California State Board of Pharmacy
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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: April 12 and 13, 2000

TIME: 8:00 a.m. - 5:00 p.m.

LOCATION: Department of Consumer Affairs
400 R Street, Hearing Room #1030
Sacramento, CA 95814

BOARD MEMBERS PRESENT:
Richard Mazzoni, President
Robert Elsner, Vice President
Darlene Fujimoto – April 13, 2000 only
Andrea Zinder
John Jones
Steven Litsey
Donald Gubbins
M. Standifer Shreve

BOARD MEMBERS ABSENT:
Holly Strom
Caleb Zia
Sandra Bauer

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

April 12, 2000

CALL TO ORDER

President Richard Mazzoni called the meeting to order at 9:00 a.m. on April 12, 2000. President Mazzoni noted that this day of the meeting was going to be devoted to updating the board's strategic plan. The business session of the board meeting would take place on April 13, 2000.

President Mazzoni introduced Andrew Hesse and Bill Stobbe of Hesse, Stobbe and Associates, who will lead the board in revising the strategic plan. He also introduced all members of the board's Team Communication Committee, who would represent staff in updating the strategic plan.

The board updated its strategic plan by performing an environmental scan.

President Mazzoni adjourned the meeting for the day at 3:30 p.m.

April 13, 2000

At 9:00 a.m., President Mazzoni welcomed all board staff to the meeting, and asked them to introduce themselves to the board members and the public present. President Mazzoni acknowledged Board Members Tom Nelson and Marilyn Shreve, noting that their terms on the board have ended. This is Ms. Shreve's last board meeting as her term officially ended June 1, 1999. President Mazzoni introduced new Board Member Don Gubbins from the Rite Aide Corporation who was appointed by Governor Davis to replace Tom Nelson.

PRESIDENT'S REPORT

President Mazzoni announced that he attended the American Pharmaceutical National Convention in Washington D.C. and found it very educational. He also attended the Texas Board of Pharmacy meeting in Austin, Texas where he had the opportunity to work on language similar to the board's regulation dealing with pharmacists' lunch breaks and quality assurance issues. He stated that this marked the beginning of a mutual cooperation with another large board and he looked forward to working with them on future issues.

COMMITTEE REPORTS AND ACTION

ORGANIZATIONAL DEVELOPMENT COMMITTEE

Mr. Elsner stated that the committee met on March 20, 2000, in a teleconferenced meeting. He commended the efforts of staff on completing the Policy and Procedures

Manual for Board Members. He asked if there were any comments on the procedure manual. There were none.

Mr. Elsner reported on the status of the board's 2000/01 Strategic Planning Session and asked if there were any comments on the prior day's activities. There were none.

Mr. Elsner outlined the board's budget change proposals for fiscal year 2001/02. He noted that during the March Organizational Development Committee, the committee recommended that the board's staff proceed with the budget change proposals to increase expenditures by $1.04 million annually. He added that the board needs to take action whether to support these future budget augments.

The budget change proposals for FY 2001-02 approved by the committee are:

Enforcement:

Consumer Complaint/Mediation Unit -- $202,000 requested augment

- Establish an 800 phone number for consumers to contact the board and add one office technical to provide support to existing 5-person staff [two of which are currently temporary (limited-term for 2 years) employees] -- $82,000
- Make permanent the two staff services analyst positions currently filled as temporary, limited term positions -- $120,000

Citation and Fine Program -- $60,000 requested augment

- Create one staff services analyst position for the proposed expansion in the cite and fine program (triggered by a regulation scheduled for hearing at the July 2000, board meeting to cite and fine for all violations of pharmacy law)

Attorney General's Office – up to $325,000 requested augment

- Obtain increased AG funding – at least $250,000 or more annually, possibly to $325,000 – to work the record number of board cases awaiting board action

Licensing:

- Add one office technician position to assist with the processing applications for individual licenses (the pharmacist, pharmacy technician, foreign graduate and intern programs for audit control, and to back up during periods of high workload) $58,000 augment requested
- Establish as a permanent position the office technician position for the wholesaler desk currently filled limited term basis -- $58,000 augment requested
- Establish one office technician position for keeping current pharmacist-in-charge transactions required for all pharmacies -- $58,000 augment requested

Communication and Public Education

- Establish an associate analyst position to oversee the public education -- $78,000 requested

Organization Development:

- Budget realignment to reflect actual expenditures (in addition to increased AG funding, recognizing that full employment in all inspector positions will eliminate salary savings that have been redirected in prior years to fund other items in the budget, e.g., travel) – estimated $200,000 requested

Dr. Fujimoto expressed concern that the proposed increase for AG funding would not be sufficient to cover future enforcement if all inspector positions become filled.

Mr. Elsner reported that increasing AG funding for enforcement functions is the board's highest priority. In order for the board to fulfill its mission to protect the public, it must receive the necessary funding.

Bill Marcus stated that even if the board determines to increase its budget for future A.G. funding, the A.G.'s Office must have sufficient time to plan for its budget increase as well.

Marilyn Shreve asked if money collected from the citation and fine program could be deposited directly in the enforcement unit to cover these higher than expected AG fees.

Virginia Herold responded that the board may only spend that money appropriated by the Legislature. Even if revenue is high or new revenue is collected, the board cannot spend this money unless it is approved in the state's budget bill.

Dr. Fujimoto asked why $75,000 for a half-time inspector position was designated for the nurse practitioner drug sample legislation (AB 1545). She asked why this amount came out of the board's budget. Ms. Herold explained that when AB 1545 went through the Legislature, the board realized it would increase the number of drug samples that may end up in pharmacies. The board then attached a fiscal impact on the bill because of the need for additional inspections.

Dr. Fujimoto asked for clarification on the budget change proposals in the amount of $150,000 that the Department of Consumer Affairs submitted on behalf of all departmental entities to authorize expenditures for various functions including board member training and for a consumer ombudsman position. She asked why it is not a part of the $800,000 in pro rata the board already pays.

Ms. Herold responded that the department prepared some BCP with the board's assistance ($62,000 for Health Integrity Data Bank, $37,000 for higher workers'

compensation rates and $29,000 for a 6 percent increase in the AG's hourly billing rate). However, other BCPs ($3,000 for board member training, $17,000 for a departmental consumer ombudsman) were developed by DCA without board input.

Mr. Elsner reiterated the board's position to continue discussions with the Department of Finance to secure funding for these BCPs, especially for increased AG funding.

MOTION: Support the budget change proposal for FY 2001-02 from the concepts prepared by staff.

M/S/C: Organizational Development Committee

SUPPORT: 7 OPPOSE: 0 ABSTAIN: 0

President Mazzoni referred to the Status Report on the Board's website and asked when the website would be operative. Ms. Herold stated that text was provided to the department for review in February and the site should be operative before July 1. President Mazzoni noted that it is very frustrating that it takes 60 days to review documents that are already in the public domain.

Ms. Harris announced that just recently licensure verification became possible through the department's website at www.dca.ca.gov. In the future this website will also contain disciplinary actions that have been officially filed as public records, as well as any final disciplinary action that has been taken. Eventually, once the board's web site is up, it will be possible to verify ownership of the board's licensees as well as the fiscal officers and pharmacists-in-charge of any site. With wholesalers, this will include the principals plus the exemptees. The board handles many license verifications over the phone and this new process will definitely help licensees.

EXECUTIVE OFFICER'S REPORT

PERSONNEL UPDATE

Ms. Harris reported that Judi Collins has been promoted to a management services technician to process applications for wholesalers and medical device retailers.

Gilbert Castillo, who has served as a supervising inspector for the last two years, will be transferred to an inspector position in mid-April. Mr. Castillo has been in a limited-term supervising inspector position since April 1998, and state requirements restrict limited-term appointments to two years. The Department of Consumer Affairs will conduct interviews to compile a new list of eligible candidates for supervising inspector later this year, at which time the board's second supervising inspector position will be filled.

Roberta Orzechowki resigned from her inspector position with the board in March.

The board has 11 of its 19 inspector positions filled. In February, Supervising Inspector Bob Ratcliff and the three inspector team leads (Joan Coyne, Dolly Harris and Judi Nurse) interviewed six applicants for inspector positions. Two candidates will be offered positions.

A new list of applicants for the inspector position classification will be compiled following interviews scheduled for early this summer. The next set of applicants interviewed will be the first applicants who have been advised about the higher salaries for the inspector classification.

Ms. Harris reported that over the next few months, all board staff will undergo annual assessments and individual development conferences to assist with staff development and organizational effectiveness.

BUDGET REPORT

Ms. Harris reported on the Budget Report as follows:

1. 1990/00 Budget Year

Revenue Projected: $5,139,969

The board decreased fees effective July 1, reducing annual revenue by an estimated $1,125,125. The projected revenue for the year is comprised of $4,593,158 in revenue from licensing fees and $446,538 in interest. During the first 8 months of the year, actual revenue has been slightly higher (about 9 percent) than projected.

The board has also collected $100,674 in cost recovery this year (which is not included in the revenue projection).

Expenditures Projected: $6,722,837

The board was authorized $5,874,009 in baseline expenditures. The board has also received supplemental funding to augment this baseline for:

- CURES -- $466,345 (which has been encumbered to fund the CURES program for the remaining two years, from the original CURES appropriation in 1996)
- Y2K -- $382,283 (to replace outdated programs and hardware modifications needed)

AG Deficiency Update

Ms. Harris reported at the January meeting that the board would prepare a deficiency request for $325,000 to cover a substantial deficient projected in the AG's budget. (A deficiency request is the method used to augment the budget late in the current year as a result of unexpected events.) The board is budgeted $521,091 in AG expenses, but spending is projected at $835,008. This amount could not have been redirected from

other line items given that the board expected to fill a number of its inspector vacancies via interviews scheduled in February, and was going to have to absorb rent increases.

Last fiscal year, the board overspent its AG appropriation by $120,000. The increase in expenditures is principally due to the increased number of cases transferred to the AG's Office for discipline, reflecting a shift in focus of board inspectors to pursue and complete the most serious cases, even though it had inspector vacancies, and to pay for representation in two lawsuits.

The board cannot curtail AG prosecution costs, especially given the board's substantial reserve in its contingency fund. Ms. Harris stated that throughout February and March, the board and the Attorney General's Office aggressively worked to provide the Department of Finance with the budget details and explanations it demanded in support of the deficiency. These negotiations and discussions were difficult and required a substantial amount of staff time. In late March, the board identified money within its current year budget that could be redirected to fund expenses at the AG's Office – salary savings from unfilled inspector positions, delay in purchasing major equipment and no need to absorb rent increases during the fiscal year for additional office space in the future – and withdrew its deficiency request from the Department of Finance.

Dr. Fujimoto expressed concern over the process required to increase funding during the fiscal year for an expenditure so vital to the public safety as AG prosecution charges, and the level of detail demanded by the Department of Finance.

Fund Condition $9,483,007

At current levels of expenditure and revenue generation, the board is estimated to have 17.6 months in reserve in its contingency fund at the end of June 2000.

2. 2000/01 Budget Year

Expected Revenue: $6,528,135

Revenue for the year is expected to be comprised of $4,860,985 in licensing fees, $454,150 in interest and $1,213,000 as the final repayment of the 1991/92 board fund money transferred to the state's General Fund.

Projected Expenditure Baseline: $6,214,000

The department's budget office projects expenditures for the year at $6,214,000. This figure includes a number of budget change proposals approved by the Administration, which is currently undergoing review by the Legislature, including:

- $238,000 for ongoing funding of the public education program (but without any staff to perform these functions),

- $45,000 for staff training and development (without any staff to coordinate training requests and perform other basic personnel functions), and
- $75,000 for a half-time inspector position created to oversee implementation AB 1545 regarding the ability of nurse practitioners and physician assistants to sign for drug samples.

In addition, the department submitted BCPs on behalf of all departmental entities to authorize expenditures for various functions; the board's share of these are:
- $62,000 for one year for the board to report data to the Health Integrity Data Bank from 1996 to present
- $37,000 for increased workers' compensation rates
- $3,000 to the department for board-member training
- $17,000 to the department for a consumer ombudsman
- $29,000 for a 6 percent increase in the hourly rate charged by the Attorney General's Office.

Fund Condition: $8,526,140

At the above projected revenue and expenditure levels and with the BCPs listed above all approved, the board will have approximately 17.5 months remaining in its reserve on June 30, 2001, which is projected to decrease to 14.7 months at the end of 2001/02 if revenue and expenditures remain constant.

3. Additional Budget Issues

Y2K Issues

In July 1999, the board received Y2K supplemental funding. The board received expenditure authority for:
- $312,166 to upgrade software that is not Y2K complaint.
- $30,000 for miscellaneous hardware.
- $39,347 in increased pro rata charges to the department for this supplemental augment.

However, the board spent only $95,000 of this ($47,000 for the modified telephone system, $8,500 for consultant services for programming and $39,000 for pro rata). Unlike other expenditures within the board's budget, any unspent money not used for Y2K issues may not be redirected for other board expenditures, and will return to the board's fund in July 2000.

President Mazzoni asked if the public had questions or comments about the Organizational Development Committee's report.

THE COMMUNICATION TEAM UPDATE

Linda Kapovich reported that the Communication Team (TCT) has held 17 team meetings to date. A total of 24 issues have been brought to the TCT. All but five of these issues have been resolved and the remaining five issues are pending with the team.

On March 22, 2000, the TCT facilitated its first all-staff strategic planning meeting. The TCT's goal for the meeting was to obtain full staff participation in preparing an environmental scan. Staff developed a list of values and proposed their own vision that will be refined at the next staff meeting.

Also, at the March 22, 2000, all-staff meeting, the TCT held its annual election. Members elected to the TCT serve a two-year term. Each year, three members rotate off and three new members are elected to serve. The three members retiring from the team are Valerie Knight, Debbie Anderson, and Linda Kapovich. The three new elected members are Cindy Drogichen-Rich, Stephanie Jones, and Linda Kapovich.

PUBLIC EDUCATION AND COMMUNICATIONS COMMITTEE

Chairperson Shreve provided her report on the activities of the Public Education and Communications Committee. She stated that there had been no meeting since the January board meeting, but the committee's activities are ongoing nevertheless.

Health Notes
Ms. Shreve reported that the review and editing of the next *Health Notes* publication, "Care of Children & Adults with Developmental Disabilities," has been completed. The publication will be mailed late April.

An interagency contract has been developed with the University of California, San Francisco, School of Pharmacy, to produce a future *Health Notes* on "Alternative Medicines." Administrative costs for this project to develop and edit the text are estimated to be $25,000. Not included in this amount is additional funding needed to design, publish and mail the issue. The total projected expenditure for this issue is approximately $90,000.

Newsletter

The anticipated mailing date for the board's newsletter, The Script, is April 25, 2000.

Telephone Survey to Measure Effectiveness of the Public Education Program

A contract was awarded in December of 1999 to Meta Information Services to conduct a telephone survey to evaluate the effectiveness of the board's public education program. The survey was also designed to establish a baseline measurement of the public's awareness and opinions of the Board of Pharmacy, the importance of medication

compliance and patients consulting with their pharmacists about medication. The survey was completed in March 2000, and the executive summary of the survey will be completed by April 28, 2000.

Consumer Columns

Since initiation of the board's consumer column program, there have been seven columns published in English and four in Spanish.

Budget Update

The board's FY 2000/01 budget for the Public Education Program (excluding the board's quarterly newsletter) is only $238,000, which does not include a staff person. Because the need for a designated staff person still exists, the board will redirect funds from the allotted amount to secure one staff person to implement and oversee the present public education program. Any other future expenditures will be based on availability of funds.

Medication Information Technology Task Force

Ms. Shreve reported on the Medication Information and Technology and Task Force Meeting held on February 23, 2000. Deputy Attorney General William Marcus provided the committee with an overview of newly enacted SB 19. He stated that California has a strong right of privacy that is included in the State Constitution, and a Confidentiality of Medical Information Act that bars unauthorized disclosures of medical information, including that maintained by pharmacies. The new provisions enacted by SB 19 are intended to heighten privacy protections, including expanding the law to include health care plans and contractors and by broadening the definition of "individually identifiable" information.

Mr. Marcus stated that under SB 19, there are strong penalties for violations. The new law broadens the ability of patients to sue for misuse of information, and also authorizes action for administrative fines or civil penalties by governmental agencies or by local or state prosecutors. Depending on the intent behind the violation and the commercial misuse of information, the fine or penalty can reach $250,000 per violation. He added that in all likelihood, court cases will establish the parameters and meaning of the law, and, because of the broad manner in which the law is written, class actions cases are likely to be a vehicle used since large penalties can be assessed.

Mr. Marcus stated that patient compliance programs may not violate the law if the sole purpose of the program is to assure patients are complying with directions for medication use established by the prescriber. However, if financial incentives or benefits are involved on the part of the entity making the contacts, the practice could be a violation of law.

Ms. Shreve stated that the task force also suggested changes to Section 4050 (a) that describe the basic professional nature of pharmacy practice. The amendments specifically include pharmacists'communication for clinical and consultative purposes:

4050. (a) In recognition of and consistent with the decisions of the appellate courts of this state, the Legislature hereby declares the practice of pharmacy to be a profession.

(b) Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, ~~and~~ drug-related therapy and communication for clinical and consultative purposes.

The task force also suggested that section 1717.2 be modified because patients can currently prevent the sharing of information in the electronic records of the pharmacy which is not an option with CURES. CURES requires the transmission of this information for Schedule II drugs, even if the patient objects. Moreover, electronic maintenance and sharing of prescription and other medical information is much more pervasive when the board's regulation on shared electronic files was drafted. The following is proposed:

1717.2 Common Electronic Files
~~(a)~~Any pharmacy which establishes an electronic file for prescription records, which is shared with or accessible to other pharmacies, shall post in a place conspicuous to and readily readable by prescription drug consumers a notice in substantially the following form:
NOTICE TO CONSUMERS:
This pharmacy maintains its prescription information in an electronic file which is shared by or accessible to the following pharmacies: By offering this service, your prescriptions may also be refilled at the above locations~~. If for any reason you do not want your prescriptions to be maintained in the way, please notify the pharmacist in charge.~~
~~(b)Whenever a consumer objects to his or her prescription records being made accessible to other pharmacies through use of electronic prescription files, it is the duty of the pharmacy to assure that the consumer's records are not shared with or made accessible to another pharmacy, except as provided in Section 1764. The pharmacist to whom the consumer communicated the objections shall ask the consumer to sign a form which reads substantially as follows~~
~~I hereby notify (name of pharmacy) that my prescription drug records may not be made accessible to other pharmacies though a common or shared electronic file.~~

~~(date)~~

~~(signature of patient)~~

~~(acknowledgment of pharmacist)~~

~~The pharmacist shall date and cosign the form, and shall deliver a copy thereof to the patient. The original shall be maintained by the pharmacy for three years from the date of the last filling or refilling of any prescription in the name of the consumer.~~

John Berger referred to section 4050 (a) and stated that "clinical and consultative purposes" should be excluded from this section because it is too broad a category and may create a laundry list. He suggested that this should be placed in section 4050 (1), where the law details pharmacists' duties.

Mr. Berger added that the board needs to take extra consideration when dealing with the electronic filing regulation because of California's constitutional guarantee of privacy.

Steve Gray noted that one of the reasons the task force made this suggestion was because of the sense of urgency due to the passage of a new law that requires licensing by the Department of Consumer Affairs of any service that gives medical advice over the telephone. This law states that pharmacists would be exempt from the separate licensing provision if communication and consultation with patients is clearly recognized as part of their scope of practice. In reviewing the scope of practice, those specific words (patient consultation) were not mentioned. He urged the board to move this forward to the Legislative Committee.

Mr. Marcus clarified that board staff is focusing on the impact of the proposed change to Section 4050. This particular issue was raised because it was the consensus of the task force that Section 4050 was too limited in the language. He noted that this section was written a few years ago and it does not properly describe an essential part of what a pharmacist does, which is to apply a scientific body of knowledge to improve and promote patient health by communication for clinical and consultative purposes.

MOTION: To support the recommendation by the Education and Communication Public Meeting to amend Section 4050 of Business and Professions Code and refer this issue to the Board's Legislative Committee.

M/S/C: FUJIMOTO/SHREVE

SUPPORT: 7 OPPOSE: 0

Ms. Shreve stated that it has been an honor to serve the Governor and the State of California as a board member for the Board of Pharmacy during the past eight years. She added that it has been a pleasure to work with Patricia Harris and Virginia Herold who lead and manage so effectively and efficiently. She commended Hope Tamraz on her efforts on the Public Education and Communications Committee in dealing with areas that were new to the board.

Ms. Shreve added that it has been five years since the establishment of the committee and the board has come a long way in educating the consumers to understand the importance of taking their medications correctly and communicating with pharmacists. She added that it was an honor to serve with her colleges on the board.

Ms. Herold referred the board to a new consumer brochure on the requirements of SB 393 which requires pharmacies to charge Medicare-eligible patients the Medi-Cal price of prescription drugs if the patients are paying for the drugs themselves. Ms. Herold acknowledged committee members and Hope Tamraz on their efforts to provide the only consumer brochure available. She noted that the April newsletter will include information regarding the pharmacists' requirements and provide details published in the brochure.

LICENSING COMMITTEE REPORT

Ms. Harris reported that there has been no Licensing Committee Meeting since the January board meeting, but a licensing staff meeting was held March 28, 2000.

Ms. Harris stated that the Licensing Committee held two informational hearings on the issue of pharmacy manpower in September of 1999 and January of 2000 - the pharmacist shortage, reciprocity, use of ancillary pharmacy personnel, and automation. The Licensing Committee will examine what if any action the board should take regarding reciprocity (the use of the NABPLEX), but this must wait until the board has completed its review of the NABPLEX examination. The board is in the process of completing the job analysis for the California examination. Once this is completed, the board will contract with the Department of Consumer Affairs, Office of Examination Resources to conduct the review of the national exam. This will begin by January 2001. However, this timeline is contingent upon the status of the job analysis for NABPLEX, which must be completed before the board's review.

The U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA) is conducting a study required under the Healthcare Research and Quality Act of 1999, to determine how many pharmacists will be needed to fill America's prescription needs. HRSA is inviting all interested parties to submit resource information, data and documented studies that verify pharmacist shortages. Comments are due by May 1, 2000.

Licensing staff recommended that the board submit comments regarding California laws governing the use of technicians to fill prescriptions, the use of technology to assist pharmacists, and the current pharmacist education process including any policy positions that the board may take in these areas. The board also may want to point out outdated and restrictive federal pharmacy requirements that restrict the ability of pharmacists to provide pharmacists care.

Electronic Transmission of Prescriptions

Ms. Harris reported that the board has received many requests to approve use of various electronic systems that allow for the transmission of prescriptions from the prescriber to the pharmacy. There are many variants that are available and the Internet offers on-line services that receive an order from a prescriber and forward it to a pharmacy for dispensing. The board's focus is on its licensees who use any electronic systems to receive or maintain prescription and patient information, and any out-of-state pharmacies who use such systems to dispense medications to California residents.

Regulation 1717.4(h) requires that any person who transmits, maintains, or receives any prescription refill electronically must also ensure the security, integrity, and confidentiality of the order and any information contained in it. The pharmacy should also take necessary steps to ensure the authenticity of the order and the authority of the person issuing it as well as the person or entity from which it is received by the pharmacy.

Board staff recommended that the board amend 1717.4, as follows:

Any person who transmits, maintains, or receives any prescription refill electronically must ensure the security, integrity, ~~and~~ confidentiality, and authenticity of the order and any information contained in it.

John Cronin stated that in most cases where transactions are occurring, there is some type of contractual relationships between the prescriber and the company that operates the technology. The company is actually the agent of the doctor or the prescriber. Ultimately, the transmission is from the company directly to the pharmacy. The relationship is only through the company and the prescriber.

Ms. Herold commented that ultimately it is the prescriber that activates the process used to electronically transmit a prescription; the pharmacy is only the receiver. Consequently, the pharmacy must ensure that that the prescription is authentic, but the prescriber must assure the process selected is confidential.

Steve Gray stated that he supports the proposed language modification to Section 1717.4.

MOTION: Amend California Code of Regulations section 1717.4, as follows:

Any person who transmits, maintains, or receives any prescription refill electronically must ensure the security, integrity, ~~and~~ confidentiality, and authenticity of the order and any information contained in it.

M/S/C: ELSNER/SHREVE

SUPPORT: 7 OPPOSE: 0

Cooky Quandt commented that in dealing with electronically transmitted prescriptions, pharmacists greatly appreciate receiving prescriptions that they can read. She added that this is a very important issue and the board should continue to look at new ways to transmit prescriptions.

Ms. Harris reported that the April Newsletter will include information on this topic.

Mr. Marcus stated that the problem with electronic transfers of prescriptions is the federal regulations that clearly define a fax as a copy of an original signed prescription. He noted that the federal government is exploring the approval of electronic data transmission for all controlled substances.

Repackaging of Dispensed Prescriptions by Another Pharmacy

Ms. Harris reported that it has been the board's position that current law does not authorize a pharmacy to repackage prescription drugs already dispensed by another pharmacy into bubble packing. This constitutes manufacturing; however, it is burdensome for pharmacies that want to perform this service to be licensed as manufacturers and meet the requirements of good manufacturing practices. It would be in the patient's best interest to authorize this service under the auspices of pharmacy practice. It is especially important in skilled nursing and assisted living facilities in order to provide for patient safety by minimizing prescription errors from inconsistent delivery systems among different patients. In skilled nursing facilities, patients have the right to choose their own pharmacies. Because of this, many facilities have to contend with different drug distribution systems, which can be problematic and increase the risk of medication errors.

The board's licensing staff recommends that Business and Professions Code Section 4033 be amended to exempt from the definition of manufacturer the repackaging of a dispensed prescription into an bubble pack by a pharmacy at a patient's request.

Dr. Fujimoto stated that she supports the recommendation. She added that this has been a long-standing issue that once resolved, will provide a substantial patient service to assisted living patients. These patients now purchase prescriptions from a variety of pharmacies and the facility must administer medications to patient using these diverse systems, which can be a source of prescription error. She recommended that pharmacies performing such services follow some type of good manufacturing practices in order to trace a prescription's origin.

Mr. Marcus stated that when laws were restructured to control the production of drugs, everything was defined as manufacturing and the traditional practices of pharmacy, such as compounding, were left as an exception that did not require registration as a manufacturer. Repackaging has traditionally been defined as part of manufacturing,

specifically Business and Professions Code, section 4033. He added that the proposed amendment is necessary to accomplish what has been discussed.

Steve Gray stated that he supports the amendment. However, several other jurisdictions are involved when an entity does repackaging including the State Food and Drug Branch of the California Department of Health Services and the Federal FDA, and both require licenses to become a repackager. He suggested that the board check applicable provisions in the Health and Safety Code and the Department of Health Services' regulations.

MOTION: Amend Business and Professions Code section 4033 to exempt from the definition of manufacturer the repackaging of a dispensed prescription into an ATC/bubble pack by a pharmacy at a patient's request.

M/S/C: FUJIMOTO/ELSNER

SUPPORT: 7 OPPOSE: 0

Application Requirements for Sites – Proposed Regulation to Exempt from Disclosure Financial Information Collected as Part of an Application Investigation

Ms. Harris reported that as part of the application process for sites, the board requires financial information so that the beneficial ownership of the site can be determined. The board requires these documents pursuant to Business and Professions Code section 4207. However, the law does not specifically exempt this financial information from disclosure if it is demanded by subpoena. Therefore, to protect this information, board staff recommends that a regulation be pursued that would expressly state this prohibition to disclose the documents.

MOTION: Pursue a regulation change that would exempt from disclosure financial information collected as part of an application investigation.

M/S/C: ELSNER/ZINDER

SUPPORT: 7 OPPOSE: 0

Requirement for "Telephone Medical Advice Service Providers"

Ms. Harris reported that Assembly Bill 285 (Chapter 535, Statutes of 1999) which became effective January 1, 2000, requires telephone medical advice services to be registered with the Department of Consumer Affairs (DCA). To qualify for registration, the business entities providing telephone medical advice services must, among other requirements:

- Ensure that all staff who provide medical advice services are appropriately licensed, certified, or registered health care providers and operating consistently with the laws governing their respective scopes of practice in the state within which they provide telephone medical advice services
- Ensure that all registered nurses providing telephone medical advice services are licensed in California
- Ensure that the telephone medical advice provided is consistent with good professional practice
- Maintain records of telephone medical advice services, including records of complaints, provided to patients in California for a period of at least five years

Pharmacists are not included in the requirements of this legislation even though they are health professionals as defined by Division 2, of the Business and Professions Code. Therefore, out-of-state pharmacists that are providing telephone medical advice must be licensed as a pharmacist in California, unless they are providing this service as part of the dispensing process through a California-registered nonresident pharmacy. The DCA is pursuing various amendments to this bill including the clarification that licensure in California is required. However, even if the amendments are not pursued, current interpretation of pharmacy law does require California licensure of pharmacists.

Ms. Harris reported that pharmacists were not specifically listed in the requirements of this legislation and this presents a conflict in the way the law was written. The Department of Consumer Affairs is pursuing these amendments to make this legislation consistent and to include pharmacists. She added that another position the board could take is any pharmacist who provides services to patients in California has to be licensed as a California pharmacist.

Mr. Marcus stated that when the board passed the first non-resident pharmacy registration laws, the board had to reconcile two highly conflicting bills.

The board discussed the various scenarios for out-of-state pharmacists who practice pharmacy in California and whether or not they should be licensed in California. And, whether the practice of pharmacy by a pharmacist who is independent of a pharmacy and practicing as an independent practitioner needs to be separately licensed in California.

COMPETENCY COMMITTEE REPORT

Report on the June 2000 Examination

The board's June examination will be administered on June 13 and 14, 2000, at the Oakland Convention Center in Oakland.

Report on the January 2000 Examination

On January 11 and 12, 2000, the board administered its January 2000 pharmacist licensure examination at the Hyatt Regency San Francisco Airport Hotel to 537 candidates. The pass/fail letters were mailed to the candidates on March 22, 1999. Performance statistics on this exam were provided to board members in the board packet.

ENFORCEMENT COMMITTEE

Chair Darlene Fujimoto reported on the Enforcement Team Meeting held March 21, 2000.

Dr. Fujimoto reported that at the request of President Richard Mazzoni, the team read and discussed correspondence received from former Supervising Inspector Ken Sain, regarding his perception of current board enforcement policies. The consensus of the team was that there have been many changes that have occurred during the last six years and Mr. Sain is no longer knowledgeable about the board's policies. The team wants to move forward with the many strategic issues resulting from the strategic plans.

The leads from the Compliance, Drug Diversion/Fraud, Pharmacist Recovery (PRP)/Probationer and Administrative teams reported on their activities. Each team provided information on their workload, significant accomplishments and presentations to outside organizations.

Dr. Fujimoto reported to the team about the success of the CURES conference held February 4, 2000.

Dr. Fujimoto reported that as one of its strategic objectives, the Enforcement Team recommended and the board approve proposed amendments to its cite and fine program that would grant the board authority to cite and fine for any violation of pharmacy law. She stated that later at this meeting there would be an informational hearing on the board's proposed language.

Dr. Fujimoto referred the board to a copy of the 1999 Strategic Plan for the Enforcement Unit, with updated activities listed.

LEGISLATION AND REGULATION COMMITTEE

Regulation Update

Ms. Harris provided an overview of the board's activities on new regulations.

Approved is:

1. Citation and Fines (Section 1775 and 1775.1) which will permit the board to cite and fine for failure of pharmacists to earn required continuing education. The regulation was approved by the Office of Administrative Law and took effect on March 31, 2000.

Awaiting Notice are:

1. Graduates of Foreign Pharmacy Schools (section 1720.1), a technical amendment to permit outside experts to evaluate foreign transcripts for semester unit equivalency.
2. Citation and Fines (sections 1775, 1775.1) to broaden the board's ability to cite and fine for any pharmacy law violation. This regulation is set for hearing in July 2000.

Pending Final Implementation are:

1. Waiver Requirements for Off-Site Storage of Records (section 1707), which would establish the standards for off-site storage of specified paper records when a waiver is granted. The board needs to complete its rulemaking file and submit it to the Department of Consumer Affairs.
2. Procedures for Refill Pharmacies (section 1707.4) which would establish requirements for pharmacies that prepare refills for other pharmacies. The regulation is currently undergoing a 15-day comment period to correct technical problems with the initially filed regulation. After close of the comment period, the rulemaking file will be resubmitted to the Department of Consumer Affairs and then the Office of Administrative Law.
3. Pharmacy Operations During the Temporary Absence of a Pharmacist (section 1714.1), establishes parameters for pharmacists in sole pharmacist pharmacies to take breaks and meal breaks without closing the pharmacy. The Department of Consumer Affairs is currently reviewing the rulemaking file for the permanent regulations, which if filed with the Office of Administrative Law before April 30, 200, will keep the emergency regulation in effect until the permanent regulation is either in effect or is disapproved.
4. Dangerous Drugs Exempt from Storage (section 17174.5) which will move to regulation lists of drugs that can be stored in non-pharmacy areas of hospitals. This regulation is undergoing modifications and will be released for a 15-day comment period once the list of items is finalized.

Information Hearing on Proposed Amendments to California Code of Regulation sections 1775, 1775.1, 1775.2, 1775.5 regarding Citations and Fines

President Mazzoni announced that the board was interested in hearing comments regarding proposed regulation sections to expand the board's ability to cite and fine for any violations of pharmacy law. He stated that comments from today would be considered in developing the board's final language for the regulation, which will be released for the required 45-day public comment period after this board meeting. He added that at the July Board Meeting, the board would hold a regulation hearing on this proposal.

Mr. Mazzoni asked those who were interested in providing information to do so.

Bruce Young, representing the California Retailers Association, asked whether the board's inspectors would still be able to issue correction orders without issuing a citation and fine. He stated that the association supports the regulation.

Steve Gray, representing Kaiser Permanente, stated that they are still in the process of reviewing the specific language of the regulation but did not have all of their comments ready at this time. First, the regulation is not specific enough. The regulation refers to pharmacy law, but what is, specifically, pharmacy law? The term is too broad. He added that before an appearance before a compliance committee, the responding pharmacist is provided only sketchy information from the board to describe the reason for his or her appearance before the committee. This description does not permit the pharmacist to adequately prepare. This will be a significant problem if the pharmacist will then be subject to a fine by the compliance committee for an event the pharmacist is not prepared to discuss or cannot recall from memory the specifics about the event. He also asked for clarity on whether the executive officer can issue only a citation without a fine.

John Cronin, representing the California Pharmacists Association, stated that he did not have much opportunity to review the regulation in advance of the meeting. He questioned whether all violations of pharmacy law is really appropriate or what the board truly intends to be able to cite and fine for. For example, the board would be able to cite and fine a pharmacy for failing to provide a patient with a Medi-Cal price quote. Mr. Cronin also asked whether there is a need for such broad authority to be provided to the board. He stated that Carlo Michelotti has stated the CPhA will oppose the regulation unless there is data available documenting the need for this regulation. He clarified that data is desired, not anecdotal information. He requested clear documentation from the board of the need for this change, before CPhA can determine its final position on the regulation.

Mr. Marcus stated that there really needs to be a middle disciplinary sanction to give the board or a committee of the board an option to impose a citation or fine.

John Berger stated that he opposes the regulation and the process it establishes because it would be demeaning to the profession. He stated that only a few regulatory boards in the Department of Consumer Affairs have adopted such regulations, and none of these regulate professionals (as opposed to vocations). He added that when pharmacists appear before a compliance committee, they don't know why they are being required to appear, especially since some of the investigations occur of incidents that are 1, 2 or 3 years old. He suggested that people scheduled for compliance committee appearances be provided with the inspector's report.

Departmental Counsel LaVonne Powell stated that in her opinion, most of the healing arts boards in the department do have such broad authority to cite and fine their licensees. Ms. Harris added that for several years summaries have been provided to those who are asked to appear before the compliance committees so that the individuals can be better prepared to respond to board member inquiries.

Alan Pope, representing Longs Drug Stores, stated that the board needs to limit cite and fine authority only for the most serious cases and offenses. He suggested that the board develop a notice of violation procedure similar to that used by the California Department of Food and Agriculture. He also suggested that the board permit fines only of those who are repeat violators. He also stated that the types of investigations initiated by the board now no longer involve jurisdictional issues involving health and safety. Instead the board is involved in minor issues like patients waiting too long. He asked that the board reconsider the proposed regulations and institute some protection for the pharmacists that are doing a good job and not utilize cite and fine as a hammer to beat pharmacists over the head.

President Mazzoni asked if there were other comments. There were none.

Legislative Report

President Mazzoni stated that the Legislative Committee met on March 24, 2000, and made recommendations for board positions on a number of pending bills.

1. Board-Sponsored Legislation

President Mazzoni stated that the committee has also been involved with the board's three sponsored bills this year

SB 1339 (Figueroa)

This bill would require all pharmacies to establish quality assurance programs to evaluate prescription errors. All data entered into such programs would be exempt from discovery in litigation. The bill's first policy hearing was set for April 10, but the bill was held over until April 24 due to lack of a quorum present to hear the bill. Bob Elsner will testify in support of the bill on behalf of the board.

AB 2018 (Thomson and Runner)

This bill would permanently establish the CURES program (by eliminating a sunset date) and would repeal the triplicate prescription requirements for Schedule II drugs. This bill is supported by a wide group of patient advocates and regulators, however, law enforcement, including the Attorney General's Office, is opposed to eliminating the triplicate without creating a single serialized prescription program where the prescription pads would still be obtained from the Department of Justice. The Assembly Health Committee passed this bill on April 11. President Mazzoni testified in support of this legislation for the board.

SB 1554 (Senate Business and Professions Committee)

This bill contains three amendments submitted by the board to correct technical problems in the code arising from the recodification of pharmacy law in 1997. The board also intends to add amendments to permit pharmacies to stock ambulances. This bill will have its first policy hearing soon in the Senate Business and Professions Committee.

2. Legislation Pending or Introduced Impacting the Practice of Pharmacy

AB 2240 (Bates)

This bill sponsored by Kaiser Permanente would permit the electronic transmission of prescriptions. The bill also would permit the electronic transmission of controlled substances prescriptions when approved by the Drug Enforcement Administration, California Department of Justice and the California Board of Pharmacy.

The Legislative Committee recommends that the board oppose AB 2240 unless it is amended to resolve the board's concerns with record keeping, changes to electronic records, controlled substances and other implementation issues.

Board Member Steve Litsey abstained from discussing or voting on this bill.

Bruce Young, representing the California Retailer's Association, stated that the board should seek an OUA position for a number of reasons. For example, the bill would permit physicians' offices to access pharmacy files, violating patient privacy.

Steve Gray, representing Kaiser Permanente, the bill's sponsor, stated that the bill provides the authority for the board to approve any electronic transmission of controlled drugs, should a federal employee approve such a waiver in the first place. As such, the board would still control when this could occur. He added that the DEA is proceeding to make changes in its regulations to permit the electronic transmission of controlled substances prescriptions, which should be completed by late summer or early fall. He stated that the pharmacy must grant access to physicians' offices before they can access pharmacy files so there would be no problem with confidentiality. Mr. Gray added that this bill is important to prevent prescription errors, because electronically transmitted prescriptions are clearer and easier to read by pharmacies than are handwritten orders. He stated that the bill would protect the public from inaccurate records and prescription errors.

MOTION: Legislative Committee: Oppose AB 2240 unless it is amended to resolve the board's concerns with record keeping, changes to electronic records, controlled substances and other implementation issues.

SUPPORT: 5 OPPOSE: 1 ABSTAIN: 1

AB 2106 (Davis)

This bill would make possession of precursors of GHB a felony.

President Mazzoni reported that the Legislative Committee recommends support of AB 2106 based on public safety.

MOTION: Legislative Committee: Support AB 2106 (Davis)

SUPPORT: 6 OPPOSE: 0

AB 2294 (Davis) - Labeling dietary supplements containing Ephedrine.

President Mazzoni reported that the Legislative Committee recommends that the board support the bill if it is amended to address the board's concerns. He stated that the committee had concerns that these products that are available over-the counter and have no prescription requirements and yet they are still dangerous. The supplements are outside of the board's jurisdiction; therefore, these provisions should be moved to the Cosmetic Act.

MOTION: Legislative Committee: Support AB 2294 with amendments to move the provisions to the Cosmetic Act.

SUPPORT: 6 OPPOSE: 0

AB 1828 (Speier) - Internet Practice of Medicine and Pharmacy.

President Mazzoni stated that the board's concern with this bill is that the board is charged with enforcing the provisions but is not authorized to be awarded penalties.

MOTION: Legislative Committee: Support SB 1828 relating to Internet practice, if it is amended to permit the board to obtain fines for cases it pursues.

SUPPORT: 6 OPPOSE: 0

AB 1759 (Papan) - Internet Public Records.

President Mazzoni reported that this bill would require the Internet posting of board documents. However, the bill does not give a starting or ending date for this information to be on the Internet. This bill would require a great number of documents to be posted on the Internet, and does not provide a management system to purge documents.

MOTION: Legislative Committee: Oppose AB 1759 unless it is amended concerns relating to the scope of documents that must be listed on the website.

SUPPORT: 6 OPPOSE: 0

AB 2329 (Ducheny) - Tribal Sovereignty

President Mazzoni reported that this bill, as currently drafted, appears to effectively prohibit any effort by any state or local government to regulate activity on tribal land. If this bill passes in its current form, the board would be unable to continue regulating pharmacies on tribal land that provide pharmacy services to non-tribal members.

MOTION: Legislative Committee: Oppose AB 2329.

SUPPORT: 6 OPPOSE: 0

SB 1940 (Bowen) - Relating to Pharmacy Records

President Mazzoni stated that the bill creates unnecessary and likely unintended obstacles to the provision of quality pharmaceutical care. It is also unclear why patient confidentiality in pharmacies is treated in isolation of other health care settings. Existing law appears to clearly address the problem identified by the author. Imposing additional requirements on medical information in the pharmacy setting without a clear demonstration of need or the deficiency in current law is not justified.

MOTION: Legislative Committee: Oppose SB 1940.

SUPPORT: 6 OPPOSE: 0

AB 1496 (Olberg) - Home Medical Product Providers

Ms. Herold asked the board to reaffirm its position on AB 1496 that would require the board to regulate non-prescription required medical products that are sometimes dispensed by MDRs and pharmacies pursuant to a prescription but can be purchased at any store. She added that this bill would require the board to regulate any medical products that may be prescribed and covered by a third-party payer. The bill is needed, according to the sponsor, to prevent fraud. However, the board does not enforce or have access to MediCal claims or those of other third-party payers, so it would be extremely difficult to identify fraud. The board is the wrong agency; the Department of Health Services would be preferable. The board had an oppose position on this bill last year.

MOTION: Oppose AB 1496.

M/S/C FUJIMOTO/SHREVE

SUPPORT: 6 OPPOSE: 0

APPROVAL OF MINUTES

Full Board Minutes – January 26, 2000

MOTION: Approve the minutes as corrected with two typographical errors.

M/S/C: JONES/ELSNER

SUPPORT: 6 OPPOSE: 0

Southern Compliance Committee Minutes – February 22, 2000

Ms. Fujimoto requested that the board move to delay the approval of these minutes until clarification is received via checking the recording tape with respect to a statement made during the meeting regarding expiration dates.

Northern Compliance Committee Minutes – February 9, 2000

MOTION: Approve as submitted.

M/S/C: ELSNER/MAZZONI

SUPPORT: 6 OPPOSE: 0

ELECTION OF BOARD OFFICERS

Mr. Mazzoni announced it was time for nominations from board members for board president.

MOTION: Elect Vice President Robert Elsner as president of the California State Board of Pharmacy

M/S/C: SHREVE/FUJIMOTO

SUPPORT: 6 OPPOSE: 0

Mr. Mazzoni requested nominations from the board for the office of vice president of the Board of Pharmacy

MOTION: Elect Board Member Steven Litsey for the office of vice president.

M/S/C: JONES/FUJIMOTO

SUPPORT: 6 OPPOSE: 0

MOTION: Elect board member Caleb Zia as treasurer

M/S/C: MAZZONI/JONES

SUPPORT: 6 OPPOSE: 0

Mr. Elsner stated that he would do everything possible to fulfill the duties and responsibilities of the position of president. He commended the board staff and stated that he looks forward to working with them. He added that committee assignments will be adjusted to accommodate vacancies. He thanked the board for their support of his nomination.

PUBLIC COMMENT

Mr. Cronin recognized board member Marilyn Shreve for her long-standing service to the board as a board member.

Mr. Marcus acknowledged outgoing board president Richard Mazzoni and added that it was a pleasure to work with him during his tenure as president.

ADJOURNMENT

There being no new business, President Mazzoni adjourned the meeting at 3:00 p.m.

CLOSED SESSION

The board moved into closed session pursuant to section 11126(c) and (3) of the Government Code to deliberate upon proposed decisions and stipulated settlements, and to receive an update on pending litigation in Doumit v. Board of Pharmacy (#98A504499) and Gonzalez v. Board of Pharmacy, Sacramento Superior Court Case #99ASO1990).