunity to work with it.

President Elsner announced that for the last year, he has had the privilege of serving as the president of the board. As his term is ending, he expressed his appreciation to the board and to staff for all of their efforts. He referred to his recent editorial in *The Script*, and he thanked the board and staff for the privilege to serve as president. President Elsner acknowledged public participation from those in the audience as well.

COMMITTEE REPORTS AND ACTION

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Chairperson Zia reported that the Communication and Public Education Committee met in a teleconference meeting with him and Bill Powers on April 12, 2001.

- Proposed Revisions to the "Notice to Consumers" poster for distribution to pharmacies.

Chairperson Zia reported that at the January 2001 Board Meeting the Communication and Public Education Committee held a public hearing for comments on a new "Notice to Consumers" poster. Under California Code of Regulations section 1707.2(f), this poster and its required wording must be posted in every pharmacy.

Chairperson Zia stated that the committee settled on draft language for the regulation, but the committee believes that the most important part of the poster will be a layout and presentation that entices patients to read the poster in the pharmacy. As such, the committee directed staff to work with the graphic artist to develop a poster that will be visually pleasing and present the information of the draft notice as fully as possible with the following priorities:

a) Questions patients should understand before taking medicine
b) Information about the board, what our role is in consumer protection, and how to contact us
c) General information about patient consultation, talking to a pharmacist and generic drugs (all other information on the draft)

Chairperson Zia reported that once the general graphic layout is in place and the wording is finalized, the committee will bring the proposed language back to the July board meeting for notice as a regulation.

MOTION: Release for public comment as a regulation at the July or October board meeting, the proposed language for the "Notice to Consumers."

SUPPORT: 9 OPPOSE: 0

Chairperson Zia directed the board to the Communication and Public Education

Committee's strategic goals for 2001/02 (continuing the same strategic goals from 2000/01), and urged the board's adoption of these goals:

1. Evaluate the results of the consumer survey and develop a consumer outreach plan – July 2001
2. Evaluate the effectiveness of board outreach programs (*Script*, *Health Notes*, consumer brochures and columns, PSAs) – January 2002.
3. Revise the "Notice to Consumers" poster for distribution to pharmacies. – January 2002.
4. Expand consumer information available on the board's web site – July 2002
5. Develop a schedule to revise and update consumer brochures – July 2001
6. Pursue a budget change proposal to create a staff position to oversee the consumer education program – July 2002.

MOTION: Approve the Communication and Public Education Committee's strategic goals for 2001/02.

SUPPORT: 9 OPPOSE: 0

- **Presentation on the California Evergreen Project – Community Outreach**

President Elsner introduced Harley Christensen, media contact for the California Evergreen and C4A Launch Community Outreach Project for Aging Californians. He announced that that the California Evergreen and C4A Launch Community Outreach Project for Aging Californians was awarded a $1,476.538 grant by the California Department of Aging under its Long-Term Care Innovation Grants.

Mr. Christensen thanked the board for the opportunity to share his vision of this project and to review ways the board and others can get involved. He distributed information on the project to board members.

Mr. Christensen stated that the California Evergreen Project is designed to educate people on how to live healthier, more productive lives as they age – through television, the Internet, and community outreach.

Mr. Christensen reported that to achieve its goals, the project's designers are planning a large-scale effort that will link television and Web programming to services in local communities. In addition, community leaders will be involved in the project's development.

Mr. Christensen requested that the Board of Pharmacy help in these efforts by endorsing the project and assisting with development efforts. He added that he is seeking corporate officers.

Mr. Christensen thanked the board for the opportunity to introduce the project.

LICENSING COMMITTEE

Chairperson Strom reported that the Licensing Committee met on April 4, 2001.

- **Proposed Statutory Amendment Regarding a Retired Pharmacist License**

Chairperson Strom stated that the committee reviewed the recommendation from staff to revise existing law regarding the issuance of a retired license to a pharmacist whose license is current and in good standing. She added that individuals with a retired license may not practice pharmacy and must pass the board's licensure examination to reinstate his/her license to active status. The board has encountered situations where a pharmacist whose license has been cancelled by operation of law pursuant to Section 4402 has sought a retired license but the request must be denied because of the restrictions in Section 4200.5. In addition, the board does encounter situations when settling disciplinary cases where it would like to offer a surrender of license with the issuance of a retired license. However, the current provisions of 4200.5 prevent this settlement option.

MOTION: Propose a statutory amendment to Business and Professions Code section 4402 relating to a retired pharmacist license as follows:

4200.5 (a) The board shall issue, upon application and payment of the fee established by Section 4400, a retired license to a pharmacist who has been licensed by the board. ~~For 20 years or longer, and who holds a license that is current and capable of being renewed pursuant to Section 4401, that is not suspended, revoked, or otherwise disciplined, or subject to pending discipline, under this chapter.~~ The board shall not issue a retired license to a pharmacist whose license has been revoked.
(b) The holder of a retired license issued pursuant to this section shall not engage in any activity for which an active pharmacist's license is required. A pharmacist holding a retired license shall be permitted to use the titles "retired pharmacist" or "pharmacist, retired."
(c) The holder of a retired license shall not be required to renew that license.
(d) In order for the holder of a retired license issued pursuant to this section to restore his or her license to active status, he or she shall pass the examination that is required for initial licensure with the board.

SUPPORT: 9 OPPOSE: 0

- **Adopt the Licensing Committee's proposed strategic objectives for 2001/2002**.

Chairperson Strom referred the board to the committee's proposed strategic objectives for 2001/02, and asked for the board's adoption of these goals.

MOTION: Adopt the Licensing Committee's proposed strategic objectives for 2001/2002 as follows:

	Strategic Objectives	Timeline
1.	Respond to emerging professional practice issues (e.g. technology, pharmacy manpower, changed practice settings, and pharmacists' role).	Ongoing
2.	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
3.	Continue the review of the North American Pharmacist Licensure Examination and determine its appropriate use in California	January 2002
4.	Pursue budget change proposals to increase resources available to meet workload.	July 2001
5.	Review the Intern program.	July 2002
6.	Review CCR 1717(e) regarding the waiver requirements to allow the delivery of prescription medications at alternative sites.	July 2002

SUPPORT: 9 OPPOSE: 0

- **Report on Application/Licensing Statistics**

Chairperson Strom reported that the committee reviewed the application and licensing reports. The application report displays the applications received, processed and pending. She added that it also reports the application processing time and how long applications have been pending. She noted that concerns have been expressed about the lack of resources has impacted the board's ability to process these applications in a more timely manner. She added that the board has automated tracking in place and the goal is to report the information at the July board meeting.

Ms. Harris reported that in 2000/01 the board requested two licensing positions, one position to assist with application processing for the licensing examination, the intern program and pharmacy technician program. The second position is for cite application tracking for wholesaler/medical device retailers and pharmacist-in-charge changes. The board did not receive approval for these positions. Ms. Harris reported that on July 1, 2001, the board is losing the medical device retailers to Department of Health Services. The board is realigning the wholesaler program whereby applicants will qualify by education and experience rather than by taking a law exam. The board will also resubmit

a budget change proposal for additional staff in July to assure that workload is handled timely, efficiently and consistently.

- **Status Report on the Review of NAPLEX**

  Chairperson Strom reported that as directed in the committee's strategic goals, the board has pursued an independent audit of the psychometric qualities of the North American Pharmacists Licensure Examination (NAPLEX).

  Chairperson Strom reported that the board contracted with the Department of Consumer Affairs – Office of Examination Resources to perform the audit. Four nationally recognized psychometricians, Norman Hertz, Barbara Showers, Kara Schmitt, and Eric Werner will perform the audit. She added that they have in-depth experience in assessing the psychometric properties desirable for high stakes occupational licensing examinations and none has any involvement with either the board's pharmacist licensure exam or the NAPLEX. She added that she also participated in the review as a representative of the board.

  Chairperson Strom reported that the independent audit team will prepare a report that describes the extent of the relationship of the NAPLEX to the 1999 Standards for Educational and Pyschological Testing (American Educational Research Association, American Psychological Association and National Council on Measurement in Education). The independent audit team will then provide recommendations to the board regarding the defensibility of the NAPLEX. The report also will be provided to the National Association of Boards of Pharmacy for a reply prior to the report becoming public. She added that the report will be completed by June 30, 2001, and presented to the board at its July board meeting. The report will be publicly released.

  President Elsner stated that many issues involving the licensure exam of pharmacists overlap with those facing the Pharmacy Manpower Task Force. He added that the Administration is also requesting that the board consider reciprocity. He noted that the board will make the final decision based on all of the facts presented by the review.

  Mr. Cronin stated that the California Pharmacists Association supports the board's full membership in NABP.

  Chairperson Strom noted that the board has received numerous requests to administer its exam more frequently and the NABPLEX is administered year round.

  Ms. Herold reported that effective July 1, 2001, the board will no longer regulate medical device retailers (MDR) and the board is now in the process of transferring its MDR regulatory program to the Department of Health Services. Consequently, MDRs will be without an entity to license them for a period of time until the Department of Health Services completes its start-up work for the program.

Ms. Herold stated that early next week (the first week in May) the board will stop sending applications to firms wishing to become MDRs. After June 1, the board will stop allowing exemptees who have switched from one site to another to apply for a transfer. She added that currently, there are a number of pending applications that the board will work with to complete the application process. However, the board does not have the authority to work with the program after July 1.

Ms. Herold stated that with transfer of the MDR program, the board is losing 615 sites, approximately 900 MDR exemptees and approximately $250,000 a year in revenue. She noted that the board's current fee for licensing MDR sites is $340. The Department of Health Services will increase the fee to $850.

- **Competency Committee Report**

Report on the June 2001 Examination

Chairperson Strom reported that the board's June examination will be administered June 19 and 20, 2001, at the Oakland Convention Center in Oakland. Grading for this exam will be conducted in Sacramento on July 25 and 26, 2001. Results will be released to candidates before September 1.

Report on the January 2001 Examination

Chairperson Strom reported that on January 9 and 10, 2001, the board administered its January 2001 pharmacist licensure examination at the Hyatt Regency San Francisco Airport for 601 candidates. The pass/fail letters were mailed to candidates on March 16, 2001, and the overall results were 272 candidates passed (45.3%) and 153 candidates failed (25.5%). Results of the January 2000 exam were 234 candidates passed (43.6%) and 155 failed (28.9%).

Ms. Strom reported that the January pass rate has increased over four percent over the last three years.

President Elsner reported that he has appointed Dr. Eunice Chung for appointment to the Board of Pharmacy's Competency Committee. He added that Dr. Chung is from Western University and has a broad-based background in internal medicine with particular strengths in cardiology and infectious diseases. He added that she is a 1997 graduate of UCSF School of Pharmacy. He added that the Competency Committee is comprised of 18 members, 2 members from each school of pharmacy, five practicing community pharmacist practitioners, two hospital pharmacists, one inspector, at least one board member and two other pharmacists. President Elsner added that Dr. Chung would serve an eight-year term.

ENFORCEMENT COMMITTEE REPORT

President Elsner announced that Darlene Fujimoto has served her maximum tenure on the board and she will vacate her position effective June 1, if another member is not appointed first. President Elsner acknowledged Dr. Fujimoto's many contributions to the board and stated that she will be missed.

Chairperson Fujimoto stated that chairing the Enforcement Committee has been a wonderful opportunity. She added that she hopes that board continues to support this committee. She referred to the extremely important role that the Enforcement Team has, which is comprised of three-quarters of the board's staff. She added that the Enforcement Committee has the primary responsibility to protect the public and it is important that the board support this endeavor by supporting staff with resources and necessary staffing levels.

Chairperson Fujimoto stated that since she started on the board over eight years ago, there have been many inspector vacancies and the situation continued to get worse. She announced that this is the first time the board has been nearly fully staffed with inspectors. She congratulated staff, the enforcement team and the board.

- **Recommendation to adopt the Compliance Guideline for Expiration Dates.**

Dr. Fujimoto referred members to the committee's guideline on expiration dating. The direction to pharmacies is that they do not dispense prescription medications that are expired. If they do, they will be cited for a violation of pharmacy law. The guideline also includes the recommendation from the United States Pharmacopoeia for establishing the expiration (beyond use) date.

Chairperson Fujimoto stated that the Enforcement Team developed a Compliance Guideline for pharmacies regarding expiration dates. Prescription medication cannot be dispensed after the expiration date on the manufacturer's container. The expiration date placed on the prescription label should be that of the effectiveness of the drug (Business and Professions Code section 4076(a)(9)) and that the expiration date on a particular container be from the manufacturer's container. Previously policy directed licensees not to use an arbitrary date. The direction that the Enforcement Team is proposing is that a pharmacy will be in violation of the law if the pharmacist dispenses an expired drug.

Steve Gray representing Kaiser Permanente stated that there is a shortage of drugs. He referred to a situation when the only available drug for a patient is an expired drug and both the doctor and the pharmacist are trying to determine what the best course of action to take in that situation. He asked the board for guidelines that would address this type of situation.

Chairperson Fujimoto responded to Mr. Gray's concerns and stated that this activity would be documented by the pharmacist as to why expired drugs were dispensed and it would be a matter of using the "pharmacist's professional judgment."

Mr. Marcus stated that the FDA has addressed this issue and a prescription label has to have a "beyond use date" as the guideline acknowledges. He read the following from the August Federal Register: "For single unit or unit dose packaging of non sterile and liquid pharmaceuticals beyond use date, pursuant to the revised 2000 US Revised Standards, must be one year, unless stability data or the manufacturer's label indicates otherwise." For multiple unit containers, the standard is that the beyond use date is the expiration date on the manufacturer's container or one year from the date of dispensing, or which ever comes first.

MOTION: Adopt the Compliance Guideline for Expiration Dates

SUPPORT: 9 OPPOSE: 0

- **Request from the California Retailers Association to allow a pharmacist-in-charge to supervise more than one pharmacy**

Chairperson Fujimoto stated that during the Enforcement Committee meeting, the committee evaluated a proposal from the California Retailers Association (CRA) that the board amend its regulation to allow a pharmacist-in-charge to supervise more than one pharmacy. The CRA also submitted this request as a proposed solution to the pharmacist shortage. She noted that the Pharmacy Manpower Task Force will consider this proposed solution in its final report to the board. The committee recommends that the item be referred to the Manpower Task Force.

MOTION: Refer the request from the California Retailers Association to allow a pharmacist-in-charge to supervise more than one pharmacy to the Pharmacy Manpower Task Force

SUPPORT: 9 OPPOSE: 0

- **Request from the California Retailers Association to eliminate the clerk-typist ratio and expand their duties.**

Chairperson Fujimoto stated that the Enforcement Committee considered another California Retailers Association (CRA) request to amend its regulation to eliminate the clerk-typist ratio and to expand clerk-typists' duties. The CRA also submitted this request as a proposed solution to the pharmacist shortage. She added that the Pharmacy Manpower Task force will consider this proposed solution in its final report to the board.

Mr. Jones stated that during a public Enforcement Committee meeting in March, the issue was discussed and the committee determined that the proposal should be referred to the Pharmacy Manpower Task Force.

MOTION: Refer the California Retailers Association's request to eliminate the clerk-typist ratio and expand clerk typists' duties to the

Pharmacy Manpower Task Force.

SUPPPORT: 9 OPPOSE: 0

- **Proposed Strategic Objectives for 2001/2002**

Chairperson Fujimoto stated that the Enforcement Team updated and reprioritized its strategic objectives for 2001/02.

Chairperson Fujimoto referred to item 15 to re-establish the CURES workgroup that includes other regulatory and law enforcement agencies to detect controlled substance violations and coordinate investigations with the corresponding timeline of July 2003. She expressed concern that the board should not wait until July 2003 to complete this.

President Elsner stated that the board would insert a timeline date of July 1, 2001 for the re-establishment of the CURES workgroup.

MOTION: Adopt the proposed strategic objectives for 2001/02.

SUPPORT: 9 OPPOSE: 0

Chairperson Fujimoto referred to the minutes of the March 13, 2001, Enforcement Team meeting and commented that quality improvement efforts included: the compilation of the customer survey results, inspection of pharmacies with the LA HALT unit, two Penal Code section 23 (PC 23) hearings, inspection of 28 unlicensed MDR facilities, an interim suspension order against a pharmacy and its owner for the sale of Russian drugs without a prescription, another successful PC 23 and ISO hearings for an impaired pharmacist, assisting the DEA on the search and arrest of a probationer for chemical sales, the monitoring of 153 probationers, and the inspection of 7 probation /PRP participants. She commended staff on a job well done.

Ms. Powell referred to the subpoena procedures outlined in the minutes. She stated that this does not accurately reflect the procedures and that more training is needed. She stated that she would re-write the procedures at Ms. Harris' suggestion.

President Elsner stated that the minutes will be revised and resubmitted to the board.

Chairperson Fujimoto referred to the workload bar graphs that Supervising Inspector Bob Ratcliff charted and she noted the high numbering of cases the board is addressing.

Chairperson Fujimoto referred to the data reflecting pharmacists recovery program and she recommended that the board seek more detailed information describing participants in the program.

Chairperson Fujimoto thanked the board for the opportunity to serve on the Enforcement

Committee and acknowledged staff for their hard work.

Mr. Jones stated that the board would like to see more public participation at committee meetings and he asked those in attendance for suggestions regarding outreach efforts.

Bruce Young, representing the California Retailers Association, commended Dr. Fujimoto's efforts on the Enforcement Committee.

Mr. Young suggested that the board establish a more timely way to establish compliance committee hearing dates after the notice of violation is issued.

LEGISLATION AND REGULATION COMMITTEE

Regulation Report and Action

Recently Approved - Exempt Dangerous Drugs and Dangerous Devices (1714.5)

Ms. Herold stated that the Office of Administrative Law approved this regulation and takes effect May 9, 2001. The regulation specifies the dangerous drugs and devices that can be stored in non-pharmacy areas of licensed health care facilities, and replaces a list of similar items that formerly existed in Business and Professions Code section 4057.

Ms. Herold thanked the California Society of Hospital Pharmacists and Kaiser Permanente who provided assistance with the regulation. She added that the regulation will be posted on the board's website and promoted in the board's next newsletter, *The Script.*

Board Approved – Pending Administrative Approval

Quality Assurance Programs (1711) – Ms. Herold stated that the formal 45-day public comment period closed April 9, 2001. Comments were received from the California Medical Association, California Pharmacists Association and Kaiser Permanente. This regulation is scheduled for a hearing later today at this board meeting.

Self-Assessment (1715) – Ms. Herold stated that the board is awaiting approval of the fiscal impact statement by the Department of Consumer Affairs to complete the rulemaking file. After this form is received, the board will submit the file to the Department of Consumer Affairs and then to the Office of Administrative Law for approval. The regulation updates the pharmacy self-assessment forms for community and institutional settings and moves the biennial completion date from March to July of each odd-numbered year.

Preprinted, Multiple Check-off Prescription Blanks (1717.3) – Ms. Herold stated the board is awaiting completion of the rulemaking file and submission to the Department of Consumer Affairs for approval. This regulation amends board requirements for

preprinted forms to permit multiple non-controlled drugs to be prescribed from the same form.

Disciplinary Guidelines (1760) – Ms. Herold stated that the board is awaiting approval of the fiscal impact statement by the Department of Consumer Affairs, so it can complete and submit the rulemaking file for review. This regulation revises the board's disciplinary guidelines for serious enforcement cases.

Citations and Fines (1775 et seq.) – Ms. Herold stated that the board is awaiting approval of the fiscal impact statement by the Department of Finance. The final day for submission of this rulemaking file to the Office of Administrative Law is May 12, 2001. The regulation will permit the board to cite and fine for any violation of pharmacy law.

- **Policy on Electronic and Facsimile Submission of Regulation Comment**

Chairperson Mazzoni stated that this year, the Legislature passed Assembly Bill 505 (Chapter 1959, Statutes of 2000) and Assembly Bill 1822 (Chapter 1960, Statutes of 2000) which amends the Administrative Procedures Act (APA). The APA is the law that governs the board's rulemaking activity. The Legislation and Regulation Committee has developed a policy for the board regarding the electronic and facsimile submission of comments on proposed regulations that is compliant with the new requirements.

MOTION: Adopt a policy of accepting e-mail or fax comments only if they contain the person's name and mailing address.

SUPPORT: 9 OPPOSE: 0

Legislation Report

1. Board Sponsored Legislation

Mr. Riches stated that the board has four sponsored legislative bills as follows.

SB 340 (Speier)

This bill makes changes to pharmacy law permitting clinics eligible for participation in the federal 340B program to contract for pharmacy services to dispense 340B drugs to clinic patients. The bill also contains provisions permitting pharmacists to make dosage form changes without consulting the prescriber. This bill is set for hearing by the Senate Business and Professions Committee on April 30, 2001.

SB 724 (Business and Professions Committee)

Mr. Riches noted that this bill contains numerous technical corrections to the pharmacy law including clarifying provisions for manufacturers, the retired pharmacist license

provisions and amendments to the provision of when temporary permits can be issued. The bill passed the Senate Business and Professions Committee on April 2, 2001 on a 4-0 vote.

AB 809 (Salinas)

This bill permits the licensing of automated dispensing devices (under the control of a pharmacist) as pharmacies in underserved areas. The bill is opposed by the United Food and Commercial Workers and the California Pharmacists Association. The bill is scheduled for hearing before the Assembly Health Committee on April 24, 2001. The board is working on amendments to remove the opposition of these groups.

AB 826 (Cohn)

This bill permits pharmacists to perform clinical and consulting functions outside a licensed setting. The bill passed the Assembly Health Committee on April 3, 2001, on a 12-0 vote. Mr. Riches noted that this bill passed the Assembly Appropriations Committee on consent calendar. The board has resolved the issues by the California Medical Association, and Kaiser and the California Medical Association now support the bill.

2. Introduced Legislation Relating to the Practice of Pharmacy

AB 108 (Strom-Martin) – Tribal Pharmacies

This bill requires the board to issue a pharmacy license to pharmacies located on Indian Trust land. Mr. Riches reported that the board took an oppose position on this bill at the January board meeting. Mr. Mazzoni stated that the oppose position by the board remains in place.

AB 207 (Mathews) – Drug Benefit Card

This bill requires Medicare supplement insurers to provide enrollees with a card containing contract information required for payment. Mr. Jones stated that the requirement for all of the information to be presented on the front of the card is getting a lot of resistance.

Mr. Young stated that both the California Retailers Association and the California Pharmacists Association are sponsors of the bill, and there is flexibility with printing the card.

MOTION: Legislative Committee: Support AB 207 (Mathews)

SUPPORT: 9 OPPOSE: 0

AB 225 (Washington) – Foster Children

Among other provisions, this bill requires the board to take disciplinary action against a pharmacist who dispenses psychotropic drugs to a ward of the court without an order from the juvenile court for the administration of psychotropic drugs to the child. The committee recommends that the board oppose the bill unless amended to remove the requirement regarding pharmacists, who would not know the status of the child in most cases.

MOTION: Legislative Committee: Oppose AB 225 (Washington) unless amended

SUPPORT: 9 OPPOSE: 0

AB 258 (La Suer) – Controlled Substances

This bill moves GHB from Schedule II to Schedule I and adds prescription drugs containing GHB to Schedule III. Mr. Riches reported that this bill was introduced this year to conform to a recent federal law change regarding how GHB is scheduled. He added that this is consistent with ongoing board efforts to try to keep the state and federal control substance schedules in conformance. Further, the author of the bill was approached to make other scheduling changes suggested by the board for conformance with federal schedules.

Mr. Marcus stated that this bill does have an affect in California because it is not scheduled as a controlled substance and it is not subject to California's controlled substance penalties.

MOTION: Legislative Committee: Support AB 258 (La Suer).

SUPPORT: 9 OPPOSE: 0

AB 394 (Maddox) – Backroom Clinics

This bill increases the penalty for unlicensed dispensing of dangerous drugs or dangerous devices to include the option of felony prosecution by county public health officers.

MOTION: Legislative Committee: Support AB 394 (Maddox)

SUPPORT: 9 OPPOSE: 0

AB 536 (Bates) – Pharmacy Technicians

This bill increases the permissible ratio of pharmacy technicians to pharmacists in a community pharmacy as follows: a) for the first pharmacist on duty, the ratio is 1:1, b)

for each additional pharmacist on duty, the ratio is 2:1. The pharmacist may decline the additional technician if he or she chooses.

MOTION: Legislative Committee – Support AB 536 (Bates)

SUPPORT: 9 OPPOSE: 0

AB 559 (Wiggins) – Epinephrine Auto-Injectors

This bill would allow trained school district personnel to administer auto-injectors, with pre-measured doses of the medication, to students to treat potentially life-threatening anaphylactic reactions due to insect stings, food allergy or other causes. This bill also permits pharmacies to sell epinephrine auto-injectors to a school district or county office of education pursuant to a written order from a physician and surgeon.

MOTION: Legislative Committee – Support AB 559 (Wiggins)

SUPPORT: 9 OPPOSE: 0

AB 1292 (Aroner) – Needles and Syringes

This bill would authorize a pharmacist in a licensed pharmacy to furnish or sell at retail hypodermic needles or syringes for human use without a prescription or permit.

Chairperson Mazzoni stated that it is the committee's recommendation to support the bill if it is amended to remove the provision regarding hypodermic licensing.

MOTION: Legislative Committee – Support AB 1292 (Aroner) if amended

SUPPORT: 9 OPPOSE: 0

AB 1589 (Simitian) – Electronic Prescribing

This bill would require the Medical Board to study the electronic transmission of prescriptions by physicians and surgeons and report its results to the Legislature before May 1, 2002.

Chairperson Mazzoni reported that it was the committee's recommendation that although this is already a standard practice, the board should support this bill if is amended to include the Board of Pharmacy as one of the entities involved in the study.

MOTION: Legislative Committee – Support AB 1589 (Simitian) if amended.

SUPPORT: 9 OPPOSE: 0

SB 119 (Haynes) – Prescribing for Minors

This bill would require a physician and surgeon, dentist, optometrist, or podiatrist before prescribing a psychiatric medication, as defined, for a minor to obtain informed consent, as specified, from the minor's parent or legal guardian and confirm that the minor has been examined by a pediatrician to eliminate the possibility that the minor's condition is the result of a physical condition.

Chairperson Mazzoni stated that the committee recommended an oppose unless amended position on this bill.

MOTION: Modify the recommendation from the Legislative Committee from oppose unless amended to oppose SB 1991 (Haynes)

M/S/C: FUJIMOTO/JONES

SUPPORT: 9 OPPOSE: 0

MOTION: Oppose SB 1991 (Haynes) unless amended.

SUPPORT: 9 OPPOSE: 0

SB 696 (Speier) – Drug Benefits

This bill would enact the Golden Bear State Pharmacy Assistance Program, participation would be voluntary for Medicare beneficiaries, pharmacies, and drug manufacturers.

Chairperson Mazzoni reported that SB 696 and SB 697 are identical bills except SB 697 makes pharmacy participation mandatory in the Golden Bear State Pharmacy Assistance Program. He added that this bill would increase the administrative burden on the pharmacist and require the pharmacist to do an insurance enrollment rather than actually counsel patients. The committee recommended that the board oppose the bill unless the provision that requires enrollment by pharmacies is amended out.

Mr. Cronin stated that the CPhA has a concern regarding the structure for distributing the rebates and that the state would collect them. Mr. Cronin stated that the CPhA has an oppose unless amended position on the bill.

MOTION: Oppose SB 696 (Speier) unless amended

SUPPORT: 8 OPPOSE: 0 ABSTAIN: 1

SB 1000 (Johannison) – Triplicate Prescription Requirement

Mr. Riches stated that this bill makes the CURES program permanent and requires the

Department of Justice by July 1 of 2002, to produce a report on how to improve the CURES system. This bill requires the Department of Justice to allocate two peace officers to proactively look at the CURES data used in enforcement cases and appropriates $140,000 from the state general fund to the Department of Justice to pay for the two positions and the cost of producing the report. The bill was heard in committee and the committee expressed the desire to extend the sunset of the CURES program rather than make it permanent.

MOTION: Support SB 1000 (Johannison) if amended to extend the sunset on the CURES program rather than eliminate it. And, to permit prescribers and pharmacists to request a patient profile from the CURES program if the patient is under their care. Existing language containing the $1 million appropriation from the board should be removed.

M/S/C: GUBBINS/FUJIMOTO

SUPPORT: 9 OPPOSE: 0

Other Legislative Issues

Mr. Cronin referred to the materials on wholesalers provided to the board and stated that some of the provisions are based on a guideline established during the rulemaking process implementing the Prescription Drug Marketing Act 1988. He added that the original proposed rule for the PDMA was issued on May 30, 1994. The final rule was issued on December 3, 1999. He noted the reference to a 5 percent limit on transfers between pharmacies and physicians that dispense. He referred to the final rule and stated that the definition section exempts a lot of activity from wholesale activity. He added that theCPhA would like to know what the justification is for the board's proposed language. He suggested that the board establish the California law consistent with the PDMA.

Mr. Cronin requested that this regulation be returned to the Legislative Committee for further evaluation and that it be removed from pending status.

MOTION: Refer this back to the Legislative Committee for further evaluation.

M/S/C: LITSEY/ZIA

SUPPORT: 8 OPPOSE: 0 (Dr. Fujimoto not present)

ANNOUNCEMENT

President Elsner announced that the October 2001 meeting dates have changed to October 15 and 16, 2001. He added that the board would conduct business October 15

for a half-day session and October 16 as a full day of board business.

LUNCH RECESS

Legislative Report – Continued

Chairperson Mazzoni recognized Mr. George Roe, a visiting board member from Seattle, Washington.

Steve Gray representing Kaiser Permanente stated that in previous discussions about board sponsoring legislation allowing repackaging of pharmaceuticals at consumer's request He asked what the board's intent is with respect to this legislation.

Mr. Riches stated that this is covered in the annual omnibus bill, SB 724.

AB 269

This bill grants the committee the power to appoint the executive officer of the board This bill establishes a three-person committee consisting of the Governor's appointment secretary, the Director of the Department of Consumer Affairs, and one representative of the effected board. Further, this bill establishes a Division of Enforcement Oversight within the Department of Consumer Affairs to evaluate and find improvements in the enforcement program of the licensing boards within the department. It also requires those boards to pay the cost of funding.

This bill is an attempt to respond to the department by the Bureau of State Audits that was released in November 2000. The audit suggested that the department should be more vigorous in its oversight of board enforcement activities.

Ms. Harris noted that regarding enforcement oversight; the board currently pays a pro-rata to the department with an audit measure to review the operations. Further, the board is also subject to a sunset review after one year and subject to audits by the Bureau of State Audits. She added that this adds another layer of cost to what is currently in place.

Ms. Teri Miller representing the California Society of Hospital Pharmacists stated that the CSHP has recommended an oppose position on the bill.

REGULATION HEARING – Quality Assurance Programs
Proposed Adoption of California Code of Regulations Section 1711

President Elsner stated that this regulation hearing is to consider action to create section 1711 of Division 17 of Title 16 of the California Code of Regulations, dealing with the quality assurance evaluation prescription errors in pharmacies.

Recent studies have highlighted the high number of medication errors and their adverse health consequences. The most notable of these studies is "To Err Is Human" published by the Institute of Medicine (IOM). This study comprehensively examines the literature on patient safety and makes numerous policy recommendations. Among those recommendations is the suggestion that all health care organizations implement quality improvement programs to reduce medical errors.

President Elsner directed the public on procedures to follow during oral testimony.

Bruce Young, representing the California Retailers Association (CRA), stated that the CRA has concerns with the regulations that stem from a recent presentation from Michael Cohen who is a leading spokesperson for the establishment of quality assurance programs in the United States and the editor of several books.

Mr. Young stated that those who report errors must feel safe to report them in a confidential non-punitive environment with legal protection, and that the focus should be on lessons learned from quality assurance programs, rather than seeking a mandate to punish pharmacies and pharmacists.

Mr. Young noted that it should be conveyed to pharmacies that this regulation would not be used in a punitive fashion or as punishment, but more to avoid repetition of errors.

Mr. Young asked the board to consider inviting Mr. Cohen to the July board meeting to advocate his position of a blameless environment. He asked the board to examine the regulation more carefully and postpone action until the July hearing. He asked the board to consider developing a position whereby pharmacists and pharmacies are not punished for mistakes.

John Jones stated that the board is not pursuing this regulation to create a device for punishing pharmacists. The board wants pharmacists to engage in meaningful quality assurance programs to prevent the recurrence of medication errors.

Mr. Young added that there is uneasiness among members that this was written by the enforcement staff.

Ms. Strom commented on behalf of the enforcement committee that this was not the intent. She added that in many instances when pharmacists come before the board and they are asked how they will prevent future errors, they simply state that they will be more careful. It becomes clear that the quality assurance process is not known, nor is it known where breakdowns occur. She added that when quality improvement programs are in place, the procedures are clear. And, if mistakes occur, it is easy to pinpoint exactly where the breakdown occurred. She added that the intent of the program is for individuals to know how their system works and to make improvements when necessary. She added that it is also important to properly handle errors with consumers.

Mr. Young stated that this regulation is generating fear among practitioners and would like the board to find a means to communicate its non-punitive intent and expectations to practitioners.

Dr. Fujimoto stated that inspectors would look at whether or not the pharmacy has a quality assurance program as a mitigating factor.

Mr. Young expressed concern that inspectors might review quality assurance programs and report mistakes to the board.

Dr. Fujimoto stated that this is not the intent of the regulation or the board.

Mr. Young asked the board to insert this intent language in the regulation.

Mr. Young asked the board to consider resubmitting the regulation to this effect.

Ms. Strom stated that the board is a consumer protection entity and it cannot promise that an individual would be absolved of all responsibility if a mistake occurs.

Mr. Young stated that there is concern and fear that pharmacies will be written up for medication errors. Mr. Young further indicated that this concern is based on the perceptions of pharmacists not the text of the regulation. He further added that the mitigation language proposed in the amendments presented at the hearing does help address this concern.

Mr. Jones summarized the proposed amendments to the regulation. He further indicated that this regulation is intended to reduce medication errors, not an effort to uncover errors for board enforcement action.

Mr. Young stated that CRA is supportive of the board's direction with this regulation, but does want to urge the board to take steps to address the fear among practitioners.

Mr. Elsner inquired if today's testimony expressing concern about the regulation is a reversal of CRA's prior position.

Mr. Young stated that it was a reversal of position.

Mr. Jones stated that he believes pharmacists have far more to fear from their employers than the board when considering the personal consequences of medication errors.

Mr. Elsner asked if the membership of the CRA is unanimous in their position on this regulation.

Mr. Young stated that CRA members are not unanimous in their concern regarding this regulation.

Ms. Powell stated that the board's responsibility is not only to protect consumers, but also to investigate further if a significant error is found.

Dr. Gubbins stated that when the board establishes a policy such as this, it creates intimidation. He stated that his concern is to follow the intent of the statute with this regulation as a peer review document to prevent errors from reoccurring, as opposed to a punitive disciplinary matter. He added that some of his initial concerns have been eased by the revisions to the language. He referred to a recent visit from Ken Caldwell of the Texas Board of Pharmacy and the suggestion he made to keep the regulations simple and to allow each employer to develop policies specific to its needs.

Mr. Jones referred to Mr. Young's comments and stated it is the inspector's job to review pharmacy procedures for correcting errors. He added that if a program is in place and the pharmacy is following procedures, there should not be a problem.

Ms. Miller stated that the CSHP supports the proposed regulation.

Ms. Miller referred to item (b) and the new definition of medication errors. She referred to the California Medical Association's recommendation to adopt a definition similar to "sentinel event" used in the hospital environment because of the potential to cause major harm or death to a patient.

Ms. Miller referred to section (c). She stated that it is important to let patients know when an error has occurred but she thought it might be better to use CMA's language without adding too many details. She stated that CSHP approves of the changes proposed by the board.

Ms. Miller referred to section (e) and the removal of the "cause examination" definition. She added that the focus should be on systems and process improvements rather than individuals

Phil Burgess, representing Walgreens, stated that: 1) Pharmacy errors and other medical errors are not intentional acts and should be treated accordingly. 2) Efforts to improve medical errors require a non-punitive blame-free approach that do not use sanctions or punishment against health care providers or professionals. 3) Each pharmacy operation is unique and, therefore, must be allowed to develop and implement quality assurance programs that are distinct to their practice settings so that quality improvement efforts can be successful. 4) Promoting the lessons learned from quality assurance programs is a better approach to patient safety than mandating error-reporting programs.

Mr. Burgess added that if the board intends to use this program as mitigating circumstances, it should change "may" to "will" in subsection (i). He added that this would encourage pharmacists' cooperation.

John Cronin, California Pharmacists Association, stated that the definition of medication error should incorporate the concept of an error. He asked if this is an enforcement regulation or a consumer safety regulation. He added that the record retention requirement is not necessary.

Mr. Elsner asked Mr. Cronin if he had specific language to reflect the changes he mentioned.

Mr. Cronin responded that he did not.

Ms. Strom expressed concern that if the records were not kept and the board was not made to be aware of a situation until much later, the board would not be able to investigate the matter.

Dr. Fujimoto stated that when the board receives complaints, it must act on them and have these records available.

Mr. Jones asked if the records aren't kept, how does someone verify if the quality assurance process was followed?

Mr. Cronin responded that the board should ask the pharmacist and assume he or she is telling the truth.

Mr. Jones asked if a lawyer was defending a pharmacist in a medication error case wouldn't the lawyer want the quality assurance documents available for the defense?

Mr. Cronin responded that the lawyer would want the documents.

Mr. Cronin stated that the regulations are too complicated for the problems the board is describing. He requested that the board simplify the regulation.

Steve Gray, representing Kaiser Permanente, stated that a change to the definition as described in the proposed regulation would be problematic for any other variations that might be authorized by law. He referred to SB 340 - a bill that contains provisions that would allow pharmacists to change dosage forms. He suggested that the board use "any other variation or change allowed by law," rather than referencing section 4073.

Mr. Gray added that his second concern is the length of time a pharmacy must retain records. He added that there is no protection for pharmacy error records in federal law. He added that the issue of protection is serious because the board wants to encourage pharmacists to participate. He stated that the records need to be retained only until the board determines there is a viable program. He added that the average pharmacy will make five or six errors per year and the average error rate is approximately one out of 20,000 prescriptions.

Mr. Gray added that a licensing board could only review confidential patient information on site, unless the board has the patient's permission. He added that the proposed language misleads pharmacists into thinking an inspector can take records from the pharmacy when this would violate the Medical Confidentiality Act.

Cooky Quandt, representing Longs Drugs Stores (Longs), stated that Longs applauds the board's action regarding quality assurance programs. She added that Longs has a quality assurance program in place for reporting errors and for the prevention of future errors.

Ms. Quandt stated that Longs supports Mr. Young's comments that this regulation should not be used in a punitive fashion or as punishment, but to avoid repetition of errors. She added that Longs also supports the comments regarding the need for simplicity in the regulations.

Ms. Quandt stated that there are many different types of pharmacies in California with each being unique in its practice. She added that because of the uniqueness, pharmacies need the ability to develop their own quality assurance programs.

She added that although the new proposed language is an improvement over the previous language, it could be simplified even more to allow the uniqueness of each type of practice.

Ms. Quandt referred to (e) 1 that states "the date of, location, and participants in the quality assurance review conducted," and she noted that an independent pharmacist would review his or her own program.

She referred to a letter dated February 6, 2001, from Longs Drugs that included proposed language for the regulation. She stated that the language was not included in the board packet. She added that Longs' proposed language simplified the regulation and made it easier to understand. Further, she added that Longs Drugs agrees to the definition of "medication error."

Ms. Quandt referred to the last paragraph in section (e), "The pharmacy shall inform all personnel that the review process is completed." She questioned whether this needs to be done after every prescription error or only in those instances where there are changes that need to be made.

Ms. Quandt stated that although the language has improved, Longs Drugs would like it simplified further.

Mr. Greg Schapansky, representing Costco Pharmacy, stated that the amendments to the regulation are appreciated. He stated that he has concerns about the implementation of the quality assurance programs.

Mr. Schapansky stated that currently his pharmacists fear the board's inspectors and

reporting errors.

Mr. Dan Wills stated that he is with a local single pharmacy and has a background in quality control with another organization. He noted that he has found that 95 percent of individuals want to do the right thing. The goal is to have something that will help those 95 percent to do better so there are fewer problems. He added that at some point, the board will be working on the other 5 percent. He stated that the best approach is never using quality assurance programs against someone punitively, but rather as a means to improve the process. He added that if it were written in the regulations that the quality assurance data would not be used against the pharmacist, no one would mind keeping the records on site.

President Elsner asked for additional comments. There were none. President Elsner closed the regulation hearing and stated that board members would discuss the proposal and submitted comments.

Mr. Zia stated that the board needs to have a program in place but did not feel it should punish the honest individuals who report errors.

Ms. Strom referred to court cases dealing with medication errors and Mr. Young's example of referral of a case where the dosages prescribed by a physician that were clearly outside of the safe dosage limit for that patient. She stated that it is not a dispensing error but a competency issue if the pharmacist did not vary from the prescribed prescription when he or she should have known not to dispense medication as prescribed. She asked if such a situation would be included in the definition of medication error.

Ms. Harris clarified that the definition of medication error proposed in the amendments to the regulation would address only those cases where the drug was dispensed other than as specified by the prescription. If a patient is harmed by a prescription as written by the prescriber, that is an error of judgment and the pharmacist should have detected the problem through reviewing the patient's profile or during patient consultation. Such cases are violations of other professional requirements but not a medication error for the purpose of this regulation.

Ms. Harris further stated that the proposed regulation is the board's most important consumer protection initiative. Medication errors are the most common complaints filed by consumers with the board.

Ms. Harris stated that the intent of the regulation is not to generate additional cases for disciplinary action. Rather that pharmacists who made an error and performed the required quality assurance review, would have it noted in the record that an error occurred and the review was performed and no further action would be taken.

MOTION: Amend subsections (b), (f), (g) and (h) of Section 1711 as follows:

(b) For purposes of this section, "medication error" means any *variation from a prescription or drug order not authorized by the prescriber*. ~~act or omission in the dispensing process that may cause or lead to patient harm.~~ Medication error, as defined in this section, does not include any *variation* ~~act or omission~~ that is corrected prior to furnishing the drug to the patient or patient's agent *or any variation allowed by law*.

(f) ~~For the purposes of this section "essential cause examination" means:A process for identifying the basic or causal factors that underlie the occurrence or possible occurrence of a medication error. An essential cause examination focuses primarily on systems and processes, not individual performance. It progresses from special causes in the dispensing process to common causes in organizational processes and identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future, or determines, after analysis, that no such opportunities for improvement exist.~~

(g) Records relating to activities undertaken as part of a quality assurance review for errors that occurred in the pharmacy, including, but not limited to, investigation or confirmation of a medication error, shall be maintained and immediately accessible in the pharmacy for at least ~~three years~~ *one year* from the date those records were created. The board may review quality assurance records in an individual pharmacy as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the pharmacy.

(h) Neither the proceedings nor records of a pharmacy's quality assurance program shall be subject to discovery in any arbitration, civil, or other proceeding except as provided in subdivision (f). No person in attendance at a meeting of a pharmacy's quality assurance committee shall be required to testify in any arbitration, civil, or other proceeding~~, except as provided in subsection (f),~~ as to what transpired at that meeting.

M/S/C: JONES/ZINDER

President Elsner stated that any amendments made by the board would go out for a 15-day comment period.

Ms. Powell stated that if the board does not receive adverse comments regarding the change, the board could make the change. Otherwise, it would need to come back to the

board.

Mr. Marcus referred to subsection (c) and he suggested the following: When a medication error "considered threatened" or "may threaten."

Mr. Marcus also suggested the following language to:

- (c) "and the steps required to correct the error and avoid or mitigate any injury. "

and to

- (e) "The pharmacy shall inform all pharmacy personnel involved in the medication error or the review process that the review process is completed and inform all pharmacy personnel of any changes in pharmacy policy or procedure…"

Mr. Marcus stated that another issue is the length of time for record retention. He added that a record that is more than one year old, no more than two years, may be important in establishing a pattern that would indicate the program is being insufficiently used.

MOTION: Mr. Mazzoni suggested an amendment to the main motion – he referred to subsection (h) and suggested the use"will" instead of "may" and to add: "and shall not be used as sole probable cause" at the end of section (h).

M/S/C: MAZZONI/GUBBINS

SUPPORT: 3 OPPOSE: 4

MOTION: Adopt section 1711 as amended (shown below):

CALIFORNIA CODE OF REGULATIONS
TITLE 16, DIVISION 17

§1711. (a) Each pharmacy shall establish and maintain a quality assurance program designed to prevent medication errors.

(b) For purposes of this section, "medication error" means any *variation from a prescription or drug order not authorized by the prescriber.* ~~act or omission in the dispensing process that may cause or lead to patient harm.~~ Medication error, as defined in this section, does not include any *variation* ~~act or omission~~ that is corrected prior to furnishing the drug to the patient or patient's agent *or any variation allowed by law.*

(c) Each quality assurance program shall be described in written policies and procedures maintained in the pharmacy and shall be

reviewed by the licensee, and revised if necessary, prior to application for renewal of the pharmacy's license. *When a medication error threatens a patient's well being, the pharmacist shall immediately communicate to the patient and the prescriber the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.* ~~The policies and procedures shall include directions for communicating the details of the error to the patient, caregiver, prescriber and other members of the health care team as appropriate. This communication shall also describe methods for correcting the error and/or reducing its negative impact on the patient.~~

(d) Each quality assurance program shall include a process designed to detect and identify medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. If the investigation indicates that the medication error is attributable, in whole or in part, to the pharmacy or its personnel, a quality assurance review shall be performed.

(e) The quality assurance review shall include investigation of the error. ~~and completion of an essential cause examination of the error.~~ *That investigation shall include a determination of the proximate cause of the medication error and shall include an evaluation of systems and processes that may have contributed to the medication error.* A written record of the quality assurance review shall be retained in the pharmacy. The written record shall contain at least the following:

1. the date of, location, and participants in the quality assurance review conducted;
2. the record of the facts relating to the medication error;
~~3. the essential cause examination;~~
3. the findings and determinations generated by the quality assurance review; and,
4. changes to pharmacy policy or procedure made pursuant to the quality assurance review, if any.
5. activities undertaken with the patient or other healthcare providers to mitigate the error.

The pharmacy shall inform all pharmacy personnel *that the review process is completed and* of any changes in pharmacy policy or procedure made pursuant to a quality assurance review.

~~(f) For the purposes of this section "essential cause examination" means:~~

~~A process for identifying the basic or causal factors that underlie the occurrence or possible occurrence of a medication error. An essential cause examination focuses primarily on systems and processes, not individual performance. It progresses from special causes in the dispensing process to common causes in organizational processes and identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future, or determines, after analysis, that no such opportunities for improvement exist.~~

(f) Records relating to activities undertaken as part of a quality assurance review for errors that occurred in the pharmacy, including, but not limited to, investigation or confirmation of a medication error, shall be maintained and immediately accessible in the pharmacy for at least ~~three years~~ *one year* from the date those records were created. The board may review quality assurance records in an individual pharmacy as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the pharmacy.

(g) Neither the proceedings nor records of a pharmacy's quality assurance program shall be subject to discovery in any arbitration, civil, or other proceeding except as provided in subdivision (f). No person in attendance at a meeting of a pharmacy's quality assurance committee shall be required to testify in any arbitration, civil, or other proceeding~~, except as provided in subsection (f),~~ as to what transpired at that meeting.

(h) *If the records specified in subdivision (e) for the individual case subject to investigation are made available to the board,* the pharmacy's compliance with this section ~~may~~ *will* be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.

(i) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

(j) This section shall become operative on January 1, 2002.

Note: Authority Cited: Section 4005 of the Business and Professions Code and Section 2 of Chapter 677, Statutes of 2000.
Reference Cited: Section 4125 of the Business and Professions Code.

M/S/C: JONES/ZINDER

SUPPORT: 9 OPPOSE: 0

LEGISLATION AND REGULATION COMMITTEE – Continued

- Proposed Strategic Goals for 2001/2002

President Elsner directed the Legislative and Regulation Committee to update the committee's strategic goals for 2001/02 and bring them to the July 2001 Board Meeting.

Ms. Harris stated that a draft version of the board's 2001/02 strategic plan would be submitted to the Department of Consumer Affairs by June 1, as required.

APPROVAL OF MINUTES

Full board Minutes – January 24, 25, 2001

MOTION: Approve the minutes as corrected

M/S/C: ZINDER/ZIA

SUPPORT: 9 OPPOSE: 0

Northern Compliance Committee Minutes – January 2001

President Elsner stated that the minutes were provided as information.

Northern Compliance Committee Minutes – April 4, 2001

President Elsner stated that the minutes were provided as information.

Mr. Mazzoni noted corrections to these minutes.

ELECTION OF OFFICERS

President Elsner stated that the board needs to elect its officers for 2001/02.

MOTION: Elect Steve Litsey as President of the Board of Pharmacy

M/S/C: JONES/ZIA

SUPPORT: 9 OPPOSE: 0

MOTION: Elect John Jones as Vice President of the Board of Pharmacy

M/S/C: LITSEY/FUJIMOTO

SUPPORT: 9 OPPOSE: 0

MOTION: Elect Caleb Zia as Treasurer of the Board of Pharmacy

M/S/C: JONES/MAZZONI

SUPPORT: 9 OPPOSE: 0

ANNOUNCEMENT

President Elsner thanked the board, its staff and its executive officers for the board's success in achieving its goals and consumer protection mandate, often with less than optimal resources. He thanked those present for their support during his year as president.

ADJOURNMENT

President Elsner adjourned the meeting at 3:37 p.m.