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 & TIME: April 24-26, 2002

LOCATION:
Wednesday, April 24, 2002
Friday, April 26, 2002
Department of Consumer Affairs
400 R Street, Hearing Room, Suite 1030
Sacramento, CA 95814

LOCATION:
Thursday, April 25, 2002
Legislative Office Building
1020 N Street, Room 100
Sacramento, CA 95814

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

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

Wednesday, April 24, 2002

CLOSED SESSION

The board moved in Closed Session pursuant to Governor Code Section 111126(c)(3) to deliberate upon disciplinary cases and to confer with Legal Counsel pursuant to Government Code Section 111126(e) regarding the following pending litigation: Crowley v Board of Pharmacy.

CALL TO ORDER

President Litsey called the meeting to order at 4:00 p.m. on Wednesday, April 24, 2002.

COMMITTEE REPORTS AND ACTION

ORGANIZATIONAL DEVELOPMENT COMMITTEE

- **Communications Team Report**

The board's Communication Team (TCT) meet quarterly to address staff concerns and issues to facilitate and improve communication within the board.

Yolanda Barnes introduced herself and stated she would provide the TCT's report to the board. She announced that she, Board Inspector Bob Kazebee and Legislative Analyst Paul Riches are the new team members elected during the last staff meeting on March 13, 2002. Ms. Barnes added that terms expired for former TCT members Cindy Drogichen-Rich, Stephanie Jones and Linda Kapovich. Ms. Barnes acknowledged their hard work and dedication.

Ms. Barnes commended the board's management in resolving issues that come before the team and responding to employees' concerns.

Ms. Barnes also reported on the team's efforts for future team building exercises planned for the July meeting.

President's Report

- **Competency Committee Appointments**

President Litsey announced that he appointed two representatives from the University of the Pacific to the board's Competency Committee. New members are Susan Ravnan replacing William Kehoe the Competency Committee's former chair, who served nearly nine years. He also appointed Linda Norton to replace Timothy Smith. Dr. Smith served

on the committee for six years. President Litsey thanked both Dr. Kehoe and Dr. Smith for their contributions to developing the board's examination.

President Litsey noted that each California school of pharmacy has representation on this committee. He added that he had requested recommendations for nominees from each of the two largest pharmacy associations to assure the committee has quality members with a diversity of expertise.

- **Selection of three Californians to Serve on the North American Pharmacist Licensure Exam (NABLEX) Committee**

  President Litsey announced the National Association of Boards of Pharmacy has appointed three former Competency Committee members to the NAPLEX Review Committee. Former board member Holly Strom and William Kehoe and Betty Dong were selected to serve on the NABLEX exam committee for a one-year term.

Announcement

President Litsey announced that Board Member Bob Elsner has been selected as Alumnus of the year from Santa Ana College. The board congratulated Mr. Elsner on being selected for this honor.

- **Report on the meetings of February 15 and April 8, 2002**

  Chairperson Elsner reported that the Organizational Committee met on February 15, specifically to address strategic planning issues. The committee again met on April 8 for its quarterly meeting and to focus on strategic planning issues. Minutes from both meetings are in the board packet.

- **Strategic Objective Proposal: Consider the feasibility of establishing the board's own computer system to track licensees and enforcement activities.**

  Chairperson Elsner reported that the board relies upon the Department of Consumer Affairs' computer system to track licensee information and data on the board's enforcement program. Chairperson Elsner noted that this system is antiquated; it was developed in the 1980s and has been patched over the years by various consultants to update it and retain its "functionality."

  Ms. Herold added that the current system is very complex in that there are 35 boards and bureaus using it. Because the board's regulation and statute program is completely different than other board's or bureau's, it cannot provide much of the data desired by the board efficiently. In order to obtain data timely, the board downloads data and uses commercially available software to perform analyses and statistics. This system is limited.

Chairperson Elsner reported that the Department of Consumer Affairs is developing a new computer system for the department and the board will undergo a lengthy interview process at the end of June to document elements of its enforcement and licensing programs. As such, a new computer system from the department may be available in one or more years.

Chairperson Elsner stated that because of the need and importance of readily available licensing and enforcement data, the committee recommends that staff explore the feasibility of the board developing its own computer programs. Part of the analysis will consider the systems and services available from the department. This analysis would be undertaken after the sunset review is completed, possibly next spring when the status of the department's new system will be better known.

Mr. Gubbins asked if other boards within the department have their own computer systems.

Ms. Herold responded that some of the larger boards within the department do.

Mr. Fong expressed concern that if the board established its own computer system, it would not have the support it has with the department's information services system. Mr. Fong also expressed concern about the possible costs of such a system. He added that the department should be involved in the feasibility study once it is initiated. Staff agreed to keep the board advised about the status of the Department of Consumer Affairs' computer system.

MOTION: Organizational Development Committee: Consider the feasibility of establishing a Board of Pharmacy computer system to track licensees and enforcement activities.

SUPPORT: 10 OPPOSE: 0

- **Proposed Budget Change Proposals for the Future**

Chairperson Elsner stated that the new fiscal year starts July 1, 2002, and budget augmentations for 2002/03 and future budget years must be submitted to the Department of Consumer Affairs in July for Administration review.

Chairperson Elsner stated that one proposal is being sought to provide supplemental funding to the board's 2002/03's budget. For the most part, the proposal's components were denied by the Department of Finance in October 2001 as part of the realignment budget change proposal. The specific proposals are:

1. Printing $60,000 for 2002/03 (to allow mailing of Pharmacy Law book to all pharmacies.
2. AG's Office (for additional AG hours needed by the Board of Pharmacy each year) $262,500 for 2002/03 and ongoing years.
3. Temporary help (clerical assistance to handle workload fluctuations and basic clerical duties, plus part-time auditor) $109,000 for 2002/03 and ongoing years.
4. Postage to cover under-funded amounts from prior years and a 10 percent rate increase scheduled to take effect July 1 $75,000 for 2002/03 and ongoing years
5. Proctor assistance with the examination $14,000 for 2002/03 and ongoing years
6. Overtime payment for hours worked $9,700 for 2003/04 and ongoing years.

Chairperson Elsner stated that, as in prior years, the Administration does not wish to increase the size of state government, so any proposal that seeks an increase in staffing would be difficult to have approved.

Chairperson Elsner reported that the board has seven vacant positions. However because of the hiring freeze, the board and is unable to develop a quarterly *The Script* newsletter because it cannot fill the editor's position.

Chairperson Elsner reported that during a public meeting with the Department of Consumer Affairs, he discussed the issue with the director of Consumer Affairs, Kathleen Hamilton, that because the board is solely funded by its licensees, the board should be able to have access to its funds. Chairperson Elsner stated that although Ms. Hamilton supports this, the Governor's decision is that if the Administration excludes special funding entities (those that received their funding from membership and license fees), it would not be fair to other state entities.

Mr. Gubbins referred to the "Notice to Consumers" poster and the 800 telephone number that the board wishes to establish and print on the poster. He asked if the board could handle the additional workload with so many vacancies in the office.

Ms. Harris responded that it is very important for consumers to have an 800 telephone number and the board is one of a few boards that do not have this. She added that the extra workload would probably need to be redirected to other staff to handle the extra calls, but if the board waits for additional staff resources via approval of a budget change proposal to implement such a service (as it has over the last few years) the board may never have this service.

John Cronin, representing the California Pharmacists Association, referred to the $600,000 funding sought for Internet drug buys. Mr. Cronin asked if the goal is to shut

down the pharmacies for such violations. He added that this is not a realistic goal, and the board should not pursue this.

Ms. Harris stated that the board receives many requests from pharmacies in California who send the board Internet sites that are in possible violation of California law. Ms. Harris added that the board is pursuing cite and fine authority for those who violate these laws. She added that the board is working with the Attorney General's Office to make a determination on this. She added that it is expensive to purchase drugs off the Internet, but the board must investigate these complaints.

Mr. Cronin requested that the board provide more detail on how it will investigate and prosecute these cases.

Mr. Jones stated that the board is taking an active role in Internet dispensing because this will protect consumers who would otherwise be in danger of this practice.

Ron Diedrich, Deputy Attorney General, stated that the board has jurisdiction against anyone who violates California pharmacy law while dispensing over the Internet.

Ms. Harris stated that the board works with federal and state entities as well as the National Association of Boards of Pharmacy in a cooperative effort to address this issue. She added that the reality is that the board has to have staff to work these cases but in order to get additional money, the board must justify the need with the Department of Finance.

MOTION: Organizational Development Committee: Develop several budget change proposals for the 2002/03 fiscal year (which will be "current year proposals" because they would augment the current budget year if approved) and several others for 2003/04:

Organizational Development 2002/03 $530,00; ongoing $618,000: Budget realignment to provide funding to budget areas under-funded in prior years, but which were partially funded from salary savings from unfilled inspector positions or redirected from other budget areas.

Specifically:

1. Printing $60,000 for 2002/03 (to allow mailing of Pharmacy Law book to all pharmacies) $158,000 (ongoing) for annual printing needs (The Script, Pharmacy Law book annually, in-house photocopying of applications)

2. AG's Office (for additional AG hours needed by the Board of Pharmacy each year)
   $262,500 for 2002/03 and ongoing years
3. Temporary help (clerical assistance to handle workload fluctuations and basic clerical duties, plus part-time auditor)
   $109,000 for 2002/03 and ongoing years
4. Postage to cover under-funded amounts from prior years and a 10 percent rate increase scheduled to take effect July 1
   $75,000 for 2002/03 and ongoing years
5. Proctor assistance with the examination
   $14,000 for 2002/03 and ongoing years
6. Overtime payment for hours worked
   $9,700 for 2003/04 and ongoing years

Seeking Submission for 2003/04 Budget Year

- Enforcement $130,000: for one analyst and one clerical person for the Complaint Unit to process complaints timely and monitor the status of complaints and investigation cases, and meet increased workload expected from establishing an 800 line for consumers that will be printed on its Notice to Consumers.
- Internet pharmacies $600,000: for drug buys and one staff person to form an aggressive drug buy unit for drugs from the Internet.

SUPPORT: 10 OPPOSE: 0

Chairperson Elsner stated that the committee has worked with Lindle Hatton over the last two months. Dr. Hatton is the facilitator for the Strategic Planning session planned on Friday, April 26. He urged the board to attend the meeting for the full day.

Chairperson Elsner stated that the Department of Finance approved a Spring Finance letter for the board to implement SB 293 (licensure of pharmacies that perform sterile compounding). The amount approved was reduced from the board's initial request, but should be sufficient to establish and maintain the program unless a large number of pharmacies apply for this specialty license. The amount of funding approved is $309,000 in 2002/03 and $272,000 on an ongoing basis.

Executive Officer's Report

Ms. Harris referred to the Spring Finance letter and stated that it has passed through both the Senate and Assembly budget subcommittees. Ms. Harris noted that some boards have

already lost their reserve funds to the General Fund and it is not certain if the board will lose its funds. She added that statutory language states that the money cannot be borrowed if it creates an adverse impact to the board. Based on the report, the board expends almost 2 million more than it takes in revenue. Ms. Harris stated that the board may have to consider a fee increase if the board's funds are loaned to the General Fund.

Ms. Harris stated that out of the seven vacant office positions, staff has submitted freeze exemptions in December for three of the most critical positions to assure ongoing operations. The exemption requests were for a casher position, a receptionist position, and an associate analyst position in the enforcement unit. Ms. Harris added that only the associate analyst position was granted an exemption in March, and recruitment for this position is underway.

Ms. Harris reported that the four other vacant positions (one clerical and one analyst position in the enforcement unit, the board's newsletter editor and the new public outreach coordinator) would remain unfilled for the foreseeable future. Staff will be temporarily transferred into these positions to assure essential functions are performed.

Ms. Harris stated that the board will no longer be able to perform a number of functions including publication of the quarterly newsletters (the January issue of The Script will be the last until a new editor can be hired), provide application status requests over the phone (instead it will respond to faxed requests on applications that are at least 60 days old), provide interactive responses to inquiries over the Internet, provide responses made to "the duty inspector," or license pharmacists "over the counter" when the examination results are released.

Mr. Fong expressed concern that without distribution of *The Script*, the board will not have the ability to inform the pharmacists and the public about important information regarding the practice of pharmacy. He asked if it is possible to seek contributions from the private sector to publish this newsletter.

Ms. Harris responded that staff would still need staff to write the text. Ms. Harris added that staff that possibly could coordinate development of *The Script*, are now working on the Sunset Report that is due in September. Ms. Harris stated that the board is keeping information current on the website.

- **Personnel Update**

  Ms. Harris reported that Linda Kapovich was promoted to a staff services analyst in February. This promotion was considered a promotion in place, reflecting the expanded autonomy Ms. Kapovich needs for the board's monthly compliance committee meetings in Northern and Southern California each month.

- **Training**

Ms. Harris reported that all inspectors were provided with information (and CE credit for attending) sessions coordinated by the board in March 2002 on Emergency Contraception, Quality Assurance Program and on drugs for food animals and drug residues in food. She thanked those who provided this training for their assistance: Mike Negrette, Diane Tobias, Mark Sey and Don Dlingborg.

President Litsey asked the board to review the following strategic goals of the Organizational Development Committee:

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

MOTION: Organizational Development Committee: Approve the strategic goals of the Organizational Development Committee

SUPPORT: 10 OPPOSE: 0

- **Future Meeting Dates**

President Litsey asked board members to review the proposed schedule of board meetings for 2003. The schedule is:

January 22, 23, 2003 – Orange County or Los Angeles (near LAX)
April 9, 10, 2003 – Sacramento
July 21, 22, 2003 – San Diego
October 29, 30, 2003 – San Francisco

ADJOURNMENT

President Litsey adjourned the meeting at 5:00 p.m. on April 24, 2002. He announced that the board meeting location for the following day would begin at 9:00 a.m. at:

Legislative Office Building
1020 N Street, Room 100
Sacramento, CA 95814

Thursday, April 25, 2002

CALL TO ORDER

President Litsey called the meeting to order at 9:00 a.m. on Thursday, April 25, 2002.

ANNOUNCEMENT

President Litsey announced that on behalf of the Board of Pharmacy, special recognition is being presented to Hope Tamraz who recently retired from state service after 18 years of exemplary service. President Litsey presented Ms. Tamraz with an inscribed clock purchased by board members.

Ms. Tamraz thanked the board and added that she enjoyed working for the Board of Pharmacy very much.

President Litsey referred to the many projects that Ms. Tamraz worked on during her career with the board including editor for the board's newsletter *The Script*, development of the Board of Pharmacy's public outreach program, coordination of the brown bag media events and coordinating and staffing the board's information booths at professional organizational events. She also assisted in the development and production of Health Notes. President Litsey added that Ms. Tamraz also assisted in the development if the board's telephone system and aided many applicants for licensure. President Litsey thanked Ms. Tamraz for all of her hard work and dedication throughout 18 years with the board.

Mr. Jones stated that several years ago the board received Board of the Year recognition for its public education program from the National Association of Boards of Pharmacy and Ms. Tamraz was instrumental in the coordination and development efforts for media events and developing the logo and brochures.

COMMITTEE REPORTS AND ACTION – CONTINUED

PUBLIC EDUCATION AND COMMUNICATIONS COMMITTEE

Chairperson Bill Powers acknowledged Ms. Tamraz's talent and professional ability and stated that she will be missed.

Chairperson Bill Powers reported that the Communications and Public Education Committee met March 26, 2002, in a teleconferenced meeting.

- **Notice to Consumers**

Chairperson Powers stated that the board would act (during the regulation hearing scheduled later in the board meeting) on a proposed revision to California Code of Regulations section 1707.2 regarding the board's Notice to Consumers that must be displayed in pharmacies or provided on a receipt to patients.

- **Patient Fact sheet on Emergency Contraception**

  Chairperson Powers stated that in January, SB 1169 took effect to create a "pharmacist's class of drugs," enabling a pharmacist to furnish emergency contraception medication to patients if there is a protocol in place with a prescriber. The patients do not have to be patients of the prescriber with whom the pharmacy has developed the protocol.

  Chairperson Powers stated that the law requires any pharmacist providing emergency contraception to provide a fact sheet prepared by the board. At the January board meeting, the board approved the temporary use of a fact sheet prepared by the Pharmacy Access Partnership, until the board develops its own fact sheet.

  Chairperson Powers stated that since the January board meeting, the Pharmacy Access Partnership's fact sheet has been printed in the February *The Script*, and added to the board's website. Staff also has gathered information on emergency contraception and attended training provided by the California Pharmacists Association on emergency contraception. A draft of the board's fact sheet may be available for committee review before the July board meeting.

- ***Health Notes***

  "Quality Assurance Programs"

  Chairperson Powers stated that the board contracted with the UCSF to develop this issue after being unsuccessful in getting a request for proposals released through the approval process in time to complete work on this project this fiscal year. The issue will aid pharmacies in complying with the board's new requirements that pharmacies establish quality assurance programs for prescription errors. The board received a one-time appropriation of $100,000 to develop this issue although this funding is only available through June 30, 2002, which now seems likely.

  "Geriatrics"

  Chairperson Powers stated that the UCSF has obtained outside funding (not from the board) to develop this manuscript, which the board will publish and distribute as a *Health Notes*. The publication of this issue will occur next fiscal year, and the Department of finance has provided $75,000 in one-time publishing and mailing costs in the 2002/03 board budget.

- **Newsletter Editor and Public Outreach Coordinator Positions Frozen by Governor's Hiring Freeze**

  Chairperson Powers reported that the Governor's hiring freeze has created a huge impediment in the board's communication and public education functions. Two key positions, the newsletter coordinator and public outreach coordinator are vacant and cannot be filed without a freeze waiver from the Department of Finance. In the next quarter, the board will seek freeze exemptions for both positions as they are key to the board's mandate and activities in this area.

- **New Consumer Labels Are Required on Over-the-County Medications beginning May 2002**

  Chairperson Powers reported that new consumer information would be required on over-the-counter medications beginning in May 2002. These labels have been compared to the required nutritional labeling required on food products to provide consumers with better and standardized information about OTC drug products.

  Chairperson Powers noted that the committee will add basic information to the board's website to provide additional information to consumers on this important change.

- **Participation in Two Major Consumer Information/Education Fairs this Summer**

  Chairperson Powers reported that Ms. Harris, Ms. Herold and he would staff public information booths this summer at two major public events:

  June 8 in San Diego, The Better Business Bureau's ScamJam 2002
  October in Sacramento, CAUSE Consumer Protection and Public Safety Foundation.

  Chairperson Powers announced that the 2002 Pharmacy Law books are available for sale through LawTech. The Script newsletter was published and distributed in February 2002.

  President Litsey asked if there were public comments.

  President Litsey referred to the hiring freeze and the effect that it has on the board, specifically in regards to not being able to publish *The Script*. President Litsey asked that the board go on record to support a request to the Governor's office that the freeze be lifted. He added that the board has six positions that it will ask the Governor to reconsider for freeze exemptions.

  Teresa Miller, representing the California Society of Hospital Pharmacists (CSHP), stated that as a result of the Board of Pharmacy staff shortage, the CSHP receives many

inquiries for legal questions that would otherwise be handled by the board. Ms. Miller added that the CSHP would submit a letter in support of a freeze exemption.

Chairperson Powers asked for a short paragraph or two that he could distribute to senior organizations for additional support letters.

Mr. Fong suggested that a template be placed on the board's website to increase accessibility.

Mr. Elsner noted that according to the San Francisco Chronicle, the Governor's Office and the Department of Finance approved 3000 exemptions to the hiring freeze. He encouraged the board to make the requests.

MOTION: Submit documentation requesting that the Governor reconsider the hiring freeze so the board can fill its key positions of editor of *The Script* and the public outreach coordinator.

M/S/C: POWERS/TILLEY

SUPPORT: 10 OPPOSE: 0

- **Proposed Strategic Goals for 2002/03**

President Litsey asked if there was discussion on the proposed strategic goals for 2002/03. There was none

MOTION: Communications and Public Education Committee: Approve the strategic goals for 2002/03 of the Communication and Public Education Committee:

1. Evaluate the results of the consumer survey and develop a consumer outreach plan.
2. Evaluate the effectiveness of board outreach programs (*Script*, *Health Notes*, consumer brochures and columns, PSAs).
3. Revise the "Notice to Consumers" poster for distribution to pharmacies.
4. Expand consumer information available on the board's website.
5. Develop a schedule to revise and update consumer brochures.

6. Pursue a budget change proposal to create a staff position to oversee the consumer education program.

SUPPORT: 10 OPPOSE: 0

LICENSING COMMITTEE

- **Report on the Meeting of March 7, 2002**

  Chairperson Don Gubbins reported on the public meeting of the Licensing Committee meeting held in Sacramento on March 7, 2002, and he noted that new committee members David Fong and Caleb Zia also were in attendance. Chairperson Gubbins stated that the main purpose of the meeting was to review the proposed solutions established by the Pharmacy Manpower Task Force to address the questions of the pharmacist shortage in California, and make recommendations on these solutions to the board.

- **Authorize the Pharmacy Technician Certification Board (PTCB) Examination as another Alternative to Qualify as a Registered Pharmacy Technician**

  Chairperson Gubbins stated that currently pharmacy technician registration can be obtained by taking an approved course, having 1500 hours of experience in the pharmacy performing specific duties, being eligible to take the board's pharmacist licensure exam or possessing an A.A. degree in a health field. Chairperson Gubbins stated that if the board approves this recommendation of the task force, it would add another qualifying method for becoming a pharmacy technician in California.

  Ms. Harris stated that the current application process would remain the same and fingerprint clearance would still be required.

  Chairperson Gubbins stated that recently the National Association of Boards of Pharmacy adopted the PTCB exam as one of their qualifiers for technicians and many applicants have successfully passed the exam. Chairperson Gubbins stated that because the PTCB exam is challenging and extensively touches on all practices of pharmacy, candidates who pass the exam are a step beyond the competency level of a candidate with an A.A. degree without any pharmacy experience.

  Steve Gray, representing Kaiser Permanente, stated that Kaiser supports the use of the PTCB examination because it is specifically designed to evaluate a technician's knowledge and capability. Mr. Gray added that the addition of the PTCB exam as a qualifying method for registration as a technician would aid in hiring technicians more quickly, especially college students and others interested in short-term employment.

Ms. Harris noted that this recommendation would require a statutory change.

Chairperson Gubbins added that the PTCB computerized exam is offered at several locations within the state.

MOTION: Licensing Committee: Authorize the Pharmacy Technician Certification Board (PTCB) exam as another method to qualify as a registered pharmacy technician.

SUPPORT: 10 OPPOSE: 0

- **Explore the feasibility of the PTCB examination as the sole qualifier for registration as a pharmacy technician and determine what expanded duties a PTCB registered pharmacy technician can perform.**

Chairperson Gubbins stated that the Pharmacy Manpower Task Force supported the following three proposed solutions but requested that the proposals be considered together:

1. Require the PTCB examination as a qualification method for technician registration. Additionally, all technicians must demonstrate a minimum level of competencies (test, classroom, and experience) in order to be registered and to provide a grandfather provision with a window of opportunity to take an exam and pass.
2. Expansion of the role of technicians could alleviate the manpower shortage when appropriate quality assurance processes are in place with the goal of increasing the pharmacist's role in performing patient care services.
3. Expansion of ratio and role of technicians could mitigate shortage when appropriate quality assurance is in place ensuring the pharmacist's role in performing patient care services.

Mr. Tilley expressed concern that this recommendation would result in a lack of on-the-job training for technicians.

Mr. Elsner stated that he also shares concern for on-the-job training but added that by approving this recommendation it would offer the advantage of a feasibility study.

John Cronin, representing the California Pharmacists Association, stated that this would provide an opportunity for the board to work with the professional associations to develop possible new roles for technicians. He suggested that the board include a statement within the recommendation.

Steve Gray representing Kaiser Permanente stated that Kaiser has concerns that this proposal will limit the availability of technicians. He offered the following language:

The Board of Pharmacy explores the feasibility of the PTCB examination as the standard for qualifying candidates to register.

Mr. Gray asked that the board consider other exams as well such as the ASHP exam that may serve just as well to test the qualifications of technicians.

Mr. Zia suggested that the board target schools of pharmacy for further input.

MOTION: Refer the Licensing Committee's recommendation back to the Committee:

Explore the feasibility of the PTCB examination as the sole qualifier for registration as a pharmacy technician and determine what expanded duties a PTCB registered pharmacy technician can perform.

M/S/C: POWERS/ZINDER

SUPPORT 4 OPPOSE: 6

MOTION: Amend the recommendation, substituting the word "standard" for the word "sole."

M/S/C: ELSNER/ZIA

SUPPORT: 7 OPPOSE: 3

MOTION: Licensing Committee: The Board of Pharmacy explores the feasibility of the PTCB examination as the ~~sole~~ standard qualifier to register as a pharmacy technician and to determine what expanded duties a PTCB registered pharmacy technician can perform.

SUPPORT: 6 OPPOSE: 4

- **Increase the number of interns a pharmacist can supervise to two**

Chairperson Gubbins stated that the Pharmacy Manpower Task Force supported this recommendation and if approved, it would increase opportunities for many interns who are sometimes licensed pharmacists from out-of-state waiting to take the California pharmacist licensure examination. Chairperson Gubbins noted that the Licensing Committee discussed the issue of the pharmacist-in-charge making decisions on the type and number of personnel needed to operate a pharmacy, based on the specific needs of the pharmacy. The committee felt it was important that pharmacists have the flexibility

of supervising two interns if the practice setting supports this organizational structure. This proposed solution requires a legislative change.

Mr. Elsner asked the board to consider substituting the word "may" supervise instead of "can" supervise.

Chairperson Gubbins stated that the intent of this recommendation is to offer flexibility in situations where a pharmacist demonstrates the ability to teach and mentor and is willing to supervise more than one intern. Chairperson Gubbins added that these mentors/teachers play a valuable role in developing future pharmacists.

Deputy Attorney General Ron Diedrich stated that this type of discretion causes many enforcement problems.

Sam Shimomura, representing Western University of Health Sciences College of Pharmacy, stated that having more than one intern would cause problems during rotations.

Bruce Young, representing the California Retailers Association (CRA), stated that the CRA submitted language in the lunch break bill several years ago that states that the discretion rests solely with the pharmacist and that he or she cannot be intimidated or forced into leaving the pharmacy open while the pharmacist is not present. This language may provide an appropriate reference for drafting this new proposal.

Shane Gusman, representing the United Food and Commercial Workers, expressed concern that such proposals may not free up the pharmacist if there are too many ancillary personnel to supervise.

Steve Gray representing Kaiser Permanente expressed concern that this issue may be too close to labor-management issues. He noted that the details should be worked out through the legislative process to provide all interested parties a chance to participate in establishing a mechanism for this. Mr. Gray added that the board should not permit more than a 2-1 ratio.

Mr. Shimamura suggested that the board establish the total number of staff that a pharmacist can supervise, including interns, pharmacy students and clerk typists.

Mr. Fong stated that pharmacist should not be limited because the situation may call for a different number of staff.

MOTION: Amend the recommendation as follows: The Board of Pharmacy supports the increase in the number of interns that a pharmacist can supervise from one to two~~-~~, at the discretion of the pharmacist.

M/S/C: ZINDER/ELSNER

SUPPORT: 10 OPPOSE: 0

MOTION: Licensing Committee: The Board of Pharmacy supports the increase in the number of interns that a pharmacist can supervise from one to two, at the discretion of the pharmacist.

SUPPORT 10 OPPOSE: 0

- **Support the increase in the number of clerk-typists that a pharmacist can supervise**

Chairperson Gubbins stated that the Pharmacy Manpower Task Force did not support this proposed solution because it eliminates the clerk-typist ratio and places no controls on the number of clerk-typists in addition to the other ancillary personnel that a pharmacist may be required to supervise.

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

Chairperson Gubbins stated that the Licensing Committee modified the proposed solution; however, it did not recommend a specific ratio. If the board adopts this recommendation, it would be added as a strategic objective for the Licensing Committee to determine how many clerk-typists a pharmacist would be authorized to supervise. This proposal would require a regulation change.

Ms. Zinder stated that she opposes this recommendation because it is open-ended and would result in more supervision responsibility for the pharmacist and less patient care.

Mr. Tilley stated that he supports this recommendation because often in small practice settings the pharmacist becomes the problem solver for the insurance companies.

Mr. Jones stated that he would favor a more flexible standard where the pharmacist could make the determination of staffing needs based on the type of the practice setting.

MOTION: Amend the language to include “at the discretion of the pharmacist”

M/S/C: POWERS/ELSNER

SUPPORT: 9 OPPOSE: 1

MOTION: Support the increase in the number of clerk-typists that a pharmacist can supervise – at the discretion of the pharmacist

M/S/C: POWERS/TILLEY

SUPPORT: 9 OPPOSE: 1

MOTION: Support the increase in the number of clerk-typists that a pharmacist can supervise at the discretion of the pharmacist.

SUPPORT 10 OPPOSE: 0

MOTION: Licensing Committee: Consolidate all staffing ratios in one, and empower the pharmacist to determine appropriate level of staffing pharmacy technicians, clerk typists, typists, interns and technician trainees.

M/S/C: JONES/ZINDER

SUPPORT: 10 OPPOSE: 0

- **Expand the authority for central fill to inpatient hospital pharmacies**

Chairperson Gubbins stated that the Pharmacy Manpower Task Force supported the proposed solution (A-4) to expand the central processing with the following caveats:

- Protect patient confidentiality,
- Assure right to face-to-face counseling
- New prescriptions are transmitted electronically to the pharmacy.
- Ability to check patient profile. Payer usually does crosschecking. (In practice, this might be impossible).
- Electronic data is available to everyone that needs it.
- If done correctly, this process is transparent to patient.
- Any other information that may be pertinent to patient care is available.

Chairperson Gubbins stated that the Licensing Committee clarified that this proposed solution is already authorized under current law. However, the current central fill regulations do not include central fill by hospital inpatient pharmacies.

Chairperson Gubbins noted that if the board approves this recommendation, it will require a regulation change and will be added to the board's strategic objectives for 2002/03.

Mr. Goldenberg stated that in the long-term care practice setting the challenge is delivery of medication in a timely manner without establishing large organizations in multiple arenas.

Ms. Harris stated that current regulation allows for central fill in the community pharmacy only. However, the board has taken the position that it is permissible to use central fill in hospital pharmacies licensed by the Department of Health Services under a consolidated license.

Steve Gray representing Kaiser Permanente stated that Kaiser supports central fill pharmacies because the technology available provides a more accurate filling of cassettes. Mr. Gray added that this technology is expensive but hospitals working together can offset the cost.

MOTION: Licensing Committee: Expand the authority for central fill to inpatient hospital pharmacies.

SUPPORT: 10 OPPOSE: 0

- **Explore the feasibility of offering the California pharmacist licensure examination more than twice a year**.

  Chairperson Gubbins stated that the Licensing Committee considered four proposals for the Pharmacy Manpower Task Force that were related to increasing the administration of the California pharmacist licensure examination or providing options to applicants who failed only one section of the examination. They were:

  - Offer the exam more than two times per year with the goal of moving toward offering the exam on a continuous basis.
  - Consider re-testing the multiple choice or essay section only if only one portion is failed and evaluate whether the essay adequately measures what it is supposed to do.
  - The task force rejects the idea of a temporary one-year license for out of state pharmacists; however it was suggested that a temporary license should be considered for an applicant who is a licensed out-of-state pharmacist and who has passed at least one section of the examinations.
  - The task force rejects the notion of increasing the number of failed attempts from four to six before an applicant has to take additional coursework.

  Mr. Riches referred to AB 2165 (Strom-Martin) that was heard in the Assembly Health Committee on April 18. The bill was passed by the committee and is scheduled for hearing in the Assembly Appropriations Committee next. Mr. Riches noted that in its

current form, this bill requires licensees to pass the NAPLEX, pass the MPJE and pass a written examination testing other specific competencies specifically dealing with oral communications skills as the qualifications for pharmacists in California.

MOTION: Licensing Committee: Explore the feasibility of offering the California pharmacist licensure examination more than twice a year.

SUPPORT: 10 OPPOSE: 0

- **Assist applicants preparing for the California pharmacist licensure examination by developing (or fostering the development of) educational programs and information on how to take the pharmacist exam and by requesting that outside agencies (schools of pharmacy and private educational organizations) develop exam workshops on how to take the California pharmacist exam.**

  Chairperson Gubbins stated that the committee discussed the importance of working with pharmacy schools to determine what examination workshops are available and to coordinate efforts with the professional associations to ensure that the information is made available to examination applicants. It was explained that the responsibility of the board is not to assist applicants or the pharmacy schools to ensure successful passage of the examination. However, the board does provide the Candidate's Guide that is mailed to every applicant. This guide explains the examination process, provides an outline of the examination content and sample questions. The committee agreed that review courses are good and should be made available to as many candidates as possible. The Task Force supported this proposal. If the board approves this recommendation, it will be added as a board's strategic objective for 2002/03.

  Mr. Goldenberg expressed concern about schools of pharmacies creating a curriculum to pass the exam versus understanding the profession of pharmacy as a scientific background.

  Chairperson Gubbins explained that there are cram courses available but the committee wants to take a more professional approach in conjunction with the pharmacy schools.

  Mr. Fong stated that there is a perception of disconnect between the board and the schools of pharmacy on the best way to prepare for the pharmacist exam. He recommended that the board work closely with the schools of pharmacy to better assist students who are preparing for the exam.

  Teresa Miller, representing the California Society of Health Systems Pharmacists (CSHP), stated that this issue was addressed by the Pharmacy Manpower Task Force to encourage outside pharmacy schools in developing a program to prepare for the exam, and CSHP is interested in this proposal. Ms. Miller suggested the following

recommendation: "preparing applicants to take the exam" instead of "how to take the California exam."

MOTION: Amend the Licensing Committee recommendation as follows: That the Board of Pharmacy assist applicants for the California pharmacist licensure examination by developing (or fostering the development of) educational programs and information on preparing to take the pharmacist exam and by requesting that outside agencies (schools of pharmacy and private educational organizations) also develop exam workshops.

M/S/C: ZIA/ELSNER

SUPPORT: 10 OPPOSE: 0

MOTION: Licensing Committee: That the Board of Pharmacy assist applicants for the California pharmacist licensure examination by developing (or fostering the development of) educational programs and information on preparing to take the pharmacist exam and by requesting that outside agencies (schools of pharmacy and private educational organizations) also develop exam workshops.

SUPPORT: 10 OPPOSE: 0

- **Support the authority to grant waivers for innovative technological and other practices to enhance the practice of pharmacy and patient care.**

  Chairperson Gubbins stated that the Licensing Committee agreed with this proposed solution for board authority to grant waivers to keep pace with innovative, technological, and other advancements to enhance the practice of pharmacy and patient care. Chairperson Gubbins added that because pharmacy is such a dynamic practice, it is important that the board have the ability to allow studies that support the advancement of patient care while ensuring patient safety.

  Ms. Harris noted that the board has a regulation allowing waivers of regulation requirements for studies conducted by schools of pharmacy. The board cannot waive statutory requirements and specific parameters of regulation requirements for this proposal. She added that this proposal would allow for a research study to assure that a proposed change of statutory requirements is appropriate and warranted.

MOTION: Licensing Committee: Support the board's authority to grant waivers for innovative, technological and other practices to enhance the practice of pharmacy and patient care.

SUPPORT: 9 OPPOSE: 0 ABSTAIN: 1

- **Recommendation to support a scholarship or grant program for pharmacy students to practice in underserved areas**.

  Chairperson Gubbins stated that Assemblywoman Virginia Strom-Martin introduced AB 2935 which would provide scholarships and grants to pharmacy students to practice in underserved areas of California. The bill proposes that payment for this scholarship program would be from a special fee paid by pharmacists and pharmacies. These fees would be paid into a fund administered by the Office of Statewide Health Planning and Development. The Task Force supported this proposed solution and the Licensing Committee agreed with the recommendation.

  John Cronin, representing the California Pharmacists Association (CPhA), stated that the CPhA does not agree that the funding for scholarships and grants should come from all pharmacists and pharmacies as part of the renewal process. He asked that the board support the concept that those who benefit from the program should pay for the program.

  MOTION: Licensing Committee: Support a scholarship or grant program for pharmacy students to practice in underserved areas.

  SUPPORT: 9 OPPOSE: 1

- **Consideration to authorize a pharmacist to be a pharmacist-in-charge at two pharmacies.**

  Chairperson Gubbins stated that the Pharmacy Manpower Task Force voted not to discuss this proposed solution. However, there was agreement that because of the pharmacist shortage and the responsibility required of the pharmacist-in-charge (PIC), it is very difficult for pharmacies to hire a PIC. Because of these dynamics, pharmacists not suitable for the position become the PIC because of the limited options faced by the pharmacy. The board's expectations of the PIC position need to be clearly identified and that pharmacy employers and the board mutually promote a positive image of the position. The pharmacist who becomes

a PIC should want to be a good mentor and role model for staff, promoting the value of good patient care and compliance with pharmacy law.

Chairperson Gubbins stated that the committee discussed that better PICs would result if a PIC could be in charge of two pharmacies. There would be at least one pharmacist in both pharmacies and the PIC would have direct responsibility for both locations, dividing time between the two operations.

Ms. Zinder expressed concern that this would place an additional burden on the PIC to supervise more staff in a situation where he or she may not be able to have adequate control.

Chairperson Gubbins clarified that this would not be mandated, but possible for those PICs who have the professional ability and are capable of taking on the challenge to teach and train others.

Mr. Powers stated that from the consumer's perspective he did not feel that this would be in their best interest and that it could be more difficult to hire qualified PICs to manage two pharmacies.

Mr. Fong stated that under regulation, every pharmacy must have a PIC. He added that the board should articulate the expectations of the PIC and build on a more positive image for PICs.

Mr. Elsner stated that consumers would be better served by a qualified PIC rather than by someone assigned to the position unwillingly.

Shane Gusman, representing the United Food and Commercial Workers, asked if this requires a regulatory change and are there any provisions that address geographical issues.

MOTION: Licensing Committee: Authorize a pharmacist to be a pharmacist-in-charge at two pharmacies.

SUPPORT: 6 OPPOSE: 5

- **Recommendation to modify the exemptee program to clarify the following program requirements: that an applicant be at least 18 years old, has completed a training program of at least 40 hours that provides the applicant with detailed and comprehensive knowledge in specified areas, and the exemptee-in-charge is based in California**

Chairperson Gubbins stated that last year the board sponsored legislation to update the exemptee licensure program. The changes, which became effective January 1, 2002, have substantially streamlined and improved the application process. A wholesaler must either hire a pharmacist or an exemptee to be in charge of the wholesale facility. The exemptee is no longer linked to a specific site as required in the past. Now, the exemptee permit is issued to a qualified individual for one year and the exemptee may work at any wholesale or manufacturing premise, or for any employer, without having to be associated with a specific location or employer. However, a wholesale facility must appoint at least one exemptee to be in charge for that location.

Chairperson Gubbins stated that the qualification requirements for an exemptee permit were also revised. To qualify as an exemptee, an individual must meet the following requirements: possess a high school diploma or GED equivalent, have one year of paid work experience related to the distribution and dispensing of dangerous drugs and dangerous devices or meet the prerequisites to take the California pharmacist licensure examination, and completion of a training program. However, the statute does not require that an applicant be 18 years old, nor does it specify that the exemptee-in-charge be California based. The Licensing Committee recommends that these components be added to the statutory requirements.

Ms. Harris stated that the inclusion of the 40-hour completed training program is not a recommendation of the Licensing Committee; this was an error.

MOTION: Amend the recommendation as follows: That the Board of Pharmacy modifies the exemptee program to clarify the following program requirements: that an applicant be at least 18 years old, has completed a training program that provides the applicant with detailed and comprehensive knowledge in specified areas, and the exemptee-in-charge is based in California.

M/S/C: ELSNER/POWERS

SUPPORT: 10 OPPOSE: 0

MOTION: Licensing Committee: That the Board of Pharmacy modifies the exemptee program to clarify the following program requirements: that an applicant be at least 18 years old, has completed a training program that provides the applicant with detailed and comprehensive knowledge in specified areas, and the exemptee-in-charge is based in California.

SUPPORT: 10 OPPOSE: 0

- **Waiver requests of California Code of Regulations section 1717(e) from St. Joseph's Immediate Care Pharmacy and Ramona Pharmacy**

  Chairperson Gubbins stated that St. Joseph Immediate Care Pharmacy is requesting a waiver of CCR section 1717(e) to deliver prescription medications to Copperopolis Family Medical Center.

  Chairperson Gubbins stated that Ramona Pharmacy is requesting a waiver of CCR section 1717(e) to deliver prescription medications to Borrego Medical Center.

  MOTION: Approve waiver requests of California Code of Regulations section 1717(e) from St. Joseph's Immediate Care Pharmacy and Ramona Pharmacy

  M/S/C: POWERS/ELSNER

  SUPPORT: 10 OPPOSE: 0

- **Delegate to the Licensing Committee the authority to waive California Code of Regulations section 1717(e) until such time as the regulation is amended and a waiver is not required.**

  Chairperson Gubbins stated that at the October board meeting, the board approved an amendment to CCR section 1717(e) that would authorize pharmacies to deliver medications to a non-pharmacy location where a patient receives health care and the patient need not be present at the location at the time of the delivery. Because of the time-sensitive nature of some of these waiver requests, it would be beneficial if the board delegated this authority to the Licensing Committee. In those instances, when the Licensing Committee cannot consider a request because it was not received timely for proper public notice, then it will be noticed for the board meeting.

  Chairperson Gubbins stated that during the past year, the board has received continuous waiver requests and this continues to be presented to the full board. This would allow the Licensing Committee to handle the requests; however, the board's regulation section 1717(e) may need to be changed to permit a committee to make this decision instead of the board.

MOTION: Refer back to the committee the recommendation that the Board of Pharmacy delegates to the Licensing Committee the authority to waive California Code of Regulations section 1717(e) until such time as the regulation is amended and a waiver from the committee, and not the board is required.

M/S/C: ELSNER/POWERS

SUPPORT: 10 OPPOSE: 0

President Litsey concluded the Licensing Committee report and asked for public comment.

Sam Shimomura, representing Western University, asked if statistical pass rate updates on schools are available following the re-grading of the June exam.

Ms. Herold responded that under the current contract, the vendor provides the initial report and re-grades are not completed until approximately two months after the statistical report is compiled. Ms. Herold added that the board can provide the number of candidates who passed the re-grade but it cannot provide additional information without amending the contract with the vendor. Staff will evaluate if it is possible to provide updated pass rate statistics by school.

ENFORCEMENT COMMITTEE

- **Proposed Cite and Fine Committee and Process**

Chairperson Jones reported that the board's planned to implement the expanded cite and fine regulations that became effective July 22, 2001, through the board's Northern Compliance Committee and Southern Compliance Committee (NCC/SCC) process. However, Deputy Attorney General Ronald Diedrich advised the board earlier this year that the current NCC/SCC processes and procedures are not consistent with the provisions of section 1775, and might run afoul of the Government Code.

Mr. Diedrich has advised that pursuant to section 1775 the committee may only investigate alleged violations and, if warranted, issue citations. This is an investigative, prosecutorial and/or advocacy function. The committee's issuance of a citation is akin to the executive officer filing an accusation after reviewing an investigation.

Section 1775 does not provide authority for the committee to also perform an adjudicative function. Additionally, committee members, who participate in the

decision to issue a citation, may not discuss the merits of the matter with any non-committee board members. To do so would probably violate the ex parte communication prohibitions of the Government Code. Further, committee members may not participate or vote in the board's determination of whether or not to uphold or modify an issued bitation, should that citation be appealed.

Mr. Diedrich also recommended that the board consider abandoning the NCC/SSC process and establish a new Cite and Fine Committee to implement section 1775. The purpose of the Cite and Fine Committee would be to determine whether or not a citation should be issued in particular cases. The purpose would not be to determine the ultimate merits of the citation, or the order of abatement and/or fine contained within the citation. That is for the hearing process, should a hearing be requested to contest the issuance of the citation.

Chairperson Jones stated that the Enforcement Committee recommends a new process with a new Cite and Fine Committee to determine whether or not a citation should be issued in particular cases.

Chairperson Jones noted that because specific investigative details and deliberations leading up to the possible issuance of a citation must be confidential, only two board members at any one time would participate as part of the committee. If more than two board members participate in reviewing a case, then the entire investigative process and prosecutorial deliberations must be done in public. This would be counterproductive to meeting the board's enforcement obligations and public protection responsibilities.

Chairperson Jones stated that as part of its investigation function, the Cite and Fine Committee may, in its discretion, request that the affected licensee appear before it. Similar to the current NCC/SCC process, the licensee may appear with a representative. The committee may also request the consumer complaint and/or others to appear before it, as part of its inquiry into the matter. The affected licensee has no independent right to demand an appearance before the committee, to be present when others appear before the committee, and/or to any investigative material, including, but not limited to, investigative reports, prior to the issuance of a citation.

However, if an affected licensee is requested to appear before the committee then the licensee will be given a summary of the violations to be reviewed at the meeting. Additionally, if the committee requests an affected licensee to appear before it, then the citation may not be issued until the licensee has failed to appear twice, according to provisions in the regulation.

If a licensee requests a hearing to contest a citation that has been issued, or the propriety of the order of abatement and/or fine contained within the citation, then

the matter shall move forward in accordance with the hearing provisions of the Administrative Procedure Act (Gov. Code Section 11500 et seq.) The Attorney General's Office will represent the committee in the proceedings.

Mr. Diedrich stated that the Citation and Fine Committee process is not consistent with citations and fines issued by most other boards and agencies. Usually, the executive officer issues citations and fines - much like the authority issued to the executive officer to file an accusation. This is followed by due process requirements found in the Administrative Procedure Act. Mr. Diedrich added that in developing the regulation's provisions, the board chose to address these issues through a committee rather than through the executive officer.

Mr. Diedrich added that this process provides more review and due process rights to licensees than other boards and agencies provide and causes no adverse action to the licensee until the issuance of a citation.

Mr. Gray, representing Kaiser Permanente, stated that this process would not provide the licensee with the opportunity of a hearing.

Mr. Cronin, representing the California Pharmacists Association, added that he felt that during the public meeting of the Enforcement Committee, that the Cite and Fine Committee would invite licensees to present their cases. He added that if this is not the case, due process issues would arise.

Mr. Diedrich noted that under the current process for filing accusations, the licensee is not granted a hearing before the accusation is filed. He added that the ultimate decision to call the licensee in for a hearing rests with the committee rather than the licensee.

MOTION:	Create a Cite and Fine Committee consistent with the provisions of California Code of Regulations section 1775, which would replace the Compliance Committee					
M/S/C:	SUPPORT:	9	OPPOSE:	0	ABSTAIN:	1

- **Proposed Process for Petitions for Reconsideration**

Chairperson Jones stated that when the board has adopted a disciplinary action against a licensee, the respondent (the licensee) could appeal or protest the board's decision by filing a petition for reconsideration. The respondent has no constitutional right to reconsideration and a petition for reconsideration is not a prerequisite to seeking judicial review. A respondent must file a petition within 30 days of the effective date of the decision.

Chairperson Jones stated that under the board's current policy, when a petition for reconsideration is received timely, staff prepares the petition for board review by mail vote whereby the board will make a decision on whether to reconsider the decision and stay the effective date of the decision to permit reconsideration.

If a petition is not submitted timely and received within a few days of the effective date, additional time still is needed to prepare a mail ballot for board consideration. In such cases the executive officer, staff counsel and the board president are consulted to determine whether there are sufficient reasons provided by the respondent to grant a stay of the decision in order for the board to vote on the petition for reconsideration.

If a decision is made to grant a stay, it is for no more than 10 days in order for the board to consider the petition through mail vote. If a stay is not granted or no action is taken, then the petition is deemed denied.

The board president considers whether there are sufficient reasons provided by the petitioner to grant or deny a request to issue a stay. The Administrative Procedure Act does not specify the grounds on which the agency may grant or deny a stay and the board's discretion in denying or granting a stay is broad. The board does not have to provide reasons for its action and inaction would be considered a denial of the request for reconsideration.

If reconsideration is granted, the board may consider the issues raised in the petition by: (1) receiving written argument from the petitioner and the Attorney General's Office (2) reviewing pertinent parts of the record or by taking additional evidence, or both, and, at its option, considering additional argument; or (3) assigning the matter back to the administrative law judge. The board considers the petition during closed session at the next regularly scheduled board meeting.

Due to the significant resources that are involved in processing petitions for reconsideration and the immediate turn-around time required, the Enforcement Committee recommends that the board delegate to the board president or in absence of the president, the vice president, the authority to either stay an effective date of a disciplinary order to allow the board to consider a petition for reconsideration, or to not take action and consider the petition denied. Further, when a decision had been made that the board delegate its authority to staff counsel to sign a stay or reconsideration order on behalf of the board president or vice president for convenience of the board president and staff.

MOTION: Delegate to the board president or in his/her absence, the vice-president, the authority to either stay an effective date of a disciplinary order to allow the board to consider a

petition for reconsideration, or not to take action and consider the petition denied. Also, that the Board of Pharmacy delegates to staff counsel the authority to sign the stay or reconsideration order on behalf of the president or vice president.

SUPPORT: 10 OPPOSE: 0

- **Request to Modify CCR 1715.6**

Chairperson Jones stated that Steve Gray from Kaiser Permanente requested that the Enforcement Committee consider a change to California Code of Regulations section 1715.6.that would require a pharmacy to only report a significant loss of controlled substances. He stated that this suggestion is consistent with the Drug Enforcement Administration's (DEA) requirement for reporting controlled substances losses.

Chairperson Jones stated that the Enforcement Team discussed this issue and determined that it would be difficult to define "significant" in regulation. He added that when the board receives a report of controlled substances losses, it is reviewed to determine if an investigation should be opened. Only a small percentage of cases are opened for investigation.

Mr. Gubbins asked how the board handles these situations.

Mr. Ratcliff stated that the form is somewhat generic in that it does not describe the full events of how the loss occurred. If the drug loss is due to employee theft, the board would send a letter or initiate an investigation to determine if the amount is significant or not. If one or two tablets were missing, the supervising inspector reviewing the DEA form 106 would determine if the board should investigate the matter.

Ms. Harris responded that the law requires that any loss be reported.

Mr. Gray stated that Kaiser raised this issue because during routine drug counts, insignificant losses were not reported, and upon discovery by a board inspector, violation notices were issued. The PIC now has a violation notice for failure to report a drug loss and for unprofessional conduct on file. It is reasonable that the PIC of a major hospital pharmacy operation could determine what is a significant drug loss, especially when the DEA has chastised the organization for wasting their time by reporting insignificant drug losses. Mr. Gray suggested that the board receive a letter from the pharmacy organization stating the insignificant drug loss, rather than reporting this to the DEA.

MOTION: That the Board of Pharmacy does not amend California Code of Regulation section 1715.6 to require a pharmacy to report only those losses of controlled substances that are deemed "significant".

SUPPORT: 9 OPPOSE: 0 ABSTAIN: 1

- **Proposed Strategic Objectives for 2002/2003**

Chairperson Jones referred to the list of proposed strategic objectives for 2002/03 as follows:

1. Meet performance expectations of 90 days for complaint mediations and investigations and 6 months for drug diversion investigations that require an audit.
2. Continue active recruitment of inspectors so that all authorized inspector positions are filled.
3. Reduce enforcement prosecution time to one year from the date the board refers the case to the Attorney General's (AG) Office by managing cases and drafting accusations and stipulations.
4. Seek legislation to mandate that the Board of Pharmacy perform periodic inspections of all board-licensed facilities.
5. Pursue permanent funding to increase Attorney General Office expenditures for the prosecution of board administrative cases.
6. Establish a disciplinary cause of action for fraud convictions similar to current cash compromise provisions related to controlled substances.
7. Secure sufficient staffing for a complaint mediation team and to support an 800 number for the public.
8. Integrate data obtained from computerized reports into drug diversion prevention programs and investigations (CURES, 1782 Reports).
9. Re-establish the CURES workgroup that includes other regulatory and law enforcement agencies to identify potential controlled substance violations and coordinate investigations.
10. Seek legislation to grant authority to the executive officer to issue a 30-day cease and decease order to any board-licensed facility when the operations of the facility poses an immediate threat to the public.
11. Perform a comprehensive review of the electronic prescribing laws related to the dispensing of controlled substances and dangerous drugs to determine those areas of law that need modification.

12. Develop board sponsored continuing education programs for pharmacists in the area of pharmacy law and the expectations of the pharmacist-in-charge and coordinate presentations at local and annual professional association meetings throughout California
13. Explore the options for restitution as a disposition for prescription error consumer complaints.

MOTION: Approve the Enforcement Committee's proposed strategic objectives for 2002/03.

SUPPORT: 10 OPPOSE: 0

Chairperson Jones stated that the open meetings of the Enforcement Committee are very positive and provide an opportunity for licensees and the public to express their concerns. Further, it provides the board inspectors with the opportunity to hear public comments.

- **Department of Consumer Affairs Proposed Complaint Disclosure Policy**

The board reviewed the proposed Complaint Disclosure Policy.

LEGISLATION AND REGULATION COMMITTEE

REGULATION HEARING – NOTICE TO CONSUMERS

Adoption of Amendment to California Code of Regulations Section 1707.2

President Litsey announced that at this point in the meeting, the board will hold a hearing to consider amendments to section 1707.2 of Chapter 17 of Title 16 of the California Code of Regulations to modify the "Notice to Consumers" that must be posted in pharmacies or printed on receipts. The exact language of the proposed regulation was released for public comment for the prior 45 days.

President Litsey referred board members to the two written comments that had been submitted by the Gray Panthers and the California Pharmacists Association.

President Litsey announced that the hearing will be opened to take oral testimony and/or documentary evidence from any person interested in the regulation. All oral testimony and documentary evidence will be considered by the board pursuant to the requirements of the Administrative Procedure Act before the board acts on the proposed amendment to the regulation or recommends changes.

President Litsey asked for anyone who desires to provide oral testimony to come forward, give his or her name and address, and if representing an organization, the name of the organization.

Before taking oral testimony, Mr. Litsey asked for questions concerning the nature of the proceedings or the procedures to be followed. There were no questions.

Joseph Partansky stated that during the last 30 years he has had experience as a behavioral scientist, an administrator and a policy analyst for an on-call drug abuse program. He added that during the 1970s he provided advice to a national Hispanic organization and recently asked the California Department of Alcohol and Drug Program to consider a collaborative effort with the Board of Pharmacy to address adverse drug reaction issues.

Mr. Partansky referred to the Americans with Disability Act, Title 2, that addresses state and local government entities. He encouraged the use of an 800-telephone number on the Notice to Consumers poster. He stated that vision or hearing impaired consumers can have assistive devices to enhance communication between them and the board, and this number would be helpful.

Mr. Partansky recommended that the text next to the telephone number on the poster include a statement regarding alternative language formats that are available. He also provided a handbook on the Americans with Disability Act to President Litsey.

Mr. Partansky urged the board to produce a Hispanic poster immediately so that it can be posted in pharmacies at the same time as the English poster.

Mr. Partansky stated that placement of the poster in the pharmacy should be mandatory at all points of sale. He added that visually challenged consumers and others need to have an adequate size poster. The information on the poster should also be placed on the board's website.

Mr. Partansky referred to section 1707.2 (b)(3) where it states: "A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge." Mr. Partansky suggested that the board review this section because it seems that it could be a violation of equal protection under the law.

Mr. Partansky recommended that the board add back in the language that states: "IF YOU HAVE ANY QUESTIONS REGARDING MEDICATIONS, PLEASE ASK TO SPEAK WITH A PHARMACIST."

He alternatively suggested to add language at the end of the section where it states: "Ask your pharmacist if you have additional questions" to add: "now, or call (pharmacy telephone number or chain store telephone number)."

Mr. Partansky requested that the board also consider adding: "For alternative formats for persons with a disability or other questions, call the California Board of Pharmacy at the 800- telephone number."

Mr. Partansky recommended that the board include the seal of the state of California on the poster and to make the background of the poster white for ease of reading.

President Litsey asked for additional comments from the audience. There were none.

Mr. Tilley asked if there would be a limit on the number of price quotes a pharmacy must provide. Ms. Harris stated that there is a limit in Business and Professions Code section 4122.

President Litsey then closed the regulation hearing.

Ms. Herold stated that after the January 2002 Board Meeting, there were a number of comments received. She added that the board is now ready to finalize the language. Ms. Herold noted that the board would have the opportunity to see the completed poster perhaps at the July 2002 Board Meeting.

Mr. Powers asked if the board could restore the sentence in subdivision (f) to the longer version of "IF YOU HAVE ANY QUESTIONS REGARDING MEDICATIONS, ASK TO SPEAK WITH A PHARMACIST."

Ms. Herold stated that during the January 2002 Board Meeting, the board focused the poster to emphasize the five questions consumers should ask their pharmacist. Ms. Herold stated that the board wanted to reduce the number of words on the poster to attract consumers' attention to these questions. She added that the board could alter the language if it wished. The phrase "Ask your pharmacist if you have additional questions" is highlighted by the size of the type, which is the second largest font on the poster.

Mr. Fong referred to a revised labeling requirement for over-the-counter medications and expressed concern about the new prescription drugs converting to over-the-counter status. He emphasized that these drugs pose the need for consumer education, and patients should ask their pharmacist about these drugs before taking them. Mr. Fong stated that the poster should incorporate this information as well.

President Litsey responded that two of the poster's questions were developed to capture this message. He referred to the language where it states: "Will the new medicine work

safely with other medicines and herbal supplements I am taking?" and, the second question that states: "What foods, drinks or activities should I avoid while taking this medicine?"

Mr. Elsner reminded the board that the language has been discussed many times before at board meetings. He urged the board to stop fine tuning the poster, get the language adopted and get the poster displayed in pharmacies.

MOTION: Adopt the amendments to Title 16, Division 17, Section 1707.2 of the California Code of Regulations – Notice to Consumers and Duty to Consult

Amend Section 1707.2 as indicated:

1707.2 Notice to Consumers and Duty to Consult.

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:
(1) ~~U~~upon request; or
(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:
(A) whenever the prescription drug has not previously been dispensed to a patient; or
(B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.

(2) When the patient or agent is not present (including but not limited to a prescription drug that was shipped by mail) a pharmacy shall ensure that the patient receives written notice:
(A) ~~O~~of his or her right to request consultation; and
(B) ~~A~~ a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

(3) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section ~~4047.9~~ 4074.

(c) When oral consultation is provided, it shall include at lease the following:

(1) ~~D~~directions for use and storage and the importance of compliance with directions; and
(2) ~~P~~precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

(d) Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:
(1) ~~T~~the name and description of the medication;
(2) ~~T~~the route of administration, dosage form, dosage, and duration of drug therapy
(3) ~~A~~any special directions for use and storage;
(4) ~~P~~precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;
(5) ~~P~~prescription refill information;
(6) ~~T~~therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;
(7) ~~A~~action to be taken in the event of a missed dose.

(e) Notwithstanding the requirements set forth in subsection (a) and (b), a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation.

(f) In every pharmacy subject to the provisions of Business and Professions Code Section ~~4333~~ 4122, there shall be prominently posted in a place conspicuous to and readable by prescription drug consumers the following notice:

"NOTICE TO CONSUMERS"

At your request, this pharmacy ~~shall~~ will provide its current retail price of any prescription without obligation. You may request price information in person or by telephone.

Ask your pharmacist if a lower-cost generic drug is available to fill your prescription.

Prescription prices for the same drug vary from pharmacy to pharmacy. One reason for differences in price is differences in services provided. ~~The services provided by this pharmacy, in addition to professional prescription dispensing and professional consultation, are checked below. In comparing prescription prices, it is important to consider the services provided.~~

~~[ ] Health Services Information~~
~~[ ] Compounded Prescription Service~~
~~[ ] Emergency Prescription Service~~
~~[ ] Prescription Delivery~~
~~[ ] Credit Service~~
~~[ ]~~

~~IF YOU HAVE ANY QUESTIONS REGARDING MEDICATIONS, PLEASE ASK TO SPEAK WITH A PHARMACIST.~~

Before taking any prescription medicine, talk to your pharmacist; be sure you know:

What is the name of the medicine and what does it do?
How and when do I take it – and for how long? What if I miss a dose?
What are the possible side effects and what should I do if they occur?
Will the new medicine work safely with other medicines and herbal supplements I am taking?
What food drinks or activities should I avoid while taking this medicine?

Ask your pharmacist if you have additional questions.

Authority cited: Sections ~~4008, 4008.2 and 4333~~, 4005 and 4122 Business and Professions Code.
Reference: Sections ~~4008, 4008.2 and 4333,~~ 4005 and 4122 Business and Professions Code.

M/S/C: JONES/POWERS

SUPPORT: 10 OPPOSE: 0

INFORMATIONAL HEARING – STERILE COMPOUNDING

President Litsey stated that the purpose of the hearing is to gather comments from the public for consideration by the board when developing the formal regulation proposal for sterile compounding.

President Litsey stated that the guidelines were developed based primarily on guidelines adopted by the American Society for Health System Pharmacists. However, elements of existing USP guidelines were incorporated into the document as well. These guidelines are the first step in implementing Senate Bill 293 (Chapter 827, Statutes of 2001), which requires pharmacies compounding sterile injectable drug products to comply with the guidelines adopted by the board.

Steve Gray, representing Kaiser Permanente, referred to Kaiser's comments made in a letter dated April 24, 2002.

Mr. Gray stated that the board's intent is to adopt guidelines, however there is substantial uncertainty and significant uneasiness about what this means in a regulatory context with the Board of Pharmacy and other California agencies. He added that the spirit is to adopt guidelines which would imply a substantial amount of flexibility in how the guidelines would apply to a particular practice setting, particular types of products, uses, etc. Mr. Gray added that it would be helpful in the process if the board could provide to the profession, a statement as to how it interprets regulations or standards versus guidelines and how it intends to move forward.

Mr. Gray stated that during the discussion of the legislation and subsequent to all of the events that brought this to the board's attention, there was haste that originated from a tragedy to put the guidelines in statute and to adopt emergency legislation. Fortunately, for the public this did not occur and instead the board would establish guidelines or standards over an 18 month period. He encouraged the board to use the full amount of time to establish the guidelines. Mr. Gray referred to legislative discussions where all parties agreed that a task force would be established. Mr. Gray encouraged the board to schedule another informational hearing.

Mr. Gray referred to the specific comments from Kaiser Permanente as follows:

1. The guidelines do not include expectations regarding the qualifications of management and supervision of a pharmacy that is about to embark into the practice of compounding injectable sterile drug products or of the personnel who are in charge of such an operation. Without such guidance it is not likely that the required policies and procedures would be adequate or even that such personnel will realize the gravity of such undertaking. Having decisions and oversight being made by a pharmacist-in-charge whose qualifications are at least as well documented, as the staff seems vital to quality assurance. It is an approach recommended by some national pharmacy organizations.
2. The guidelines are both too specific and not specific enough. They limit viable options that would still provide for compounding of quality products, e.g., the use of pass-through cabinets instead of anterooms and still are cost-responsible. By not allowing the treatment of a formerly "high risk" compounded product as a "moderate risk" product when used as a component they not only reduce the viability of the guidelines but actually discourage the use of proper testing and quality measures in favor using an emergency or urgent need exception.
3. As "guidelines' the document omits consideration of the intended use of the product in categorization of risk levels. In doing so, it

ignores other published recommendations specific to the compounding industry. For example, the tragedy, which prompted this effort, involved an intrathecal use, which should consider processes different from using the same type of product by a different route of administration, i.e., a quantative endotoxin test instead of a merely qualitative test.

4. The guidelines overlook a serious probable cause of improper compounding and supervision. The guidelines should call for the preparation of a documented product-specific compounding plan that is approved by a pharmacist prior to the initiation of any compounding procedures. Of course there should be pharmacist-documented checking of each vital step and final approval, but when and how these must be done should be called out in the plan explicitly.

Mr. Gray suggested that the board consider a broader act of the guidelines within the health care scenario because California is facing a crisis in terms of health care costs. While some people are losing their full coverage, others are under-covered. Mr. Gray referred to the statistics provided by the Pacific Business Group on Health presentation whereby it provided the percentage of employers who intend to drop health care coverage all together within the next 24 months resulting from cost increases of 20-35 percent. Likewise, employees and consumers cannot bear the burden. The result is more and more people are losing their health coverage due to high cost.

Mr. Gray added that it is important that the board consider the cost impact of establishing guidelines.

Virginia White, representing the California Society of Health System Pharmacists, referred to their members' efforts to review the proposed guidelines and offered general comments and recommendations to the guidelines.

Ms. White stated that the USP has drafted a revision to their information standard on sterile compounding in home care and broadened it to apply to sterile compounding in all settings. She added that the FDA Advisory Committee on Compounding provided recommendations to the USP that it took under advisement.

Ms. White stated that the guidelines have been published for public comment and it is anticipated that the guidelines will be published in November 2002 for January 2003 enforcement.

Ms. White stated that the board's guidelines should not be redundant or conflicting with federal law. Ms. White added that current CSHP members are

formalizing all of the comments into specific recommendations for the current proposed guidelines.

John Cronin, representing the California Pharmacists Association, stated that the CPhA established a small task force to discuss the board's guidelines and he referred to comments made in a letter dated April 1, 2002.

Mr. Cronin stated that the guidelines are overly detailed, micromanage and deal with compounding sterile products when the statute focuses on sterile injectables.

Mr. Cronin stated that the board should establish standards that are flexible for different practice settings. He added that a basic standard should be for pharmacies that compound sterile injectable products, to take reasonable steps to assure that the product is sterile. He added that pharmacies cannot guarantee that every compounded product is sterile, because the entire product would have to be destroyed in order to test it.

Mr. Cronin requested that the proposed guidelines be more limited, reasonable, appropriate and enforceable. There is fear among retail pharmacies that compound products and sterile injectable products because of competition outside California.

Mr. Shimomura, representing the American Society of Health-System Pharmacists (ASHP) highlighted areas of concern. The ASHP's guidelines are reviewed and revised every five years. This policy of revolving review reflects ASHP's belief that guidance documents evolve because of the advances in technology, new knowledge from research, and lessons from experience at a particular facility.

Mr. Shimomura stated the ASHP Guidelines are copyrighted material and if the board substantially changes the meaning or intent, ASHP has concerns about this.

Barry Smith, a licensed pharmacist , offered written testimony.

Mr. Smith stated that having owned multiple pharmacies over the years, he now owns one pharmacy with an emphasis on compounding.

Mr. Smith stated that he prepares sterile non-preserved intrathecal solutions, sterile IV solutions for bag additions, and sterile ophthalmic preparations, usually on short notice and in a non-batch mode. Almost all of the procedures involve using raw, unsterilized powders, and have been defined in the proposed regulations as Category III. Mr. Smith added that they have a Certified Class 1000 clean room, a class 10 horizontal hood, and a class 10 vertical chemo hood. They also do environmental testing on the heat sterilizer and autoclave, and use

local hospitals lab to test for growth on a percentage of but not all sterile products. Batch items are quarantined until test results come back.

Mr. Smith referred to the following concerns with the proposed regulations:

1. Checking potency on every sterile drug product.

   Mr. Smith stated that potency testing is an expensive and time-consuming step to perform on every preparation. Having checked with only one recommended company to do this testing, in Tennessee, they want $200 per drug (some preparations have multiple ingredients, and how about the preservatives, pH agents, and isotonic ingredients or buffers). The procedure involves days of shipping, plus 3 to 5 days to get the results

2. Regarding separation of quality control functions and production functions.

   Mr. Smith stated that in his pharmacy, just one pharmacist usually does compounding of sterile products, although there are three pharmacists on staff, all of them capable and trained to perform sterile compounding. He added that they have the ability to test in house for Pyrogens, and an incubator to test for growth, but, if the pharmacy is a one-pharmacist store, how do you separate these two functions?

3. End product sampling must be kept for three years.

   Mr. Smith stated that he knows that there is an exemption for extemporaneously prepared, non-batch preparations, but how can he prove to a board inspector three years later that end product testing occurs on a one time prescription such as Vancomycin Ophthalmic, or Morphine Clonidine Pump.

4. A properly designed and maintained barrier isolator to provide an aseptic environment and a class 100 clean room are required.

   Mr. Smith stated that their hood certification company told them that a anteroom is needed if they want to go to class 100 room. He added that this is already 100 times cleaner than either major hospitals or all of the JCAHO accredited IV preparation pharmacies in the area, and their hoods are rated better than 10.

5. Regarding running particle counts before any procedure and determining positive pressure environment.

Mr. Smith stated that particle counts are determined by their hood and room certification company, which is used by all people in the area who have hoods, on a once a year basis. It is his understanding that, none have their own particle counter. Although his clean room was designed by professionals for ½ lb positive pressure, he currently does not have any method of determining the pressure. He asked how he could determine the pressure before each procedure.

6. Regarding testing components being quarantined until properly identified, tested, or verified by a pharmacist.

   Mr. Smith asked if certificates of analysis from the chemical company enough? He asked if they need to become qualified in spectrophotometers and add that equipment to their list. He added that most pharmacists have not been trained in those techniques.

7. Regarding the requirement that a sterile product.must have an appropriate laboratory determination of conformity.

   Mr. Smith stated that this addresses his initial concern. He added that even with the exemption for extemporaneous preparations, he is uncomfortable with the concept that he could be challenged three years down the road for documentation on the final product that he was unable to accomplish because of time constraints.

   Mr. Smith stated that it appears that the person or persons that wrote the proposed regulations is attempting to impose the restrictions that are placed on manufacturers who are preparing large batches of any formation, and who have large staffs, and microbiology labs to maintain quality control. Manufacturing is not what pharmaceutical compounding is all about. It involves problem solving for individual patients and prescribers, usually in individual or small quantity preparations. During his service as a board member 20 years ago, his intent was to be involved in regulations that allowed a pharmacist to provide the best pharmaceutical service possible, and remain within the law. He encouraged the board to take the same position and allow them to continue to provide a needed pharmaceutical service.

There being no further comments, President Litsey adjourned the informational hearing on the proposed guidelines for sterile compounding.

LEGISLATION AND REGULATION COMMITTEE – Continued

Regulation Report and Action

Regulations Approved in 2002

- **Quality Assurance Programs (1711)**

  Ms. Zinder stated that this file was approved by the Office of Administrative law on January 14, 2002, and became effective January 14, 2002.

Other Items on the Regulation Calendar for 2002

- **1706.3 – Privacy of Financial Records**

  This regulation will specify that financial records submitted to the board as part of a site license application are confidential.

- **1707.2 – Notice to Consumers**

  This regulation will substantially revise the posted notice to consumers required by section 1707.2.

- **1707(e) – Delivery of Medications**

  This regulation will eliminate the waiver process established by 1717(e). This waiver process permits pharmacies to depot drugs for delivery to patients at non-pharmacy locations. Instead, the regulation will permit pharmacies to depot drugs at any location where the patient receives health care services.

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

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

- **1720.4 – Foreign Graduates**

  This regulation will specify the procedure for foreign graduates who cannot obtain verifiable transcripts to become eligible to take the pharmacist license examination.

- **1745 – Partial Filling of Schedule II Prescriptions**

  This regulation will make the partial fill regulation consistent with recent statutory changes to Schedule II prescription requirements

- **1751 – Sterile Compounding**

  This regulation will establish guidelines for the compounding of sterile drug products. Draft guidelines will be the subject of an informational hearing at the April 2002 board meeting.

- **1732.05 – Continuing Education**

  This regulation will recognize continuing education credits approved by other California health professions licensing boards.

- **Section 100 Changes**

  This submission will make technical corrections to existing regulations. Consistent with Assembly Bill 1496, these corrections will include the repeal of sections dealing with medical device retailers and the removal of medical device retailer from any other regulations.

Legislation Report and Action

- **AB 269 (Correa) – Board Mission**

  Ms. Zinder stated that this bill would clarify existing law and make it easier for all interested parties to identify the fact that "consumer protection" is the highest priority of each and every DCA board and bureau.

  Mr. Riches stated that the author of AB 269, Assemblyman Correa, is the Chair of the Assembly Business and Professions Committee and during an interim hearing in Orange County, he received input regarding the Department of Consumer Affairs' licensing boards mandates and operations specific to public protection. Mr. Riches added that this is an effort to make it clear that public protection is the first priority for boards and bureaus within the Department of Consumer Affairs.

  MOTION: Legislation and Regulation Committee: Support AB 269 (Correa) to establish public protection as the highest priority of all the licensing boards in the DCA.

SUPPORT: 10 OPPOSE: 0

- **AB 1921 (Richman) – Continuing Education**

  Ms. Zinder stated that this bill was intended to train physicians, nurses and pharmacists on how to respond in natural disasters, terrorist incidents, or any other public health emergency.

  Ms. Zinder reported that this bill died in committee.

- **AB 2191 (Migden) – Confidentiality: Medical Records**

  Ms. Zinder reported that this bill would prohibit pharmaceutical companies, or agents or representatives of pharmaceutical companies, from disclosing medical information regarding a patient without first obtaining authorization.

  MOTION: Legislation and Regulation Committee: Support AB 2191 (Migden), if amended to clarify that a pharmacy is not included in the definition of "pharmaceutical company" in the bill.

  SUPPORT: 10 OPPOSE: 0

- **AB 2935 (Strom-Martin) – Pharmacist Scholarships**

  Ms. Zinder reported that this bill would declare the intent of the Legislature to fund the California Pharmacist Scholarship and Loan Repayment Program by imposing a surcharge on pharmacists and pharmacies, due at licensure renewal, to be deposited in a fund that would be continuously appropriated, without regard to fiscal year, to the office for the administration of the program.

  MOTION: Legislation and Regulation Committee: Support AB 2935, if amended to require pharmacies, not pharmacists, to fund the program through a surcharge on license renewal.

  SUPPORT: 10 SUPPORT: 0

- **SB 1558 (Figueroa) – Drug Samples**

Ms. Zinder stated that this bill permits certified nurse midwives, certified nurse practitioners, and physician assistants to request and receive drug samples.

John Cronin, representing the California Pharmacists Association, asked if nurse practitioners and other practitioners are asserting that they can order drug samples outside of their protocols.

Steve Gray, representing Kaiser Permanente, stated that pharmacists do not understand the issue and although Kaiser's has a neutral position on this bill, he encouraged discussions between the Board of Pharmacy and the Board of Nursing to resolve different interpretations. Mr. Gray added that this is a problem that places patients in the middle and causes delays in therapy.

Theresa Miller, representing the California Society of Hospital Pharmacists (CSHP), stated that the CSHP is exploring a support if amended position and requesting that bill sponsors incorporate pharmacists operating under protocol in clinics to have the same authority to order sample drugs.

MOTION: Legislation and Regulation Committee: Support SB 1558, if amended to require nurse practitioners, physician assistants or certified nurse midwives to make regular reports to their supervising physician of the samples ordered and restrict these practitioners to ordering drug samples only for drugs included in their protocol.

SUPPORT: 10 OPPOSE: 0

- **SB 1750 (Speier) – Dietary Supplements**

Ms. Zinder stated that this bill addresses the misuse of dietary supplements with herbal or natural ephedrine products by requiring warnings to be printed on the product label, along with a toll-free number for consumers to report adverse reactions to the FDA MedWatch hotline. The bill also prohibits sale of the products to minors.

MOTION: Legislation and Regulation Committee: Support SB 1750 if amended to remove the age restriction included in the bill because the requirement unfairly

requires cashiers to make age determinations at the point of sale.

SUPPORT: 10 OPPOSE: 0

- **SB 1785 (Vasconcellos) – Hypodermic Needles**

Ms. Zinder stated that this bill would authorize a licensed pharmacist to sell hypodermic needles or syringes to a person without a prescription under specified conditions.

MOTION: Support SB 1785 (Vasconcellos)

SUPPORT: 10 OPPOSE: 0

- **SB 2018 (Figueroa) – Board Funds**

Ms. Zinder stated that this bill specifies that no funds deposited in any of the special funds of the Professions and Vocations Fund is subject to a continuous appropriation. She added that this legislation would resolve difficulties in legislative procedure encountered by many licensing boards.

MOTION: Support SB 2018 (Figueroa)

SUPPORT: 10 OPPOSE: 0

- **SB 2024 (Figueroa) – State Personnel**

Ms. Zinder stated that under existing law a "six-month rule" was established to require the State Controller to eliminate any positions in state government that remain vacant for more than 6 months in a given fiscal year. As introduced, this bill specified that the six-month rule shall not apply during a hiring freeze.

Ms. Zinder stated that the application of the six-month rule during a hiring freeze would result in the arbitrary elimination of staff positions without consideration of existing statutory obligations and workload considerations. This bill would remedy that problem.

MOTION: Support SB 2024 (Figueroa)

SUPPORT: 10 SUPPORT: 0

- **SB 2655 (Mathews) - Extend CURES Program**

Ms. Zinder stated that the board is sponsoring AB 2655 (Matthews) to extend the CURES program and move to a monitoring program like that in Nevada. The bill was amended to permit practitioner access to CURES data for their patients and to permit the Department of Justice (DOJ) to screen CURES data and send practitioner's profiles of their patient(s) when a potential pattern of abuse is indicated by the CURES data. The bill passed the Assembly Health Committee 18-0 on April 9, 2002. Board staff met with the DOJ in February to discuss this legislation. The DOJ expressed a preference to eliminate the sunset provision and keep CURES indefinitely. However, the DOJ indicated a willingness to support extending CURES for 5 years if the board agrees to not sponsor legislation to repeal the triplicate requirement prior to that sunset date.

The board was notified in April that CURES would be paid for by both the general fund and various board funds. The Medical Board, Pharmacy Board, Dental Board, and Osteopathic Board will all contribute to pay for CURES. The board will be obligated to pay $34,000 per year to support CURES.

MOTION: Legislation and Regulation Committee: Not sponsor legislation to repeal the triplicate requirement prior to the sunset date for CURES.

SUPPORT: 10 OPPOSE: 0

- **Request by Department of Health Services to support SB 1278 (Speier) -Medicare Drug Discount**

  Ms. Zinder stated that existing law requires pharmacies participating in the Medi-Cal program to provide eligible Medicare recipients with the Medi-Cal price for prescription drugs. She added that this bill repeals the sunset provision.

  Mr. Tilley expressed concern that this would create not only additional work for the pharmacy but more paperwork and another poster.

  Mr. Elsner expressed concern that pharmacies are not informing consumers of the Medi-Cal discount program.

  John Cronin, representing the California Pharmacists Association, stated that the discount program is not intended for those who have other insurance and he added that this system is being abused and

creates a huge burden on pharmacies. He added that the CPhA would like this bill amended to incorporate the results of the cost study under the Medi-Cal reimbursement scheme.

Mr. Powers suggested that the board contact Senator Speier's office regarding the status of the cost study. He added that senior organizations support this bill because it is one of the few bills that reduced the cost of prescription drugs and although it causes expense to the pharmacy, without this program, some seniors will not buy their prescriptions because of the expense.

Mr. Tilley stated that he has completed the paperwork for the discount program through Medi-Cal provider numbers for many of his pharmacies but the process is slow and the paperwork is delayed by several months with the Department of Health Services. He added that another bill is designed to speed up the approval process of Medi-Cal provider numbers.

Ms. Harris stated that it is mandated that the cost study report be completed by July 1, 2002.

- **Proposed Strategic Objectives**

Chairperson Zinder referred to the following proposed strategic objectives:

1. Secure the passage of legislation extending the board's sunset date.
2. Revise the Notice to Consumers required by 16 CCR 1707.2.
3. Adopt a regulation that specifies that financial records submitted to the board as part of a site license application are confidential.
4. Adopt a regulation that will permit pharmacies to depot drugs for delivery to patients at non-pharmacy locations where the patient receives health care services.
5. Revise board regulations concerning electronic prescribing to conform with Assembly Bill 2240 and require pharmacists to confirm the authenticity of any electronic prescription in which there is an uncertainty or ambiguity.
6. Adopt a regulation that will specify the procedure for foreign graduates who cannot obtain verifiable transcripts to become eligible to take the pharmacist license examination.
7. Revise the regulation concerning the partial filling of Schedule II prescription requirements.
8. Adopt a regulation that establishes guidelines for the compounding of sterile drug products.

9. Revise existing board regulations to make technical corrections required by recent legislation.
10. Adopt a regulation recognizing continuing education credits for courses approved by other health care licensing boards.
11. Change committee policy to have the committee meeting preceding the April board meeting, be a public meeting.

Mr. Powers suggested that the board contact the Attorney General's Office to inquire about drug pricing.

MOTION: Legislation and Regulation Committee: Approve the Legislation and Regulation Committee's proposed strategic objectives.

M/S/C: POWERS/ZINDER

SUPPORT 10 OPPOSE: 0

MOTION: Seek assistance from Deputy Attorney General's liaison Ron Diedrich to report any available information to the board regarding drug pricing.

M/S/C: POWERS/ZINDER

SUPPORT: 10 OPPOSE: 0

- **AB 2045 (Mathews) – Pharmacists: Disciplinary Actions**

Ms. Zinder stated that this bill specifies that no disciplinary action shall be taken against licensed pharmacists in the course of their ownership, management, administration, or operation of a pharmacy or other entity licensed by the Board of Pharmacy (Board), if the action is based solely on unprofessional conduct committed by another pharmacist.

Deputy Attorney General Ron Diedrich outlined the following significant issues with AB 2045:

1. This bill is in direct conflict with a number of the board's current statutes and regulations:
    - B & P C Section 4113 (b) – requires that the pharmacist-in-charge be responsible. This bill would release that responsibility.

- B & P C Section 4301 (o) – Provides the pharmacist who abets the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board.
- California Code of Regulation Section 1726 (c), which makes preceptors responsible for all of the professional activities of the intern.
- California Code of Regulation Section 1793(3) where pharmacists are responsible for non-licensed personnel activities in the pharmacy.

2. It is counter to goals and objectives that were voted on.
    - It is the board's desire to increase the ratio of the pharmacist-in-charge with technicians and interns.
3. Consumer protection.
    - The pharmacist has more responsibility but will not be held responsible for the activities that they have responsibility over.

MOTION: Legislation and Regulation Committee: Support AB 2045 (Mathews)

M/S/C: ZINDER/POWERS

SUPPORT: 4 OPPOSE: 0 ABSTAIN: 4

MOTION: Oppose AB 2045 unless amended

M/S/C: JONES/GOLDENBERG

SUPPORT: 9 OPPOSE: 0 ABSTAIN: 1

- **AB 2165 (Strom-Martin) – Pharmacy Licensure**

Mr. Riches stated that this bill would replace the existing California licensure examination administered by the Board of Pharmacy with the national exam known as the North American Pharmacist Licensure Examination (NAPLEX) coupled with a California-specific Multi-State Pharmacy Jurisprudence Examination.

Mr. Riches stated that this would be comparable to the board's exam with the addition of the communications skills portion.

Mr. Cronin referred to the board's strategic plan and asked how the board could approve an examination process that does not test communications skills.

Mr. Gubbins noted that from his experience taking the NABPLEX two years ago, communications skills are needed for this exam. He added that Pharmacy schools should determine the communications skills needed for applicants.

Mr. Zia referred to the strict English requirements for foreign graduates and suggested that the board impose a Test of Spoken English and TWE as part of its examination.

Ms. Herold stated that since 1991, all foreign graduates must take and pass the test of spoken English before they can take the board's licensing examination. She added that if pharmacists cannot communicate adequately in English, either they were licensed before 1991 or they graduated from a domestic school.

Ms. Herold referred to a bill enacted a year ago for health care practitioners and she noted that the Department of Consumer Affairs is working with the UCSF to require pharmacy students to take a second language to increase western cultural competency.

Ms. Herold stated that the most difficult problem the board faces is that the bill refers to a written measure of oral proficiency and according to exam experts, you cannot measure oral competency with a written form. Ms. Herold added that psychologists and marriage and family counselors are two professions that used oral examinations in the past but now use only written exams because of the difficulty in validating an oral examination.

Mr. Goldenberg asked if there is a way to perform an evaluation of communication skills prior to accepting an application from a candidate.

Mr. Riches stated that Universities might be the right entity to perform such an evaluation. Mr. Riches added that the Test of Spoken English is not validated for the English speaking population but rather a non-native English speaking population.

Mr. Riches stated that this bill requires the administration of three separate examinations, the NABLEX, the multi-state jurisprudence law exam and the written exam.

MOTION: Close debate on AB 2165

M/S/C: POWERS/FONG

SUPPORT: 10 OPPOSE: 0

MOTION: Oppose AB 2165 unless amended.

M/S/C: TILLEY/FONG

SUPPORT: 7 OPPOSE: 3

Public Comment

Virginia White, representing UCSF, requested that the board send a different message to the author indicating that the prior version of the bill was acceptable.

Mr. Riches stated that the board issued a support letter on the prior version of the bill based on the policy action taken by the board last July. The board is currently on record as supporting the prior amended version of the bill.

Mr. Partansky referred to the Notice to Consumers and the removal of the telephone number for pharmacy advice. He added that this also leaves out the possibility of utilizing a translation service that does not facilitate communications with those who speak a different language.

Mr. Partansky stated that the board is not fulfilling its obligation under the Americans Disability Act for the hearing impaired.

President Litsey thanked everyone for their comments and stated that the respective committees of the board will consider the comments made.

APPROVAL OF MINUTES

Full Board Minutes
(January 23 and 24, 2002)

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

MOTION: Approve the January 23 and 24, 2002 Board Meeting minutes.

M/S/C: ELSNER/POWERS

SUPPORT: 10 OPPOSE: 0

ELECTION OF OFFICERS

President

MOTION: Elect John Jones as board president

M/S/C: GOLDENBERG/TILLEY

MOTION: Nominations are closed with unanimous consent.

M/S/C: TILLEY/FONG

SUPPORT: 10 OPPOSE: 0

Vice President

MOTION: Nominate Don Gubbins for Vice President.

M/S/C: ZIA/GOLDENBERG

MOTION: Nominate Andrea Zinder for Vice President

M/S/C: POWERS/TILLEY

SUPPORT FOR DON GUBBINS: 6
SUPPORT FOR ANDREA ZINDER 4

Treasurer

MOTION: Nominate Caleb Zia for Treasurer

M/S/C: ELSNER/TILLEY

SUPPORT: 10 OPPOSE: 0

NEW BUSINESS

Mr. Goldenberg suggested that the board coordinate pharmacy activities in California to respond to emergency situations and bio-terrorism.

Mr. Cronin, representing the California Pharmacists Association, suggested that the board contact the CPhA and other organizations for input.

Another comment from the audience was a suggestion for the board to consider using photo identification on pharmacist's licenses to prevent identity fraud.

Mr. Fong asked about HIPPA and the board's role.

Ms. Harris stated a state office is specifically mandated to address the HIPPA issues and implementation and enforcement issues are not the responsibility of the Board of Pharmacy but dealt with either the Federal or State level.

Mr. Gray, representing Kaiser Permanente, stated that he understood the role of State office was to advise the State on how to implement HIPPA within its own facilities and operations. He suggested that the issue be addressed as a future Board of Pharmacy agenda item because no one is advising California how HIPPA rules fit with California rules.

ADJOURNMENT

There being no further business, President Litsey adjourned the meeting at 5:30 p.m.

April 26, 2002

STRATEGIC PLANNING

Under the direction of the board's Strategic Planning facilitator Lindle Hatton, the board met to revise the strategic plan. The board finalized the vision and mission statements and did an environmental scan using a SWOT (strength, weaknesses, opportunities, and threats) and STEP (socio-cultural, technologic, economic, and political-legal issues that will impact the board over the next 3-5 years) process. The board will continue revising the strategic plan over the next few months.

Final Vision and Mission Statements:

Vision Statement:

Healthy Californians through quality pharmacist's care.

Mission Statement:

The Board of Pharmacy protects and promotes the health and safety of Californians by pursuing the highest quality of

pharmacist's care through education, communication, licensing, legislation, regulation, and enforcement.