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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

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

DATE: **October 25 and 26, 2006**

LOCATION: **Sheraton Gateway San Francisco Airport Hotel**
600 Airport Blvd.
Burlingame, CA 94010

BOARD MEMBERS PRESENT:

William Powers, President
Kenneth Schell, Pharm. D., Vice President
Ruth Conroy, Pharm. D.
D. Timothy Dazé
Stanley Goldenberg, R.Ph.
Clarence Hiura, Pharm. D.
Henry Hough
Susan Ravnan, Pharm. D.
Robert Swart, Pharm. D.
Andrea Zinder

STAFF PRESENT:

Virginia Herold, Interim Executive Officer
Karen Cates, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judith Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Joshua Room, Deputy Attorney General
LaVonne Powell, DCA Staff Counsel
Spencer Walker, DCA Staff Counsel
Anne Sodergren, Legislation and Regulation Manager
Kim deLong, Analyst
Victor Perez, Analyst

CALL TO ORDER

President Powers called the board meeting to order on October 25, 2006, at 9:00 a.m.

INTRODUCTIONS

President Powers welcomed two board members who were attending their first meeting, Susan Ravnan, Pharm.D. and Timothy Dazé, public board member.

President Powers welcomed Spencer Walker, Department of Consumer Affairs Staff Counsel. Mr. Walker will replace LaVonne Powell who has been reassigned to other agencies in the department.

President Powers welcomed students who were in attendance from Touro University, UC San Francisco and the University of the Pacific.

President Powers acknowledged former board members John Jones, Glenn Yokoyama and David Fong, who were in the audience.

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Chairperson Schell provided the report on the Communication and Public Education Committee Meeting held on September 22, 2006.

- **Discussion Regarding Development of AB 2583's Requirements to Modify the "Notice to Consumers"**

Chairperson Schell stated that Assembly Bill 2583 (Nation) was signed by the Governor and became Chapter 487, Statutes of 2006. This law requires the board to add to the Notice to Consumers, a statement that describes a patient's right to obtain medication from a pharmacy:

1. even if a pharmacist has ethical, moral or religious grounds against dispensing a particular drug, in which case protocols for getting the patient the medication are required.
2. unless based upon the pharmacist's professional training and judgment that dispensing a drug is contrary to law or the drug would cause a harmful drug interaction or otherwise adversely affect the patient's medical condition.
3. unless the medication is out of stock or not available from the pharmacy.
4. unless the patient cannot pay for the medication or pay any required co-payment.

Chairperson Schell stated that the "Notice to Consumers" referenced in this bill refers to a requirement that the board provide a poster to pharmacies that must be displayed in an area conspicuous to and readable by prescription drug consumers (16 CCR section 1707.2(f)).

As reported at the July Board Meeting, the committee believes that the addition of this material to the Notice to Consumers will be a challenge because the current poster is very full of text already. Moreover, the new content does not really mesh with the focus of the current Notice to Consumers.

Chairperson Schell referred to a draft that encompasses the required text and also informs patients about their rights to medication and pharmacists' consultation.

Chairperson Schell stated that the board may review and modify this statement during the board meeting. The information required to be displayed on the Notice to Consumers by AB 2583 will eventually need to be promulgated in a regulation. The discussion at this meeting is important to this adoption process.

Ms. Zinder referred to the draft of the required text where it states that "if the pharmacist has ethical, religious or moral reasons for not personally providing you with a specific medicine, the pharmacy must provide an alternative means for you to obtain it." She asked if it is the pharmacy or the pharmacist that needs to provide an alternative means. She asked if it would be clear if both the pharmacy and the pharmacist were mentioned.

Chairperson Schell stated that it is his understanding that it is a joint obligation between the employer and the pharmacist to develop a system to assure that patients receive the medication that they need.

Mr. Room stated that no licentiate shall obstruct the delivery of a prescription drug to a patient. He added that that the individual would be answerable if he or she doesn't facilitate the alternative means of delivery, but having protocols in place is the responsibility of the employer or the pharmacy.

Dr. Ravnan suggested that the language be divided out better to facilitate ease of reading. She stated that the format is too busy.

Ms. Herold stated that the intent was not to create an adversarial relationship between patients and pharmacists in cases when the pharmacist determines that a prescription cannot be filled due to a contraindication or because the order was not legally written. She added that the intent is that the patient is entitled to the medication unless the pharmacist determines that the prescription cannot be filled.

Ms. Herold stated that the SCR 49 Medication Error Task Force is recommending that patients receive a higher quality consultation and the task force is considering a modification to the Notice to Consumers poster to articulate the consultation requirement.

Dr. Hiura stated that he objects to the requirement of two posters because some of his colleagues have small pharmacies with little room to hang posters on the wall. Also, many of his patients are of a different ethnic origin and he did not feel that they would take the time to read the information. He added that he would like the information to be contained on one poster.

MOTION: That the Board of Pharmacy develop a second Notice to Consumers.

M/S/C: DAZÉ/GOLDENBERG

SUPPORT: 8 OPPOSE: 1

Steve Gray, representing Kaiser Permanente, stated that Kaiser Permanente fully supports the concept of making the poster available. He added that when the Board of Pharmacy puts out a public notice such as this, it is often interpreted not only as policy but also an interpretation of law. These can evolve into a legal confrontational situation when there are many things at stake.

Pharmacies must understand their obligation under the law. He stated that the law requires pharmacies to have protocols that are intended to provide an alternative means to obtain these products and no pharmacy can guarantee that an alternative means will meet the needs of the patient. There are situations such as mail order where the law does not require consultation or requires the pharmacist to talk to every patient regarding their first prescription.

Dr. Gray expressed concern that the pharmacist would be required to answer questions about medications "any time." He also referred to the statement: "Information from a pharmacist is important to your health because it can make certain you know what is important about your medicine therapy. Pharmacists are educated to be the experts in medicine therapy." He suggested that the board tone this down.

Staff was directed to work on the language and bring it back to the next meeting.

- **Update on the Development of Consumer Fact Sheet Series with UCSF's Center for Consumer Self Care**

Chairperson Schell stated that two and one half years ago, the board approved a proposal by the committee to integrate pharmacy students into public outreach activities. The project involves UCSF pharmacy students developing one-page fact sheets on diverse health care topics for public education.

The UCSF Center for Consumer Self Care works directly with the students to develop the fact sheets, which are then reviewed by faculty members and then by the board.

The board distributes these fact sheets at community health fairs and has them available online. The fact sheet format is intended to be attractive whether printed or photocopied.

So far, nine fact sheets have been developed. These fact sheets are:

General Pharmaceutical Care Issues

1. "Is Your Medicine in the News?"
2. "Generic Drugs . . . Real Medicines at High Quality, Low Cost"
3. "Lower Your Drug Costs So You Can Keep On Taking Your Medicines"
4. "Don't Flush Your Medicines Down the Toilet"

Medicine Safety

5. "What's the Deal with Double Dosing? Too Much Acetaminophen, That's What!"
6. "Ever Miss a Dose of Your Medicine? Here are some Tips"
7. "Thinking of Herbals? Check Carefully Before You Take Them with Medicines"

Health Topics

8. "Diabetes – Engage Your Health Team"
9. "Did You Know? Good Oral Health Means Good Overall Health"

These fact sheets are currently being translated by the board into Spanish, Vietnamese and Chinese.

At the September committee meeting, four new fact sheets were unveiled. The committee and staff provided comments and revisions. After completion of editing and review, the fact sheets will be released. The fact sheets under development are:

- An Aspirin a Day? . . . Maybe, Check it Out!
- Uncommon Sense for the Common Cold
- Medication Errors Mistakes Happen . . . Protect Yourself!
- Putting the Chill on Myths about Colds and Flu

- **Update on Activities of the California Health Communication Partnership**

Chairperson Schell stated that in 2004, the board voted to become a founding member of the California Health Communication Partnership. This group is spearheaded by UCSF's Center for Consumer Self Care to improve the health of Californians by developing and promoting consumer health education programs and activities developed by the members. Members include other regulatory boards and professional associations and the FDA. The function of the group is to develop or disseminate integrated public information campaigns on priority health topics identified by the partnership members.

At the September Communication and Public Education Meeting, Bill Soller, PhD, of the Center for Consumer Self Care, made a presentation about the recent activities of the partnership.

The current campaign is cancer screening: "It's Your Life – Do It Today" and is aimed at men and women aged 50-75 years of age.

The committee discussed other topics, including development of an outreach campaign on generics, which is another planned project of the partnership.

- **Update on *The Script***

  Chairperson Schell stated that the September issue of *The Script* was mailed to pharmacies and wholesalers. Board Analyst Victor Perez graphically designed this issue instead of the graphics unit of the State Printing Plant. The Pharmacy Foundation of California will mail this issue to California pharmacists.

  The next issue of the newsletter is being developed for publication for January 2007. It will focus on new legislation and regulations.

- **Development of New Consumer Brochures**

  Chairperson Schell stated that the board has recently conveyed a job offer to an individual to provide consumer and licensee outreach. Development of public education materials will be one of her responsibilities.

  One of the hottest topics in the popular media recently has been medical errors, including medication errors. The board has been actively involved in a number of activities aimed at reducing errors, including the quality assurance program requirements that mandate that pharmacies evaluate every prescription error.

  Staff is beginning to build the components for a segment of the board's Web site to address medication errors. It will include data such as that presented at the July 2006 Board Meeting on prescription error data identified by the board through investigations of consumer complaints. It will also include information from other sources – ways to prevent errors, frequently confused drug names, etc. It will have links to other Web sites as well.

  Mr. Goldenberg referred to the proposed brochure on the Beers list of medications that should not be provided to elderly patients. He added that a new federal guideline for long-term care regarding such medication would be released in December. He added that the Beers list no longer contains Dr. Beer's name listed because of the concern expressed by Dr. Beer that the list was not being used as it was intended when it was created. Dr. Beer requested that updating and changing the list also include removal of his name for government use.

- **Recent Study of Patient Medical Literacy**

  Chairperson Schell stated that the committee discussed a recent report by the National Center for Education Statistics that found that most people had only intermediate health literacy. This means

that "a majority of U.S. adults will have some difficulty using health-oriented materials with accuracy and consistency." The study, based on data from the 2003 National Assessment of Adult Literacy, involved 19,000 individuals. The data indicate that that fewer than one in six persons is proficient in health literacy.

Low health literacy results in patients not understanding medical instructions and terms, and leads to higher costs and poor health outcomes.

Generally:

- Whites and Asian adults had higher health literacy rates than blacks, Hispanics and American Indians.
- Hispanic adults had the lowest health literacy rates.
- Adults older than 65 had lower health literacy rates than younger age groups.
- Women had slighter higher health literacy than men.

These statistics attest to the importance of patient education – by pharmacists and other health care providers as well as by this board. The data also emphasize the need to provide appropriate tools for patients to educate themselves.

- **Update on Public Outreach Activities**

Chairperson Schell stated that the board strives to provide information to licensees and the public. It has a number of consumer materials to distribute at consumer fairs and attends as many of these events as possible, where attendance will be large and staff is available.

The board has a PowerPoint presentation on the board containing key board policies and pharmacy law. This is a continuing education course, typically provided by a board member and a supervising inspector. Questions and answers typically result in a presentation of more than two hours, and is well received by the individuals present.

From July 1 – October 15, the board provided five continuing education presentations, and public outreach to consumers or the profession at six events.

- **Subcommittee on Medicare Part D Plans**

Chairperson Schell stated that there was no meeting of the board's Subcommittee on Part D Plans this quarter. The committee is comprised of Board Members Andrea Zinder and Stan Goldenberg, who is chair.

The next meeting will be November 30 in Sacramento. Representatives of the California Department of Health Services and the federal Centers for Medicaid and Medicare Services will attend along with consumer advocacy groups. The goal in holding these meetings is to provide a forum for discussion and problem solving among the agencies.

- **Meeting Summary**

  Chairperson Schell referred to the summary of the Communication and Public Education Committee Meeting held September 22 provided in the board packet.

- **Board of Pharmacy Web Site Update**

  Ms. Herold stated that the board has been developing its Web site over the last year and she announced that that board is now "live" with the new home page. She introduced Kim deLong, the board's Web Master.

  Ms. deLong distributed copies of the new home page. She added that the new home page contains the same information, however, the content was redesigned to be more user friendly and it also meets new requirements regarding state-hosted Web sites that take effect January 2007. She asked the board to forward any ideas, concerns or comments to Ms. Herold so they can be addressed, because the Web site is intended for everyone's use.

LICENSING COMMITTEE

- **Report on the Meeting of September 20, 2006**

  Chairperson Conroy reported on the Licensing Committee Meeting on September 20, 2006, held in Sacramento.

- **Request to Recognize the School of Pharmacy at the University of Charleston for Purposes of Issuing California Pharmacist Intern Licenses**

  Chairperson Conroy stated that after the September 20th Licensing Committee Meeting, the board received a request from the University of Charleston seeking board approval for purposes of issuing California intern pharmacist licenses. Current board regulation 16 CCR section 1719 states that a "recognized school of pharmacy" means a school accredited or granted candidate status by the Accreditation Council for Pharmacy Education (ACPE). The University of Charleston has "pre-candidate" status with ACPE, and according to ACPE is progressing toward candidate status.

  Chairperson Conroy stated that approval would mean that the University of Charleston's students could work as interns in California pharmacies.

  MOTION: That the Board of Pharmacy recognize the School of Pharmacy at the University of Charleston for purposes of issuing California pharmacist intern licenses.

  M/S/C: POWERS/HIURA

  SUPPORT: 9 OPPOSE: 0

- **Emergency Preparedness for California Pharmacy**

  Chairperson Conroy stated that one of the Governor's key initiatives is emergency preparedness. Currently within the Department of Health Services is the Emergency Preparedness Office, which was formed to coordinate state government planning for emergencies.

  Chairperson Conroy stated that the board has an important role in this because the provision of pharmaceuticals and who will provide them will certainly be an important component in any disaster response.

  Chairperson Conroy introduced Mark Chew, Chief Pharmacist from Orange County in Public Health and Bio-Terrorism. Dr. Chew stated that an ongoing work group is addressing a solution to the problems pharmacists face during disaster response. A major concern is that patients are cut-off from their health care providers.

  Dr. Chew gave a PowerPoint presentation on the problems encountered when providing care in emergency situations. He talked about how warehouses and other available sites could be used during a disaster to provide emergency care to the public.

  Dr. Chew stated that licensing issues are also a problem during disasters because licensed and non-licensed individuals volunteer for activities such as distributing and repackaging medications. He added that the federal Medical Reserve Corp organizes this activity. He stated that during the emergency in Louisiana, pharmacy students ran pharmacies or medication areas. Dr. Chew added that the goal is to provide care to the public during a disaster.

  Chairperson Conroy introduced Dana Grau, PharmD, senior pharmaceutical consultant in the Emergency Pharmaceutical Services Unit of the Department of Health Services Emergency Preparedness Office.

  Dr. Grau stated that the mission of the Emergency Pharmaceutical Services Unit is in place to protect the health of citizens in California. Dr. Grau provided information about his agency's role in planning and preparing for disaster response against large-scale public health emergencies, including bioterrorism attacks, nuclear attacks, disease outbreaks such as pandemic influenza as well as natural disasters such as those caused by hurricanes and earthquakes.

  Dr. Grau described the Strategic National Stockpile (SNS) as a national repository of antibiotics, chemical antidotes, antitoxins, life–support medication, IV administration, airway maintenance supplies and medical and surgical items. The stockpile will supplement and re-supply state and public agencies for any emergency, anywhere at anytime within the US. The stockpile is shipped to the designated location within 12 hours. Additional shipments arrive, if needed, within 24 to 36 hours. When necessary, the inventory of the stockpile can be modified to contain only several pharmaceuticals.

The SNS is organized for flexible response. The first line of support lies within the immediate response 12-hour Push Packages. These 50-ton caches of pharmaceuticals, antidotes and medical supplies are designed to provide rapid delivery of a broad spectrum of assets for an ill-defined threat in the early hours of an event. The Push Packages are positioned in strategically located, secure warehouses, ready for immediate deployment to a designed site within 12 hours of the federal decision to deploy SNS assets.

If the incident requires additional pharmaceuticals and/or medical supplies, a follow-up managed inventory will be shipped to arrive within 24 to 36 hours. If the agent is well defined, managed inventory can be tailored to provide pharmaceuticals, supplies and/or products specific to the suspected or confirmed agent.

The DHS wants to ensure that the board is aware of DHS' plans so that concerns can be addressed initially and licensees and the public will have better knowledge about the board's requirements and be willing and comfortable volunteering to participate in an emergency.

Current California law, Business and Professions Code section 4062 provides the board with broad waiver authority (this provision was written and sponsored by the board):

> **4062.** (a) Notwithstanding Section 4059 or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.
> (b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

Also, a section of law dealing with refills could aid pharmacists in providing medication to patients in an emergency:

> **4064.** (a) A prescription for a dangerous drug or dangerous device may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being.
> (b) The pharmacist shall inform the patient that the prescription was refilled pursuant to this section.

(c) The pharmacist shall inform the prescriber within a reasonable period of time of any refills dispensed pursuant to this section.
(d) Prior to refilling a prescription pursuant to this section, the pharmacist shall make every reasonable effort to contact the prescriber. The pharmacist shall make an appropriate record, including the basis for proceeding under this section.
(e) The prescriber shall not incur any liability as the result of a refilling of a prescription pursuant to this section.
(f) Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

The board's prior policy in response to any inquiries from licensees who are responding to declared emergencies is perhaps simply stated as: take care of patients, and make certain they get their needed medication.

Chairperson Conroy stated that over the coming months the board will work with the DHS on developing a plan on how the board would respond to disaster response efforts if a declared emergency occurs.

Mr. Goldenberg stated that the board recently met with the National Association of Boards of Pharmacy during a regional meeting. He added that disaster preparedness was a topic. He stated that he also recently attended a meeting in Los Angeles where the subject arose because the city is very high on the list of cities that would be very difficult to evacuate during a disaster. It was conveyed that the public should be prepared to be independent for the first seven days of a disaster.

Mr. Goldenberg stated that pharmacies are the most accessible health care entities existing and he suggested that the board leave a legacy by developing action in advance of a disaster. He added that he was recently asked by a young pharmacist on how he could register to volunteer in the event of such an emergency and because there are seven schools in California, there is a great opportunity for many students to volunteer. Pharmacists need to envision themselves and train for responding to disasters and public health emergencies.

Chairperson Conroy referred to a draft policy statement and stated that the intent is to publicly release the statement by placing it on the board's Web site and highlighting the information in the next issue of the board's newsletter.

Dr. Grau thanked the board for comments and support of these activities. He added that the policy statement is a good beginning to recruit pharmacists, provide a comfort zone for them to respond and provide training necessary to perform better in an emergency.

Mr. Hough stated that he agreed that the board has to be proactive before a disaster occurs but the underlying common solution is communication. He suggested that there be a communication plan.

Dr. Ravnan stated that she supports these efforts and that she and her husband have volunteered with their local federal Medical Reserve Corp.

Ms. Herold stated that during the last year and a half she and board staff have worked with the Governor's Disaster Response Planners including the Department of Health Services and the board's enforcement staff.

Ms. Herold stated that the Department of Health Services is concerned about the location of warehouses storing stockpiles and she questioned how the drugs would be stored and whether the facilities need to be licensed. The DHS feels that these locations need to be licensed.

Mr. Goldenberg suggested the use of posters to inform the public of available warehouse locations in case of an emergency.

Steve Gray, representing Kaiser Permanente, stated that communication is a critical component and was conveyed by the board in the draft statement. He added that the policy statement would start the lines of communication before a disaster occurs so pharmacists are not reluctant to apply their skills and services. He encouraged the board to move forward.

Dr. Gray suggested using military technicians and pharmacists during a disaster.

Dr. Chew referred to two Web sites where interested parties could sign up to volunteer: www.medicalreservecorps.gov or www.medicalvolunteer.ca.gov

MOTION: Licensing Committee: That the Board of Pharmacy adopt a policy statement for pharmacies when providing emergency response and to authorize Ms. Herold to make minor adjustments to the document and return it to the board for further consideration of legal issues.

M/S/C: POWERS GOLDENBERG

SUPPORT: 9 OPPOSE: 0

Disaster Response Policy Statement

The California State Board of Pharmacy wishes to ensure complete preparation for, and effective response to, any local, state, or national disaster, state of emergency, or other circumstance requiring expedited health system and/or public response. Skills, training, and capacities of board licensees, including wholesalers, pharmacies, pharmacists, intern pharmacists, and pharmacy technicians, will be an invaluable resource to those affected and responding. The board also wishes to encourage an adequate response to any such circumstance affecting residents of California, by welcoming wholesalers, pharmacies, pharmacists, intern pharmacists, and pharmacy technicians licensed in

good standing in other states to assist with health system and/or public response to residents of California.

The board encourages its licensees to volunteer and become involved in local, state, and national emergency and disaster preparedness efforts. City or county health departments, fire departments, or other first responders can provide information on local opportunities. The Emergency Preparedness Office of the California Department of Health Services is a lead agency overseeing emergency preparedness and response in California, particularly regarding health system response, drug distribution and dispensing, and/or immunization and prophylaxis in the event of an emergency. At the federal level, lead contact agencies include the Department of Health and Human Services, the Centers for Disease Control, and/or the Department of Homeland Security and its Federal Emergency Management Agency (FEMA). Potential volunteers are encouraged to register and get information at www.medicalvolunteer.ca.gov (California) and www.medicalreservecorps.gov (federal).

The board also continues to be actively involved in such planning efforts, at every level.
The board further encourages its licensees to assist in any way they can in any emergency circumstance or disaster. Under such conditions, the priority must be protection of public health and provision of essential patient care by the most expeditious and efficient means. Where declared emergency conditions exist, the board recognizes that it may be difficult or impossible for licensees in affected areas to fully comply with regulatory requirements governing pharmacy practice or the distribution or dispensing of lifesaving medications.

In the event of a declared disaster or emergency, the board expects to utilize its authority under the California Business and Professions Code, including section 4062, subdivision (b) thereof, to encourage and permit emergency provision of care to affected patients and areas, including by waiver of requirements that it may be implausible to meet under these circumstances, such as prescription requirements, record-keeping requirements, labeling requirements, employee ratio requirements, consultation requirements, or other standard pharmacy practices and duties that may interfere with the most efficient response to those affected.[1] The board encourages its licensees to assist, and follow directions from, local, state, and national health officials. The board expects licensees to apply their judgment and training to providing medication to patients in the best interests of the patients, with circumstances on the ground dictating the extent to which regulatory requirements can be met in affected areas. The board further expects that during such emergency, the highest standard of care possible will be provided, and that once the emergency has dissipated, its licensees will return to practices conforming to state and federal requirements.

Furthermore, during a declared disaster or emergency affecting residents of California, the board hopes that persons outside of California will assist the residents of California. To facilitate such

[1] Expanded powers in the event of a disaster are also granted to the Governor and/or other chief executives or governing bodies within California by the California Emergency Services Act [Cal. Gov. Code, §§ 8550-8668] and the California Disaster Assistance Act [Cal. Gov. Code, §§ 8680-8690.7], among others. Section 8571 of the Government Code, for instance, permits the Governor to suspend any regulatory statute during a state of war or emergency where strict compliance therewith would prevent, hinder, or delay mitigation.

assistance, in the event of a declared California disaster or emergency, the board expects to use its powers under the California Business and Professions Code, including section 900 and section 4062, subdivision (b) thereof, to allow any pharmacists, intern pharmacists, or pharmacy technicians, who are not licensed in California but who are licensed in good standing in another state, including those presently serving military or civilian duty, to provide emergency pharmacy services in California.[2] The board also expects to allow nonresident pharmacies or wholesalers that are not licensed in California but that are licensed in good standing in another state to ship medications to pharmacies, health professionals or other wholesalers in California. Finally, the board also expects to allow use of temporary facilities to facilitate drug distribution during a declared disaster or state of emergency. The board expects that its licensees will similarly respond outside of the state to disasters or emergencies affecting populations outside California, and will pursue whatever steps may be necessary to encourage that sort of licensee response.

- **Request to Add the Exam for the Certification of Pharmacy Technicians as a Qualifying Method for Pharmacy Technician Registration**

Chairperson Conroy stated that currently, pharmacy technicians may become qualified for registration in California by one of four methods:

1. Possessing an associate degree in pharmacy technology.
2. Completing a course of training specified by the board in regulations (accredited by ASHP, provided by the armed forces, or at least 240 hours of instruction covering specific topics).
3. Graduating from a school of pharmacy recognized by the board.
4. Being certified by the Pharmacy Technician Certification Board.

A new pharmacy technician examination has been brought to the board's attention, the Exam for the Certification of Pharmacy Technicians (ExCPT).

The ExCPT is accepted by Connecticut, New Jersey, Minnesota, Oregon and Virginia as a qualifying route for registration. Kenneth W. Schafermeyer, PhD, RPh, Director of Education for the Institute for the Certification of Pharmacy Technicians, which develops this exam, attended the Licensing Committee Meeting on September 20 to provide information about this examination.

The exam is computer administered six or seven days a week in 700 locations nationwide. The National Community Pharmacists Association and the National Association of Chain Drug Stores support use of the exam, and were involved in its development.

The ExCPT is a competing exam to the PTCB exam, which is developed by the American Pharmacists Association, American Society of Health-System Pharmacists, Illinois Council of Health-System Pharmacists, Michigan Pharmacists Association and the National Association of

[2] See also the Interstate Civil Defense and Disaster Compact [Cal. Gov. Code, §§ 177-178], the Emergency Management Assistance Compact [Cal. Gov. Code, §§ 179-179.5], and the California Disaster and Civil Defense Master Mutual Aid Agreement [executed 1950], regarding cooperation among the states.

Boards of Pharmacy. Over 250,000 technicians have become certified via use of this exam nationally since 1995. Currently the PTCB is a paper-and-pencil examination administered periodically, although plans are to have it go computer administered in February 2007. It has a higher fee.

The committee asked staff to review the ExCPT and see if it meets the requirements of Business and Professions Code section 139, which establishes requirements for examination programs for California-licensed occupations. Staff will collect and compile this information and provide a report to a future meeting of the Licensing Committee, and then to the board.

The board took no action on this subject pending the evaluation.

- **Update on AB 595 on Compounding by Pharmacies and Recent Action by the US District Court, Western District of Texas**

Chairperson Conroy stated that in 2004, the Licensing Committee formed a Workgroup on Compounding to evaluate whether a distinction could be made between compounding by a pharmacy and manufacturing operations that are performed by a drug manufacturer. This workgroup formed in part due to a request from the Department of Health Services seeking the board's determination of when a pharmacy is compounding, and when a pharmacy has become a drug manufacturer, and thus subject to licensure by the Department of Health Services or federal Food and Drug Administration.

This workgroup was comprised of staff from the board, the Department of Health Services, compounding pharmacies, pharmacy associations and others. Over the course of 2004, the group met quarterly. However, the group was unable to develop standards to distinguish when a pharmacy has crossed from compounding into manufacturing, and thus would be subject to licensure as a manufacturer. Instead, a legislative proposal and draft regulations were developed to establish standards for pharmacies that compound medication, leaving to the Department of Health Services or FDA the determination of when a pharmacy is manufacturing.

In 2005, the board sponsored the proposed statutory provisions in legislation introduced as AB 595 (Negrete-McLeod). In August 2005, AB 595 was on the floor of the Senate when opposition from the Department of Health Services was formally announced. During 2006, the board and interested stakeholders worked to remove the Department of Health Services' opposition, but the board was never successful. The Department of Health Services remained opposed to various provisions, but primarily the provisions that would have allowed a pharmacy to contract with another pharmacy to compound medication for the first pharmacy. Amendments desired by the Department of Health Services would have required a separate pharmacy license and annual inspections for pharmacies that compound medication for other pharmacies.

At the very end of the 2006 Legislative Session, after months of effort to remove or reduce DHS' opposition, amendments to AB 595 appeared in print that were aimed at reducing this opposition. However, Kaiser, CPhA and Grandpa's Pharmacy came out in opposition to these amendments.

Whereas these amendments had been agreed generally upon earlier, the bill died on Senate Third Reading on November 30, 2006 (DHS never removed its opposition).

In early September, after the board advised the author to drop AB 595, the board obtained a court decision restricting the FDA's regulation of pharmacy compounding based on a lawsuit filed in Texas.

During the Licensing Committee Meeting on September 20, Deputy Attorney General Joshua Room provided an overview of the likely minimal impact the Texas decision might have upon California. He provided a similar description to the board at this meeting.

Mr. Room referred to a court decision on August 30, 2006, from Texas (Federal Court District 5) that arose from the conflict or tension between pharmacies compounding as part of their pharmacy practice and the authority and jurisdiction of the federal FDA to inspect these pharmacies and verify that the compounding done by the pharmacies has not crossed over into the realm of manufacturing. This decision will have no effect in California which is part of the 9th District Court.

The proposed regulations for compounding pharmacies that were developed in 2004 as part of the Compounding Workgroup will be brought to the next Licensing Committee.

Ms. Herold stated that the regulations provide specific requirements for pharmacies that perform compounding and are important for consumer protection. She added that the draft language includes labeling requirements and potency testing requirements.

- **Transfers of NAPLEX Scores to Other States**

Chairperson Conroy stated that according to a survey done by the NABP last year, 26 states will not accept a North American Pharmacist Licensure Examination (NAPLEX) score if the applicant initially earned that score from being qualified to take the examination by California, and after passing the exam, later applies to become licensed as pharmacist in these states.

Dr. Conroy stated there is a process by which an applicant who has not yet taken the NAPLEX may ask that his or her NAPLEX score be sent to multiple states. However, not all candidates do this before taking the exam, or discover later that they wish to become licensed as a pharmacist in another state. If the latter occurs, a license transfer is required (which essentially is a transfer of the NAPLEX score and license verification) to the new state. The applicant is still required to meet any additional licensure requirements in the new state (e.g., pass the Multistate Pharmacist Licensure Exam for that state).

At the July Board Meeting, the board directed that staff determine why 26 states will not accept NAPLEX scores earned in California if later the pharmacists wish to transfer the score to become licensed in that state.

It has not been possible to complete the review but the survey will be completed and shared at the next board meeting. However, Ms. Herold contacted the NABP for its insight, and was advised that:

1. California's acceptance of NAPLEX scores only if earned after January 1, 2004, may account for much of the reason why California scores are not accepted by these states; essentially because California does not fully accept NAPLEX scores earned by their pharmacists, but instead requires retaking the NAPLEX for many of a state's pharmacists.
2. Misunderstanding about what exams California will accept from their states (e.g., requiring passing of the old California licensure exam) may be another factor.

The NABP believes that education about California's requirements may help resolve some of this problem. Ms. Herold will contact these states one at a time to conduct the survey and hopes to provide education as well as obtain information.

- **Foreign Pharmacy Graduate Equivalency Commission Certifications**

Chairperson Conroy stated that California law requires foreign-educated pharmacists to be certified by the Foreign Graduate Equivalency Commission (FPGEC) to satisfy the educational equivalency requirement with that of domestic pharmacy school graduates.

Since 1991, California has required foreign-educated pharmacists to pass the Test of Spoken English (TSE) as a condition of taking the California pharmacist licensure examination. The TSE is administered by Educational Testing Service worldwide, and has been validated to assess the spoken English proficiency of those for whom English is not their original language.

In 1997, the FPGEC began requiring a TSE score of 50 as a component of FPGEC certification. Recognizing the duplication of this requirement with California's TSE requirement, California law was amended in the late 1990s to require foreign-educated candidates who became FPGEC certified before January 1, 1998 to continue to provide a passing score on the TSE. Those certified after January 1, 1998, no longer needed to provide the board with a TSE score (due to the FPGEC's TSE requirement).

In a few months, Educational Testing Service will no longer administer the TSE, but instead roll these requirements into the TOEFL iBT exam. The FPGEC has begun accepting the TOEFL iBT exam as part of its requirements to become FPGEC certified in place of the TSE.

In recent months, the board has heard from several foreign-educated pharmacists who became FPGEC certified before 1998, and thus are required to complete the TSE requirement; however, these applicants have been unable to pass the TSE. The applicants have expressed concern about how they will qualify to take the pharmacist licensure examination in California if the TSE is no longer administered.

The FPGEC has agreed to recertify these individuals who have not earned a passing TSE upon passage of the TOEFL iBT.

- **ACPE Celebrates Its 75 Birthday**

  Chairperson Conroy stated that the committee viewed a brief video-montage DVD prepared by the Accreditation Council for Pharmacy Education, showing the history of this organization since its formation 75 years ago. The pictorial review showed changes in pharmacy over this period.

- **An Overview of 340B Drug Programs**

  Chairperson Conroy directed the committee to materials in the packet describing 340 B Drugs. The material was provided for information only, and was not an endorsement of the provider's program.

- **Competency Committee Report and Test Statistics For the CPJE Earned from April 1-September 30, 2006**

  Chairperson Conroy noted that the statistical performance scores for the CPJE from April 1 through September 30, 2006 are available in the board's packet. Dr. Conroy stated that a quality assurance review of the exam started in mid-August and was completed at the end of September.

  The Department of Consumer Affairs has a contract for test administration services used by a number of regulatory entities in the department for occupational license testing. It is through this contract that the board administers the CPJE. The contract is set to expire in December 2006, but monthly extensions will be available for several months. Unless a new contract is in place, the board may be unable to use these test facilities for the CPJE after all extensions have run out (Spring 2007). A new request for proposals has been released, and a contract should be awarded on October 20; however, several prior contracts awarded for this service have been appealed and the contracting process has been invalidated. The board's staff continues to watch this process closely.

  The Competency Committee met for its annual work and planning session in August. New members have been added to the committee so that the committee could be split into two groups. This will reduce the time commitment and work required of each committee member which still remains substantial.

INTERNS

Luke So, a third year pharmacy student at UCSF, and co-president of the American Pharmacists Association Academy of Student Pharmacists Chapter addressed the board. Mr. So stated that the students came to the board meeting today because they are interested in learning what the board does and to support the board in all of its activity.

Mr. So said the students are here today to specifically support an issue that will be presented later during the meeting regarding expanding the intern requirement hours to include other activities not traditionally found in pharmacy, but related to the duties of a pharmacist.

RECOGNITION OF PHARMACISTS CELEBRATING 50 YEARS OF SERVICE

President Powers stated that at the July 2005 Board Meeting, the board initiated a program to identify and publicly commend those pharmacists with 50 years of licensure as pharmacists.

The pharmacists so honored receive a letter from the board's president and a commendation certificate. Each is invited to a future board meeting to be publicly recognized. Additionally, his or her name is published in *The Script.*

Since July 2005, the board has acknowledged 591 pharmacists: 18 pharmacists have been acknowledged since the July 2006 Board Meeting.

Stanley Poncetta

The board recognized pharmacist Stanley Poncetta who provided great service to the consumers of California. Mr. Goldenberg read the certificate that he presented to Mr. Poncetta's family:

> The California State Board of Pharmacy acknowledges Stan Poncetta for his contribution to the public in providing pharmaceutical care to patients in a manner that was inspirational, gracious and humanitarian.
>
> Pharmacist Poncetta dedicated his life to caring for people. As an owner of a retail pharmacy and a closed-door institutional pharmacy, pharmacist Poncetta and his partners established computer and modified unitdose systems that are cornerstones of senior care pharmacy today.
>
> Upon completion of a three-year lay leadership program of the Catholic Diocese of San Jose, Pharmacist Poncetta established the Judeo Christian Concept with Care; the company that created senior care video training for nurses. This led him to establish Models for Hope, a non-profit facility bringing seniors together with foster children and orphans.
>
> In 2004, health problems caused Pharmacist Poncetta to step away from his charitable efforts. He passed away in 2005.
>
> The California State Board of Pharmacy commends Stan Poncetta's service and memory.

Mr. Goldenberg stated that Stan Poncetta had an infectious smile in addition to being dedicating from his heart and sole, to the care of all Californians and especially senior citizens. Mr. Goldenberg presented the plaque to Pharmacist Poncetta's wife and children who were in attendance.

Mrs. Poncetta expressed gratitude to the board for this recognition in honor of her husband. She introduced her son Scott, son Greg and her daughter Molly. She added that their oldest daughter Hildy was unable to attend.

Mrs. Poncetta stated as a family they were aware how special and unique her husband was but the family did not realize the extent of how many lives he touched. During her husband's service, the church overflowed with mourners and she continues to hear from people whose lives he touched.

Mrs. Poncetta thanked the board for this recognition.

Recognition of Pharmacists with 50 Years of Licensure

William V. Stenberg

Dr. Conroy introduced Mr. Stenberg and presented him with a Board of Pharmacy pin.

Mr. Stenberg thanked the board for the privilege of the award. He stated that he started his profession in a small corner pharmacy with manual typewriters that has now progressed to computers and automated bins to count the drugs they now dispense. He added that it has been a privilege to serve the community and he appreciates the recognition.

Richard I. Fox

Dr. Hiura introduced Mr. Fox and presented him with a Board of Pharmacy pin.

Mr. Fox thanked the board for inviting him to accept this award. He stated that he owned his drug store in South San Francisco for 35 years and then worked at Sav-On Pharmacy for 12 years. He added that he currently volunteers at the Samaritan House in Redwood City.

Mr. Fox stated that he has seen both good and bad changes concerning the practice of pharmacy over the years but the profession has become more respected and he hopes that it continues to be on equal status with other medical professions. He thanked the board for this acknowledgment.

Richard E. Rogers

Dr. Schell introduced Mr. Rogers and presented him with a Board of Pharmacy pin.

Mr. Rogers stated that the past 50 years have gone by very fast and he hoped that the students in the audience have an equal 50 years ahead of them to look forward to.

Mr. Rogers stated that he owned two pharmacies, one in Ventura and one in Santa Maria. He was secretary and president of the Ventura County Pharmacists Association from 1964 to 1966. During the last 10 years he has worked part-time with Longs Drugs.

ACKNOWLEDGMENTS

Dave Fong

President Powers recognized former Board Member Dave Fong, who was in the audience. He added that Dr. Fong made considerable contributions to the board in protecting consumers in California and he will be missed. President Powers provided Dr. Fong with a commemorative clock, purchased by the board members.

Dr. Fong stated that serving on the board provided him with a great opportunity working with good mentors and peers. He added that he came away from the experience with a good understanding of what it means to protect consumers in California and the role the board has towards accepting and committing to its responsibilities. Dr. Fong also acknowledged board staff, the board members and Ms. Herold and Ms. Harris.

ENFORCEMENT COMMITTEE

President Powers stated that he was unable to attend the last Enforcement Committee meeting on September 28. Mr. Goldenberg provided the report to the board of the meeting.

- **Discussion and Action Regarding DEA's Proposed 90-Day Rule for Prescriptions for Schedule II Controlled Substances**

Mr. Goldenberg stated that in California, pharmacy law provides that prescriptions for Schedule II controlled substances are valid for six months. Specifically:

> **11166.** No person shall fill a prescription for a controlled substance after six months has elapsed from the date written on the prescription by the prescriber.

Federal and state law prohibits refilling a Schedule II prescription; instead requiring a separate, original prescription for what would otherwise be a refill order (same drug, same instructions, same quantity). Many prescriptions are written for a 30-day supply, essentially to match insurance policy coverage that provides a prescription drug benefit.

As a result, for patients on long-term therapy involving Schedule II drugs, the patient must obtain separate prescriptions, written each month for ongoing therapy. This often requires monthly visits with the prescriber simply to obtain the prescription.

The DEA recently released a proposed rule to allow prescribers to prescribe up to a 90-day supply of Schedule II controlled substances during a single office visit. This would allow prescribers to provide patients with three 30-day prescriptions at once, writing "do not fill before" until a specified

date on the additional prescriptions so that patients do not have to return simply to obtain a new prescription.

According to the DEA, the proposed rule "will make it easier for patients to obtain their needed medications for conditions such as chronic pain or ADHD, and will ensure that physicians 'have the latitude to prescribe in a manner consistent with their sound medical judgment, while enabling DEA to fulfill its legal obligation to prevent drug abuse and diversion'."

This proposal conforms to longstanding board policy to allow a prescriber to write multiple prescriptions for Schedule II drugs, with a "do not fill before" date entered on the additional prescriptions. However, federal interpretation of the federal law prohibited this practice – unless this regulation is put into effect.

Mr. Goldenberg stated that this matter was not discussed at the Enforcement Committee, and a motion is required if the board wishes to provide comments in support of this proposed regulation. Comments are due November 6.

Ms. Herold stated that board staff believes that this policy is in the public interest and wants to go on record as encouraging the DEA to implement this policy.

Dr. Swart expressed concern that doctors could use this policy to control the amount prescribed to only a 30-day supply at a time, and this would cause patients to return to the doctor each time a prescription is needed.

Ms. Herold stated that patients are not limited to a 30-day supply of drugs by California or federal law, and the perscriber could, for example, write a prescription for 180 days. However, the overlay of the law coupled with the insurance company policy usually caps patients with a 30-day supply.

Steve Gray, representing Kaiser Permanente, stated that the policy should not be written for a maximum of 90-day supply because patients could be entitled to a 100 or a 120-day supply for their one co-pay, reducing medication costs. He questioned why there was a 90-day supply limit when unit of use is containers are sometimes in bottles of 100.

Dr. Gray added that the serial prescriptions could benefit patients by not oversupplying drugs in hospice situations when a physician wants to assure that patients have enough narcotics to last through the painful last days of their lives.

Dr. Gray stated that Kaiser wants to assure that multiple prescriptions can be written on the same day for the amount needed. He added that the problem occurs when a prescription is written for a 100-day supply when the patient is not expected to live that long. He stated that Kaiser wants hospice physicians to be responsible in writing these prescriptions.

Mr. Room stated that the board could issue a statement supporting the idea of allowing the prescriber to write multiple prescriptions on a given day without the subsequent prescription being treated as a refill.

Mr. Dazé suggested that counsel draft a statement as a motion.

MOTION: That the Board of Pharmacy submit a statement in support of the DEA's proposed rulemaking to allow prescribers to write multiple prescriptions on a given day with a do-not-fill before date for Schedule II controlled substances with an addendum that the board also does not believe that the rule needs to be limited to a 90-day supply of medication.

M/S/C: SCHELL/DAZÉ

SUPPORT: 9 OPPOSE: 0

- **Combat Methamphetamine Epidemic Act of 2005 Implementation**

Mr. Goldenberg stated that on September 30, 2006, the second phase of the "Combat Methamphetamine Epidemic Act of 2005" took effect. This act sets conditions and limits for the sale of over-the-counter pseudoephedrine, ephedrine and phenylpropanolamine products, and establishes a new category of scheduled products. These products are subject to sales restrictions, storage requirements and record keeping requirements.

Among the requirements are:

1. An individual may purchase no more that 3.6g of pseudoephedrine in one day.
2. An individual may purchase no more than 7.5g of pseudoephedrine in any 30-day period.
3. The purchaser must present a state or federal government issued photo ID at the time of purchase.
4. A written or electronic logbook containing all sales transactions must be kept for at least two years from date of purchase.
5. For each sale, the name and address of the purchaser, product name, quantity, and date and time must be entered into the logbook.
6. Products packaged for individual sale containing less than 60 mg of pseudoephedrine are exempt from the logging requirement, but the product must be kept behind the counter.
7. The pharmacy must confirm that the information provided by buyer matches that provided on the ID card.
8. The buyer must provide a signature verifying the information provided is correct.

Each pharmacy needs to submit to the US Attorney General's Office a self-certification that all individuals who sell such products have undergone the required training. The self-certification is done online, and goes directly to the US Attorney General's Office.

Mr. Goldenberg encouraged organizations to review the valuable reference material included in the board packet.

- **Formulary of Drugs Under Development by the Bureau of Naturopathic Medicine for Naturopathic Doctors**

Mr. Goldenberg reported that at the September 28, 2006, Enforcement Committee Meeting, Gloria St. John, Executive Director of the California Naturopathic Doctors Association, provided information about California's regulation of naturopathic doctors, a relatively new licensing program enacted by SB 903 (Burton) in 2003.

Mr. Goldenberg stated that Ms. St. John was invited to present information at this meeting; however, she was unable to attend. Instead, Carl Hangee-Bauer, chairperson of the Bureau of Naturopathic Medicines Advisory Council under the Department of Consumer provided information about naturopathic doctors and the development of a California formulary for naturopathic doctors.

Today there are about 200 naturopathic doctors licensed in California by the Bureau of Naturopathic Medicine, a bureau in the Department of Consumer Affairs. Naturopathic Doctors (ND) must earn 60 hours of continuing education to renew their licenses every two years, of which at least 20 hours must be in pharmacotherapeutics. According to the California Naturopathic Doctors Association, naturopathic medicine is a form of primary care that is an art, science, philosophy and practice involving diagnosis, treatment and prevention of illness.

Naturopathic doctors are allowed by California law to prescribe hormone and epinephrine for anaphylaxis independently and to prescribe Schedule III through IV drugs under protocol with an MD. To furnish and order drugs, NDs must obtain a furnishing number from the bureau, which requires completion of a 48-hour course in pharmacology.

Naturopathic doctors can administer, order and prescribe food, extracts of food, nutraceuticals, vitamins, amino acids, minerals, enzymes, botanicals and their extracts, botanical medicines, homeopathic medicines, all dietary supplements and non prescription drugs, consistent with the following routes of administration: oral, nasal auricular, ocular, rectal, vaginal, transdermal, intradermal, subcutaneous, intravenous, and intramuscular. The bureau states that NDs may use ocular and intravenous routes of administration only if they are clinically competent to do so.

Senate Bill 907 (Chapter 485, Statutes of 2003) specified that the Bureau of Naturopathic Medicine establish a Naturopathic Formulary Committee to determine the formulary from which naturopathic doctors will prescribe. The committee is comprised of an equal number of physicians, pharmacists, and naturopathic doctors. The committee is to make recommendations regarding the prescribing, ordering and furnishing authority of an ND and the required supervision and protocols for these

functions. The formulary is to be submitted to the Legislature by January 1, 2007 regarding the prescribing and furnishing authority of an ND, and the required supervision and protocols for the use of IV and ocular routes of prescription drug administration.

Currently 13 states license NDs, and nine of these states allow NDs to prescribe independently with no MD oversight. No state reports disciplining NDs for prescribing. The Naturopathic Formulary Committee concluded that there are only a limited number of MDs who possess the training and philosophy needed to supervise NDs. Moreover, the few MDs who do qualify have difficulty obtaining adequate malpractice coverage. Based upon these factors, the committee believes that MD supervision of NDs is untenable.

<u>The Naturopathic Formulary Committee recommends:</u>

1. Inclusion Formulary: Pursue changes to California law to allow NDs to be able to independently prescribe without MD supervision from the committee- recommended formulary.
2. IV Therapy: NDs should be able to practice without MD supervision after completing specific CE comprised of a 25-hour course, with 14 hours of practicum, and a refresher course every five years. Upon completion, NDs will be able to independently administer drugs listed in the IV formulary via the IV route.
3. Chelation Therapy: Any ND who performs this therapy (used to detoxify for heavy metal exposures) must complete a 12-hour CE course in addition to the IV therapy course.

Dr. Hangee-Bauer referred to the draft formulary developed by the Naturopathic Formulary Committee.

Dr. Ravnan expressed concern about increased medication errors affecting all patients and stated that the number one cause of medication errors caused by lack of drug knowledge. She asked if the naturopathic doctor program integrates the pharmacist and the training education of naturopathic doctors.

Dr. Hangee-Bauer stated that pharmacists are involved with teaching courses to naturopathic doctors at Southwest College but he does not have direct knowledge of how other schools handle this.

Dr. Ravnan referred to clinical practice and she stated that the majority of experience comes from working side-by-side with the pharmacist to gain this type of knowledge. Dr. Ravnan expressed concern that naturopathic physicians have not been incorporated into established training programs with other health care professionals.

Dr. Hangee-Bauer stated he believes that it is very important to work with pharmacists to practice safety and protect the public. He added that naturopathic doctors naturally consult with their peers and pharmacists to avoid prescription errors. In the naturopathic doctor's practice, prescribing drugs is usually not the first step taken but when he prescribes, Dr. Hangee-Bauer said he calls the pharmacist to consult about the best method of prescribing.

He continued that patients are often referred to other health care professionals but with any competent health care professional, the practitioners need to understand the limits of their knowledge.

Mr. Goldenberg stated that the goal of this presentation is to educate pharmacists about the practice of naturopathic doctors and the limitations of their activity.

Dr. Hangee-Bauer stated that based on the implementing provisions in SB 907, NDs can independently prescribe natural synthetic hormones and epinephrine prophylactics. Furthermore, Schedule III and IV drugs could be prescribed in conjunction with written MD protocols.

Mr. Room stated that the goal of the formulary committee is to develop this exclusionary list of Schedule III and IV drugs that would not require MD supervision. Schedule III and IV drugs that are not on that list would still have to be prescribed under protocol with an MD.

Dr. Hangee-Bauer stated that the committee is also charged with surveying the landscape and determining what is being done in other states, the types of training involved what the law in California allows. The committee will then make recommendations based on this finding.

Mr. Room stated that pharmacists must be aware that when they receive prescriptions from NDs, the pharmacists must know whether the drug is on the formulary, if the drug needs to be filled under protocol with the MD, or if it's a drug that can be independently prescribed. He added that that this is pushing a great deal of required knowledge onto the pharmacist.

Mr. Goldenberg asked Dr. Hangee-Bauer to submit to the board thoughts and discussion items on how to disseminate information to pharmacists in California.

- **Plan B Emergency Contraception Becomes Over-the-Counter for Patients 18 and Older**

Dr. Goldenberg stated that in mid-August, the FDA reclassified Plan B from prescription status to over-the counter (OTC) status for emergency contraception for patients aged 18 and older. For patients 17 years and younger, Plan B remains a prescription drug.

In California existing law contains provisions that allow a specially qualified pharmacist to prescribe and dispense emergency contraception, using a variety of drugs, including Plan B (California Business and Professions Code section 4052, and California Code of Regulations section 1746).

Although OTC, Plan B may be sold only by pharmacies and must be kept behind the pharmacy counter. Anyone, a pharmacist, pharmacist intern, pharmacy technician or clerk may sell the drug. Individuals who are 18 and order may purchase the drug. No records of these sales are required.

If the patient purchasing Plan B is younger than18, then the pharmacist, if qualified, may write a prescription for Plan B or any other medication authorized in the state protocol for emergency

contraception or in the protocol established with a physician. In this case, the emergency contraception drug is a prescription drug, and all requirements for dispensing prescription drugs apply, including consultation by the pharmacist.

Also, other drugs listed in the state protocol for emergency contraception remain prescription drugs (not over-the-counter), regardless of the age of the patient or purchaser.

In response to questions asked of the board initially upon the FDA's reclassification, staff developed draft questions and answers. During the Enforcement Committee Meeting, these Qs and As were slightly modified to those provided in the board packet.

The material will be added to the board's Web site.

- **Report of the Work Group on E-Pedigree**

Mr. Goldenberg stated that at the September Meeting, Supervising Inspector Nurse provided a PowerPoint presentation on changes to California's e-pedigree requirements that were amended into SB 1476 (Chapter 658 Statutes of 2006), which was signed by the Governor two days after the Enforcement Committee meeting. A copy of Dr. Nurse's PowerPoint presentation was provided in the board packet**,** and provides a good overview of components enacted in SB 1476.

Senate Bill 1476 delays implementation of e-pedigree requirements in California until 2009, with the board having the ability to delay implementation until January 1, 2011.

The board drafted additional amendments into SB 1476 that would clarify that the e-pedigree system must be interoperable through all levels in the distribution system, that serialization is needed down to the product container level, that the board must be notified if counterfeit drugs or fraudulent pedigrees are suspected, that drugs returned to a wholesaler must maintain the same pedigree, that repackagers must maintain the pedigree into repackaged items, and that drug samples do not require pedigrees.

The board will need to develop regulations to specify some components enacted in SB 1476. This includes the process for notifying the board about counterfeit drugs, and what license number must be entered into the pedigree.

Acting Chairperson Goldenberg emphasized at the meeting that the e-pedigree work group meetings over the next few years will be crucial in developing necessary regulations and moving forward timely with implementation of these requirements that are necessary to ensure a safe distribution system for patients.

During the committee meeting, EPCglobal provided a PowerPoint Presentation about the industry's progress in developing unified standards for electronic pedigrees. There continues to be progress in development, and testing on a "last call working draft" version of a standard is underway. The

purpose of this standard is to ensure that different entities in the supply chain can all access the pedigree and interpret it in the same manner.

Among the issues to be resolved include decommissioning of a chip to protect patient privacy, item level tagging – e.g., whether high frequency or ultrahigh frequency would be best. It may be the third quarter of 2007 before the standard for item tagging is ready.

EPCglobal reported on a pilot study conducted; recently six companies were given seven of the most challenging scenarios and test data to create pedigrees against. A total of 42 pedigrees were tested. Their pedigrees were compared, line-by-line, with the expected outcome from the standard. There were no changes from the standard.

McKesson provided a brief overview of the "On Track" pilot program underway among various entities in the supply chain regarding e-pedigree issues such as data sharing, track and trace visibility, tag data components, tag frequency and reading ranges, and changes needed in current business processes. Generation 1 will be completed in December 2006, when a generation 2 study will begin.

Johnson and Johnson reported working on implementation of the e-pedigree requirements but they believe implementation is still 4-5 years away. The infrastructure is not ready, and that not all products really need electronic pedigrees.

During 2006-08, Johnson and Johnson will be working on building the structure to use e-pedigrees, and test 3-5 products using both RFID and 2-D bar code technology.

In 2010, the standards will be deployed, and they believe that 50 percent of their products will be tagged by 2011. But Johnson and Johnson believe that implementation cannot be fully achieved until 2011-2012.

The company emphasized the importance of interoperability – of one standard used by everyone, and indicated that regulations to require a specific standard may be required.

Heidi Barsuglia representing the California Retailers Association (CRA) stated that at the last Enforcement Committee Meeting, CRA was asked to solicit comments from their chain pharmacy members regarding a timeline on implementing electronic pedigree technologies after manufacturers and distributors implemented interoperable technologies. CRA solicited the information and heard back from all of the companies. CRA will submit a letter detailing the comments.

Ms. Barsuglia stated that all of their members are stressing the need for retailers to engage in on-going active involvement with upstream supply chain components as they are implementing. Members are telling CRA that they will need to test the passing of e-pedigree between each pharmacy and its wholesalers. Both large and small retailers will also need to develop methods for storing and accessing the electronic pedigree and it is believed that such a data base will grow into an extremely large data base in a very quick time.

Ms. Barsuglia continued that CRA is hearing repeated concerns from their members about capacity issues and making the systems compatible to chain pharmacy and to other systems. She added that some companies have higher levels of automation and greater information technology support resources and believe that they will be able to implement within one year of other supply chain suppliers. One company reported that they could potentially be up and running within 6 months. The companies with lower levels of automation and relatively lower levels of resources in general, believe that it may take them up to two years to complete the testing and implement all the necessary processes and technologies. She added that the CRA would submit a letter detailing the comments.

Ms. Barsuglia stated that one standard is needed because pharmacies are at the end of the process and cannot function with multiple electronic pedigree systems with each system requiring unique equipment. At this stage, the CRA cannot offer a timeline for implementation because they are waiting for the drug manufacturers and wholesalers to refine the standards. The CRA also emphasized that they are participating in the On Track and EPCglobal standards setting and pilot tests of electronic pedigrees.

Ms. Herold stated that it appears that the standard for the electronic pedigree is continuing to evolve and it is anticipated that this will be completed by the end of January 2007. She added that at the next Enforcement Meeting scheduled on December 12, in Sacramento, the committee would review the time lines provided in the charts distributed by EPCglobal. The material will be presented in a power pointed display so everyone in attendance can understand where we are and the steps that need to be taken.

Kathy Lynch, representing the California Pharmacists Association, stated that they have been working very closely with the California Retailers Association on this issue.

The CPhA has distributed information including a CEO message and a weekly legislative update to keep pharmacists informed prior to the January 2009 implementation date. Implementation depends on the technologies that is developed and in the mean time meetings continue with people throughout the state to discuss this.

Ron Bone, representing McKesson, stated that he was encouraged by the annual EPCglobal Meeting held in Los Angeles and another meeting held in Washington D.C. with the DEA. The DEA has been requested to give the authority to use the NDC number as part of a drug's serialized number. He added that the meeting went well and the DEA understood its requirement and acknowledged the opportunities they have for enforcement.

Mr. Hough referred to the use of complex computer base systems to maintain large quantities of data. He asked how this could be managed.

Mr. Bone replied that many people will be involved in building suitable interoperable solutions.

Mr. Goldenberg stated that Gene Alley of Stat Pharmaceuticals was scheduled to come to the board meeting and provide a presentation, however, Mr. Alley was not present.

Mr. Goldenberg stated that effective December 2, 2006, the FDA's requirements for drug pedigrees go into effect, after years of delay following enactment of the Prescription Drug Marketing Act in 1988. These requirements require a paper pedigree for drugs that are distributed outside the "authorized" distribution channel (from manufacturer, to specific authorized wholesaler, to pharmacy). This is a very limited pedigree. So secondary wholesalers, such as Stat, must obtain and pass paper pedigrees to their purchasers. California's law, which is set to take effect in January 2009, is much stronger and requires electronic pedigrees for all drugs through the distribution channel identifying every change in ownership from the manufacturer to the pharmacy.

The federal pedigree rule will take effect nationwide on December 2, 2006. In recognition of the problem that pharmacies that may not always be certain who is an authorized distributor, the board added the following provisions into its amendments of SB 1476:

> 4163.1. It is the intent of the Legislature that commencing on January 1, 2007, and continuing through the full implementation of the pedigree requirements specified by Section 4163, manufacturers and wholesalers shall use best efforts to provide in the most readily accessible form possible, information regarding the manufacturer's specific relationships in the distribution of dangerous drugs with wholesalers.

ORGANIZATIONAL DEVELOPMENT COMMITTEE

Chairperson Goldenberg reported on the meeting of October 18, 2006.

Committee Appointments 2006-2007

President Powers referred to the committee assignments provided in the board packet as follows:

Communication and Public Education Committee, Ken Schell, Chair
Hank Hough, Bill Powers and Andrea Zinder

Organizational Development, Stan Goldenberg, Chair
Bill Powers

Enforcement Committee, Bill Powers, Chair
Ruth Conroy, Stan Goldenberg, Rob Swart

Legislation and Regulation Committee, Andrea Zinder, Chair
Tim Dazé, Ken Schell, Hank Hough

Licensing Committee, Ruth Conroy, Chair
Clarence Hiura, Susan Ravnan

Competency Committee
Susan Ravnan, Ken Schell

Subcommittee on Medicare Drug Benefit Plans, Stat Goldenberg, Chair
Andrea Zinder

- **Report of the NABP Districts 7 and 8 Meeting in Anaheim**

Chairperson Goldenberg stated that the NABP Districts VII and VIII Meeting was held at Disneyland on October 4-7. The board hosted this meeting where there were over 95 attendees and speakers. Seven of the board's 10 members attended at least portions of this conference.

Among the topics were:

- parameters for the development of an ethics program based upon the experiences of the Medical Board of California,
- a discussion session with the schools and board member attendees on intern experience,
- pandemic planning for pharmacy,
- a presentation by the FDA on pedigree requirements required by the Prescription Drug Marketing Act,
- new requirements for sales of pseudoephredrine by pharmacies, and
- Medicare Part D Issues.

Chairperson Goldenberg commended staff and Board President Bill Powers for an outstanding meeting. Comments he heard from attendees included that the meeting was enjoyable and the topics were well received. Board Staff Hope Tamraz, Kim deLong, Victor Perez and Robert Ratcliff worked hard at getting this program done well.

- **Board Member Procedure Manual Revision**

Chairperson Goldenberg stated that for a number of years, the board has provided its specially developed *Board Member Procedure Manual* to board members to aid them as a reference in performing board duties. This manual is in addition to the new board member orientation training provided to the board members by the Department of Consumer Affairs.

The board reviewed proposed revisions to the manual.

MOTION: Organizational Development: That the Board of Pharmacy approve the revised Board Member Procedure Manual

SUPPORT: 9 OPPOSE: 0

- **Personnel Update**

Chairperson Goldenberg stated that there have been a number of changes in the board's staff since the beginning of July. Four Sacramento headquarters employees are on or were off work for various reasons; three of these individuals have returned to work at least part time.

Three employees have transferred away from the board for other state positions:

1. Cashier Veronica Hagen is leaving the board for a position in the Personnel Office of CalPERS, where there is a day-care center onsite.
2. Vicki Betker, a consumer services analyst who has been with the board for approximately 10 years, is leaving the board for an analyst position located in the downtown area of Sacramento to facilitate her commute.
3. Julie Baker has decided to return to her prior employer, the California Highway Patrol. Ms. Baker was hired as a board receptionist in April and for the last few months, was working to learn the duties currently performed by Candy Place.

Since the last board meeting, the board has hired:

1. Carla Shulz, from the Secretary of State's Office, who is an enforcement technician.
2. Jenny Nguyen as a seasonal file clerk for the Licensing Committee
3. Lori Haley, who is an office technician and processing applications for the pharmacy technician and pharmacist examination desks.
4. Tracy Shintaku, who was with the Board of Equalization, who will respond to subpoenas and other public records requests.
5. A public outreach analyst who will start in December.

In November, the board will also lose to retirement:

Candy Place, who has been with the board for 10 years as an administrative analyst. Ms. Place has been a very strong support to the executive office and board members over the years.

Also:

The board is getting a new departmental counsel, Spencer Walker. Mr. Walker will replace LaVonne Powell, who has been the board's counsel for several years. Ms. Powell will continue with the board for six months as Mr. Walker learns about the board and the Department of Consumer Affairs.

Recruitment is underway for the following positions:

1. Management Services Technician – to replace Ms. Place's position
2. Enforcement Analyst – to replace Ms. Betker's position
3. Office Technician – to replace Ms. Hagen's position
4. Office Technician – to fill a board receptionist position.

Inspector and Supervising Inspector Vacancies

The board has four inspector vacancies and one supervising inspector vacancy.

Recruitment for new pharmacists is stalled until salary adjustments for all inspectors are secured. For example, two recent inspectors who left the board transferred to public section pharmacist positions where they will make at least $24,000 more annually than at the board. This salary inequity has been a long-standing problem. The board's management is seeking a salary adjustment for its pharmacists, a $24,000 annual "recruitment and retention differential" paid by some state employers of pharmacists, like the Department of Health Services.

In early June, the board submitted a proposal to create such a salary differential, since the board's inspectors perform duties comparable, if not more difficult, than those of other state pharmacist positions. At the July Board Meeting, the board unanimously supported this proposal. In August and September, the board received positive support for the proposal from the Department of Personnel Administration and the Department of Finance, but the actual approval has not yet been conveyed.

If approved, inspector salaries will increase to $102,312 and supervising inspector salaries to $110,376, which is still below private-sector pharmacist salaries. The annual expense of these salaries to the board will be $552,000.

Meanwhile, the board is working with the department's Personnel Office to schedule a new civil service examination from which pharmacists can be hired to work for the board. This process will take at least three more months, and the board hopes to fill these positions early next year. This is a priority for the board's senior staff. However, until a salary differential can be part of the recruitment salary, it will be difficult to recruit quality pharmacists for these important positions.

Vacancies on the Board

There are three openings on the Board of Pharmacy itself: two public members and one professional member. All are gubernatorial appointments.

- **I-Licensing Project Update**

  Ms. Herold stated that approximately seven DCA agencies have the ability to provide online license renewal due to participation in a project started under the Davis Administration. However, the state's budget crisis in the early 2000s prevented the Board of Pharmacy from joining this project, although the board has been striving to be added for years.

  The DCA is moving ahead with a project so other agencies can offer online application and renewal of licenses. A feasibility study report has been approved by the Department of Finance, and the board is in the first tier of new agencies that may be able to offer this service in the future. Ms. Herold added that she is one of the project's "executive sponsors," and participates in the steering committee for this project and may need to testify before the legislature or various other agencies to urge implementation of this project.

  The board is projected to spend $50,000 this fiscal year on programming specifications needed for board programs. In the next two years, the board will spend $143,000 (2007-08) and $199,000 (2008-09) as its share of costs to implement this system department-wide.
  A detailed design meeting of key board staff with the programmers is scheduled for October 31. The board is at least two years from implementing this system.

  Ms. Herold stated that the board is committed to this project because it will allow licensees to renew their licenses on line. She added that currently licensing renewal processing time with the department runs 6-8 weeks.

  Ms. Herold stated that the Legislature has indicated that in order to get the funding in the budget to do this, the Department of Finance and the Department of General Services will be part of the contracting process and will sit in on the steering committees. There are specific reports outlining progress that have to go back to the Legislature over the next 2-3 years as the department implements this I-Licensing program.

  Dr. Schell requested that the board direct Ms. Herold to ask if the Department of Consumer Affairs can use an existing contract in state government that is already in progress.

  Ms. Herold stated that she would make the request on behalf of the board.

  President Powers requested that stakeholders also raise this concern with the Department of Finance and the administration to help speed up the progress.

- **Update on the Executive Officer Recruitment Process**

  Chairperson Goldenberg stated that at the July 27, 2006 Board Meeting, the board members voted to select a committee for the recruitment of a new Executive Officer. The Selection Committee consists of members Stan Goldenberg and Ken Schell. Joanne Ong, a representative of the

Department of Consumer Affairs Human Resources, and Karen Cates will provide liaison assistance to the committee.

At the July Board Meeting, Virginia Herold was appointed as the Interim Executive Officer.

The committee met on August 31, 2006 and approved the job duty statement and advertisement for the Executive Officer position. They also determined that November 1, 2006 would be the final filing date for this position.

The advertisement was posted on Sunday, September 17, 2006 with the San Diego Tribune, Los Angeles Times, San Francisco Chronicle and the Sacramento Bee. The posting with the Los Angeles Times and the Sacramento Bee included a 30-day online Internet ad. The job announcement is also posted on the State Personnel Board's Web site.

The Selection Committee is planning to meet during this board meeting to review the applications received as of October 23, 2006 for this position to and to develop interview questions.

The Selection Committee will conduct initial interviews.

Dr. Schell stated that the board has determined that it will not rush into this process, as it is important to recruit the right candidate for the position. A more definitive report would be submitted to the board by the January board meeting.

- **Budget Report**

Ms. Herold presented a budget overview of the board's and state government's budget processes in a PowerPoint display.

Budget Report for 2005/06
Final budget figures for the prior fiscal year that ended June 30, 2006, were graphically presented in the board packet.

Revenue: $10,231,000 (Note this figure includes $3 million repaid from the 2001-02 General Fund loan)
Expenditures: $7,335,000

Current Year's Budget 2006/07
Revenue Projected: $9,277,920

Revenue for the next fiscal year is estimated to be comprised of $5,791,000 in fees and $157,000 in interest on money in the board's contingency fund.

The board is also projected to receive the final repayment of $3 million from the 2001 loan of $6 million from the board's fund to the state's General Fund during a period of California's budget crisis. There is an additional $233,000 in interest that will be paid that is linked to the loan.

Final revenue for the year also includes additional amounts actually collected from cost recovery and citations and fines. During the first quarter of this fiscal year, the board collected $75, 815 in fines and $21,105 in cost recovery.

Expenditures Projected: $8,250,000
Expenditures for this fiscal year are similar to last year's. Some of the changes include:

- Restoration of 2.5 of the 10 positions the board lost during the budget restrictions of the early 2000's. ($208,000)
- An increase of $91,000 to cover increased hourly fees that will be charged by the Office of the Attorney General for legal fees (the hourly rate is now $158, up from $112 in 2003)
- A reduction in rent of approximately $98,000 due to the relocation of the board's office to Natomas.

Board Fund Condition
The board's fund condition is an indicator of its "solvency," meaning whether the revenue collected is sufficient to sustain board expenditures, and if so, for how long.

Over the last few years, the board's annual expenditures typically have exceeded its annual collected revenue. Normally this would be a huge problem that would trigger budget cutbacks or fee increases, but the board has had a surplus of money in its fund (which can be thought of as the board's savings account). The board has been trying to spend down this surplus for several years, eliminating a surplus condition caused by the 1999 repayment of a loan to the state's General Fund (during another budget crisis in the early 1990s).

The board must watch its fund condition, however, because if it gets low or into a deficit, the board will run out of money for annual operations (since expenditures exceed revenue collected). The Business and Professions Code provides that the board should maintain a reserve of 12 months of annual expenditures as a prudent reserve. However, state budget officials do not agree that this much money needs to be kept as the board's reserve. They prefer a reserve of 3-6 months.

The board ended the last fiscal year (on June 30, 2006) with a projected reserve of $7,285,000. This is 10.6 months of expenditures.

The board's fund condition projections over the next few years (as estimated in August 2006) are:

- 2006-07: A reserve of 10.4 months is projected.
- 2007-08: A reserve of 5.9 months is projected.
- 2008-09: A reserve of 1.2 months is projected.

A fee increase may be needed to take effect July 1, 2008 to prevent a deficit during 2008-09. Board staff will continue to watch these figures closely.

Dr. Schell expressed concern that the board is taking too long to process license renewals and he has received complaints about the unanswered phone calls at the board. He suggested moving forward with a fee increase to add staff.

Ms. Herold explained that one of the board's challenges is to continue to function at the same level as when the board had 10 more staff positions that were lost during the last few years in hiring freezes. The telephone system has been changed to allow access to board receptionists sooner. However, the board does not redirect staff to respond to calls unless applications have been submitted for 30-60 days. E-mail is also used by staff to correspond with applicants. Lastly, renewals are done by the Department of Consumer Affairs centralized cashiering unit and not by the board. The board has held three meetings with high-level departmental staff since April about the slowness in processing renewals. Articles have been placed in *The Script* to encourage licensees to renew their licenses as soon as they get their renewal application.

Board staff is aware that both the application processing and status calls are very important to licensees.

Board Member Expenditures and Reimbursements
Ms. Herold referred to the travel expenses and compensation of board members claimed during this fiscal year in the board packet.

Board members are paid for their attendance at board meetings. If they are interested in pursuing payment for other duties, board members can receive $100 for every 8 hours they spend reading board materials, voting on mail ballots or otherwise performing approved duties. (Travel time is not reimbursed.)

- **Strategic Plan for 2006-2011**

  At the July 2006 Board Meeting, the board approved the board's new strategic plan for 2006-2011.

  The board's graphic designer, Victor Perez, has formatted the plan into the new document that was provided to the board.

- **Approval of the Full Board Minutes from the July 27, 2006 Board Meeting**

  President Powers asked if there were any corrections to the board minutes of July 27, 2006. There were none.

MOTION: Approve the board minutes from the July 27, 2006 board meeting

M/S/C: POWERS/GOLDENBERG

SUPPORT: 9 OPPOSE: 0

LEGISLATION AND REGULATION COMMITTEE

- **Regulatory Process – Presentation by Anne Sodergren, Legislative Coordinator**

  Ms. Sodergren presented a PowerPoint display to the board describing the rulemaking process.

  Board Action on Regulations

  Chairperson Zinder stated that the board has the opportunity to act on two regulations. Each of these regulations has undergone the required 45 days of public comment and is ready for board action at this meeting. Both regulations were released without a public hearing scheduled, and no hearing was requested.

- **Proposed Repeal of Title 16 California Code of Regulations Section 1717.2 – Notice of Electronic Prescription Files**

  Chairperson Zinder referred to the rulemaking documents provided in the board packet. She stated that the repeal of this outdated regulation would remove a barrier that prevents pharmacists, in certain situations, from having full knowledge of all the prescription drugs that a patient is taking. Removing this barrier will result in better patient care while protecting patient medical record privacy. The regulation was promulgated in the 1980s when pharmacies first started using computers and before HIPAA and California laws to protect patient privacy.

  This proposal was publicly noticed in August 2006. No comments were received during the comment period.

  MOTION: That the Board of Pharmacy repeal section 1717.2 of Division 17 of Title 16 of the California Code of Regulations section 1717.2 – Notice of Electronic Prescription Files as follows:

  Board of Pharmacy
  Specific Language for Repeal of Section 1717.2

  Repeal Section 1717.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~§1717.2. Notice of Electronic Prescription Files.~~

~~(a) Any pharmacy which establishes an electronic file for prescription records, which is shared with or accessible to other pharmacies, shall post in a place conspicuous to and readily readable by prescription drug consumers a notice in substantially the following form:~~

~~NOTICE TO CONSUMERS:~~

~~This pharmacy maintains its prescription information in an electronic file which is shared by or accessible to the following pharmacies:~~

~~By offering this service, your prescriptions may also be refilled at the above locations. If for any reason you do not want your prescriptions to be maintained in this way, please notify the pharmacist-in-charge.~~

~~(b) Whenever a consumer objects to his or her prescription records being made accessible to other pharmacies through use of electronic prescription files, it is the duty of the pharmacy to assure that the consumer's records are not shared with or made accessible to another pharmacy, except as provided in Section 1764. The pharmacist to whom the consumer communicated the objection shall ask the consumer to sign a form which reads substantially as follows:~~

~~I hereby notify (name of pharmacy) that my prescription drug records may not be made accessible to other pharmacies through a common or shared electronic file.~~

~~(date) (signature of patient)~~

~~(acknowledgment of pharmacist)~~

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

~~Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.~~

M/S/C: POWERS/DAZÉ

SUPPORT: 9 OPPOSE: 0

- **Proposed adoption of Title 16 California Code of Regulations section 1784 - Self-Assessment of a Wholesaler by the Designated Representative-In-Charge**

Chairperson Zinder referred to the rulemaking documents provided in the board packet.

Chairperson Zinder stated that this regulation would require for the designated representative-in-charge (DRC) of a licensed wholesaler to complete a self-assessment form to ensure compliance with pharmacy law. This self-assessment form will aid wholesalers in complying with legal requirements and therefore increase public safety as a result of this compliance. Additionally, the proposal would make the pharmacy inspection process more meaningful and provide relevant information to wholesalers and their DRC. This regulation is modeled after a similar requirement for pharmacies—pharmacies must perform a self-assessment every two years or upon a change in the pharmacist-in-charge.

Chairperson Zinder stated that this proposal was publicly noticed in August 2006. No comments were received during the comment period. However because of changes in federal and state law, revisions must be made to update the draft necessitating an additional 15-day comment period. The board may adopt this proposal at this board meeting and delegate to the Interim Executive Officer the authority to submit the rulemaking file if no negative comments are received during the required 15-day notice period.

MOTION: That the Board of Pharmacy adopt section1784 to Division 17 of Title 16 of the California Code of Regulations – Self Assessment of a Wholesaler by the Designated Representative-In-Charge as follows if no negative comments are received:

Board of Pharmacy
Specific Language to Add Section 1784

Add Section 1784 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1784. Self-Assessment of a Wholesaler by the Designated Representative-in-Charge.

(a) The designated representative-in-charge of each wholesaler as defined under section 4160 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:
(1) A new wholesaler permit is issued, or

(2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a wholesaler is responsible for compliance with this subdivision.
(3) There is a change in the licensed location of a wholesaler to a new address.
(c) The components of this assessment shall be on Form 17M-26 (rev. 8/14/2006) entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.
(d) Each self-assessment shall be kept on file in the licensed wholesale premises for three years after it is completed.
(e) The wholesaler is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4201, and 4160 Business and Professions Code.

M/S/C: SCHELL/CONROY

SUPPORT: 9 OPPOSE: 0

Approved Regulations

- **Addition of 16 CCR Section 1727.1 - Exemption for Intern Address from Posting Online**

The Office of Administrative Law approved the board's rulemaking to allow the addresses of records of intern pharmacists to be removed by posting on the board's Web site. The regulation took effect on October 1, and the board's technical staff is working to remove this component from the board's Web site.

The addresses of record of intern pharmacists will still be available upon written request to the board.

Pending Regulations
Board Approved – Pending Administration Approval

The Interim Executive Officer provided a brief update on the status of two regulations as follows:

- **Repeal 16 CCR Sections 1713 and 1717(e) – Prescription Drop Boxes and Automated Self-Use Delivery Device for Refill Prescriptions**

On April 26, 2006, the board voted to amend section 1717(e) and adopt section 1713. These actions would allow pharmacy patients the ability to use a vending-like machine located near a pharmacy counter to obtain their refill medication. The regulation would also allow the use of prescription drop-off boxes outside a pharmacy as a means to leave prescriptions for pharmacies to later pick up and fill.

Staff completed the necessary 15-day notice in May 2006 to incorporate changes approved by the board during the April Board Meeting. No new comments were received relevant to the specific changes made by the board, so the rulemaking file was submitted to the department for administrative review and approval in August 2006.

The Department of Consumer Affairs is still reviewing this file. After completion of this review, the rulemaking file will then be provided to the Office of Administrative Law, which has 30 working days to review it. This regulation will be effective early next year.

- **Adopt Amendments to 16 CCR Section 1793.7 and add Section 1793.8 – Pharmacy Technicians Checking Pharmacy Technicians in an Acute Care Pharmacy**

  On April 26, 2006 the board approved an amendment to section1793.7 and to adopt CCR 1793.8 to define the conditions under which a pharmacy technician may check the work of another pharmacy technician.

  Board staff added materials to the rulemaking file (to formally admit underlying studies, written legal opinions and other relevant background information) which required a 15-day notice. The rulemaking file was submitted to the department for administrative review and approval in August 2006.

  The Department of Consumer Affairs is still reviewing this file. After completion of this review, the rulemaking file will then be provided to the Office of Administrative Law, which has 30 business days to review it. This regulation will be effective early next year.

  Board Approved – Awaiting Notice

  Chairperson Zinder stated that there are several board-approved regulations awaiting notice that are included in the packet.

- **Proposed Amendment of 16 CCR Section 1706.2 – Abandonment of Application Files for Veterinary Food-Animal Drug Retailer, Hypodermic Needle and Syringe Distributor and Designated Representative**

  This section contains provisions establishing when an applicant has abandoned an application. However, applications for Veterinary Food-Animal Drug Retailers, Hypodermic Needle and Syringe Distributors and Designated Representatives are not included. This proposal would add these licensing programs to the regulation to make the board's application processes consistent.

- **Proposed Amendment to 16 CCR Section 1709.1 – Replace the term "Exemptee-in-Charge" with "Designated Representative-in-Charge" (Section 100 Technical Change)**

  This section replaces the term "Exemptee-in-Charge" with "Designated Representative-in-Charge."

- **Proposed Amendment to 16 CCR Section 1760 - Disciplinary Guidelines**

  This rulemaking would allow the board to use a revised 2007 edition of the Disciplinary Guidelines when deciding appropriate discipline action to take for violations of Pharmacy Law. Final revisions are being completed and this proposal will be noticed so that action can be taken at the January 2007 Board Meeting.

- **Proposed Amendment to 16 CCR Section 1775.4 – Reschedule of an Office Conference to Contest a Citation**

  In 2003, the board revised its system for issuing citations to make the procedures more consistent with other agencies within the Department of Consumer Affairs. During the revision process, a provision from CCR 1775(a) that permits an individual or entity to reschedule an office conference only once was left out of the regulation. This proposal will restore this provision.

- **Proposed Amendment to 16 CCR Section 1780 – Update the USP Standards Reference Material (Section 100 Technical Change)**

  This modification would update the specific edition of USP used as standard reference in this regulation.

- **Proposed Amendment to 16 CCR Section 1780.1 and 1781 – Replace the term "Exemptee" with "Designated Representative"**

  This proposed regulation change would merely reflect in regulations a statutory change in nomenclature of and from "exemptee" to "designated representative" that was enacted in 2004.

- **Proposed Repeal 16 CCR Section 1786 – Exemptions for a Supplier**

  This section is outdated and needs to be repealed. This provision requires a supplier to immediately return a certificate of exemption to the board if an exemptee leaves the employment of a wholesaler. This regulation is based on prior Pharmacy Law which linked an exemptee license (designated representative) to a specific licensed wholesaler location.

- **Board omnibus regulation provisions involving technical clean up for 2006**

  16 CCR § 1709.1 - Designation of Pharmacist in Charge
  16 CCR § 1780 - Minimum Standards for Wholesalers
  16 CCR § 1780.1 - Minimum Standards for Veterinary Food-Animal Drug Retailers
  16 CCR § 1781 - Exemption Certificate

Board Approved – Proposed Language to be Developed

At the April Meeting, the board agreed to move forward with a proposed regulation on the process and criteria to approve accreditation agencies for pharmacies that compound sterile injectable sterile drug products. Language will be developed for the next Legislation and Regulation Committee.

Board Approved – Awaiting Conformance with California Building Standards Rulemaking Process

- **Addition to the California Building Code – 24 CCR 490A.3 and 505.12.2 Related to Compounding Parenteral Solutions; Technical Changes to the Building Code Relating to Pharmacies**

On April 26, 2006, the board voted to amend the language in the California Building Code, Title 24, California Code of Regulations, section 490A.3 and 505.12 with respect to the building standards for pharmacies that compound parenteral solutions. This summer, the Building Standards Commission advised the board that there is a new process to submit items into the California Building Code. The board will pursue this new format in the future to secure the adoption of these standards into the building code.

There was no further discussion.

Legislation Report and Action

Chairperson Zinder stated that the board packet includes review of legislation approved on the previous year.

Board-Sponsored Legislation

- **SB 1476 (Figueroa) (Chapter 658, Statutes of 2006)- Board Sunset Extension Bill**

This bill extends the board's sunset date for two years, from 2008 to 2010. The board's sunset report will be due to the Legislature in September 2008. The bill also extends a report on those who fail the pharmacist licensure examination four times and must take remedial education until 2008.

In addition, this legislation delays the implementation date for electronic pedigree requirements on prescription medicine sold in California from January 2007 to January 1, 2009. The bill also allows the board to extend implementation until 2011 if the board believes the technology is not yet ready.

Additional provisions exclude drug samples from e-pedigree requirements and exclude until 2010 injectable medicines that are not dispensed to patients, but administered by providers directly to patients. The electronic pedigree system must be interoperable through all distribution levels, serialized to the product container level, and drugs returned to wholesalers must retain the initiating

pedigree. The board must be notified about suspected or actual counterfeiting and repackagers must continue the pedigree through repackaging operations.

The board's Enforcement Committee continues quarterly meetings with manufacturers and wholesalers to monitor the implementation progress of the electronic pedigree requirement. This bill was signed by the Governor on September 29, 2006.

- **SB 1475 (Senate Business and Professions and Economic Development Committee) Omnibus Bill (Chapter 659, Statutes of 2006)**

  This bill:

  1. Allows a check-off box on electronic prescriptions that, if marked by a prescriber, would prevent generic substitution at a pharmacist's discretion.
  2. Clarifies requirements for reporting to the board when a license is impaired to the extent it affects the licensee's safe practice or the licensee has stolen or diverted drugs.
  3. Establishes the authority to issue a temporary sterile injectable compounding license following a change of ownership
  4. Exempts government-owned wholesalers from having to post a $100,000 bond.
  5. Exempts drug manufacturers who hold a biologics license application form the FDA from having to post a $100,000 bond.
  6. Makes technical and conforming changes in the licensure requirements for clinics.

  This bill was signed by the Governor on September 29, 2006.

- **AB 2408 (Negrete McLeod) (Chapter 777, Statutes of 2006) Pharmacists, pharmacies and nonresident pharmacies**

  This bill reorganizes the pharmacist protocol provisions in Business and Professions Code section 4052 into four more readable sections. The bill also:
  -- specifically states that the practice of a pharmacist occurs within and outside a pharmacy.
  -- adds a statement that "pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities."

  There are several other changes made in disciplinary provisions regarding nonresident pharmacies.

  The bill formerly contained provisions important to the board that were vigorously opposed by the California Medical Association. These provisions were amended out of the bill in late August. The provisions removed would have identified three primary types of pharmacies, although any pharmacy could do all three functions (dispensing, prescription processing, advice/clinical center).

  The bill also contained a list of professional duties that pharmacists typically perform (for which they educated and which are tested on the NAPLEX and CPJE exams) that are not listed in law. Provisions describing the functions pharmacists perform were

-- interpreting, verifying and implementing drug orders and prescriptions
-- dispensing pursuant to legitimate drug orders and prescriptions
-- ensuring proper drug storage, documentation, inventory, labeling and recordkeeping
-- maintaining accurate, complete and confidential patient profiles and records
-- supervising pharmacy technicians and other ancillary personnel in the pharmacy
-- designing and implementing quality assurance procedures and protocols
-- compounding drug products pursuant to prescription and for prescriber office use
-- maintaining safe, secure and sanitary conditions in licensed premises
-- collaborating with prescribers and other health care providers regarding patient care
-- implementing standardized procedures and protocols regarding patient care
-- administering or furnishing drugs or biologicals where permitted by law
-- initiating, adjusting or implementing patient drug regimens as authorized by law
-- performing cognitive services, including drug utilization reviews and management, medication therapy reviews and management, and patient counseling and consultation

It was the last provision that drew CMA's opposition.

This bill was signed by the Governor on September 29, 2006.

- **AB 595 (Negrete McLeod) Pharmacy: Compounding of Prescription Drugs**.

This bill would have established standards for pharmacies that compound medications pursuant to a prescription or via contract with another pharmacy. In 2004, the Licensing Committee formed a Workgroup on Compounding to evaluate whether a distinction could be made between compounding by a pharmacy and manufacturing operations that are performed by a drug manufacturer. This workgroup formed in part due to a request from the Department of Health Services seeking the board's determination of when a pharmacy is compounding, and when a pharmacy has become a drug manufacturer, and thus subject to licensure by the Department of Health Services or federal Food and Drug Administration.

However, the group was unable to develop standards to distinguish when a pharmacy has crossed from compounding into manufacturing, and thus would be subject to licensure as a manufacturer. Instead, a legislative proposal and draft regulations were developed to establish standards for pharmacies that compound medication, leaving to the Department of Health Services or FDA the determination of when a pharmacy is manufacturing.

The board sponsored the proposed statutory provisions in this bill. In August 2005, AB 595 was on the floor of the Senate when opposition from the Department of Health Services was formally announced. During 2006, the board and interested stakeholders worked to remove the Department of Health Services' opposition, but we were never successful. The Department of Health Services remained opposed to various provisions, but primarily the provisions that would have allowed a pharmacy to contract with another pharmacy to compound medication for the first pharmacy. Amendments desired by Health Services would have required a separate pharmacy license and annual inspections for pharmacies that compound medication for other pharmacies.

And at the very end of the 2006 legislative session, after months of effort to remove or reduce DHS' opposition, amendments to AB 595 appeared in print that were aimed at reducing DHS' opposition. However, Kaiser, CPhA and Grandpa's Pharmacy came out in opposition to these amendments, although former Executive Officer Patricia Harris feels that these amendments had been agreed upon earlier, the bill was dropped at the end of the session (DHS never removed its opposition).

Enacted Legislation Related to the Practice of Pharmacy

- **AB 225 (Negrete McLeod) (Chapter 698, Statutes of 2006): Electronic prescription information**

  This bill aligns state law with federal law allowing healthcare facilities to receive nonmonetary goods and services (e.g., palm pilots) for the purposes of transmitting prescription information electronically without violating the kickback provisions contained in Business and Professions Code section 650.

  This bill was signed by the Governor on September 29, 2006.

- **AB 2198 (Houston) (Chapter 350, Statutes of 2006): Health Care: Controlled Substances and Dangerous Drugs**

  This bill revises and recasts existing law relating to the prescribing or administration of drugs for the treatment or management of pain in the Medical Practices Act, and provides that physicians who have a medical basis for prescribing or administering dangerous drugs or controlled substances shall not be subject to disciplinary action or prosecution under specified circumstances. It also revises the provisions relating to physicians who prescribe, dispense or administer a controlled substance to an addict or habitual user and broadens the Intractable Pain Treatment Act to allow physician's to prescribe or administer certain drugs for the treatment of pain or a condition causing pain, including but not limited to, intractable pain.

  This bill was signed by the Governor on September 20, 2006.

- **AB 2373 (Plescia) (Chapter 775, Statutes of 2006): Automated drug delivery system**

  This bill expands the use of automated drug delivery systems (ADDS) in nursing facilities and makes other changes related to the stocking of ADDS. In addition, it exempts drugs dispensed from an ADDS machine from existing law labeling requirements if the drugs are in blister pack cards.

  This bill was signed by the Governor on September 29, 2006.

- **AB 2583 (Nation) (Chapter 487, Statutes of 2006): Dispensing prescription drugs and devices: refusal to dispense**

  This bill requires the board's Notice to Consumers to be revised to contain a statement describing patients' rights to prescription drugs or devices, and to inform patients of their right to timely access to prescribed drugs and devices even if a licentiate refuses to dispense a drug or device based on ethical, moral, or religious grounds.

  The board must promulgate a regulation to make this change. Board staff developed the regulatory language required to implement this legislative change, which was discussed under the Communication and Public Education Committee report at this meeting.

  This bill was signed by the Governor on September 26, 2006.

- **AB 2877 (Frommer) (Chapter 720, Statutes of 2006): Prescription drugs: importation: procurement**

  This legislation requires the Department of Health Services (DHS) to establish a Web site to facilitate purchasing prescription drugs at reduced prices and requires that the Web site include price comparisons of at least 150 commonly prescribed prescription drugs, including typical prices charged by pharmacies in the state. In addition, it requires the Department of General Services (DGS) to report to the Legislature on specified activities related to the procurement of prescription drugs.

  This bill was signed by the Governor on September 29, 2006.

- **AB 2911 (Nunez) (Chapter 619, Statutes of 2006): California Discount Prescription Drug Program**

  This bill establishes the California Discount Prescription Drug Program (Program) in the Department of Health Services (DHS) to use manufacturer rebates and pharmacy discounts in order to reduce prescription drug prices and improve the quality of health care for eligible Californians.

  This bill was signed by the Governor on September 29, 2006.

- **AB 2986 (Mullin) (Chapter 286, Statutes of 2006): Controlled substances: prescription requirements**

  This bill brings California law into conformance with the federal National All Schedules Prescription Electronic Reporting (NASPER) Act of 2005 by including Schedule IV controlled substances within the CURES (Controlled Substances Utilization Review and Evaluation System) system. Beginning January 1, 2007, Schedule IV medications dispensed in California by pharmacies and prescribers must be reported to CURES.

The bill requires pharmacies and prescribers dispensing controlled drugs to submit CURES data weekly. The bill also adds new items into the patient's data field in CURES, such as a telephone number.

This is an important bill to pharmacies' operations that will require pharmacies potentially to modify their software programs to comply with the requirements. The board is developing a fact sheet for pharmacies on this bill.

Ms. Herold stated that the reporting requirement has been moved up to a weekly reporting instead of monthly. Also, they changed some of the data element fields and the board will distribute the information on its Web site to identify the changes.

Mr. Gray, representing Kaiser Permanente, indicated that there are some changes to data elements required that will necessitate changes to the security prescription forms. Pharmacists are asking if prescriptions without additional data are valid and should pharmacists still accept old forms? Dr. Gray requested a discussion with Department of Justice.

Interim Executive Officer Herold responded that the board will not aggressively enforce provisions and instead will seek to education licensees over the next few months. The board may seek legislation to clarify when absolute compliance with the new provisions is needed. Department of Justice is currently undergoing transition with new leadership.

Deputy Attorney General Room offered to facilitate this discussion as the liaison with Department of Justice.

Interim Executive Officer Herold indicated that it is unlikely that the Department of Justice will invalidate old security prescription forms. In the past board has provided guidance for licensees.

This bill was signed by the Governor on September 14, 2006.

- **AJR 40 (Chan) (Resolution Chapter 60, Statutes of 2006): Medicare Prescription Drugs**

  This measure memorializes the United States Congress and President to enact H.R. No. 3861, "The Medicare Informed Choice Act of 2005."

  This resolution was chaptered by the Secretary of State on June 1, 2006.

- **AJR 49 (Nation) (Resolution Chapter 136, Statutes of 2006): Direct-To-Consumer Prescription Drug Advertisements**

  This resolution requests that the United States Food and Drug Administration aggressively monitor and regulate direct-to-consumer television advertising of prescription drugs by pharmaceutical companies and memorializes the President and the Congress of the United States to ban television advertising of prescription drugs.

This resolution was filed with the Secretary of State on September 7, 2006.

- **SB 1305 (Figueroa) (Chapter 64, Statutes of 2006): The Medical Waste Management Act**

  This legislation prohibits a person from knowingly placing home-generated sharps waste in commercial and residential solid waste collection containers after September 1, 2008.

  This bill was signed by the Governor on July 12, 2006.

- **SB 1430 (Alquist) (Chapter 874, Statutes of 2006): The Local Pandemic and Emergency Health Preparedness Act of 2006**

  This bill permits the director of the Department of Health Services to declare a health emergency and the local health officer to declare a local health emergency in the jurisdiction in specified instances. The bill permits a local health officer to issue an order to first responders for the purpose of immediately isolating exposed individuals in specified instances and with specified limitations.

  The Governor signed this bill on September 30, 2006.

Legislation related to the Practice of Pharmacy that Failed Passage

AB 2308 (Plescia) Ambulatory Surgical Centers: Licensure.
The bill was vetoed.

AB 21 (Levine) Pharmacists: Contraceptive Devices
This bill failed passage.

AB 71 (Chan) Pharmaceuticals: Adverse Drug Reactions: Office of CA Drug Safety Watch
This bill failed passage.

AB 75 (Frommer) Pharmaceutical Assistance Program
This bill failed passage.

AB 283 (Koretz) Pseudoephedrine: Retail Sale.
This bill failed passage.

AB 651 (Berg) California Compassionate Choices Act
This bill failed passage.

AB 657 (Karnette) Pharmacies: Prescription Containers
This bill failed passage.

AB 1908 (Karnette) Medi-Cal: Pharmacy Reimbursement

This bill failed passage.

AB 2057 (Cogdill) Controlled Substances.
This bill failed passage.

AB 2730 (Nation) Medi-Cal: Contract Drug List: Advertising
This bill failed passage.

AB 2743 (Matthews) Pharmacists: Ancillary Personnel
This bill failed passage.

AB 2856 (Hancock) Informed Consent: Prescription Medication Off-Label Use.
This bill failed passage.

SB 380 (Alquist) Drugs: Adverse Event Reporting
This bill failed passage.

SB 592 (Aanestad) Acute Care Hospitals: Inpatient Pharmacy Technician Services
This bill failed passage.

SB 1366 (Aanestad) Controlled Substances
This bill failed passage.

SB 1683 (Scott) Pharmaceutical Information: Clinical Trial Data
This bill died in the Senate.

- **NEW BUSINESS ITEMS FOR FUTURE MEETINGS**

President Powers asked if there were additional matters from the board or audience for future board meetings.

There were no comments.

- **ADJOURNMENT**

There being no further business, President Powers adjourned the meeting at 4:00 p.m.

Thursday, October 26, 2006

CLOSED SESSION

The board moved into closed session pursuant to Government Code section 11126(c)(3) to deliberate upon disciplinary matters.

Petitions

- **Petition for Reinstatement**
  Leon Fries

- **Reduction of Penalty**
  Lieu Kieu Pham

- **Early Termination of Probation and Reduction of Penalty**
  Ryan Russell

ADJOURNMENT

There being no further business, President Powers adjourned the meeting at 12:45 p.m.