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

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

DATE & TIME: July 21 and 22, 2003

LOCATION: **Shelter Pointe Hotel and Marina**
1551 Shelter Island Drive
San Diego, CA 92106-3102

BOARD MEMBERS PRESENT:
John Jones, President
Donald Gubbins, Vice President
Dave Fong
Stanley Goldenberg
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
Joan Coyne, Supervising Inspector
Dennis Ming, Supervising Inspector
Ron Diedrich, Deputy Attorney General
Dana Winterrowd, Department Legal Counsel

Monday, July 21, 2003

CALL TO ORDER

President Jones called the meeting to order at 9:00 a.m. on Monday, July 21, 2003.

ANNOUNCEMENTS

- **Acknowledgments**

  President Jones welcomed pharmacy residents Adrienne Matthews and Chung Lu from Prescription Solutions to the board meeting. He also acknowledged former board members Darlene Fujimoto, Robert Elsner, Raffi Simonian, and Richard Mazzoni in the audience. He also announced that Collette Galvez, staff attorney for the Center for Public Interest Law, University of San Diego, was present.

- **Continuing Education Credits Available for Attending the Meeting**

  President Jones stated that that continuing education hours may be earned by pharmacists who wish to learn more about the issues and operation of the board by attending a board meeting. A pharmacist may acquire six CE hours once a year by attending one full day of the board's quarterly meetings. (Board members are not eligible for this CE.) A pharmacist must attend the full business day of the board meeting to earn the continuing education credit; no partial credit will be given for attendance at part of a meeting.

COMMITTEE REPORTS AND ACTION

PUBLIC EDUCATION AND COMMUNICATIONS COMMITTEE

Chairperson Powers stated that the Public Education Committee met on June 4, 2003, in the board's Sacramento Office and he referred to the minutes of the meeting provided in the board packet.

- ***The Script***

  Chairperson Powers stated that the March 2003 *The Script* was printed and mailed to California pharmacists in May through a grant provided to the CPhA's Education Foundation by the Rite Aid Corporation. The board is grateful for this collaboration and assistance.

  The next issue of *The Script* is being developed and should be mailed in September.

- **Update on *Health Notes***

  Chairperson Powers stated that the "Drug Therapy Considerations in Older Adults" issue of *Health Notes* was published and mailed at the end of April. This issue was developed by UCSF with federal funding, and the CSHP obtained a grant to print the issue. The board paid for postage and graphic design services.

  The committee next plans to revise "Pain Management" (published in 1998) to update the issue regarding new drug therapies for pain and currently pending legislative changes that will eliminate the triplicate prescription requirements and establish new requirements for prescribing controlled drugs. The committee will seek partnerships with the private sector to reduce the costs of producing this issue. This issue should be ready by January 2004.

  Chairperson Powers stated that the committee discussed future plans for other issues. "Women's Health" also needs revision to reflect changes in hormone replacement therapy. One issue of *Health Notes* is typically published annually. Concepts for three other issues also exist, but no work is planned on these items at this time.

- **Consumer Brochure on Buying Drugs from Other Countries**

  Chairperson Powers stated that the board has produced its brochures on purchasing prescription drugs for lower costs. There are three parts:

  1. Ways consumers can reduce their expenses for prescription drugs

  2. Discount programs for prescription drugs available to the public

  3. Purchasing drugs from foreign countries and why this may be hazardous

  Chairperson Powers stated that the goal is to provide patients with information so that they may make informed decisions about where they obtain their prescription drugs. The drug discount program component will be updated periodically so that the list is current and accurate.

  For the time being, the board will produce these brochures in house.

- **Public Outreach and Education Activities**

  Chairperson Powers stated that the board has shown its interest and enthusiasm for attendance at consumer information forums and fairs to provide publications and information about the board.

The board has also developed a continuing education course in a Power Point format to present to pharmacists and others about the board, enforcement issues, legislative issues and questions and answers about pharmacy law. This is a two-hour program provided by board members and board staff.

Chairperson Powers stated that recent outreach activities since the last board meeting are listed in the committee's strategic plan status report, and include staffing booths at three major consumer fairs, providing the board's CE course at three local association meetings and presentations at two major conventions.

- **Development of Public Outreach Plan with the Department of Consumer Affairs**

Chairperson Powers stated that board staff began working with the Department of Consumer Affairs on public education and outreach, implementing Sunset Review recommendations of the Joint Legislative Sunset Review Committee and Department of Consumer Affairs. The department encouraged this partnership as a means to develop additional public education materials.

Chairperson Powers stated that an action plan has been developed by the department to develop printed materials and media events. This plan includes:

1. development of patient education materials from "Hot Topics,"
2. distribution of patient information materials from the National Council on Patient Information and Education (NCPIE), and
3. generic newspaper columns on health related topics.

There are also components for press releases promoting purchasing drugs for less and October is "Talk about Prescription Month." Lastly, additional press releases surrounding the new prescribing requirements for controlled substances.

- **Hot Topics Series Concludes**

Chairperson Powers stated that the board-sponsored series "Hot Topics in Pharmacy" concluded its monthly seminar series in May. This series of six seminars started in October 2002. The board cosponsored this series with the UCSF's Center for Consumer Self Care and the Department of Consumer Affairs. The seminars provided valuable information, but attendance was low perhaps due to the location (the seminars were presented in the Capitol).

Chairperson Powers stated that there are many events that the board will participate in and he encouraged both board and staff participation.

Dr. Fong asked if there is an opportunity for public service announcements that inform the public of this material.

Ms. Herold stated that October is "Talk About Prescription Month" and the board is working with the Department of Consumer Affairs on this effort. A press kit of consumer information including the fact sheet will be developed from the "Hot Topic" Seminars conducted earlier in the year. The goal is to have a packet of information available in October when the press release is issued offering an example of the topics consumers might want to learn about or talk to their pharmacist about.

Mr. Goldenberg suggested a more long-term alignment with professional organizations or larger pharmaceutical organizations so communication can be readily available on a variety of topics.

Former board member Robert Elsner stated that the biggest consumer problem is the potential for counterfeit prescriptions and consumers need to realize that they have no guarantees of efficacy or legitimacy with drugs that are imported or purchased. He encouraged the board to make consumers aware that these problems exist.

Don Sherral from Palm Springs, California, stated that as someone who has been in the pharmacy business for 55 years, he's noticed that the main concern for consumers is the high cost of prescriptions.

Mr. Goldenberg referred to a recent article in the Los Angeles Times about counterfeiting drugs in China and its government's attempt to address the issues. He added that everyone needs to work together to assure that consumers are educated and understand the danger. He stated that usually the drugs that are used in the most acute situations are counterfeited because of their cost factor.

Chairperson Powers stated that the issue of counterfeiting is tied to affordability of prescription drugs and consumers would not purchase prescription drugs from out of the country if these drugs were affordable in California. He added that this problem would continue until the cost issue is resolved.

ENFORCEMENT COMMITTEE REPORT

Board Member Goldenberg reported on the Enforcement Committee Meeting of July 2, 2003.

Request to Amend Title 16, Section 1711(c) of the California Code of Regulation – Notification of Prescription Error.

Mr. Goldenberg stated that modifications to existing board regulations were requested regarding the pharmacist's responsibility when notifying the patient and prescriber of a prescription error. Working with the stakeholders, proposed language was drafted to allow for the pharmacist's professional judgment when situations do not require immediate notification or when the patient has not taken the wrong medication.

Mr. Goldenberg noted that the Enforcement Committee Meeting summary notes that the language did not include situations that the prescriber should be notified if there is significant harm because the patient's therapy was delayed as a result of the error. Supervising Inspector Robert Ratcliff stated that proposed language now includes situations where a significant delay in therapy results in a medication error.

Teri Miller, representing the California Society of Health Systems Pharmacists, stated that the CSHSP is pleased with the draft language and appreciates the board's willingness to work with them on developing the language.

MOTION: Enforcement Committee: Amend California Code of Regulations, Title 16, Section 1711(c), to clarify the pharmacist's responsibility when notifying the patient and prescriber of a prescription.

SUPPORT: 7 OPPOSE: 0

- **Recommendation Regarding Business and Professions Code Section 4059.5 – Wholesale Delivery when the Pharmacy is Closed**

Mr. Goldenberg stated that a request was made that the board consider its interpretation of Business and Professions Code section 4059.5 to allow for the delivery of prescription drugs to a secured area when a pharmacy is closed. The law requires that the dangerous drugs must be delivered to the licensed premises and signed for and received by the pharmacist-in-charge or, in his or her absence, another pharmacist designated by the pharmacist-in-charge.

Mr. Goldenberg stated that due to various local ordinances and environmental factors, sometimes delivery of prescription drugs must take place after the pharmacy is closed. It was requested that the board consider the delivery of the prescription drugs to a secured area as the prescription drugs still being in transit. It is when the pharmacy takes possession of the drugs that the drugs would be considered delivered to the pharmacy in compliance with 4059.5. The wholesaler would be responsible until such time that the pharmacy took possession.

During the Enforcement Committee Meeting, the committee recommended that once the drugs are delivered to the secured area, they are the responsibility of the pharmacy.

Bruce Young, representing the California Retailers Association (CRA), stated that the CRA appreciates that the board recognized the problems community pharmacies have when cities place traffic control that deliveries can only be made during off hours and that parity with hospitals was also considered by the board.

Dr. Fong stated that if the board approves this modification, he encouraged board members to meet with stakeholders to include this within the Sunset Review bill.

MOTION: Enforcement Committee: Interpret Business and Professions Code section 4059.5 to allow the delivery of prescription drugs to a secured are when a pharmacy is closed and to seek a statutory change consistent with this interpretation.

SUPPORT: 7 OPPOSE: 0

- **Off-Site Entry of Hospital Medication Orders – Delegation of Approval Pursuant to Health and Safety Code Section 11164.5.**

Mr. Goldenberg stated that Dr. Cacciatore of CardinalHeath presented a proposal at the Enforcement Committee meeting to license a pharmacy service center in California. This would be an office-based, licensed pharmacy staff with experienced hospital pharmacists. The hospital would transmit new drug orders to the service center after the hospital pharmacy closes or when needed via fax or digital imaging. Pharmacists at the pharmacy service center would remotely access the hospital computer system and review orders, perform prospective drug use review, and approve orders within 60 minutes. Pharmacists would also be available via a toll free number to answer medication questions from nursing and medical staff.

The pharmacy service center would have access to the hospital pharmacy computer system through a secure, virtual private network. The pharmacy service center would also enter into a business associate agreement with the hospital and would be in full compliance with HIPAA and state privacy laws.

Mr. Goldenberg stated that Business and Professions Code section 4071.1 allows pharmacists to electronically enter drug orders into a hospital's computer from any location outside the pharmacy or hospital with the permission of the pharmacy or hospital. Health and Safety Code section 11164.5 allows electronic data transmission or computer entry of prescriptions for controlled substances if

authorized by federal law and with the approval of the Board of Pharmacy and the Department of Justice.

Dr. Cacciatore stated that CardinalHealth would submit a community pharmacy application for licensure of this facility. He also stated that he would submit a written request for approval of the Health and Safety Code section 11164.5 to enter in the hospital computer system controlled substances. He would submit a request for approval to the Department of Justice and the Board of Pharmacy.

Mr. Goldenberg stated that the committee agreed that the licensure of this facility as a community pharmacy was appropriate and directed staff to work with the Department of Justice regarding the approval process as provided in the Health and Safety Code for controlled substances. The committee recommends that the executive officer be delegated the authority as part of the licensing process to approve these requests.

Mr. Goldenberg stated that this proposal is a new area that would benefit consumers by placing a pharmacist into the prescribing and dispensing arena and would especially benefit rural communities. He added that the board should license this activity from an enforcement standpoint in order to monitor the development.

President Jones explained that the company is targeting graveyard shifts in hospitals that cannot be staffed any other way, to provide a beneficial pharmacy service for patients. The company also has an agreement with the DEA to seek approval from the state boards where they conduct business and to seek approval from the DEA on handling controlled substances during the night, reviewing charts and releasing medications from a hospital where they are not currently located but have some involvement.

Dr. Fong asked if the board would then need to license call centers staffed by pharmacists.

Ms. Harris stated that it would depend on how each call center is set up, whether it has access to computer records and if patient profiles are in a secured area. She added that billing centers are exempt under the Civil Code under confidentiality provisions for filling purposes from patient privacy.

Mr. Goldenberg stated that one of the key elements is the inclusion of controlled substances and the ability to screen, process and interact with the order before it gets to the patient in an acute environment. He added that as the board moves forward, the Licensing Committee would need to be a part of the decision making process.

Mr. Powers stated that he supports moving forward with the recommendation.

Mr. Tilley asked if other distributors and wholesalers have such agreements. Ms. Harris stated that wholesalers may own pharmacies and there is nothing in the law that prohibits them from owning a pharmacy. The law prohibits prescriber to ownership.

Deputy Attorney General Ron Diedrich stated that the board is faced with two separate issues; a license is not needed under section 11164.5, but approval from the Board of Pharmacy and the Department of Justice for controlled substances is.

Dr. Fong expressed concern that more information is needed to make a decision and he stated that if the board approves this request, many others would make similar requests.

Ms. Harris stated that this request is to give the authority to work with the Department of Justice on the electronic process for controlled substances.

Steve Gray, representing Kaiser Permanente, asked the board to consider the issue carefully. He added that Kaiser Permanente was the sponsor of the legislation that created both sections of the law and this occurred when the DEA introduced its regulations to transmit or enter controlled substance electronically. Dr. Gray stated that there was no intent to have a license married to the entry of prescriptions and separating the two is appropriate.

Dr. Gray stated that he supports the executive officer approving these requests but suggested that the requests be considered by authenticity, integrity. irrefutability and confidentiality.

Mr. Gray stated that the Joint Commission requires pharmacists on duty to review prescription orders. He added that serious errors occur when orders are not reviewed.

Mr. Diedrich stated that the board has specific statutory authority under Health and Safety Code section 11164.5 to either grant or deny the request. And, nothing prohibits the board from making its approval conditional upon appropriate conditions.

Mr. Goldenberg asked how the board could develop guidelines with the Licensing and Enforcement Committees so the approval process is consistent.

MOTION: Enforcement Committee: Delegate to the executive officer as part of the licensing process the authority to appropriate

requests submitted pursuant to Health and Safety Code section 11145.5.

SUPPORT: 5 OPPOSE: 0 ABSTAIN: 2

- **Importation of Prescription Drugs from Canada**

Mr. Goldenberg stated that the board would continue its discussion regarding the importation of drugs from Canada. The board is waiting for legal opinions from the Attorney General's Office.

Dr. Fong referred to storefront pharmacies that open without licenses and asked how the board handles this.

President Jones stated that the board will respond to consumer complaints regarding these companies.

Dr. Fong stated that everyone must be on the same playing field and abide by the same laws and regulations as everyone else. Why should these businesses be exempt from pharmacy law and regulation.

Mr. Diedrich stated that the Attorney General's Office is reviewing and researching these types of questions

Mr. Powers stated that until the issue of high prescription cost is resolved, consumers would continue to seek lower priced prescription drugs. He added that he worked with Senator Alarcon on this issue with the specific intent of getting the state involved in lowering the cost of prescriptions. He stated that current law protects the economic interest of pharmaceutical firms in the country, rather than protecting consumers.

John Cronin questioned how the board could distinguish how it would enforce section 4343 of the Business and Professions Codewhen the language clearly states that no one *shall* display a sign in a pharmacy without a license.

President Jones stated that John Olmstead, of San Diego County, stated that California has set a precedent for establishing pharmacists care by opening the door to these types of outlets without enforcing section 4343 of the Business and Professions Code. He added that it places consumers in danger when they receive medications from out of the country that the pharmacist has no control over. He added that patients are afraid to tell their pharmacist that they have purchased prescriptions from out-of-country, and this makes it impossible to monitor their pharmaceutical care.

President Jones referred to a recent issue of *Health Affairs* where it states that approximately 27 percent of people do not receive prescription drug treatment because they cannot afford it and 20 percent were not compliant with their medication regimen because it was financially difficult to purchase their prescriptions. He added while some patients cannot afford their medications, others simply do not want to spend the money when they can purchase their prescriptions at a lower cost somewhere else.

Dana Winterrowd stated that section 4001.1 was recently added to the Business and Professions Code. This section establishes that the board's highest priority is protection of the public when exercising its licensing, regulatory and disciplinary functions.

John Cronin stated that the FDA provided testimony before Congress that the Canadian import problem from out of the United States has become such a problem that the Custom's Department and the FDA no longer have the resources to handle this increasingly serious source of counterfeit drugs coming into the United Sates.

Steve Gray, representing Kaiser Permanente, questioned why the public is not provided with a list of the counterfeit drugs that are discovered and he suggested that the board publish this information.

Ms. Zinder stated that it is time for the board to take a position that drug prices must be regulated in this country to avoid importation.

President Jones stated that this issue would continue to be an agenda item for the Enforcement Committee and board meetings.

- **Report on the meeting of the Medical Board/Pharmacy Board Joint Task Force on Prescriber Dispensing**

Mr. Goldenberg stated that the Medical Board of California and the Board of Pharmacy held a joint task force meeting on the issue of prescriber dispensing on May 27, 2003. The task force reached consensus on the following:

1. Under current law, an individual prescriber can own his/her own prescription stock and dispense to his or her own patients as specified and such practice should be allowed to continue with the goal of strengthening and educating prescribers regarding the record keeping requirements;
2. Allow a medical group to dispense prescription medications pursuant to a special permit issued by the Board of Pharmacy and specified conditions that require one physician from the medical group to be responsible and accountable for the security of the prescription

medications, record keeping requirements, and a consultant pharmacist reviews the dispensing process;
3. Establish the authority for a pharmacy to place an automated dispensing device in a prescriber's office; and
4. Provide for joint oversight by the appropriate licensing agencies.

Mr. Goldenberg stated that the task force agreed that staff from the two boards would work together to draft language for each board to consider as a possible joint legislative proposal for 2004.

Ms. Harris stated that the committee would not meet again but each board would draft language and each respective board would make a decision. If this moves forward with legislation, it will go to the Licensing Committee and then return to the board for final approval.

John Cronin requested that the Enforcement Committee in the future address compounding and labeling requirements with refill centers and allowing specialized pharmacies to compound on behalf of other pharmacies.

President Jones suggested that Mr. Cronin submit a written request by the end of August for the Enforcement Committee to address the issues at the next scheduled meeting on September 17.

LICENSING COMMITTEE

- **Request from the Community Health Accreditation Program (CHAP) for Approval to Accredit Pharmacies pursuant to Business and Professions Code section 4127.1(d)**

Chairperson Hiura introduced Terry Duncombe, President and CEO of CHAP, to answer questions regarding their request to be accepted by the board as an accreditation agency for sterile compounding pharmacies. Chairperson Hiura stated that Business and Professions Code section 4127.1(d) requires pharmacies that compound sterile injectable drug products to obtain a special pharmacy license from the board. In order to obtain such a license, the pharmacy must first be inspected by the board and found in compliance with board standards for sterile compounding. The bill exempts pharmacies that are accredited by the Joint Commission on the Accreditation of Healthcare Organizations or other accreditation agencies approved by the board from the license requirements. At the last meeting, the board approved Accreditation Commission on Healthcare (ACHC) as an accreditation agency. Exempted pharmacies still must comply with board regulations regarding sterile injectable compounding, but do not have to obtain a separate license.

Chairperson Hiura stated that at the Licensing Committee meeting on June 24, Supervising Inspector Dennis Ming reported that he had inspected a CHAP-accredited pharmacy and found it to be in compliance. Based on discussion with representatives from CHAP, the Licensing Committee recommended approval contingent on a second

inspection of a CHAP accredited pharmacy and submission of additional paperwork that compares the standards between CHAP and JCAHO.

Mr. Goldenberg asked about the inspection process when a pharmacy is JCAHO.

Supervising Inspector Dennis Ming responded that inspectors would continue to conduct inspections because these pharmacies are required to be in compliance with section 1751 of the California Code of Regulations.

Dr. Ming suggested that accreditation agencies that are approved by the Board of Pharmacy could use an inspection checklist for compliance so the surveyors will know what board inspectors are looking for to ensure compliance with the sterile injectable compounding regulations.

Ms. Herold stated that accrediting agencies will be important in assuring that sterile compounding pharmacies located out-of-state and shipping medications into California are meeting the California board's standard under this nationwide regulation because board inspectors could not inspect these out-of-state pharmacies. She added that the out-of-state Boards of Pharmacy were asked to perform the inspections, but these entities may not be able to undertake this workload.

MOTION: Licensing Committee: Approve the request from the Community Health Accreditation Program (CHAP) that pharmacies accredited by CHAP are exempt from licensure pursuant to Business and Professions Code section 4127.1(d) and to grant this request for a period of three years.

SUPPORT: 7 OPPOSE: 0

- **Request for a Specialized Clinic Permit for the UC Davis Veterinary Medical Teaching Hospital (VMTH)**

  Chairperson Hiura reported that according to the University of California's VMTH, the teaching hospital is an academic veterinary clinical training facility as well as a very large, complex veterinary practice. The standard of practice in veterinary medicine, as described in the Veterinary Practice Act, is the provision of drugs to a client by the veterinarian, through veterinary practice, subsequent to a veterinarian-client-patient relationship being established.

  By 1988, the VMTH had evolved into a very diverse and complex practice where a centralized pharmacy function was recognized to be extremely important relative to (1) assuring consistency of pharmaceutical practice, (2) having the most current pharmaceutical information available to the VMTH's clients (by way of the veterinarians), (3) improving the students' education relative to the most current

pharmacy practice and regulations, and (4) having the ability to order the appropriate drugs for such a complex practice quickly and efficiently. These factors led VMTH management to the conclusion that the pharmacy activity could best be managed under licensure through the Board of Pharmacy, rather than under the auspices of the individual veterinarians and Veterinary Practice Act.

At that time, the board determined that the closest fit for licensure was an exempt hospital pharmacy permit or a "drug room" permit. This is a permit that is issued to hospitals that have less than 100 beds.

However, last year, during a routine inspection, it was determined by the board that this permit was not the appropriate licensure, and the only option was for licensure as a community pharmacy, which does not fit the needs of the VMTH. The other issue is that VMTH uses many human drugs that are not available through veterinary drug wholesalers and human drug wholesalers are making business decisions not to sell the drugs to VMTH even though pharmacy law does not preclude them from doing so.

Various options were discussed. An option was suggested that a "specialized" clinic permit be designed that would require a consultant pharmacist oversight. It would allow for a common stock and provide a means for the VMTH to obtain a DEA permit. This option would require legislation.

MOTION: Licensing Committee: Support the proposal that the UC Davis Medical Teaching Hospital pursue legislation that would authorize a specialized "clinic" permit that would allow the dispensing of human and veterinary drugs from a common stock and the ability to obtain a DEA permit.

SUPPORT: 7 OPPOSE: 0

- **Request from ACPE for Comments to Establish National Standards for Pharmacy Technician Training.**

Chairperson Hiura stated that the ACPE has initiated a profession-wide dialog concerning the possible development of national standards and an accreditation process for pharmacy technician education and training. The ACPE is the national agency for the accreditation of professional degree programs in pharmacy and providers of continuing pharmaceutical education.

The decision on whether or not to proceed with the development of national standards will be decided at ACPE's meeting in January 2004. If the decision is to establish a national standard, then ACPE anticipates that the process, from initiation to implementation will take about three years.

ACPE has invited organizations and individuals to submit written comments by October 31, 2003, that would be considered during its discussion. It was suggested that the board submit written comment to advise ACPE of California's education and training requirements for registration and the "pharmacy technician trainee" designee that allows practical training for the technician.

Ms. Harris stated that ACPE was asked to address the issue of standardizing technician training nationwide. She added that the board's comments would advise the ACPE of California's requirements for registration and education.

Teri Miller, representing CSHP, stated that this proposal was initiated because of the variety of training standards that exist throughout the country. She added that an organization comprised of representatives from the American Pharmacists Association, ASHP, the Illinois Council of Pharmacists and Michigan did not feel it was appropriate to develop training standards but recognize the need for them to exist. As a result, they asked the ACPE to develop standards for technician training programs. She added that this is an initial stage to consider whether to move forward or not.

MOTION: Licensing Committee: Submit comments to the ACPE regarding its requirements for registration as a pharmacy technician and the ability for pharmacy technician "trainees" to obtain practical experience in a pharmacy.

SUPPORT: 7 OPPOSE: 0

- **Report on the Implementation of the Licensure and Inspection Program for Pharmacies that Compound Injectable Sterile Drug Products**

Chairperson Hiura stated that effective July 1, 2003, a pharmacy that compounds injectable sterile drug products that is not accredited by the JCAHO, ACHC and now CHAP, be specifically licensed by the Board of Pharmacy. For the prior four months, board staff has been implementing this program. Application forms have been developed, programming for licensing records performed, training of staff provided in processing applications and conducting inspections and hosting information sessions with the profession conducted.

Supervising Inspector Dennis Ming stated that the board estimates that it has received more than 150 applications for sterile compounding licenses. Approximately 90 percent of these sites have undergone board inspections. Approximately 75-80 percent of these are in compliance with board regulations and licensed. Dr. Ming stated that the board has raised the bar in terms of compliance and standards for pharmacies that are doing sterile compounding. He added that licensees are cooperative and they are complying with the program requirements. Mr. Ming stated that all board inspectors have been trained to perform these inspections to assure consistency in the process.

Dr. Ming explained that once a pharmacy passes inspection and after he has reviewed the inspection report, office staff will issue the compounding license, provided all other pharmacy requirements are met. Thereafter, renewal of this special compounding license will coincide with the renewal of the pharmacy's primary pharmacy license.

Ms. Harris commended Dr. Ming and staff on the extraordinary effort made to get this program up and running in just three months. She added that this is another example of staff working beyond expectations and rising to the occasion.

Ms. Harris referred to the board's Web site address that contains the compounding pharmacy application and the self-assessment form that pharmacies can review to learn the elements inspectors will check during inspections. She added that the board also sent a letter to all state boards of pharmacy, advising them of California requirements.

President Jones recognized, on behalf of the entire board, the tremendous effort that was put forth and stated that the bar has been raised on consumer protection.

- **Report on the June 4, 2003, Meeting of the Ad Hoc Committee on Pharmaceutical Benefit Managers (PBM) Regulation – Discussion of Recommendations**

  Mr. Powers stated that this meeting focused on the development of a drug formulary, prescription drug coverage, the P&T Committee process and the role of costs in establishing formularies.

  The committee determined that it would offer the opportunity for recommendations for the regulation of PBMs at the July Board meeting. Staff were asked to review model legislation for regulating PBMs and review what pending legislation exists in other states, and in Maine which just enacted some legislation dealing with PBMs. Some of the other issues deal with transparency in the contracting process between PBMs and manufacturers, the need for public audits and the amount of money collected in rebates.

  Mr. Powers stated that the committee is willing to hold another meeting to discuss possible legislation, and requested that the proponents and opponents to PBM regulation answer the questions from the Sunrise Questionnaire. This questionnaire is used by the Department of Consumer Affairs and the Senate Business and Professions Committee to assist in the analysis of the need for new regulatory programs.

LEGISLATION AND REGULATION COMMITTEE

Regulations Report and Action

Approved Regulations

Section 1732.05 – Continuing Education
Chairperson Zinder reported that the Office of Administrative Law (OAL) recently approved this regulation that recognizes continuing education credits approved by other California health professions licensing boards as acceptable for pharmacists' CE without a petition.

Pending Regulations

Chairperson Zinder reported on the following:

Section 1751 – Sterile Compounding
This regulation will establish guidelines for the compounding of sterile drug products. This regulation is awaiting publication of a second 15-day notice.

Section 1775 et seq. – Citation and Fine
This regulation designates the executive officer as the issuing authority for citations and fines. The regulation also consolidates and recasts existing board regulations relating to citations and fines. This is pending review by the Department of Consumer Affairs, and will be filed with the OAL therafter.

Regulations Awaiting Notice

Chairperson Zinder stated that the board has a number of regulations awaiting formal notice.

Section 1707.5 – Hospital Central Fill
This regulation will permit central refill operations for hospitals. The board conducted an informational hearing on the proposal at the October 2002 board meeting.

Section 1709.1 – Pharmacist-in-Charge at Two Locations
This regulation will permit a pharmacist to serve as pharmacist-in-charge at two locations. It is anticipated that language will be available at the public meeting of the Legislation and Regulation Committee on September 11, 2003.

Section 1715 – Pharmacy Self Assessment
This regulation will update the pharmacy self-assessment form to reflect recent changes in pharmacy law. An informational hearing is required.

Section 1717.4 and 1717.2 – Electronic Prescriptions and Electronic Records
This regulation will make any needed changes to board regulations to conform to recent changes in law. An informational hearing is required.

Section 1717.4 – Authentication of Electronic Prescriptions
This regulation will require pharmacists to authenticate electronic prescriptions. An informational hearing is required.

Section 1784 – Wholesaling
This regulation will impose dollar volume limits on wholesale drug transfers by pharmacies, impose dollar volume limits on transfers between wholesalers, and require pedigrees for drug shipments under specified circumstances. The Enforcement Committee conducted an informational hearing on this proposal at its July 2, 2003, meeting.

Mr. Riches responded that the regulation is designed to address ongoing problems with wholesale drug diversion. Initially it was an attempt to codify the 5 or 10 percent limit regarding the amount of wholesale transactions a pharmacy can engage in before becoming a wholesaler. Draft language in a prior version included a pedigree requirement for drugs sold in wholesale transactions. Mr. Riches added that the Enforcement Committee considered this regulation in detail at the last meeting. A new draft of the regulation include provisions to prevention of counterfeiting.

Mr. Tilley asked if this would require larger chain drug stores and entities that have multiple locations to become wholesalers.

Mr. Riches stated that the board received many comments regarding the challenges posed to distribution operations by the 5 – 10 percent rule, so this component was excluded. He added that it was not the intent of the regulation to interfere with legitimate businesses. Mr. Riches stated that one of the challenges the Enforcement Committee is faced with is to characterize illegitimate wholesale transactions and develop a method to prevent this type of business practice.

President Jones stated that the board specifically requested suggestions from interested parties to achieve the board's goal without obstructing legitimate business interests. He added that the counterfeit drug issue is a major problem that warrants a tracking system to protect the public.

Section 1793.3 – "Clerk-Typist" Ratio
This regulation will eliminate the clerk/typist ratio. An informational hearing is required.

Pending Legislation

Chairperson Zinder described pending legislation of interest to the board.
Senate Bill 361 (Figueroa)

This bill contains the recommendations from the Joint Legislative Sunset Review Committee regarding the board including:

- Adoption of NAPLEX and a jurisprudence exam.
- Addition of two public members to the board.
- Specification that non-pharmacists can be board inspectors.
- Revision of pharmacy technician qualifications.

The bill also contains the board's omnibus items for 2003.

Chairperson Zinder stated that this bill passed the Assembly Business and Professions Committee on July 9, 2003 on a 13-0 vote. The bill will next go to the Assembly Appropriations Committee. The bill has no opposition at this time and the Governor is expected to sign the bill.

The bill was recently amended to require periodic evaluation of the NAPLEX and designation of three of the pharmacist seats on the board as follows:

- A pharmacist who is a union member.
- A chain community pharmacy representative (more than 75 stores).
- An independent community pharmacy representative (four or fewer stores).

Chairperson Zinder stated that the board has a support position on this bill.

Status of Bills with a Board Position

AB 261 (Maddox) - Backroom Clinics

Chairperson Zinder stated that this bill would increase the penalty for unlicensed dispensing of dangerous drugs or dangerous devices to include the option of felony prosecution. She added that the sponsors believe that the public health threat posed by backroom clinics warrants granting prosecutors the opportunity to charge these cases as felonies. The board has a support position on this bill. The bill died in committee.

AB 746 (Matthews) – Medi-Cal Fraud

This bill would requires the board to revoke a license after a second conviction for Medi-Cal fraud. The board has a support position on this bill. It was passed by the Senate Business and Professions Committee with significant amendments.

AB 1363 (Berg) – Hypodermics

Chairperson Zinder stated that this bill is intended to increase the availability of clean needles and syringes to reduce the transmission of blood-borne diseases such as hepatitis and HIV. The bill would accomplish this by both removing the prescription requirement for needles and syringes, and broadening the law

permitting clean needle exchange programs operated by local governments. The board has a support position on this bill: This is a two-year bill.

AB 1460 (Nation) – Laboratory Directors

This bill permits pharmacists to act as a laboratory director if they receive training required of laboratory directors and the laboratory performs only waived tests. The board has a support position on this bill which is now a two-year bill.

SB 151 (Burton) – Triplicate Prescriptions

This bill eliminates the triplicate requirement for Schedule II prescriptions and requires a tamper-resistant prescribing pad for all written controlled substance prescriptions. The bill also adds Schedule III drugs to CURES tracking. The board has a support position on this bill and it is expected to be passed by the Assembly Appropriations Committee.

SB 175 (Kuehl) – Veterinary Drugs

This bill adds veterinary drugs to the definition of dangerous drugs. The board has a support position on this bill: This bill is on the Assembly Floor.

SB 393 (Aanestad) - Technician Checking Technician

Chairperson Zinder stated that this bill implements much of the board's existing policy supporting technicians-checking-technicians in hospitals. The board has a support if amended position on the bill to specify the training required for pharmacy technicians who are permitted to check technicians in statute rather than in future board regulations. This is a two-year bill.

SB 490 (Alpert) – Emergency Contraception

This bill would provide that a pharmacist may dispense emergency contraception either under a protocol with a physician or pursuant to a protocol approved by the Board of Pharmacy and the Medical Board. The board has a support position on this bill. This bill is now on the Assembly Floor.

SB 506 (Sher) – Animal Drugs

This bill requires the board to collect reports of wholesale sales of all antibiotics in California. The board has an oppose position on this bill. This is a two-year bill.

SB 545 (Speier) – Emergency Contraception

This bill limits the nature of the consultation and the fee that may be charged by pharmacists dispensing emergency contraception. The author accepted amendments to resolve the board's opposition. These amendments include restoring the training requirement and eliminating restrictions on the consultation provided by the pharmacist. The board now has a neutral position on the bill.

Dr. Fong expressed concern about the set fee a pharmacist can charge for this service. He stated that depending on the activity, there should be commensurate charges that should not be set in legislation.

Mr. Tilley stated that he feels that the board should oppose this bill.

Mr. Powers stated this is a needed service that should be supported, especially to low-income women. He added that he supports this bill.

Mr. Goldenberg expressed concern that one hour of continuing education is not adequate for dispensing emergency contraception.

John Cronin, representing the California Pharmacists Association, stated that the CPhA opposes this bill because proponents, in an effort to increase access to emergency contraception, will decrease access with the suggested cap on fees. He added that this represents an attack on the expansion of pharmacists' scope of practice. Mr. Cronin added that this effort was lead by consumer groups rather than the pharmacy profession. He added that the board should not view this issue as an economic issue but rather a scope of practice issue. Mr. Cronin recommended an oppose position on this bill.

Colette Galvez, representing the Center for Public Interest Law, stated that the board should not base its decision to take a position on a bill solely on the economic interest of pharmacists.

Teri Miller, representing the California Society of Hospital Pharmacists, stated that the CSHP agrees with the CPhA's position. She suggested that the board could support the bill with amendments to recommend that the same rule apply to any health care professional providing emergency contraception services.

Mr. Riches stated that recent amendments to the bill attempts to address similar activity by other practitioners.

MOTION: That the Board of Pharmacy change its oppose position to neutral on SB 545 (Speier) – Emergency Contraception

M/S/C: ZINDER/POWERS

SUPPORT: 5 OPPOSE: 2

SB 774 (Vasconcellos) – Hypodermic Needles

This bill eliminates the prescription requirement for hypodermic needles and syringes. The board has a support position on this bill. The bill is currently in the Assembly Health Committee.

Bills of Interest

Chairperson Zinder provided an overview of bills of possible interest to the board.

AB 57 (Bates) – Places MDMA into Schedule II. This bill was placed in the Assembly Inactive File.

AB 186 (Correa) – This bill makes technical changes to the Pharmacy Law relating to optometrists. This bill was passed by the Senate Business and Professions Committee.

AB 521 (Diaz) – This bill requires pharmacists to notify patients of harmful drug interactions. This is a two-year bill.

AB 1196 (Montanez) –This bill permits nurse practitioners to order Schedule II drugs. This bill is on the Senate Floor.

SB 292 (Speier) – This bill requires prescription labels to have a description of the drug. This bill is on the Assembly Floor.

AB 292 (Yee) – Interpreters: Prohibition of Use of Children
Chairperson Zinder stated that this bill would prohibit any agency that receives state funds from using a child under the age of 15 as an interpreter. Mr. Mazzoni representing Altertsons, expressed concern that type of situation occurs daily in pharmacies for patients to do not speak English and whose second-generation children do.

Collette Galvez, representing the Center for Public Interest Law, stated that this bill was originally targeted at children as interpreters in law enforcement, legal proceedings and many other state governmental settings. An exception exists for emergencies but the issue is that children under a certain age are inappropriately drawn into health care or legal decisions when they are not competent to participate in nor can they be relied on to translate accurately. She added that this is an inappropriate role for children but sometimes no other options are available.

MOTION: That the Board of Pharmacy contact Assembly Member Yee, the author of AB 292 regarding the board's concerns about the complexity of the bill and a recommendation that this become a two-year bill so the board has time to address its concerns.

M/S/C: POWERS/ZINDER

SUPPORT: 7 OPPOSE: 0

Chairperson Zinder stated that the next Legislation and Regulation Committee Meeting is scheduled for September 11, 2003, in Sacramento. This will be a public meeting.

ORGANIZATIONAL DEVELOPMENT COMMITTEE

Board President's Report

- **Board Wins National Association of Boards of Pharmacy's (NABP) Fred T. Mahaffey Ward**

  President Jones announced that the board won the NABP's Fred T. Mahaffey Award for the board's efforts in developing the quality assurance program requirements for prescription errors. President Jones explained that the board is very proud of this achievement as it comes during a time when severe budget constraints were imposed. He added that this was the second time in six years that the board has won this award. He added that having received this award is noteworthy in that California is not a full member of the NABP. He congratulated board members and staff for making this possible and helping to bring the board up to a high level of prominence among all of the boards in the United States.

- **Public Outreach Program**

  President Jones stated that the board has developed outreach programs for pharmacists throughout California. He added that this two-hour program enables the board to meet with many pharmacists at one time to explain how the board works, provide law and regulation updates and offers an opportunity for pharmacists to talk with supervising inspectors. These programs have been presented at the Outlook Meeting for the CPhA in Anaheim, California, local chapters of CPhA in San Diego, Orange County and Santa Rosa, and the CSHP Long Beach Chapter. President Jones announced that a similar event is scheduled in Santa Barbara for the CSHP.

  President Jones stated that this outreach effort maximizes the board's travel costs and provides an important educational focus of the board.

- **Board Direction and Budget Constraints**

  President Jones stated that the board is challenged, as all government agencies are, with fiscal budget constraints. As such, the board is focusing on its core consumer protection responsibilities and redirecting funding to assure that it gets the job done specifically in areas of licensing and enforcement. He added that the board understands that other areas may suffer as a result but it is important that adequate funding be directed to these important consumer protection areas.

  President Jones stated that the board is focused on resolving consumer complaints in a timely manner and assuring that the turn-around time for responding to complaints does not slip to an unacceptable level.

  President Jones stated that the board has eliminated its out-of-state travel and to lower further travel expenses is reducing meetings of inspectors to two meetings per year. These meetings are very beneficial to inspectors, hearing first hand the issues and concerns facing the board.

- **NABPLEX**

  President Jones stated that if SB 361 is enacted, the board will be eligible to use NAPLEX instead of providing its own exam in January. The board plans to have the NABPLEX and the California exam available as soon as possible after the first of the year.

Report on the Meeting of June 30, 2003

Chairperson Gubbins reported on the Organizational Development Committee Meeting of June 30, 2003.

- **Approval of Strategic Plan for 2003-05**

  Chairperson Gubbins stated that at the April Board Meeting, the board devoted a portion of one day to revise its strategic plan. The changes made during this process have been incorporated into the plan. In the last quarter, each committee has reviewed the final objectives and tasks for that committee. These components are now incorporated into a draft strategic plan that needs board approval.

  MOTION: Organizational Development Committee: The board's Strategic Plan for 2003-05

  SUPPORT: 7 OPPOSE: 0

- **Budget Update for 2002/03 and 2003/04**

  10 Percent Reduction in Personnel Services is Ordered for 2003/04

  Chairperson Gubbins stated that the state is facing a huge budget deficit now estimated at $38 billion.

  A number of additional cost containment controls have been placed on state agencies besides hiring freezes and the elimination of vacant positions. In the last year:

  1. The board lost four positions and $185,000 in associated funding for these positions (June 2002)
  2. By February 2003, all out-of-state travel requested was denied
  3. Also in February, all agencies were required to cut their in-state travel budgets by 35 percent (In the case of the board, this was $52,100).
  4. All training requests, contracts and purchases underwent additional review by the department as a means to reduce expenses, and approval was significantly harder to attain
  5. On April 1, the Administration directed all agencies to cut their personnel services budgets by 10 percent for 2003/04, and to prepare a list of surplus employees to lay off.
     This was a $347,000 reduction for the board, and will be met by:

     a. The elimination of all vacant positions (six positions)
     b. The elimination of overtime payments
     c. and a substantial reduction in board member honoraria

     However, the board did not have to lay off any staff, although it will have to continue to redirect work and stop performing some functions in order to complete the most important tasks

  6. On June 30, the board lost the six additional positions that were vacant

- **Board Member Compensation**

  Chairperson Gubbins stated that the board must redirect approximately $20,000 from board member compensation for the year to make the 10 percent cut in personnel services. The committee recommends that board members be compensated only if money is available at the end of the year.

  MOTION: Organizational Committee: Alter the board's compensation policy for board members to:

  1. Members will be compensated only for attendance at board meetings, which is $100 per day of the board meeting.

Travel expenses will not be affected and will continue to be paid by the board, and are funded from other areas of the board's budget (this was not part of the 10 percent cut ordered in personnel services).

2. Members who work additional time on board business may still submit these hours for reimbursement but the hours will be held until the end of fiscal year 2003/04. If sufficient funds remain, the board members will be reimbursed for eight-hour increments, just as they are now. If funding is not available for this purpose, no additional compensation will be provided.

SUPPORT: 7 OPPOSE: 0

- **Ethics Training for Board Members**

  Chairperson Gubbins announced that it is time again for all board members and designated staff to take state-mandated ethics training. He added that this training must be completed during 2003, and can be taken online or via a video and will require approximately 1.5 hours to complete. Four board members have completed the training so far.

- **Status Update on the Joint Legislative Sunset Review – Recommendations of the JLSR Committee and Department of Consumer Affairs**

  Chairperson Gubbins stated that the Joint Legislative Sunset Review Committee (JLSRC) and the Department of Consumer Affairs issued a number of joint recommendations, and each made several individual recommendations for the board. He added that the Organizational Development Committee has been tracking these recommendations.

  Nearly all the law change recommendations have been inserted into SB 361.

  President Jones asked if there were any comments by the board or the public on the sunset review recommendations and status update report. There were none.

- **Findings of the Operational Audit of the Board by the Department of Consumer Affairs, Internal Audits Office**

  Chairperson Gubbins stated that the Department of Consumer Affairs' Internal Audits Office released the report of its operational audit of the board in March 2003. This audit started October 1, 2002, and was completed in February 2003. The audit looked at the board's internal controls, compliance with all state requirements, the licensing of pharmacists and technicians, enforcement matters and cashiering. (The department typically audits every agency undergoing sunset review.)

Again, the Organizational Development Committee has been tracking these recommendations to review board progress. Chairperson Gubbins referred to the recommendations and the board's activities to achieve them. Progress reports to the department on the board's actions to incorporate these changes will be prepared every six months. Copies of these status reports will be shared with the board in the future.

- **Personnel Update**

  Chairperson Gubbins stated that all vacant positions on June 30th were eliminated.

  The board lost the following positions:

  - Three inspectors (one new position for compounding, one from the promotion of Dennis Ming, and one "technical" inspector position that last year was reclassified from an analyst position to an inspector position while the board sought approval for a 4th supervising inspector position – which when the board filled the supervising inspector position, left another inspector position vacant)
  - One associate analyst (licensing of sites, created by the retirement of Sandi Moeckly at the beginning of 2003)
  - One office technician (licensing of sites, created by the promotion of Suelynn Yee for licensing compounding pharmacies)
  - One office technician (receptionist who resigned in February)

  All board managers will effectively receive a 5 percent reduction in their state compensation starting in July to cover retirement contributions that were made by the state for the past few years. In addition managers will not receive a 5 percent raise negotiated several years ago for union-represented employees (all other board employees). Meanwhile the Administration is bargaining with all unions representing state employees on future conditions of employment.

  The board was able to secure training for new inspectors from the National Crime Investigation and Training (NCIT) in investigating and writing. All board inspectors and complaint handlers now have completed this training.

  Ms. Herold stated that the board has lost 10 positions (20 percent) in the last year. In addition, the board has taken on the added responsibility that the Compounding Program has added along with its mandatory inspections. She added that the board would continue to have a difficult time over the next year to redirect funds and working to become more efficient. Moreover, a budget letter issued July 8, 2003, explains the Governor's direction to state agencies regarding his expectations for the next two years. It is clear that there will be no program expansions or new programs, and any program growth can occur only if other programs are cut.

Ms. Harris stated that staff would begin working with both the Licensing Committee and the Enforcement Committee as certain program components or procedures are identified as discretionary or can be consolidated. For example, the board may want to consider whether it will continue the mandate of issuing hypodermic licenses. Another area for consideration is the intern program which the board will review this year. Staff will identify areas for elimination or consolidation and refer them to the appropriate committee for review and consideration.

Steve Gray, representing Kaiser Permanente, stated that with the expected passage of SB 151, the board would have a new responsibility to approve printing companies for the new security paper prescription pads. He suggested that this be added to the agenda.

President Jones stated that the criteria for approving the new companies is straightforward and provides a business opportunity for those who are interested.

APPROVAL OF MINUTES

Full Board Minutes
(April 29 and 30, 2003)

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

MOTION: Approve the April 29 and 30, 2003, Board Meeting Minutes

M/S/C: POWERS/HIURA

SUPPORT: 7 OPPOSE: 0

PUBLIC COMMENT ON MATTERS NOT ON THE AGENDA

John Cronin, representing the California Pharmacists Association, referred to the new board procedure to post board packet material on the Web site. He commended the board for this but requested that the material be posted as soon as possible in advance of the meeting.

ADJOURNMENT

There being no further business, President Jones adjourned the meeting at 4:05 p.m.

Tuesday, July 22, 2003

CLOSED SESSION

The board moved into Closed Session pursuant to Government Code Section 11126(a) regarding personnel matters to perform the evaluation of the Executive Officer.

The board moved into Closed Session to confer with Legal Counsel pursuant to Government Code Section 11126(e) regarding the flowing pending litigation: Doumit v Board of Pharmacy, Sacramento Superior Court Case #98A504499 and Tain, et al, v Board of Chiropractic Examiners, et al., San Francisco Superior Court Case # CGC-03-419378

REINSTATEMENT

The board moved into closed session pursuant to Government Code section 11126(c)(3) to deliberate upon disciplinary cases and the petitions for reinstatement.